

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, 2025

☐ 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
(State or Other Jurisdiction of
Incorporation or Organization)
960 San Antonio Road
Palo Alto, CA
(Address of Principal Executive Offices)

92-1062542
(I.R.S. Employer
Identification No.)

94303
(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 \$402.50 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 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, 2025 (the last trading day of the registrant’s second fiscal quarter of 2025), as reported on the Nasdaq Capital Market, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$32.4 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 April 2, 2026, the registrant had 8,491,267 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 2026 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant’s fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SCILEX HOLDING COMPANY
ANNUAL REPORT ON FORM 10-K
FISCAL YEAR ENDED DECEMBER 31, 2025
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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;
- 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 of future regulatory, judicial and legislative changes in our industry;
- Anticipated regulatory and legal developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- Our ability to obtain and maintain regulatory approval of any of our products and product candidates;
- Our ability to research, discover and develop additional product candidates;

- Our ability to grow and manage growth profitably;
- Our ability to obtain and maintain intellectual property protection and avoid infringing on the rights of others;
- Our ability to execute our business plans and strategy;
- Our ability to prevent, respond to, and recover from a cybersecurity incident;
- The effect of any geopolitical conflicts or new or increased international tariffs, including mitigation efforts and economic effects, on our business operations, including but not limited to our clinical studies and clinical trials;
- The effect of global economic and political developments;
- Regulatory developments related to crypto assets and crypto asset markets;
- A determination that we are an investment company under the Investment Company Act of 1940 (the “1940 Act”);
- Our ability to successfully adopt and execute our new cryptocurrency treasury strategy;
- Any changes in the accounting treatment of cryptocurrency holdings;
- General volatility in the cryptocurrency market; 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.

We have adopted a cryptocurrency treasury strategy in which we intend to invest in bitcoin, Ethereum and other blockchain-linked cryptocurrencies. We intend to accumulate such cryptocurrencies as a long-term treasury asset. Our goal is to acquire and grow our overall cryptocurrency position and utilize professional treasury strategies to both increase our cryptocurrency holdings, while driving revenue via a range of staking and related yield-generating activities. In the future, we plan to evaluate additional cryptocurrency holdings and transactions, including but not limited to strategic investments and/or acquisitions of operating companies that we view as aligned with our cryptocurrency treasury strategy. For more information, please see the section titled “*Business — Our Treasury Strategy*.”

Overview of 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 2025, 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 RxOmege Therapeutics LLC (a/k/a Romege Therapeutics, LLC) (“Romege”), dated as of June 14, 2022, which agreement was subsequently amended on January 16, 2025 (such agreement, as so amended, the “Romege 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 — Romege License and Commercialization Agreement.*”

Overview of 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.

In April 2025, Scilex Bio, Inc. (“Scilex Bio”), our subsidiary, signed an agreement with NeuroBiogen Company (“NBG”) to grant Scilex Bio an exclusive worldwide license to the franchise KDS2010 drug candidate to develop and commercialize in metabolic diseases (including obesity and type 2 diabetes) and neurodegenerative diseases, including Alzheimer’s, Parkinson’s and other CNS diseases. The lead program in the proposed joint venture is an oral tablet product candidate that is currently in Phase 2 trials in obesity and Alzheimer’s disease indications.

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.

KEY PROGRAMS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3 / PIVOTAL	APPROVED	IP	MILESTONES / KEY COMMENTARY
ZTlido® (1.8% lidocaine topical system equivalent to 5% lidocaine)	Approved for the treatment of Postherpetic Neuralgia-PHN related pain					▪ 2031	▪ Launched in the U.S. in October 2018
GLOPERBA® (colchicine USP) oral solution (For the prevention of painful gout flares in adults)	Approved for the prevention of painful gout flares in adults					▪ 2036	▪ 2H 2022: In-licensed U.S. rights ▪ June 2024: U.S. launch ▪ January 2025: In-licensed Ex-US rights
ELYXYB® (celecoxib) oral solution (Acute Treatment of Migraine)	Approved for acute treatment of migraine					▪ 2036	▪ 1Q 2023: In-licensed U.S. / Canadian rights ▪ 2Q 2023: U.S. launch ▪ 2Q 2025: Canada migraine approved ▪ 2Q 2025: Acute pain filed
	Filed acute pain indication with FDA in January 2025						
SP-102 (SEMDEXA™) (Lumbar Radicular / Sciatica Pain)	Fast Track					▪ 2036	▪ Scilex Pharmaceuticals has global promotional rights to SP-102 (SEMDEXA) ▪ 2H 2023: FDA agreed on NDA path ▪ 2025: Initiated 2 nd Phase 3 trial
SP-103 Lidocaine Topical System 5.4% (3X) (Acute Pain)	Fast Track for Low Back Pain					▪ 2031	▪ 2Q 2023: Completed Two Positive Phase II trials ▪ 2025: Initiate pivotal trial for acute pain ▪ 3Q 2022: Received Fast Track for low back pain
SP-104, Delayed Burst Low Dose Naltrexone (Fibromyalgia)	Prepare Phase II Trial					▪ 2041	▪ 1H 2022: Completed Phase I trial(s)

Our Commercial 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 30 people, targeting over 3,500 primary care physicians, pain specialists, neurologists, 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 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:
 - o 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.
 - o 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:

- o 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.
 - o 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 from multiple Phase 2 clinical trials) with the novel viscous gel formulation of SP-102, and we initiated the second Phase 3 study in September 2025.
- **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 Treasury Strategy

The Company plans to continue to adopt treasury strategy during the year 2026, under which the principal holding in its treasury reserve on the balance sheet will be allocated to cryptocurrency, and specifically a long-term strategy of holding Ethereum, bitcoin, BNB, Doge and/or other blockchain-linked cryptocurrencies. Additionally, we intend to monitor ongoing developments in the regulatory environment around cryptocurrencies, including pending federal legislation, and may modify or expand our treasury strategy to the extent we determine compliant with federal rules and regulations and not giving rise to a requirement that the Company register as an investment company under the Investment Company Act of 1940 (the “1940 Act”). Although we believe that Ethereum, bitcoin, BNB, Doge, and/or other blockchain-linked cryptocurrencies in which we have invested or may invest are based on proven blockchain technology and supported by established infrastructure pertaining to custody and transacting in such cryptocurrencies, our cryptocurrency treasury strategy will be subject to the risks described in the section of this Form 10-K titled “*Risk Factors*” under the heading “*Risks Related to Cryptocurrency*.”

Our Decision to Adopt a Cryptocurrency Treasury Strategy

Our Board of Directors and senior management have been examining potential uses of cash, including acquisitions of cryptocurrency. After studying various alternatives, we decided that investing in cryptocurrency is currently a better use of our cash. Cryptocurrency, which is digital assets that are issued by and transmitted through an open-source protocol, collectively maintained by a peer-to-peer network of decentralized user nodes, will be our principal treasury holding on an ongoing basis, subject to market conditions and our anticipated cash needs. Specifically, we expect that a significant amount of the holdings in our treasury reserve will consist of Ethereum, bitcoin, BNB, Doge, and/or other cryptocurrencies that are intrinsically linked to a blockchain system, and the value of which is derived from or is reasonably expected to be derived from the use of the blockchain system. As we embark on our new acquisition strategy, our Board intends to proactively evaluate our use of cash, ensuring we maintain adequate working capital.

Other than acquiring cryptocurrency with our liquid assets that exceed working capital requirements, our cryptocurrency treasury strategy may also involve issuing debt or equity securities or engaging in other capital raising transactions with the objective of using a significant portion of the proceeds to purchase cryptocurrency from time to time, subject to market conditions. We view cryptocurrency potentially as a core holding and expect to accumulate cryptocurrency following this offering. We have not set any specific target for the amount of cryptocurrency we seek to hold, although under the treasury strategy we intend to adopt we will maintain a significant amount of our holdings as Ethereum, bitcoin, BNB, Doge, and/or other blockchain-linked cryptocurrencies. We will continue to monitor market conditions in determining whether to engage in financings to purchase additional cryptocurrency. This overall strategy also contemplates that we may (i) periodically sell cryptocurrency for general corporate purposes, including to generate cash for treasury management (which may include debt repayment or the repurchase of our securities, if appropriate at such time), for acquisitions, or for strategies that generate tax benefits in accordance with applicable law, (ii) enter into additional capital raising transactions that are collateralized by our cryptocurrency holdings, and (iii) pursue strategies to create income streams or otherwise generate funds using our cryptocurrency holdings. Although we intend to refine and formally adopt a treasury strategy as soon as practicable, at this time, we do not have a specific policy governing the percentage of our treasury holdings that will be any particular cryptocurrency, as the Company is in the process of establishing a cryptocurrency advisory board that it expects to provide valuable insight and contribute to the development of such strategy.

Cryptocurrency Advisory Board

We intend to establish a cryptocurrency advisory board to assist in developing and managing our cryptocurrency treasury strategy. This advisory board is expected to be comprised of members of our Board of Directors who have relevant experience as well as independent experts in the cryptocurrency space.

Asset Manager

We intend to engage a third-party asset manager to execute the day-to-day management of our cryptocurrency holdings, in accordance with our treasury strategy and subject to the oversight of our cryptocurrency advisory board.

Custody

Our cryptocurrency will be held offline in cold storage with one or more third-party providers. Digital assets like cryptocurrency depend on private keys to retrieve and transfer funds.

We plan to hold our cryptocurrency in custody accounts at either a U.S.-based, institutional-grade custodian that has demonstrated a record of regulatory compliance and information security or offshore third party managed custody accounts, which the Company will control. As we further execute on our strategy, we may expand our holdings to multiple similar custodians. However, as of the date of this Annual Report on Form 10-K, we have not yet entered into a custodial arrangement with any such custodian. In the event that we are not able to enter into such a custodial arrangement prior to or shortly following the consummation of the relevant transaction, the development and implementation of our treasury strategy would be delayed, which could cause a material adverse effect on our business, prospects, and market price of our listed securities. If we are not able to enter into a custodial agreement prior to or shortly following the consummation of the relevant transaction, we will maintain the net proceeds from this transaction that we intend to use to purchase cryptocurrency as cash deposits or cash management instruments, such as U.S. government securities or money market mutual funds until such time that we enter into a custodial arrangement for our cryptocurrency holdings.

Accounting

Cryptocurrency accounting guidance has been evolving. According to the American Institute of Certified Public Accountants' "Accounting for and auditing of Digital Assets practice aid," bitcoin and certain other cryptocurrency would satisfy the definition of an indefinite-lived intangible asset and would be accounted for under ASC 350, Intangibles - Goodwill and Other issued by Financial Accounting Standards Board, or FASB. Under these guidelines, bitcoin and other cryptocurrency holdings would be accounted for initially at cost and subject to impairment losses if their fair value fell below carrying value. In December 2023, the FASB issued Accounting Standards Update No. 2023-08, Accounting for and Disclosure of Crypto Assets (ASU 2023-08), which revised cryptocurrency accounting treatment. Under this new guidance, the valuation of cryptocurrency is to be measured based on fair value.

Hedging Strategy

We have not adopted a hedging strategy with respect to cryptocurrency. However, we may from time to time engage in hedging strategies as part of our treasury management operations if deemed appropriate.

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, President, and Chairperson, Henry Ji, Ph.D, who has over 25 years of global biopharmaceutical and biotechnology experience.

Henry Ji has over 25 years of experience in the biotechnology and life sciences 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. Mr. Ji co-founded Sorrento Therapeutics, Inc. and has served as a director since 2006, as its CEO and President since September 2012, and as Chairman of its board of directors since 2017. Mr. Ji also founded Vivasor Inc. and has served as CEO and President, and as Chairman of its board of directors since 2024. During his tenure at Sorrento, he has engineered and led a phenomenal growth of Sorrento through acquisition and mergers including Bioserv, Scilex Pharmaceuticals, Concorthis Biotherapeutics, Levena Biopharma, LACEL, TNK Therapeutics, Virttu Biologics, Ark Animal Health and Sofusa Lymphatic Delivery Systems. Mr. Ji has served as Sorrento's Chief Scientific Officer from November 2008 to September 2012 and as its Interim CEO from April 2011 to September 2012. Prior to Sorrento, Mr. Ji founded BioVintage, Inc., a research and development company focusing on innovative life sciences technology and product development, and has served as its President since 2002. From 2001 to 2002, Mr. Ji served as Vice President of CombiMatrix Corporation, a publicly-traded biotechnology company that

develops proprietary technologies, including products and services in the areas of drug development, genetic analysis, molecular diagnostics and nanotechnology. During his tenure at CombiMatrix Corporation, Mr. Ji was responsible for strategic technology alliances with biopharmaceutical companies. From 1999 to 2001, Mr. Ji served as Director of Business Development, and in 2001 as Vice President of Stratagene Corporation (later acquired by Agilent Technologies, Inc.) where he was responsible for novel technology and product licensing and development. In 1997, Mr. Ji co-founded Stratagene Genomics, Inc., a wholly owned subsidiary of Stratagene Corporation, and served as its President and Chief Executive Officer from its founding until 1999. Mr. Ji previously served as a director of Celularity Inc. (Nasdaq: CELU) from June 2017 to July 2021. Mr. Ji is the holder of several issued and pending patents in the life science research field and is the sole inventor of Sorrento's intellectual property. Mr. Ji has a Ph.D. in Animal Physiology from the University of Minnesota and a B.S. in Biochemistry from Fudan University. Mr. Ji has demonstrated significant leadership skills as President and Chief Executive Officer of Stratagene Genomics, Inc. and Vice President of CombiMatrix Corporation and Stratagene Corporation. Mr. Ji has served as the President and CEO of Semnur Pharmaceuticals as well as Executive Chairperson and a member of our Board since September 22, 2023, and previously served as our Executive Chairperson and a member of our Board from November 2022 to August 2023. Prior to that, he served as Legacy Scilex's Executive Chairperson and a board member from March 2019 to November 2022. Mr. Ji has served on the board of directors of Scilex Pharmaceuticals Inc., our wholly owned subsidiary ("Scilex Pharma"), since November 2016, and he served as the Chief Executive Officer of Scilex Pharma from November 2016 to March 2019. Mr. Ji has served as Semnur's Treasurer and Secretary and a board member since its inception in 2013. Mr. 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 pharmaceutical 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 Sorrento Therapeutics, Inc., Bioserv, Scilex Pharmaceuticals, Concorthis Biotherapeutics, Levena Biopharma, LACEL, TNK Therapeutics, Virtu Biologics, Ark Animal Health, Sofusa Lymphatic Delivery Systems, CombiMatrix Corporation, Stratagene Corporation, Stratagene Genomics, Inc., and Celularity Inc. 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 and Product Candidate 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 2025, 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. In March 2025, the FDA approved the generic 1.8% lidocaine patch, and accordingly, a prescription for ZTlido may be able to be substituted by a generic product.

Current Treatment Landscape and Limitations of Existing Treatments

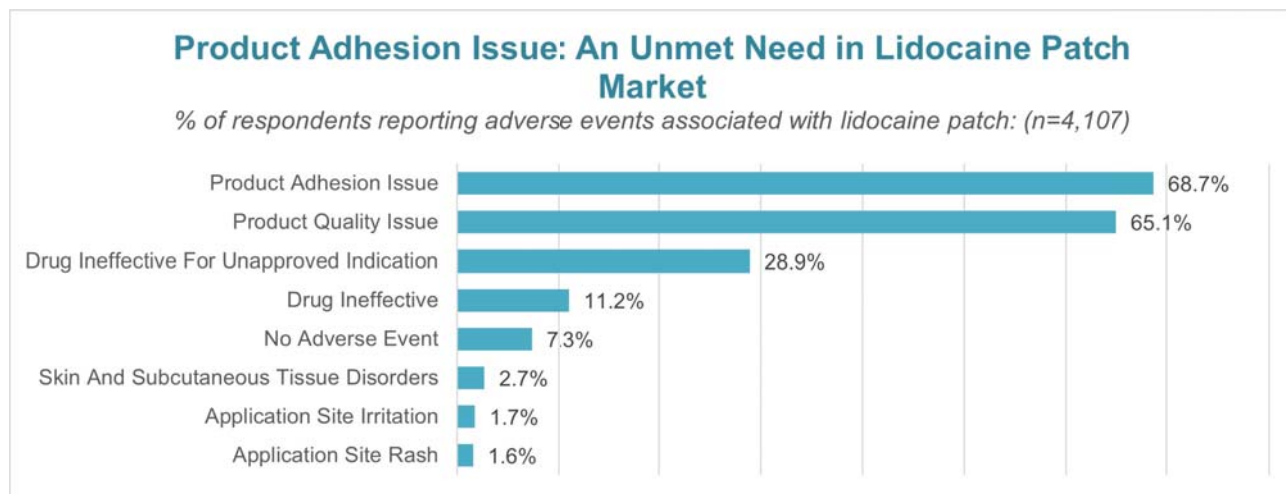
The recommended first-line treatment for the relief of neuropathic pain associated with PHN includes topical lidocaine, gabapentinoids (which have been associated with the potential for abuse as well as numerous adverse events), antidepressants and a multi-modal approach. Topical lidocaine and gabapentinoids 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, and Revision 2 to Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs Guidance for Industry in April 2023. 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 $3 \pm 2\%$ 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 $3 \pm 2\%$ 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

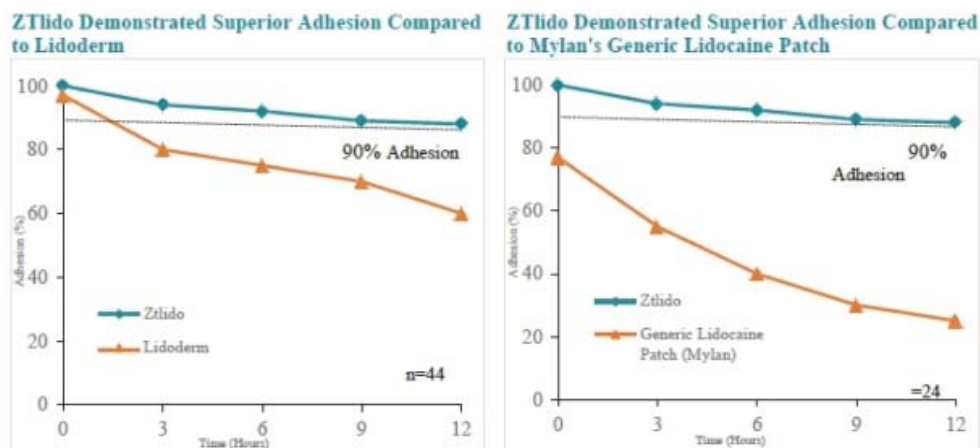
Benefits of ZTlido		ZTlido		Lidoderm		Teva's Lidocaine Patch		Generic Mylan's Lidocaine Patch	
Adhesion	Unique adhesion technology	Single-layer non-aqueous polymer matrix	DIA multi-	Single-layer aqueous (hydrogel)	DIA base	Unique technology	adhesion	Single-layer non-aqueous polymer matrix	DIA multi-
	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	
	Reduced drug load	36 mg/patch	1.8%	700 mg/patch	5%	700 mg/patch	5%	140 mg/patch	5%
Drug Delivery Efficiency	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 over 30 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

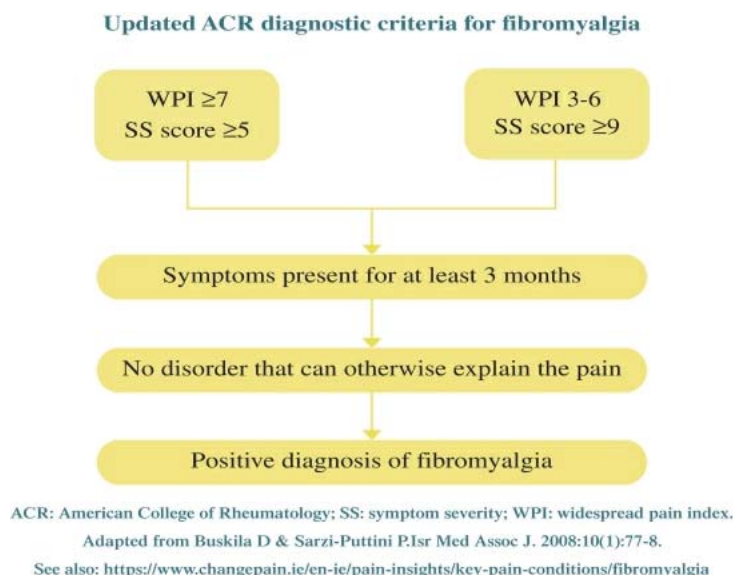
that rheumatologists encounter, seen in 15% of evaluated patients. Approximately 8% of patients cared for in primary care clinics have fibromyalgia. Prominent fibromyalgia researchers and specialists estimate the economic burden of fibromyalgia in the United States to be between \$12 billion to \$14 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.



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.

In April 2025, Scilex Bio signed an agreement with NBG to grant Scilex Bio an exclusive worldwide license to the franchise KDS2010 drug candidate to develop and commercialize in metabolic diseases (including obesity and type 2 diabetes) and neurodegenerative diseases, including Alzheimer's, Parkinson's and other CNS diseases. The lead program in the proposed joint venture is an oral tablet product candidate that is currently in Phase 2 trials in obesity and Alzheimer's disease indications.

Commercialization and Market Access

Sales & Marketing

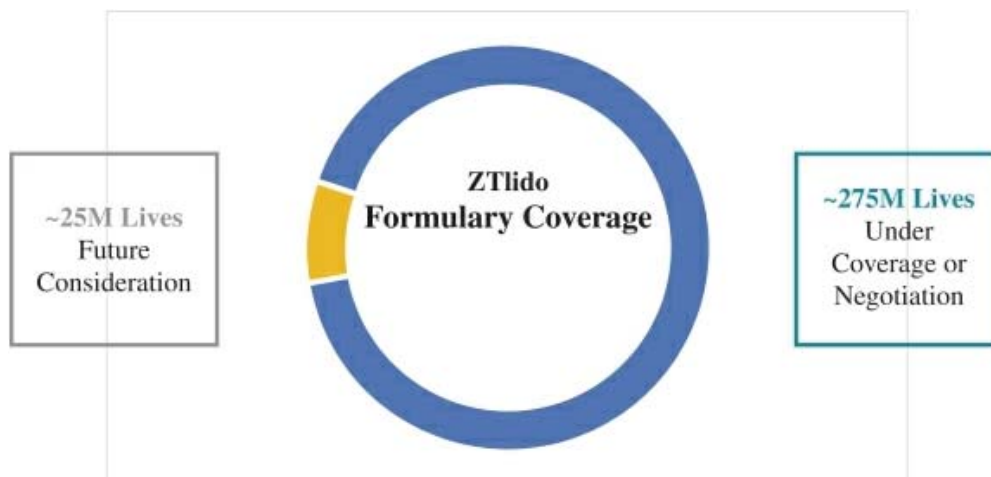
On May 12, 2025, Scilex signed an agreement with Syneos Health Commercial Services, LLC to provide sales force outsourcing activities which the outsourced sales force would continue to dedicate all of their efforts to Scilex products. This transition continues to provide a robust and integrated commercial 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 30 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 3,500 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, 2025, ZTlido had gained approximately 5.6% market share of the lidocaine patch prescription market across the territories we cover in the United States. 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.

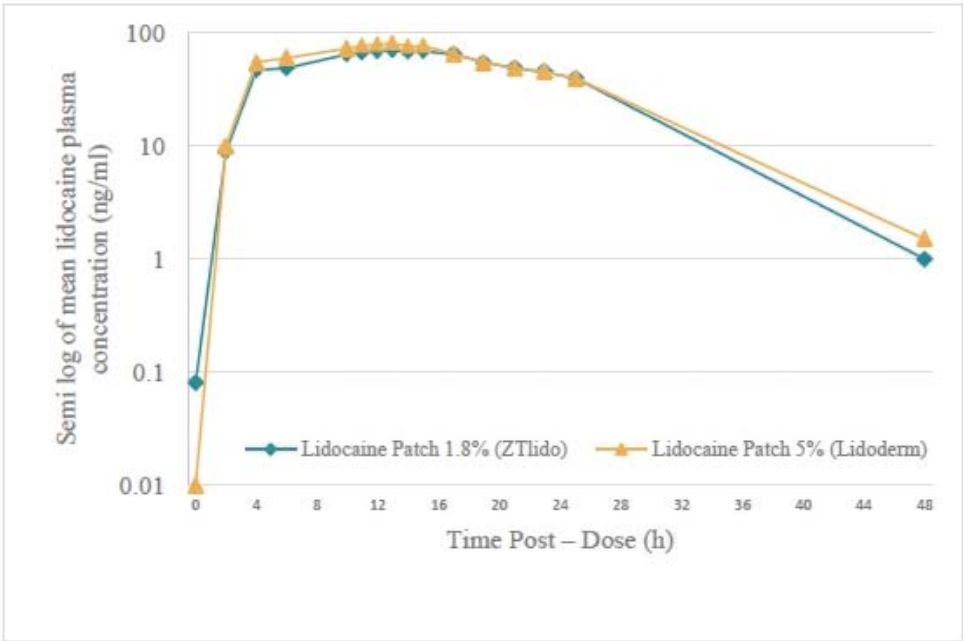
ZTlido Study Details

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 C_{max} 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.

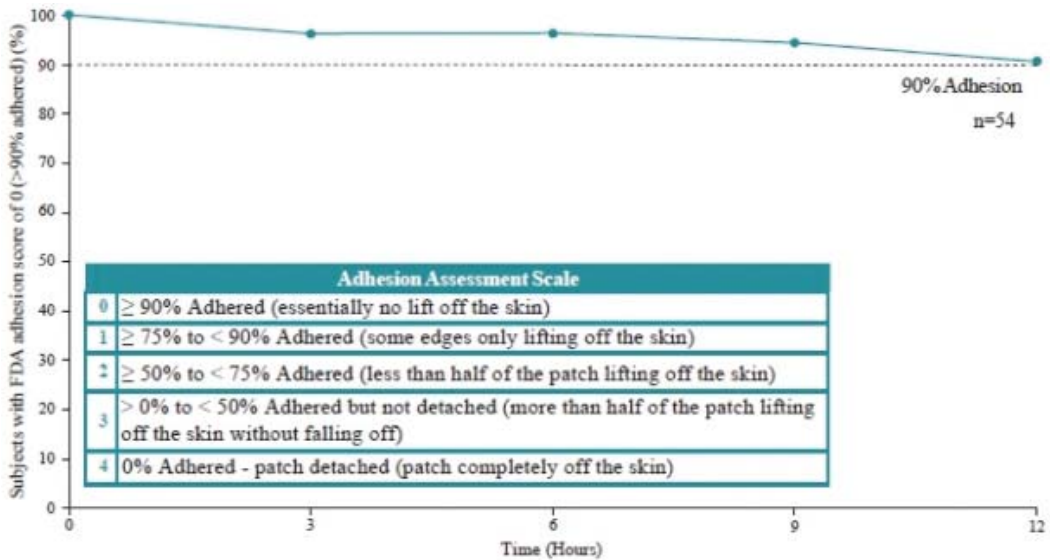
Mean Lidocaine Plasma Concentration Time Profiles - Semilog Scale



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



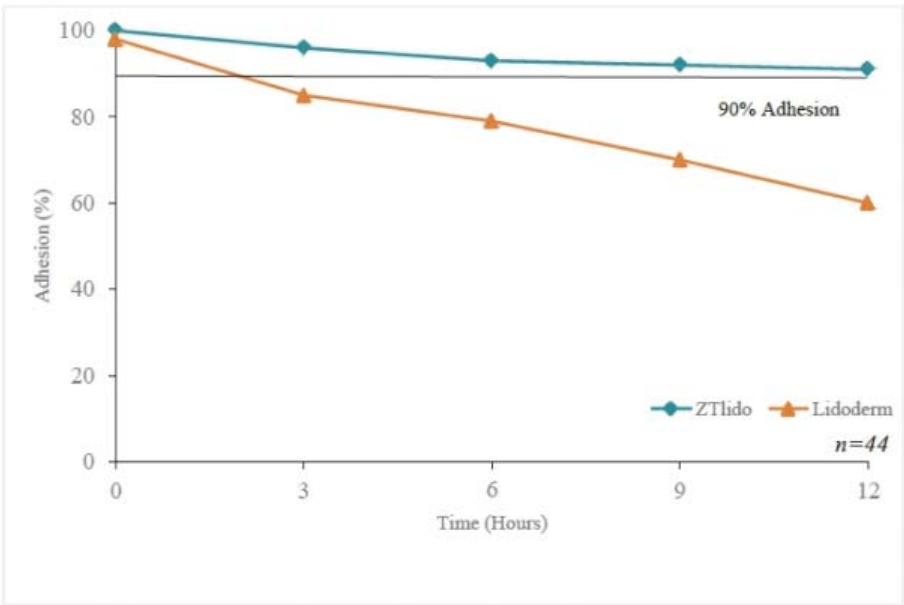
This study was considered the pivotal adhesion study for marketing approval and is summarized in the product label.

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

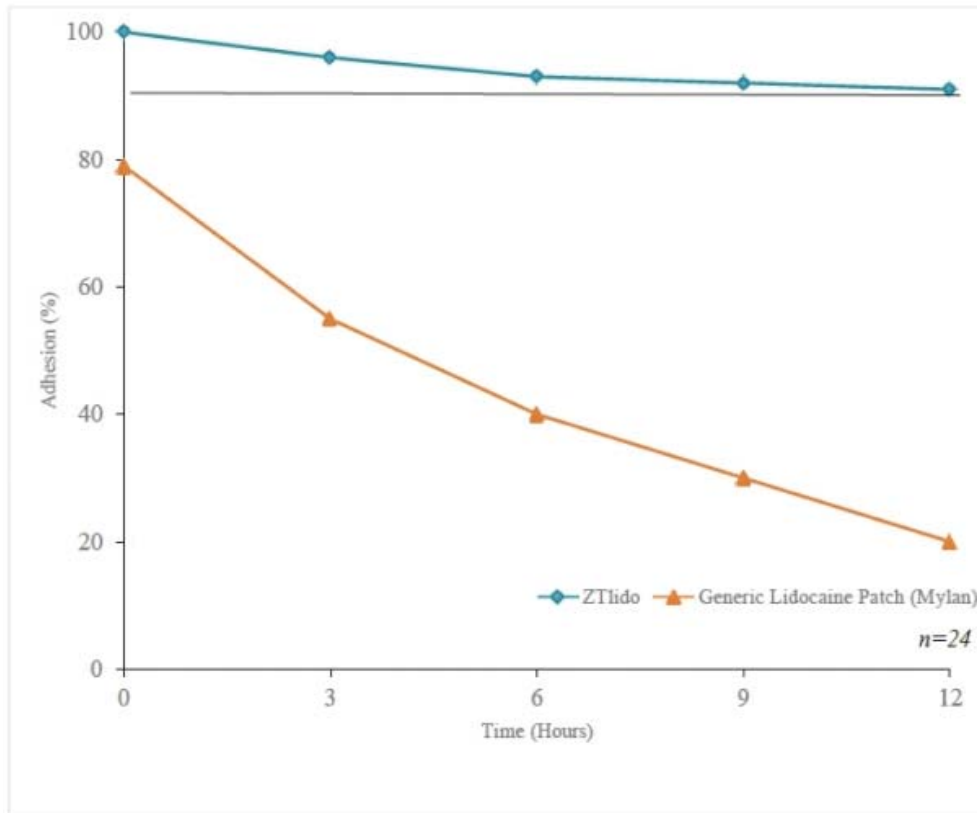


Head-to-Head Adhesion Study versus Mylan’s Generic - SCI-LIDO-ADH-003

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:

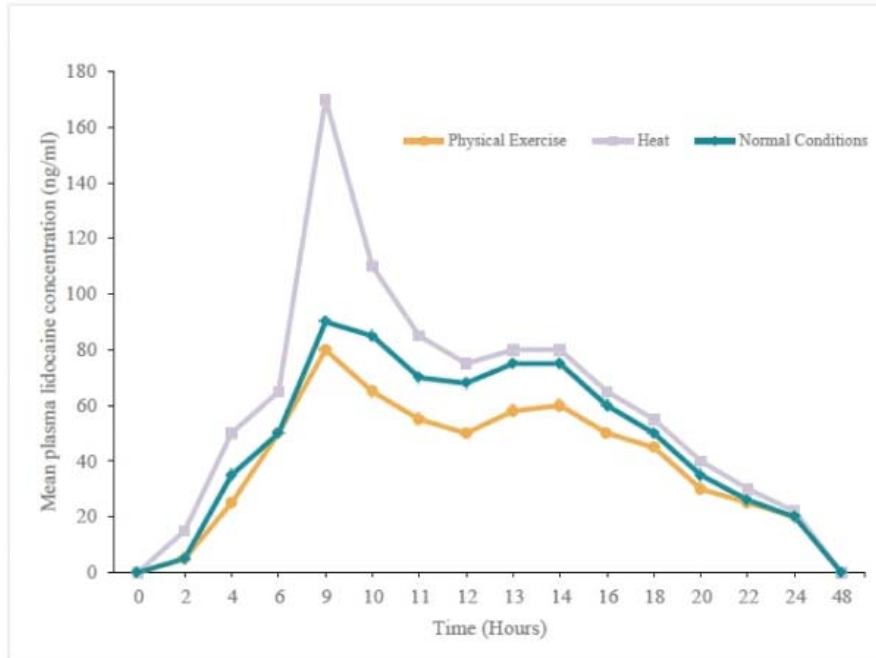
- Treatment A sought to assess the PK and adhesion performance of ZTlido under physical exercise conditions. In this treatment period, subjects were instructed to perform exercise for 30 minutes on a stationary bike achieving a heart rate of 108 beats per minute, with continuous heart monitoring during 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 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 C_{max}, 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-PHOTO-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. We reported CLEAR trial results in multiple scientific congresses and published results in peer-review journal PAIN, in addition to multiple other publications of phase 2 results..

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:

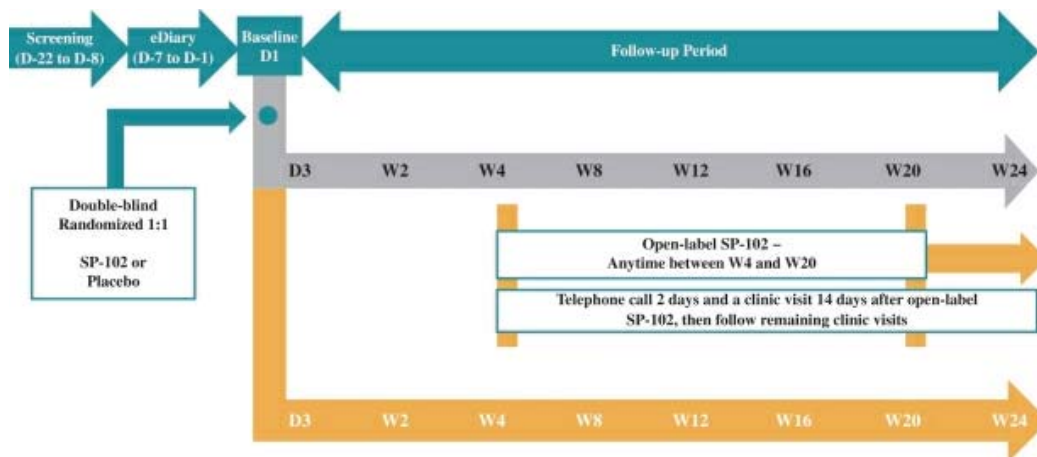
- Repeat injections of SP-102 showed continued pain reduction with no unexpected adverse events based on preliminary results from the SP-102-03 study;
- SP-102 showed an extended local activity with epidural administration in the ES-1504 study;
- SP-102 showed an extended residence time and tolerability 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 $\geq 2\%$ of subjects were low and balanced between SP-102 and placebo. TEAEs occurring with an incidence $\geq 2\%$ 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)

Endpoint	SP-102 N=202 Mean Change from Baseline ⁽¹⁾	Placebo N=199 Mean Change from Baseline	LSM (SE)	95% CI	P-value
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.

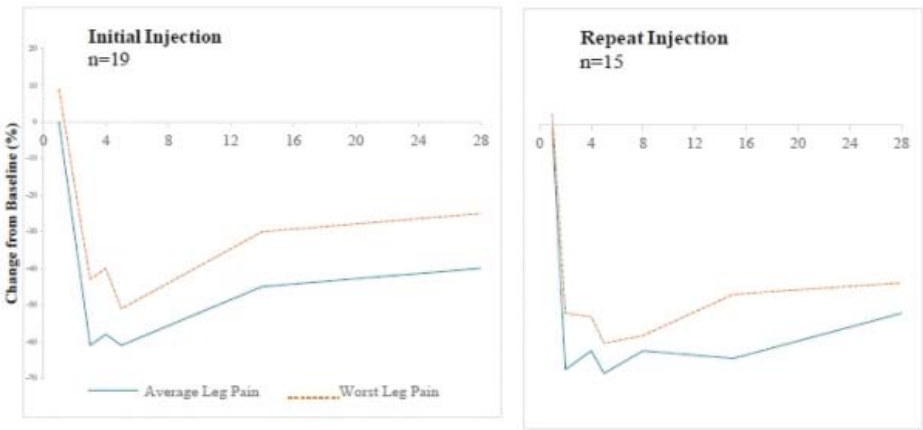
CI: confidence interval; ITT: intent-to-treat (randomized population)

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 counts 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 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 AUC_{inf} 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 (“T_{max}”) following epidural injection of SP-102. The median T_{max} 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 level 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 unexpected new 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 unexpected new 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 that 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 characterizes 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 HCl 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 headaches 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 Pharmacopoeia. 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 — 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.

Overview of the Cryptocurrency Industry and Market

Cryptocurrency refers to digital assets that are issued by and transmitted through an open-source protocol, collectively maintained by a peer-to-peer network of decentralized user nodes. These networks host public transaction ledgers, known as blockchains, on which cryptocurrency holdings and all validated transactions that have ever taken place on the cryptocurrency's network are recorded. Balances of cryptocurrency are stored in individual "wallet" functions, which associate network public addresses with one or more "private keys" that control the transfer of the cryptocurrency. The blockchain can be updated without any single entity owning or operating the network.

There are numerous digital assets and many entities, including consortia and financial institutions, are researching and investing resources into private or permissioned blockchain platforms or digital assets that do not use proof-of-work mining like the bitcoin network. For example, in late 2022, the Ethereum network transitioned to a "proof-of-stake" mechanism for validating transactions that requires significantly less computing power than proof-of-work mining. Other alternative digital assets include "stablecoins," which are designed to maintain a peg to a reference price because of their issuers' promise to hold high-quality liquid assets (such as U.S. dollar deposits and short-term U.S. treasury securities) equal to the total value of stablecoins in circulation. Stablecoins have grown rapidly as an alternative to bitcoin and other digital assets as a medium of exchange and store of value, particularly on digital asset trading platforms.

Additionally, central banks in some countries have started to introduce digital forms of legal tender. For example, China's central bank digital currency ("CBDC") project was made available to consumers in January 2022, and governments including the United States and the European Union have been discussing the potential creation of new CBDCs.

Cryptocurrency Industry Participants

The primary cryptocurrency industry participants are miners, investors, and traders, digital asset exchanges and service providers, including custodians, brokers, payment processors, wallet providers, and financial institutions.

Miners. Miners range from cryptocurrency enthusiasts to professional mining operations that design and build dedicated mining machines and data centers, including mining pools, which are groups of miners that act cohesively and combine their processing power to mine cryptocurrency blocks.

Investors and Traders. Cryptocurrency investors and traders include individuals and institutional investors who, directly or indirectly, purchase, hold, and sell cryptocurrency or cryptocurrency-based derivatives. On January 10, 2024, the SEC issued an order approving several applications for the listing and trading of shares of spot bitcoin exchange-traded products (“ETPs”) on U.S. national securities exchanges. While the SEC had previously approved exchange-traded funds where the underlying assets were bitcoin futures contracts, this order represents the first time the SEC has approved the listing and trading of ETPs that acquire, hold, and sell cryptocurrency directly. ETPs can be bought and sold on a stock exchange like traditional stocks, and provide investors with another means of gaining economic exposure to cryptocurrency through traditional brokerage accounts.

Digital Asset Exchanges. Digital asset exchanges provide trading venues for purchases and sales of cryptocurrency in exchange for fiat or other digital assets. Cryptocurrency can be exchanged for fiat currencies, such as the U.S. dollar, at rates of exchange determined by market forces on cryptocurrency trading platforms, which are not regulated in the same manner as traditional securities exchanges. In addition to these platforms, over-the-counter markets and derivatives markets for cryptocurrency also exist. The value of a cryptocurrency within the market is determined, in part, by the supply of and demand for the cryptocurrency in the global cryptocurrency market, market expectations for the adoption of the cryptocurrency as a store of value, the number of merchants that accept the cryptocurrency as a form of payment, and the volume of peer-to-peer transactions, among other factors.

Service providers. Service providers offer a multitude of services to other participants in the cryptocurrency industry, including custodial and trade execution services, commercial and retail payment processing, loans secured by cryptocurrency collateral, and financial advisory services. If adoption of a cryptocurrency network continues to materially increase, we anticipate that service providers may expand the currently available range of services and that additional parties will enter the service sector for such cryptocurrency network.

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. 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 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, 2025, and 2024, we purchased inventory in the amount of \$3.4 million and \$5.0 million, respectively, under the Commercial Supply Agreement.

The Commercial Supply Agreement will remain in effect until the termination of the Product Development Agreement. Additionally, either we or the Developers may terminate the 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 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 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 22,267 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, 2025, 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 “SEMNU 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 benefits 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 subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant or its products to a variety of administrative or judicial sanctions, such as imposition of a clinical hold, the FDA's refusal to approve pending applications, withdrawal of an approval, inspection scrutiny, issuance of untitled or warning letters, product recalls or withdrawals from the market, 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;
- 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 drug product candidate for its proposed indication;
- submission to the FDA of an NDA or other marketing application (collectively, an "NDA"), requesting marketing approval for one or more proposed indications, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacturing and quality controls ("CMC") for the proposed new drug and proposed 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 full clinical hold or partial clinical hold within that 30-day time period. Under a full clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Under a partial clinical hold, there may be delay or suspension of only part of the clinical work requested under the IND. Following issuance of a clinical hold or partial clinical hold, a clinical trial (or full clinical trial in the case of a partial clinical hold) may only resume after the FDA has notified the sponsor that the trial may proceed. 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. Semnur is conducting a second phase 3 confirmatory trial SP-102-05 (CLEAR-2) globally, with investigative sites in India and the U.S. Trial will enroll patients with lumbosacral radicular pain (sciatica) to meet requirements for product registration in the U.S. and globally.

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 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. The FDA's decision to approve a drug product using the results of a single adequate and well-controlled Phase 3 trial depends both on the quality and quantity of the evidence and considers trial design, trial endpoints, and statistical methodologies, as well as the availability of other confirmatory evidence or reliance on a previous finding of effectiveness of an approved drug when scientifically and legally permissible.

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.

Concurrently 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 proposed indications are incorporated into an NDA requesting approval to market the product. The application may include both negative or ambiguous results of preclinical and clinical trials as well as positive findings. In addition, proposed labeling and descriptions of the manufacturing process and controls, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are required to be submitted to the FDA as part of an NDA. The submission of an NDA is subject to the payment of substantial user fees, and a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for the specified indication(s), and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality, and purity. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the product's safety and efficacy to the satisfaction of the FDA. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of 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 additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

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

During the drug 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 involve 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 will require that a sponsor of a drug receiving accelerated approval perform additional adequate and well-controlled post-marketing clinical trials. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product approved under the accelerated approval pathway. FDA has issued draft guidance that proposes criteria it will evaluate to determine if a trial is underway, including whether enrollment in the trial has been initiated. Since the FDORA amendments, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval of 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 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.

Pediatric Trials

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

Post-Approval Requirements

Once 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. NDA holders using contract manufacturers, laboratories, or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. 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, distribution and tracking and tracing requirements, and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among other things, standards for direct-to-consumer advertising, prohibitions against promoting 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.

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. The constituent parts of a combination product retain their regulatory status, for example, as a drug or device, and as such, we may be subject to additional requirements related to the manufacture and distribution of any such products, including ZTlido.

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 where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. This regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product (the "listed drug"), or published literature, in support of its application. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the listed drug has been approved, or for any new indication sought by the 505(b)(2) applicant.

Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an abbreviated new drug 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 reference 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.

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA at least one of the following (1) no patent information on the drug product that is relied upon by the ANDA or 505(b)(2) NDA (known as the reference drug) 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, the principal decisions about reimbursement for new drug products are often made by the Centers for Medicare and Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS). CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for products exists among third-party payors. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication, and which can change over time. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs, in order for the company's products to be considered as a formulary option. Nonetheless, product candidates may not be considered by individual payors to be medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that a preferred formulary position or an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not ensure 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 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 2010 (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 owed 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, while the ACA remains in effect in its current form, it is possible that the ACA will be subject to judicial or Congressional challenges in the future. 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 eliminated 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. For example, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs. Any health care reform measures will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or other policy or the impact of potential legislation or other policy on us.

Other legislative and administrative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. For example, the Budget Control Act of 2011, among other things, in connection with subsequent legislation, reduced Medicare payments to providers, on average, by 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect into 2032. Under the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021 and subsequent legislation would trigger reductions in Medicare payments to providers, but 2025 legislation eliminated the impact of the estimated budget deficit increases by setting the scorecard used to determine the need for such reductions (sequestration) equal to zero. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may impact the ability of relevant agencies to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, former President

Biden signed into law the Inflation Reduction Act of 2022, which among other things, contains two specific provisions affecting pricing for 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. Various industry stakeholders, including pharmaceutical companies, have lawsuits pending against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. HHS has generally won the substantive disputes in these cases, but certain of these cases continue to be appealed. The current Administration has also issued public statements and other executive orders about its commitment to lowering the cost of prescription drugs and has sought additional voluntary agreements to reduce drug pricing from certain pharmaceutical manufacturers.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. In some cases, states appear interested in public policy designed to encourage drug importation from other countries and bulk purchasing. In January 2024, the FDA authorized Florida’s Agency for Health Care Administration’s drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow as other states have submitted importation program proposals. The Trump Administration has publicly supported such state-directed importation programs, and FDA has taken steps to facilitate such states in initiating such programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, various activities, including but not limited to sales, marketing and scientific/educational grant programs, must comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the federal False Claims Act and similar state laws, each as amended. Failure to comply with such requirements could potentially result in substantial penalties to us. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope.

The federal Anti-Kickback Statute prohibits any person, including a pharmaceutical manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-

Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment of government funds, or knowingly makes, uses, or causes to be made or used a false statement material to a false or fraudulent claim, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay money to the government. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Some of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, 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. Additionally, the FTC's Health Breach Notification Rule applies to health apps and other similar technologies and includes breach notification requirements. The SEC also implemented rules around incident reporting, requiring cybersecurity incidents to be reported 4 business days after determining that an incident is material. 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.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202 (the "Bulk Transfer Rule"). The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny

or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition, and operating results.

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, as amended by the California Privacy Rights Act, and its implementing regulations (the “CCPA”), created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data, the right to limit the use and disclosure of sensitive personal information (including health information). The CCPA places increased privacy and security obligations on entities handling certain personal data of California residents or households, limits data use and mandates audit requirements for higher risk data. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and PHI. The CCPA is enforced by the California Privacy Protection Agency, a data protection authority, which has the power to issue substantive regulations resulting in increased privacy and information security enforcement. Several other states have implemented similar consumer privacy laws that took effect in the past year or will take effect in the near future and states have implemented or are considering laws that specifically focus on the processing of personal data related to individuals’ health, including California’s Confidentiality of Medical Information Act and Washington’s My Health My Data Act. 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. Federal laws require the implementation of systems to provide, capture, and maintain information about transactions involving drug products distributed within the United States and the

trading partners who engaged in such transactions. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. 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. 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. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025. 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.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK and Swiss Data Protection Authorities as well as the EU-U.S. Data Privacy Framework.

If we are unable to implement a valid solution to transfer personal data from the EEA to the United States or other countries that have not been deemed to provide an essentially equivalent level of data protection, we may face increased exposure to regulatory action, substantial fines, or injunction orders to stop processing personal data from EEA, Swiss, or UK residents. Any inability to import personal data to the United States may also restrict our clinical trials activities in the EU; limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to EU data privacy and security laws; and require us to increase our data processing capabilities in the EU and the UK at a significant expense. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The types of challenges we face in the EEA, Switzerland, and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

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.

Government Regulation of Cryptocurrency

The laws and regulations applicable to cryptocurrency and digital assets are evolving and subject to interpretation and change.

Governments around the world have reacted differently to digital assets; certain governments have deemed them illegal, and others have allowed their use and trade without restriction, while in some jurisdictions, such as the U.S., digital assets are subject to overlapping, uncertain, and evolving regulatory requirements.

As digital assets have grown in both popularity and market size, the U.S. Executive Branch, Congress, and a number of U.S. federal and state agencies, including the Financial Crimes Enforcement Network, the Commodity Futures Trading Commission (the “CFTC”), the SEC, the Financial Industry Regulatory Authority, the Consumer Financial Protection Bureau, the Department of Justice, the Department of Homeland Security, the Federal Bureau of Investigation, the IRS and state financial regulators, have been examining the operations of digital asset networks, digital asset users and digital asset exchanges, with particular focus on the extent to which digital assets can be used to violate state or federal laws, including to facilitate the laundering of proceeds of illegal activities or the funding of criminal or terrorist enterprises, and the safety and soundness and consumer-protective safeguards of exchanges or other service-providers that hold, transfer, trade or exchange digital assets for users. Many of these state and federal agencies have issued consumer advisories regarding the risks posed by digital assets to investors. In addition, federal and state agencies, and other countries have issued rules or guidance regarding the treatment of digital asset transactions and requirements for businesses engaged in activities related to digital assets.

Depending on the regulatory characterization of cryptocurrency, the markets for cryptocurrency in general, and our activities in particular, our business and our cryptocurrency acquisition strategy may be subject to regulation by one or more regulators in the United States and globally. Ongoing and future regulatory actions may alter, to a materially adverse extent, the nature of digital assets markets, the participation of industry participants, including service providers and financial institutions in these markets, and our ability to pursue our cryptocurrency strategy. Additionally, U.S. state and federal and foreign regulators and legislatures have taken action against industry participants, including digital assets businesses, and enacted restrictive regimes in response to hacks, consumer harm, or criminal activity stemming from digital assets activity. U.S. federal and state energy regulatory authorities are also monitoring the total electricity consumption of cryptocurrency mining, and the potential impacts of cryptocurrency mining on the supply and dispatch functionality of the wholesale grid and retail distribution systems. Many state legislative bodies have passed, or are actively considering, legislation to address the impact of cryptocurrency mining in their respective states.

The CFTC takes the position that some digital assets, including bitcoin, fall within the definition of a “commodity” under the Commodities Exchange Act of 1936, as amended (the “CEA”). Under the CEA, the CFTC has broad enforcement authority to police market manipulation and fraud in spot digital assets markets in which we may transact. Beyond instances of fraud or manipulation, the CFTC generally does not oversee cash or spot market exchanges or transactions involving digital asset commodities that do not utilize margin, leverage, or financing. In addition, CFTC regulations and CFTC oversight and enforcement authority apply with respect to futures, swaps, other derivative products, and certain retail leveraged commodity transactions involving digital asset commodities, including the markets on which these products trade.

The SEC and its staff have taken the position that certain other digital assets fall within the definition of a “security” under the U.S. federal securities laws. Public statements made by senior officials and senior members of the staff at the SEC indicate that the SEC does not consider bitcoin to be a security under the federal securities laws, and the approval of the spot bitcoin ETPs support this view. However, such statements are not official policy statements by the SEC and reflect only the speakers’ views, which are not binding on the SEC or any other agency or court and cannot be generalized to any other digital assets.

In addition, because transactions in cryptocurrency provide a degree of anonymity, they are susceptible to misuse for criminal activities, such as money laundering. This misuse, or the perception of such misuse, could lead to greater regulatory oversight of cryptocurrency and cryptocurrency platforms, and there is the possibility that law enforcement agencies could close cryptocurrency platforms or other cryptocurrency-related infrastructure with little or no notice and prevent users from accessing or retrieving cryptocurrency held via such platforms or infrastructure. For example, in her January 2021 nomination hearing before the Senate Finance Committee, Treasury Secretary Janet Yellen noted that cryptocurrencies have the potential to improve the efficiency of the financial system but that they can be used to finance terrorism, facilitate money laundering, and support activities that threaten U.S. national security interests and the integrity of the U.S. and international financial systems. The Office of Foreign Assets Control has issued updated advisories regarding the use of virtual currencies, added a number of digital asset exchanges and service providers to the Specially Designated Nationals and Blocked Persons list, and engaged in several enforcement actions, including a series of enforcement actions that have either shut down or significantly curtailed the operations of several smaller digital asset exchanges associated with Russian and/or North Korean nationals.

As noted above, activities involving cryptocurrency and other digital assets may fall within the jurisdiction of more than one financial regulator and various courts and such laws and regulations are rapidly evolving and increasing in scope. On March 9, 2022, former President Biden signed an executive order relating to cryptocurrencies. While the executive order did not mandate the adoption of any specific regulations, it instructed various federal agencies to consider potential regulatory measures, including the evaluation of the creation of a U.S. CBDC. On September 16, 2022, the White House released a framework for digital asset development, based on reports from various government agencies, including the U.S. Department of Treasury, the Department of Justice, and the Department of Commerce. Among other things, the framework encourages regulators to pursue enforcement actions, issue guidance and rules to address current and emergent risks, support the development and use of innovative technologies by payment providers to increase access to instant payments, consider creating a federal framework to regulate nonbank payment providers, and evaluate whether to call

upon Congress to amend the Bank Secrecy Act and laws against unlicensed money transmission to apply explicitly to digital asset service providers.

There have also been several bills introduced in Congress that propose to establish additional regulation and oversight of the digital asset markets. In particular, on July 17, 2025, the Digital Asset Market Clarity Act (the “CLARITY Act”) was passed by the U.S. House of Representatives with bipartisan support and will now be delivered to the Senate for consideration. The CLARITY Act provides a regulatory framework for digital assets by clarifying the roles of the SEC and CFTC in oversight of various digital assets and transactions in digital assets. The CLARITY Act defines several categories of digital assets: digital commodities and permitted payment stablecoins, which would be subject to the jurisdiction of the CFTC, and excluded digital commodities, such as securities, which would be subject to the jurisdiction of the SEC.

Employees and Human Capital Resources

As of December 31, 2025, we had approximately 34 full-time employees, including three employees who have M.D.s or Ph.D.s. Within our workforce, 7 employees were primarily engaged in research and development, 8 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.

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 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 Cryptocurrency

- Our cryptocurrency treasury strategy has not been tested.
- Absent federal regulations, there is a possibility that certain cryptocurrencies may be classified as “securities” or be determined to be offered and sold as a “security.” Any such classification of a cryptocurrency would subject us to additional regulation and could materially impact the operation of our business.
- If we were deemed to be an investment company under the 1940 Act, applicable restrictions likely would make it impractical for us to continue segments of our business as currently contemplated.
- We may be subject to regulatory developments related to crypto assets and crypto asset markets, including the corresponding risk of enforcement actions against us, which could adversely affect our business, financial condition, and results of operations.
- Changes in the accounting treatment of cryptocurrency holdings could have significant accounting impacts, including increasing the volatility of our results.
- Our management will rely upon the advice of an asset manager through an asset management agreement to assist in executing a narrowly focused investment strategy, which may not yield the desired return.
- Cryptocurrency price volatility may materially depress asset valuations, necessitating substantial cash reserves or liquidity buffers to maintain operational resilience. These risks are compounded by the lack of comprehensive regulation governing cryptocurrency trading platforms, which face material exposure to fraud, market manipulation, security breaches, and operational failures that could materially and adversely affect the value of our cryptocurrency holdings.
- We are not subject to legal and regulatory obligations that apply to investment companies such as mutual funds and exchange-traded funds, or to obligations applicable to investment advisers.
- If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our cryptocurrency, or if our private keys are lost or destroyed, or other similar circumstances or events occur,

we may lose some or all of our cryptocurrency and our financial condition and results of operations could be materially adversely affected.

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. In January 2025, we received approval from Health Canada’s Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for ELYXYB for the acute treatment of migraine with or without aura in Canada and in-licensed the rights to commercialize GLOPERBA outside the U.S. 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 Pharmaceuticals, Inc., then a majority-owned subsidiary of our company (“Legacy 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 \$374.1 million and \$72.8 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, and 2024, we had an accumulated deficit of approximately \$921.8 million and \$563.1 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 impose certain operating and financial covenants that restrict our operating and financial flexibility. 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.

On September 21, 2023 (the “Oramed Closing Date”), 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.

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 the ATM Sales Agreement (each as defined below), we made mandatory prepayments 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 Tranche B Investors, the “Tranche B Noteholders”) senior secured convertible notes in the aggregate principal amount of \$50,000,000 (the “Tranche B Notes”), which notes are 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 payments of an aggregate amount of \$15,000,000 were made in November and December 2024. As of December 31, 2025, the outstanding principal amount, as well as the accrued interest and fees, of the Oramed Note was \$28,192,316.82, 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, and subsequently extended to March 31, 2026 pursuant to the Option Agreement (as defined and described in Note 8 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K).

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. 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 60 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.

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 a certain amount, a failure in payment of principal, as well as any bankruptcy, insolvency or reorganization event.

In addition, failure to comply with the covenants under the Oramed Note or Tranche B Notes could result in an event of default. The events of default under the Oramed Note include, among others, a change of control of our company and under the Tranche B Notes include, among others, any material adverse effect on our business, properties, assets, liabilities, operation, condition or prospects.

Upon an event of default under the Oramed Note or the Tranche B Notes, 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 and the holders of the Tranche B Notes are entitled to certain conversion and redemption rights, respectively. We may not have sufficient funds or may be unable to arrange for additional financing to repay such indebtedness or to make any accelerated or redemption payments, and Oramed and/or the Tranche B Noteholders could seek to enforce their security interests in the collateral securing such indebtedness or other remedies available to them under the Oramed Note or Tranche B Notes, respectively, 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 or the Tranche B Notes could have a negative effect on our business, financial condition and results of operations.

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 agreement governing our future indebtedness.

We may be unable to comply with the covenants of our debt agreements with The St. James Bank.

We must comply with certain affirmative and negative covenants under our debt agreements with The St. James Bank. On December 1, 2025, we entered into that certain Non-Recourse Loan and Securities Pledge Agreement (as amended, the “Scilex-St. James Loan

Agreement”) with The St. James Bank & Trust Company Ltd. (“St. James”), and on December 15, 2025, SCLX JV, our independently managed subsidiary, entered into that certain Non-Recourse Loan and Securities Pledge Agreement with St. James (the “SCLX JV-St. James Loan Agreement”, and together with the Scilex-St. James Loan Agreement, the “St. James Loan Agreements”). We may not be able to satisfy all such covenants or obtain any required waiver or amendment, in which event St. James could refuse to make further extensions of credit to us and could require all amounts borrowed under the St. James Loan Agreements, together with accrued interest and other fees, to be immediately due and payable. In addition to allowing St. James to accelerate the repayment of amounts borrowed, several events of default under the St. James Loan Agreements could require us to pay interest at a rate higher than the interest rate effective immediately before the event of default. Following an event of default, if St. James accelerates the repayment of all amounts borrowed, together with accrued interest and other fees, we may not have sufficient cash available to repay the amounts due, and we may be forced to seek to amend the terms of the St. James Loan Agreements or obtain alternative financing, which may not be available to us on acceptable terms, if at all. In addition, if we fail to pay amounts when due under the St. James Loan Agreements or upon the occurrence of another event of default, St. James could proceed against the collateral granted to it pursuant to the St. James Loan Agreements. As of March 31, 2026, we have nil shares of common stock of Datavault AI Inc. pledged as collateral under the Scilex-St. James Loan Agreement, and under the SCLX JV-St. James Loan Agreement, SCLX JV currently has nil shares of our Common Stock pledged as collateral. If St. James proceeds against the collateral, such assets would no longer be held by us or SCLX JV, respectively, which would have a significant adverse effect on our business, financial condition and results of operations.

On March 11, 2026, we filed a lawsuit (the "Scilex-St. James Loan Complaint") against St. James, certain affiliates thereof (collectively with St. James, the "Wade Defendants") and Bank of New York Mellon Corporation ("BNY") in connection with the St. James Loans and certain treatment of the shares pledged as collateral therefor, asserting (1) federal securities fraud (against all defendants); (2) state securities fraud (against the Wade Defendants); (3) fraudulent inducement (against the Wade Defendants); (4) unlawful conversion (against all defendants); and (5) negligence (against BNY). There can be no assurance that we will be successful in litigating such claims against St. James, the Wade Defendants or BNY. Following the filing of the Scilex-St. James Loan Complaint, St. James sent us a notice of default asserting, inter alia, that the filing of the Scilex-St. James Loan Complaint constituted an event of default under the Scilex-St. James Loan.

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 “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, 2025, our cash and cash equivalents were approximately \$5.0 million, and we had an accumulated deficit of approximately \$921.8 million. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the 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, 2025, and 2024, 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 and expect to continue incurring losses for the foreseeable future. Further, we had an accumulated deficit of approximately \$921.8 million as of December 31, 2025 and approximately \$563.1 million as of December 31, 2024. 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, GLOPERBA and ELYXYB 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.

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, 2025. 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, causing 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 timeframe 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, 2025, 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, 2025, 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 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 supply requirements for sodium hyaluronate. Although we are currently in the process of identifying and certifying new suppliers to fulfill our future clinical and commercial supply requirements for sodium hyaluronate, we may not be able to 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 Legacy 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, Legacy 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 Tulex Statement of Work, 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 requirements and, when located outside the U.S., applicable foreign requirements, 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 requirements, 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 requirements could result in sanctions being imposed on us, including clinical holds, delays in obtaining product approvals, 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 current Good Manufacturing Practice ("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 on 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 milestones 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, 2025, 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, 2025, 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 protected, including being sufficiently 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 for 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 or conduct significant remediation 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 impedes 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 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.

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 sufficient data 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 we may withdraw the product from the market or suspend distribution or initiate product recalls. 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 contamination or other quality defects 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 defects. 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, product testing, 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.

Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technology required to manufacture our product candidates may be unique to the original manufacturer and we may have difficulty transferring such skills or technology to another third party. The process of changing manufacturers is extensive and time-consuming and could cause delays or interruptions in our product candidate supply. Further, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with all applicable regulations and guidelines, including cGMPs, and that the post-change material is comparable to pre-change. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

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, and following the resignation of our former Chief Executive Officer and President, Jaisim Shah, we are highly dependent upon our executive officers, including Henry Ji, Ph.D., our Chief Executive Officer, President and Chairperson, and Stephen Ma, our Chief Financial Officer and Chief Operating 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, 2025, we had approximately 34 full-time employees, which reflects the transition of our sales force to a third-party agency (see Note 13 titled “*Commitments and Contingencies*” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information). 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 the Semnur Business Combination will actually maximize the value of Legacy Semnur and/or the SP-102 asset for us or our stockholders.

As previously announced, our Board authorized our management to explore ways in which to maximize the value of Legacy Semnur, and SP-102 (SEMDEXA™), the product candidate held by Legacy 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, Legacy Semnur entered into an agreement and plan of merger (as may be amended or restated from time to time in accordance with its terms, including by Amendment No. 1 thereto, dated as of April 16, 2025, and Amendment No.2 thereto, dated as of July 22, 2025, 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 “Semnur Business Combination”). The Semnur Business Combination was completed on September 22, 2025, pursuant to the Semnur Business Combination Agreement, and Denali Merger Sub merged with and into Legacy Semnur, the separate corporate existence of Denali Merger Sub ceased, and Legacy Semnur became the surviving corporation and a wholly owned subsidiary of Denali. In connection with the consummation of the Semnur Business Combination, Denali changed its name to “Semnur Pharmaceuticals, Inc.” (“Semnur”) and Scilex became a majority owner thereof upon consummation of the Semnur Business Combination.

There is no assurance the Semnur Business Combination will actually maximize the value of Legacy Semnur and/or the SP-102 assets for us or our stockholders. In addition, we remain liable for significant transaction costs, including legal, accounting and financial advisory fees.

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

Conducting business internationally involves a number of risks, including:

- multiple, sometimes conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors or any of our third-party suppliers;
- failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- cost and availability of shipping and other means of product transportation;
- foreign currency exchange rate fluctuations;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, and similar anti-bribery and anti-corruption laws in other jurisdictions, for example, by failing to maintain accurate information and control over sales or distributors’ activities.

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

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

Social media is increasingly being used to communicate about our research, product candidates, investigational medicines and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of non-compliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media 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 Israel and Hamas.

More recently, the escalating conflict with Iran and related military actions throughout the Middle East have caused significant uncertainty, including increased fuel prices and shipping channel disruptions, adding to disruptions to global economic conditions caused by Russia's invasion of Ukraine and sanctions against Russia. U.S. military intervention in Venezuela also could cause disruptions to global economic conditions and affect the stability of those regions. It is not possible to predict the broader consequences of these ongoing conflicts. It is also not possible to predict with certainty these ongoing conflicts and additional adverse effects on existing U.S. macroeconomic conditions and financial markets, all of which could impact the business, financial condition, and results of operations of the Company as well as our ability to raise capital. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. In addition, the closure of any additional national or regional commercial banks could lead to further economic instability.

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

Risks Related to our Intellectual Property

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, 2025, 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, 2025, 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 developments, 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.

There can be no assurance that we will successfully develop or commercialize the technology in-licensed pursuant to the Datavault License Agreement or the Vivasor-Datavault License Agreement.

On November 3, 2025, we entered into a license agreement with Datavault (the “Datavault License Agreement”), pursuant to which Datavault granted us a worldwide, exclusive, non-transferable license, with the right to sublicense, under the patents and know-how specified therein to among other things, research, develop, make, have made, use, sell, have sold, offer for sale, import, export, register, market, promote, advertise, commercialize and distribute the Proprietary Materials (as defined in the Datavault License Agreement). We plan to use the technology under the Datavault License Agreement to develop a real-world-asset-tokenization (RWA)

in the biotech and pharmaceutical industry, on which our products and product candidates data will potentially be centralized and tokenized for monetization purposes.

On December 20, 2025, Vivasor entered into a license agreement with Datavault (the “Vivasor-Datavault License Agreement”). Pursuant to the Vivasor-Datavault License Agreement, Datavault granted us a worldwide, exclusive, non-transferable license, with the right to sublicense, under certain patents and know-how to, among other things, research, develop, make, have made, use, sell, have sold, offer for sale, import, export, market, promote, commercialize and distribute products incorporating the licensed technology (the “Vivasor Licensed Product”) within a defined target market.

There is no assurance that we will ever successfully tokenize our products or product candidates or that we will experience market reception for our products in development or increased market reception for our existing products or the acceptance of RWA pathway/technologies in the biotech and pharmaceutical industry, or that we will ever generate revenue from the Vivasor Licensed Products. To date, we have paid approximately \$2.5 million for the Datavault license and, as of December 31, 2025, the \$20.0 million license fee under the Vivasor-Datavault License Agreement remains payable. We plan to devote resources to the development and commercialization of the real-world-asset-tokenization and of the Vivasor Licensed Products. Our efforts to develop and commercialize such technology and products may require significant resources and may never be successful.

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 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 "*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 “SEMNU 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 秦皇島恒駿商貿有限公司 (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 relatively new court system, there is little 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 “*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 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 occur 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 terms 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 did not agree that the clinical data collected from the single Phase 3 CLEAR-1 trial was sufficient to support the safety and efficacy of SEMDEXA, given the risks associated with interventional procedures. The FDA requested that a confirmatory trial be conducted, noting the absence of any existing FDA-approved epidural steroid product for the treatment of sciatica. The FDA provided guidance regarding expectations for this additional trial needed prior to a 505(b)(2) NDA filing, including expectations for the size of the safety database and specific safety monitoring requirements. Specifically, the FDA requested that the confirmatory Phase 3 CLEAR-2 trial include a larger safety database to further validate the safety and efficacy of SEMDEXA. In February 2024, we had a Type D meeting with the FDA to preview the newly designed trial with the FDA, in order to reduce the potential need for any other additional confirmatory trials prior to a 505(b)(2) NDA filing. During the Type D meeting, the FDA provided further guidance with respect to the requirements needed to help best position us to be able to satisfy the requirements for a 505(b)(2) pathway approval. 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. There remains substantial uncertainty as to how, if at all, the current U.S. administration will seek or continue to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. State governments may also attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. This 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 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 43 days beginning on October 1, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities in 2020. Additionally, the current administration announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. For example, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. If a prolonged government shutdown occurs, if funding for the FDA or other federal agencies (including their workforce) is reduced or if future global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

International data protection laws, including the EU’s and UK’s GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR imposes several data protection requirements in the EU, as well as fines for violations that can reach up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to

notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information, including the right to access, correct and delete their data. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025. In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025, or the DUAA, was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. The provisions within the DUAA will come into force through 2026, and it remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation.

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

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

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

Actions of the current U.S. 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 monitorship, 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 current administration or efforts, if any, to modify the ACA or its implementing regulations, or portions thereof, will impact our business. Litigation and legislation over the ACA and other healthcare reform measures are likely to continue, with unpredictable and uncertain results. Further, additional legislative changes to and regulatory changes under or related to the ACA remain possible.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of, on average, 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032, 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 into 2032. 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. presidential executive orders, U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reform government program reimbursement methodologies for pharmaceutical products, 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."* Furthermore, recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set." 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 or implemented 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. Furthermore, recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

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 current 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. At least two U.S. Courts of Appeals for the Fifth and Eighth Circuits have ruled in favor of state laws that prohibit drug manufacturers from interfering with how a 340B covered entity distributes 340B drugs to patients. Litigation continues related to the implementation of the 340B program.

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. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, the prices of which are scheduled to become effective January 1, 2026. On January 17, 2025, HHS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025, the prices of which will be effective starting January 1, 2027. Each year thereafter, more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. 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. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of march-in rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not generally been exercised, it is uncertain whether that will continue under the new framework. It is unclear whether or how much such rights may be exercised although the current Administration has indicated a willingness to explore the use of such rights.

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 name 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 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 April 2, 2026, our closing stock price ranged from \$3.99 to \$518.03. 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;
- 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 the Middle East, and regime change in Venezuela;
- effects of natural or man-made catastrophic events;
- effects of public health crises, pandemics and epidemics; and
- other events or factors, many of which are beyond our control, such as the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions.

Further, the global equity markets in general have recently experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions that may be unrelated to our operating performance. More recently, the escalating conflict with Iran and related military actions throughout the Middle East have caused significant uncertainty, including increased fuel prices and shipping channel disruptions, adding to disruptions to global economic conditions. 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.

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.

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 dividends, 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 222,117 shares of Common Stock (which number of shares accounts for the automatic annual increase on January 1, 2026), 217,302 shares of Common Stock (which number of shares accounts for the annual increase on January 1, 2026) and 40,000 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 “November 2022 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 of 1933, as amended (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 November 2022 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 maintain compliance with the continued listing standards of Nasdaq could result in a delisting of our Common Stock.

On November 1, 2024, we received the Notice from Nasdaq notifying us that, because the closing bid price for our shares of Common Stock, had been below \$1.00 per share for 30 consecutive business days, we did not comply with 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.

Under Nasdaq Listing Rules, we had 180 days, or until April 30, 2025, to regain compliance with the Minimum Bid Price Requirement. Following the completion of the Reverse Stock Split, on April 30, 2025, the Company received notification from Nasdaq that it had regained compliance with the minimum closing bid price requirement under Nasdaq Listing Rule 5550(a)(2).

On November 21, 2024, we received a second letter from Nasdaq advising us that we were not in compliance with Nasdaq’s continued listing requirements under the Nasdaq Listing Rule 5250(c)(1) (“Listing Rule 5250(c)(1)”) as a result of our failure to file the Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the “2024 Q3 Form 10-Q”) in a timely manner. Listing Rule 5250(c)(1) requires listed companies to timely file all required periodic reports (the “Timely Reporting Requirement”) with the SEC. Under Nasdaq rules, we had 60 calendar days from receipt of such notice, or until January 20, 2025, to submit a plan to regain compliance with the Listing Rule. We regained compliance with Listing Rule 5250(c)(1) by filing the 2024 Q3 Form 10-Q on January 17, 2025.

If, in the future, we are unable to maintain compliance with Nasdaq Listing Rules, Nasdaq could determine to delist our securities from trading on its exchange and if we are then 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.

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 2024 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.

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

On July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act (the "OBBBA") was signed into law. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the TCJA, allowing for accelerated tax deductions for qualified property and research expenditures, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in calendar year 2025 and others implemented through calendar year 2027. The aggregate impact of the OBBBA remains uncertain.

Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. The impact of these tax reforms on holders of our Common Stock is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock.

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, 2025, we have 6,958,204 outstanding SPAC Warrants (as defined below), which are currently exercisable for an aggregate of up to 198,807 shares of our Common Stock (on a post-Reverse Stock Split basis) 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 \$402.50 per whole share (on a post-Reverse Stock Split basis). "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, following the Scilex Business Combination and the Reverse Stock Split, entitle the holder of each whole warrant to purchase 1/35th of a share of Common Stock at a price of \$402.50 per whole share (the "Public Warrants"), and (ii) the 6,840,000 warrants (which are currently exercisable for an aggregate of up to 195,429 shares of Common Stock, on a post-Reverse Stock Split basis) 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 (which are currently exercisable for an aggregate of up to 78,172 shares of Common Stock) were subsequently forfeited and 3,104,000 (which are currently exercisable for an aggregate of up to 88,686 shares of Common Stock, on a post-Reverse Stock Split basis) were transferred to Sorrento, in each case in connection with the Scilex Business Combination) (the "Private Warrants").

As of December 31, 2025, we have outstanding (i) 3,803,447 February 2024 BDO Firm Warrants which are currently exercisable for an aggregate of up to 108,686 shares of our Common Stock, the exercise price of which is \$59.50 per share; (ii) 470,588 February

2024 BDO Representative Warrants, which are currently exercisable for an aggregate of up to 13,446 shares of our Common Stock, the exercise price of which is \$74.38 per share; (iii) the Deposit Warrant, which is currently exercisable for an aggregate of up to 3,250,000 shares of our Common Stock, at an exercise price of \$1.20 per share and (iv) 1,200,000 April 2024 RDO Placement Agent Warrants, which are currently exercisable for an aggregate of up to 34,286 shares of our Common Stock, the exercise price of which is \$43.75 per share.

On October 8, 2024, we issued the October 2024 Noteholder Warrants to purchase an aggregate of 214,284 shares of Common Stock. On the same date, we also issued the October 2024 Placement Agent Warrants to purchase an aggregate of 104,848 shares of Common Stock, which became exercisable 180 days following the date of issuance. The current exercise price of both the October 2024 Noteholder Warrants and the October 2024 Placement Agent Warrants is \$36.40 per share. On July 22, 2025, we entered into the Warrant Exchange Agreements with the Tranche B Investors, pursuant to which the October 2024 Noteholder Warrants to purchase up to 107,142 shares of Common Stock were surrendered in exchange for the Exchange Warrants to purchase an aggregate of 500,000 shares of Common Stock at an exercise price of \$40.00 per share. Oramed waived its right to participate in the exchange.

On December 13, 2024, we issued the December 2024 RDO Pre-Funded Warrants to purchase an aggregate of 68,604 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 1,642,871 shares of Common Stock and the StockBlock Warrants to purchase an aggregate of 131,472 shares of Common Stock, which became exercisable 180 days following the date of issuance. The exercise price of both the December 2024 RDO Common Warrants and the StockBlock Warrants is \$22.72 per share and \$25.81 per share, respectively.

On September 30, 2025, we issued the September 2025 Warrants to purchase an aggregate of 275,000 shares of Common Stock, which are currently exercisable for an aggregate of 275,000 shares of Common Stock, the exercise price of which is \$20.00 per share.

On November 25, 2025, we issued a warrant (the “November 2025 Investor Warrant”) to purchase an aggregate of 1,356,594 shares of Common Stock, which are currently exercisable for an aggregate of 1,356,594 shares of Common Stock. On the same date, we also issued to StockBlock, Rodman & Renshaw LLC, or their respective designees warrants (the “November 2025 Placement Agent Warrants”) to purchase up to an aggregate of 72,352 shares of Common Stock, which are currently exercisable for an aggregate of 72,352 shares of Common Stock. The exercise price of both the November 2025 Investor Warrant and the November 2025 Placement Agent Warrants is \$29.00 per share.

To the extent the SPAC Warrants, the February 2024 BDO Firm Warrants, the February 2024 BDO Representative Warrants, the Deposit Warrant, the Fee Warrant, the April 2024 RDO Placement Agent Warrants, the October 2024 Noteholder Warrants, the October 2024 Placement Agent Warrants, the December 2024 RDO Common Warrants, the StockBlock Warrants, the Exchange Warrants, the September 2025 Warrants, the November 2025 Investor Warrant and the November 2025 Placement Agent 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. There is no guarantee that the Warrants will ever be in the money prior to their expiration, and as such, the Warrants may expire worthless. See below risk factor, *“The 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.”*

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, 2025, the exercise price for our SPAC Warrants is \$402.50 per whole share of Common Stock. On April 2, 2026, the closing price of our Common Stock on the Nasdaq Capital Market was \$7.44. If the price of our shares of Common Stock remains below \$402.50 per whole 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, as noted above, on April 2, 2026, the closing price of our Common Stock on the Nasdaq Capital Market was \$7.44, making almost all of the Warrants out-of-the-money. If the price of our shares of Common Stock remains below the exercise prices of such 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 such out-of-the-money warrants will be in the money prior to their expiration and, as such, 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 \$630.00 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.

Risks Related to Cryptocurrency

Our cryptocurrency treasury strategy has not been tested.

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

Absent federal regulations, there is a possibility that certain cryptocurrencies may be classified as “securities” or be determined to be offered and sold as a “security.” Any such classification of a cryptocurrency would subject us to additional regulation and could materially impact the operation of our business.

Cryptocurrency refers to digital assets that are issued by and transmitted through an open-source protocol, collectively maintained by a peer-to-peer network of decentralized user nodes. We believe that cryptocurrencies intrinsically linked to a blockchain system, and the value of which is derived from or is reasonably expected to be derived from the use of the blockchain system, such as bitcoin, are not securities, but neither the SEC nor any other U.S. federal or state regulator has formally taken such a position. Despite the Trump Administration’s Executive Order titled “*Strengthening American Leadership in Digital Financial Technology*” which includes as an objective “protecting and promoting the ability of individual citizens and private sector entities alike to access and to maintain self custody of digital assets,” cryptocurrency has not yet been classified with respect to U.S. federal securities laws, although, as of the date of this Annual Report on Form 10-K, the CLARITY Act is under consideration by the U.S. Senate following its passage by the House of Representatives and would provide greater certainty around the characterization of cryptocurrencies in which we intend to invest. Therefore, while (for the reasons discussed below) we believe that bitcoin, Ethereum and other cryptocurrencies intrinsically linked to a blockchain system are digital commodities and not “securities” within the meaning of the U.S. federal securities laws, and

registration of the Company as an investment company under the 1940 Act, is therefore not required under the applicable securities laws, we acknowledge that, in the absence of applicable legislation, a regulatory body or federal court may determine otherwise. Therefore, our belief, even if reasonable under the circumstances, would not preclude legal or regulatory action based on such a finding that cryptocurrency is a “security,” which would require us to register as an investment company under the 1940 Act.

Additionally, the characterization of trading in cryptocurrencies as the offer and sale of securities could present an additional regulatory risk in respect of application of the Securities Act, and Exchange Act. Pursuant to the Securities Act, offers and sales of securities must be registered with the SEC or exempt from such registration. If cryptocurrency trading were deemed to be the offer and sale of securities, requiring registration with the SEC or an applicable exemption from such requirement, platforms on which cryptocurrencies may be purchased or sold may not be operating in compliance with applicable laws and regulations and be forced to curtail or cease operations, in which case our cryptocurrency treasury strategy would be materially and adversely affected.

As part of our analysis of U.S. federal securities law, we take into account a number of factors, including the various definitions of “security” under U.S. federal securities laws and federal court decisions interpreting the elements of these definitions, such as the U.S. Supreme Court’s decisions in the *Howey* and *Reves* cases, as well as court rulings, reports, orders, press releases, public statements, and speeches by the SEC Commissioners and SEC Staff providing guidance on when a digital asset or a transaction to which a digital asset may relate may be a security for purposes of U.S. federal securities laws. We have also reviewed the pending CLARITY Act’s characterization of digital assets as digital commodities or stablecoins, and otherwise as securities or other non-digital commodity instruments. Our belief that bitcoin, Ethereum and other blockchain-linked cryptocurrencies in which we intend to invest are not “securities” and are not offered and sold as such is premised, among other reasons, on our belief that such cryptocurrencies do not meet the elements of the *Howey* test. For instance, ownership of bitcoin, Ethereum and other blockchain-linked cryptocurrencies do not convey the right to receive any interest, rewards, or other returns.

We acknowledge, however, that the SEC, a federal court or another relevant entity could take a different view in the absence of applicable clarifying legislation. The regulatory treatment of cryptocurrency is such that it has drawn significant attention from legislative and regulatory bodies, in particular the SEC which has previously stated it deemed cryptocurrency a security. Application of securities laws to the specific facts and circumstances of digital assets is complex and subject to change. Our belief, even if reasonable under the circumstances, would not preclude legal or regulatory action based on a finding that cryptocurrency, or any other digital asset we might hold is a “security.” As such, we are at risk of enforcement proceedings against us, which could result in potential injunctions, cease-and-desist orders, fines, and penalties if cryptocurrency was determined to be a security or offered and sold as a security by a regulatory body or a court. Such developments could subject us to fines, penalties, and other damages, and adversely affect our business, results of operations, financial condition, and prospects.

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

The emergence or growth of digital assets other than cryptocurrencies we may hold could have a material adverse effect on our financial condition. There are numerous alternative digital assets and many entities, including consortia and financial institutions, are researching and investing resources into private or permissioned blockchain platforms or digital assets. For example, some cryptocurrency networks utilize proof-of-work mining. Others use a “proof-of-stake” mechanism for validating transactions that requires significantly less computing power than proof-of-work mining. If the mechanisms for validating transactions in alternative digital assets are perceived as superior to the mechanisms used by the digital assets in which we invest, those digital assets could gain market share.

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

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

If we were deemed to be an investment company under the 1940 Act, applicable restrictions likely would make it impractical for us to continue segments of our business as currently contemplated.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an “investment company” if (i) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities or (ii) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding, or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) on an unconsolidated basis. Rule 3a-1 under the 1940 Act generally provides that notwithstanding the Section 3(a)(1)(C) test described in clause (ii) above, an entity will not be deemed to be an “investment company” for purposes of the 1940 Act if no more than 45% of the value of its assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) consists of, and no more than 45% of its net income after taxes (for the past four fiscal quarters combined) is derived from, securities other than U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, securities issued by employees’ securities companies, securities issued by qualifying majority owned subsidiaries of such entity, and securities issued by qualifying companies that are controlled primarily by such entity. We do not believe that we are an “investment company” as such term is defined in either Section 3(a)(1)(A) or Section 3(a)(1)(C) of the 1940 Act.

Historically, we have been focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. However, we anticipate that we will begin focusing on pursuing opportunities to expand our portfolio into coins, digital assets and cryptocurrency. With respect to Section 3(a)(1)(A) of the 1940 Act, following this offering, a significant portion of the proceeds of the offering will be used to acquire cryptocurrency, which may be an amount in excess of 40% of our total assets. Since we believe cryptocurrency is not an investment security, we do not hold ourselves out as being engaged primarily, or propose to engage primarily, in the business of investing, reinvesting, or trading in securities within the meaning of Section 3(a)(1)(A) of the 1940 Act.

With respect to Section 3(a)(1)(C), we believe we satisfy the elements of Rule 3a-1 and therefore are deemed not to be an investment company under, and we intend to conduct our operations such that we will not be deemed an investment company under, Section 3(a)(1)(C). We believe that we are not an investment company pursuant to Rule 3a-1 under the 1940 Act because, on a consolidated basis with respect to wholly-owned subsidiaries but otherwise on an unconsolidated basis, no more than 45% of the value of the Company’s total assets (exclusive of U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, and cash items) consists of, and no more than 45% of the Company’s net income after taxes (for the last four fiscal quarters combined) is derived from, securities other than U.S. government securities, shares of registered money market funds under Rule 2a-7 of the 1940 Act, securities issued by employees’ securities companies, securities issued by qualifying majority owned subsidiaries of the Company, and securities issued by qualifying companies that are controlled primarily by the Company.

Cryptocurrency and other digital assets, as well as new business models and transactions enabled by blockchain technologies, present novel interpretive questions under the 1940 Act. There is a risk that assets or arrangements that we have concluded are not securities could be deemed to be securities by the SEC or another authority for purposes of the 1940 Act, which would increase the percentage of securities held by us for 1940 Act purposes. The SEC has requested information from a number of participants in the digital assets ecosystem, regarding the potential application of the 1940 Act to their businesses. For example, in an action unrelated to the Company, in February 2022, the SEC issued a cease-and-desist order under the 1940 Act to BlockFi Lending LLC, in which the SEC alleged that BlockFi was operating as an unregistered investment company because it issued securities and also held more than 40% of its total assets, excluding cash, in investment securities, including the loans of digital assets made by BlockFi to institutional borrowers.

If we were deemed to be an investment company, Rule 3a-2 under the 1940 Act is a safe harbor that provides a one-year grace period for transient investment companies that have a bona fide intent to be engaged primarily, as soon as is reasonably possible (in any event by the termination of such one-year period), in a business other than that of investing, reinvesting, owning, holding, or trading in securities, with such intent evidenced by the company’s business activities and an appropriate resolution of its board of directors. The grace period is available not more than once every three years and runs from the earlier of (i) the date on which the issuer owns securities and/or cash having a value exceeding 50% of the issuer’s total assets on either a consolidated or unconsolidated basis or (ii) the date on which the issuer owns or proposes to acquire investment securities having a value exceeding 40% of the value of such issuer’s total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. Accordingly, the grace period may not be available at the time that we seek to rely on Rule 3a-2; however, Rule 3a-2 is a safe harbor and we may rely on any exemption or exclusion from investment company status available to us under the 1940 Act at any given time. Furthermore, reliance on Rule 3a-2, Section 3(a)(1)(C), or Rule 3a-1 could require us to take actions to dispose of securities, limit our ability to make certain investments or enter into joint ventures, or otherwise limit or change our service offerings and operations. If we were to be deemed an investment company in the future, restrictions imposed by the 1940 Act—including limitations on our ability to issue different classes of stock and equity compensation to directors, officers, and employees and restrictions on management, operations, and transactions with affiliated persons—likely would make it impractical for us to continue our business as contemplated, and could have a material adverse effect on our business, results of operations, financial condition, and prospects.

We may be subject to regulatory developments related to crypto assets and crypto asset markets, including the corresponding risk of enforcement actions against us, which could adversely affect our business, financial condition, and results of operations.

As cryptocurrency and other digital assets are relatively novel and the application of state and federal securities laws and other laws and regulations to digital assets is unclear in certain respects, it is possible that regulators in the United States or foreign countries may interpret or apply existing laws and regulations in a manner that adversely affects the price of cryptocurrency. The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, which could materially impact the price of cryptocurrency or the ability of individuals or institutions such as us to own or transfer cryptocurrency.

In June 2023, the SEC filed complaints against Binance Holdings Ltd. (“Binance”) and Coinbase, Inc. (“Coinbase”), and their respective affiliated entities, relating to, among other claims, that each party was operating as an unregistered securities exchange, broker, dealer, and clearing agency and seeking to shut down the exchanges. In November 2023, the SEC filed a complaint against Payward Inc. and Payward Ventures Inc., together known as Kraken, also alleging, among other claims, that Kraken’s crypto trading platform was operating as an unregistered securities exchange, broker, dealer, and clearing agency, and seeking to shut down the exchange.

In 2025, the SEC dismissed its civil enforcement actions against several major crypto asset trading platforms, including Coinbase, Kraken, and Binance, which had been alleged to have been operating as unregistered securities exchanges, brokers, dealers, and clearing agencies, among other claims. While these dismissals may signal a shift in regulatory approach or enforcement priorities, there remains significant uncertainty regarding the application of federal securities laws to crypto assets, including bitcoin, and the trading of such assets. Future regulatory actions, changes in interpretation, or new legislation could adversely affect our ability to hold, acquire, or utilize bitcoin and other cryptocurrencies, and could materially impact our business, financial condition, and results of operations.

If cryptocurrency is determined to constitute a security for purposes of the federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of cryptocurrency and in turn adversely affect the market price of our Common Stock. Moreover, the risks of us engaging in a cryptocurrency treasury strategy have created, and could continue to create complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

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

In December 2023, the FASB issued ASU 2023-08, which upon our adoption will require us to measure in-scope cryptocurrency assets at fair value in our statement of financial position, and to recognize gains and losses from changes in the fair value of our cryptocurrency in net income each reporting period. ASU 2023-08 will also require us to provide certain interim and annual disclosures with respect to our cryptocurrency holdings. The standard is effective for our interim and annual periods beginning January 1, 2025, with a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the annual reporting period in which we adopt the guidance. The Company adopted ASU 2023-08 in 2025. The adoption did not have a material impact on the Company’s financial statements as the Company did not hold any crypto assets as of the adoption date. During the third quarter of 2025, the Company began holding crypto assets, which are accounted for in accordance with ASU 2023-08. See Note 6 for related disclosures.

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

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

cryptocurrency.

Our management will rely upon the advice of an asset manager through an asset management agreement to assist in executing a narrowly focused investment strategy, which may not yield the desired return.

We intend to hire a third-party asset manager, to execute the day-to-day management of our cryptocurrency holdings. Our management and cryptocurrency experts will have broad discretion in the management and oversight of our cryptocurrency treasury policy and application of the net proceeds from any future offering by the Company and could execute an investment strategy or spend the proceeds in ways that do not improve our results of operations or enhance the value of our Common Stock. The failure to apply these funds effectively could result in financial losses that could cause the price of our Common Stock to decline.

Cryptocurrency price volatility may materially depress asset valuations, necessitating substantial cash reserves or liquidity buffers to maintain operational resilience. These risks are compounded by the lack of comprehensive regulation governing cryptocurrency trading platforms, which face material exposure to fraud, market manipulation, security breaches, and operational failures that could materially and adversely affect the value of our cryptocurrency holdings.

Our cryptocurrency treasury strategy could materially and adversely affect our business, financial condition and results of operations, primarily due to the inherent price volatility of cryptocurrency and the impact of accounting standards. Cryptocurrencies can be highly susceptible to sharp price swings, which can significantly impact our financial statements, especially under mark-to-market accounting. To mitigate these risks, companies holding significant amounts of cryptocurrencies must maintain substantial capital reserves to absorb potential declines in asset value without compromising their overall financial health. This heightened need for liquidity reflects the increased risk associated with holding cryptocurrencies and underscores the importance of robust risk management strategies when navigating the uncertainties of the digital asset market. Digital asset trading platforms handling cryptocurrencies and particularly small-cap cryptocurrencies are relatively new and often operate without the oversight typical of regulated securities or commodities markets. Many platforms, particularly those based outside the United States, are subject to limited or inconsistent regulatory standards and often do not provide transparent information about their ownership, management, or compliance practices. This lack of oversight increases the risk of fraudulent activities such as artificial trading volume, wash trading, and market manipulation-issues that have been documented in unregulated cryptocurrency markets and could similarly affect cryptocurrency trading. Reports have indicated that a significant portion of trading volume on unregulated digital asset trading platforms may be artificially inflated or non-economic in nature.

Manipulative behavior on cryptocurrency exchanges can distort market prices and lead to unexpected losses for investors. As a result, reduced market confidence in these platforms could negatively impact the liquidity and value of cryptocurrencies. We may hold substantial amounts of cryptocurrencies and must be vigilant about these risks, as trading activity that is not reflective of genuine market interest can lead to volatility and potential losses.

The operational integrity of digital asset trading platforms is another critical risk factor. Many of these platforms may lack robust security measures, making them vulnerable to hacking, fraud, and other operational problems. As we may hold large quantities of cryptocurrencies, we must consider the risk of security breaches, which could materially and adversely affect our business, financial condition and results of operations.

We may use a significant portion of the net proceeds from any one or more future offerings by the Company to purchase additional cryptocurrency, the price of which has been, and will likely continue to be, highly volatile.

We may use a significant portion of the net proceeds from any one or more future offerings by the Company to purchase additional bitcoin, Ethereum, BNB, Doge, and/or other blockchain-linked cryptocurrencies in accordance with our treasury strategy. Cryptocurrency is a highly volatile asset. Cryptocurrency does not pay interest, but if management determines to stake the cryptocurrency tokens in treasury, rewards can be earned on cryptocurrency. The ability to generate a return on investment from the net proceeds from any offering by the Company will depend on whether there is appreciation in the value of Ethereum, bitcoin, BNB, Doge, and other blockchain-linked cryptocurrencies following our purchases of such cryptocurrency with the net proceeds from any future offering by the Company and whether the Company is successful in pursuing other strategies to create income streams or otherwise generate funds using its cryptocurrency holdings. Future fluctuations in Ethereum's, bitcoin's, BNB's, Doge's, and other blockchain-linked cryptocurrencies' trading prices may result in our converting cryptocurrency purchased with the net proceeds from any offering into cash with a value substantially below the net proceeds from such an offering.

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

federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of cryptocurrency or the ability of individuals or institutions such as us to own or transfer cryptocurrency. For example, the U.S. executive branch and SEC, among others in the United States and abroad, have been active in recent years, and laws including the European Union’s Markets in Crypto Asset Regulation and the U.K.’s Financial Services and Markets Act 2023 became law. It is not possible to predict whether, or when, any of these developments will lead to Congress granting additional authorities to the SEC or other regulators, or whether, or when, any other federal, state or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of digital asset markets to function or the willingness of financial and other institutions to continue to provide services to the digital assets industry, nor how any new regulations or changes to existing regulations might impact the value of digital assets generally and cryptocurrency specifically. The consequences of increased or different regulations of digital assets and digital asset activities could adversely affect the market price of cryptocurrency and in turn adversely affect the market price of our Common Stock. Moreover, the risks of engaging in a bitcoin treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

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

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

Cryptocurrencies do not pay interest or dividends.

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

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

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

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

Security breaches and cyberattacks are of particular concern with respect to cryptocurrency. Blockchain-based cryptocurrencies and the entities that provide services to participants in the cryptocurrency ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. For example, in October 2021, it was reported that hackers exploited a flaw in the account recovery process and stole from the accounts of at least 6,000 customers of the Coinbase exchange, although the flaw was subsequently fixed and Coinbase reimbursed affected customers. In May 2025, Coinbase experienced a significant breach of

sensitive customer data and the misappropriation of digital assets resulting from the bribery of overseas insiders, leading to substantial financial losses for affected customers and prompting Coinbase to make certain operational adjustments, including increasing investment in insider-threat detection and automated response systems and opening a new support hub in the United States, and adding stronger security controls and monitoring across all locations. Similarly, in November 2022, hackers exploited weaknesses in the security architecture of the FTX Trading digital asset exchange and reportedly stole over \$400 million in digital assets from customers.

A successful security breach or cyberattack could result in:

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

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

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

We will face significant risks relating to disruptions, forks, 51% attacks, hacks, network disruptions, or other adverse events or other compromises to the cryptocurrency blockchains, which could materially and adversely impact our business, financial condition and results of operations.

Blockchain networks are maintained by decentralized networks of participants, and as such are susceptible and vulnerable to a variety of risks, including disruptions, security breaches, and fundamental technical issues. Both networks are vulnerable to attacks by malicious actors who gain control of a significant portion of the network's mining hash rate, a scenario commonly referred to as a 51% attack. In such an event, the attacker could double-spend transactions, reverse previously confirmed transactions, or otherwise disrupt the normal operations of the network. Successful 51% attacks have historically undermined trust in affected blockchain networks and could materially decrease the value of cryptocurrency assets.

Additionally, forks, or splits in the underlying protocol, may occur when participants fail to reach consensus on proposed upgrades or changes. Forks can lead to the creation of duplicate networks, confusion among market participants, dilution of the original network's value, and disruption of the network's operations. Hard forks, in particular, can materially and adversely impact the perceived stability and value of digital assets, leading to reduced demand and price declines.

Further, hacks and other security breaches targeting the core infrastructure of blockchain networks or major participants, such as exchanges and custodians, could severely impact the reputation and market confidence in these networks. Exploits of protocol-level

vulnerabilities could also compromise the integrity of the cryptocurrency blockchains, resulting in a substantial loss of value.

The success and growth of cryptocurrency assets depend significantly on their continued security, stability, and scalability. Any technical failures, consensus breakdowns, governance disputes, or regulatory interventions that diminish confidence in the networks or impair their functionality could lead to a material decline in their market prices, which could materially and adversely impact our business, financial condition and results of operations. A sustained or significant decrease in the price or liquidity of cryptocurrencies, whether due to 51% attacks, forks, hacks, network disruptions, or other adverse events, could negatively impact our business, financial condition, and results of operations. Furthermore, even the perception that any of these events could occur may lead to significant market volatility and price declines, adversely affecting our business, financial condition and results of operations.

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

Our cryptocurrency is currently in custody accounts with Biconomy PTE.LTD (Biconomy"). If our custodially-held cryptocurrencies are considered to be the property of Biconomy, or a future custodians' estates in the event that Biconomy or any such custodian were to enter bankruptcy, receivership or similar insolvency proceedings, we could be treated as a general unsecured creditor of Biconomy, or such custodian, inhibiting our ability to exercise ownership rights with respect to such cryptocurrencies and this may ultimately result in the loss of the value related to some or all of such assets. A series of recent high-profile bankruptcies, closures, liquidations, regulatory enforcement actions and other events relating to companies operating in the digital asset industry, the closure or liquidation of certain financial institutions that provided lending and other services to the digital assets industry, and the filing and subsequent settlement of a civil fraud lawsuit have highlighted the counterparty risks applicable to owning and transacting in digital assets. These bankruptcies, closures, liquidations and other events have likely negatively impacted the adoption rate and use of cryptocurrencies. Additional bankruptcies, closures, liquidations, regulatory enforcement actions or other events involving participants in the digital assets industry in the future may further negatively impact the adoption rate, price, and use of cryptocurrencies, limit the availability to us of financing collateralized by such assets, or create or expose additional counterparty risks. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our cryptocurrencies. Even if we are able to prevent our cryptocurrencies from being considered the property of a custodian's bankruptcy estate as part of an insolvency proceeding, it is possible that we would still be delayed or may otherwise experience difficulty in accessing our cryptocurrencies held by the affected custodian during the pendency of the insolvency proceedings. Any such outcome could have a material adverse effect on our financial condition and the market price of our listed securities.

Our strategy contemplates that we may seek to generate premium income by selling call options related to cryptocurrencies and, as such, we may be subject to counterparty risk.

Our cryptocurrency treasury strategy contemplates that we may pursue strategies to create income streams or otherwise generate funds using our cryptocurrency holdings (for example, generating premium income by selling call options related to cryptocurrencies). Options are bi-lateral agreements that expose the Company to counterparty risk. A counterparty (the other party to a transaction or an agreement) to a transaction with the Company may be unable or unwilling to make timely payments or otherwise honor its obligations. Further, there is a risk that no suitable counterparties will be willing to enter into, or continue to enter into, option contracts with the Company and, as a result, the Company may not be able to achieve its investment objectives.

We intend to pursue an income generating strategy whereby we sell call options and do not intend to enter into put option contracts or to purchase call options. To the extent that we expand our option trading strategy, we would be subject to additional potential counterparty risks. If the counterparty or its affiliate to a transaction involving put options or the Company buying call options becomes insolvent, bankrupt or defaults on its payment obligations to the Company, the value of an investment held by the Company may decline. Additionally, if any collateral posted by the counterparty for the benefit of the Company is insufficient or there are delays in the Company's ability to access such collateral, the Company may not be able to achieve its investment objectives.

Risks Related to Artificial Intelligence

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

subjected to competitive harm, potential legal liability, and brand or reputational harm. Further, if we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed.

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

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. In addition to these oversight activities, the Audit Committee and the Board play a pivotal role in ensuring the Company’s cybersecurity strategy aligns with its overall risk management framework. They are responsible for reviewing and approving major cybersecurity policies, monitoring the effectiveness of the Company’s risk mitigation efforts, and staying informed about significant incidents or threats that may impact business operations. The Board also ensures that management has the resources and authority needed to implement cybersecurity initiatives and provides guidance on prioritizing investments in information security.

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, legal counsel, Internal Control and Human Resources senior management to discuss the necessary measures to take prior to and during an incident. Management’s responsibilities extend to the day-to-day administration of cybersecurity policies, processes, and practices. This includes proactively monitoring for threats, conducting vulnerability assessments, responding to incidents, and providing regular training to employees. In the event of an incident, the Incident Manager collaborates closely with executive leadership, keeping them informed of the incident’s status and coordinating response actions. Management is also tasked with continuously improving the Company’s cybersecurity posture by learning from past incidents and adapting policies and procedures accordingly. Furthermore, management ensures compliance with recognized frameworks such as the NIST Cybersecurity Framework and oversees the engagement of third-party providers for independent risk assessments. The Board and the Audit Committee receive prompt updates from management regarding any cybersecurity risks that meet reporting thresholds and are briefed on lessons learned after the recovery phase, reinforcing their role in strategic oversight and accountability.

The Senior Director of IT, in collaboration with a team of IT professionals, legal counsel, Internal Control, and Human Resources,

implements programs designed to protect information systems from cybersecurity threats and manage material risks. With over 20 years of experience, the Senior Director of IT is responsible for overseeing the prevention, detection, mitigation, and remediation of cybersecurity threats and incidents in real time. Senior management monitors these activities and reports significant threats and incidents to the Audit Committee. Management's operational responsibilities are complemented by the Board's strategic oversight, ensuring that the Company stays ahead of evolving cybersecurity risks and maintains a comprehensive risk management strategy.

Risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our Company, including our business strategy, results of operations, or financial condition as of December 31, 2025. For more information, please see the risk factor disclosures included in Item 1A of this Annual Report on Form 10-K. This ongoing assessment and communication between management and the Board ensures that cybersecurity risks are managed effectively and that both operational and strategic responses are aligned with the Company's objectives.

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 required by this Item is incorporated by reference to Note 13 titled "*Commitments and Contingencies*" and Note 16 titled "*Subsequent Events*" of the Notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

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 April 2 2026, there were 120 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 with respect to the stock dividend of Series 1 Mandatory Exchangeable Preferred Stock, par value \$0.0001 per share, announced in October 2024, which dividend lapsed, unpaid, by the terms of the Certificate of Designations for such series of preferred stock, 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.

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

Except as previously reported in our Current Reports on Form 8-K, we did not undertake any unregistered sales of our equity securities during the year ended December 31, 2025.

We did not repurchase any shares or other units of any class of our equity securities registered under Section 12 of the Exchange Act during the year ended December 31, 2025.

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."

On April 15, 2025, we effected a reverse stock split of our Common Stock at a ratio of 1-for-35 (the "Reverse Stock Split"). Unless otherwise noted, the share and per share information in this Annual Report on Form 10-K reflects the effect of the Reverse Stock Split.

Overview

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 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 "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 third-party dedicated sales force of over 30 people, targeting 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians who we believe treat the majority of PHN patients. We also 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 January 2025, we in-licensed the rights to commercialize GLOPERBA outside of the U.S. 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. In January 2025, we received approval from Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for ELYXYB for the 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, which is in the second Phase 3 study initiated in September 2025, (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"), 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 the treatment of fibromyalgia, for which Phase 1 trials were completed.

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, and initiated the second Phase 3 study in September 2025. 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. 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. 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 chronic neck pain associated with muscle spasms. 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 are examining SP-103 as a treatment for chronic neck pain associated with muscle spasms, a condition with high unmet need which we expect could affect over 20 million patients in the United States as of 2023. On October 20,

2024, we announced the successful end of a Phase 2 meeting with the FDA, leading to an agreed path forward to a new drug application (including other marketing applications, an “NDA”) for our product candidate, SP-103.

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 into 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 sufficient revenue 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 \$374.1 million and \$72.8 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of approximately \$921.8 million. As of December 31, 2025, we had cash and cash equivalents of approximately \$5.0 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.

We have adopted a cryptocurrency treasury strategy in which we intend to invest in bitcoin, Ethereum and other blockchain-linked cryptocurrencies. We intend to accumulate such cryptocurrencies as a long-term treasury asset. Our goal is to acquire and grow our overall cryptocurrency position and utilize professional treasury strategies to both increase our cryptocurrency holdings, while driving revenue via a range of staking and related yield-generating activities. In the future, we plan to evaluate additional cryptocurrency holdings and transactions, including but not limited to strategic investments and/or acquisitions of operating companies that we view as aligned with our cryptocurrency treasury strategy.

On September 25, 2025, we entered into a Securities Purchase Agreement (the “Datavault SPA”) with Datavault AI Inc., a Delaware corporation (“Datavault”), pursuant to which Datavault agreed to issue and sell, and we agreed to purchase, 15.0 million shares (the “Datavault Shares”) of common stock of Datavault (“Datavault Common Stock”) in the initial closing which occurred on September 26, 2025 (the “Initial Datavault Closing”) and a pre-funded warrant (the “Datavault Pre-Funded Warrant”) to purchase 263,914,094 shares of Datavault Common Stock in a subsequent closing (the “Subsequent Closing”), for an aggregate purchase price of \$150 million in Bitcoin (“BTC”) (based on the spot exchange rate for BTC as published by Coinbase.com at 8:00 p.m. (New York City time) on the trading day immediately prior to the date of the Initial Datavault Closing, or September 25, 2025 (such rate, the “Spot Exchange Rate”)). Pursuant to the Datavault SPA, the Subsequent Closing was subject to the satisfaction of the condition that the stockholders of Datavault approve the issuance of the shares of Datavault Common Stock underlying the Datavault Pre-Funded Warrant. On November 24, 2025, Datavault obtained such stockholder approval at its annual meeting. On November 25, 2025, the Subsequent Closing was consummated with us transferring an amount of BTC (based on the Spot Exchange Rate) in satisfaction of the payment of the remainder of the aggregate purchase price to Datavault and Datavault issuing the Datavault Pre-Funded Warrant to

us. On November 25, 2025, following the Subsequent Closing, we exercised the Datavault Pre-Funded Warrant in full for an aggregate exercise price of approximately \$26.4 thousand, paid in cash.

Recent Developments

Vivasor Business Combination

On December 5, 2025 (the “VHC Transaction Date”), the Company entered into a Share Transfer Agreement with EAR SPV LLC, a Delaware corporation (“EAR SPV”) and Vivasor Holding Company (“VHC”), a privately held biotechnology company, pursuant to which, among other things, EAR SPV agreed to sell, and the Company agreed to buy, all 6,101,468 shares of VHC’s Series A-1 Preferred Stock, par value \$0.00001 per share, held by EAR SPV, for an aggregate purchase price of \$9.0 million (“VHC Business Combination”). The Company evaluated VHC under the VIE model in accordance with ASC 810 and accounted for the transaction as a business combination using the acquisition method of accounting in accordance with ASC 805. The identifiable assets acquired and liabilities assumed of VHC were recorded at their estimated fair values as of the VHC Transaction Date.

Q Scan Convertible Promissory Note

On January 29, 2026, we entered into a convertible promissory note (the “Q Scan Note”) with Quantum Scan Holdings, Inc. (“Q Scan”). Pursuant to the Q Scan Note, the Company loaned Q Scan an aggregate of \$20 million. The Q Scan Note had a maturity date of October 29, 2026, and would commence accruing interest at a rate of 3.66% per annum commencing on April 29, 2026.

The Company and Q Scan entered into a common stock purchase agreement, dated January 29, 2026 (the “Q Scan Stock Purchase Agreement”). Pursuant to the Q Scan Stock Purchase Agreement, Q Scan agreed to sell to the Company, and the Company agreed to purchase from Q Scan, an aggregate of 193,021,436 shares of common stock of Q Scan (the “Q Scan Stock Purchase”) for an aggregate purchase price of approximately \$27.5 million. The closing of the Q Scan Stock Purchase shall occur within five business days of written notice delivered by Q Scan to the Company. The Q Scan Stock Purchase Agreement contains customary representations, warranties and covenants of the Company and Q Scan.

Oramed Warrant

On February 19, 2026, we entered into a warrant agreement (the “Oramed Warrant”) with Oramed Pharmaceuticals, Inc. (“Oramed”) pursuant to which Oramed deferred its right to receive an amortization payment related to the Tranche B Notes in exchange for our issuance of a new warrant to purchase an aggregate of 100,000 shares of Common Stock (the “February 2026 Warrant”) at an initial exercise price of \$20.00 per share. The deferred amortization payment was made to Oramed in November 2025. For more information, please see the sections titled “*Management’s Discussion and Analysis of Financial Condition and Results of Operations — Tranche B Notes*” and “*Management’s Discussion and Analysis of Financial Condition and Results of Operations — Oramed Warrant.*”

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.

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.

Goodwill Impairment

Goodwill impairment is recorded in connection with the impairment testing of our goodwill, and is performed at least annually and more frequently if changes in facts and circumstances indicate that the fair value of our reporting units may be less than their carrying amount. In connection with the preparation of our financial statements for the fourth quarters of 2025, we performed quantitative goodwill impairment tests which resulted in a total goodwill impairment of \$73.4 million related to business combination with Vivasor. See Note 7 to our consolidated financial statements for additional information.

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 13 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 5 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 the (i) Oramed Note with \$7.7 million principal amount outstanding as of December 31, 2025, (ii) non-refundable deposit in the aggregate principal amount of \$10.0 million (the “FSF Deposit”) and satisfied in November 2024 by the delivery of the Additional Product to Endeavor, (iii) senior secured convertible notes issued in October 2024 in the principal amount of \$50.0 million (the “Tranche B Notes”) with \$17.9 million principal amount outstanding as of December 31, 2025, and (iv) purchased revenue liability associated with the Purchase and Sale Agreement (the “ZTlido Royalty Purchase Agreement”) that we entered into in October 2024 with certain institutional investors (collectively, the “ZTlido Royalty Investors”) and Oramed and (v) purchased revenue liability associated with the Purchase and Sale Agreement (the “Gloperba-Elyxyb Royalty Purchase Agreement”) that we entered into in February 2025 with certain institutional investors (collectively, the “Gloperba-Elyxyb Royalty Investors”) and Oramed. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

(Gain) loss on Debt Extinguishment

(Gain) loss on debt extinguishment related to (gain) loss related to debt extinguishment during the period. See Note 5 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 for the twelve months ended December 31, 2025, primarily consists of interest on Scilex-St. James Loans, Vivasor debts, interest on the balances due for government and commercial rebate programs, and interest related to the deferred consideration for GLOPERBA license acquired from Romeg in 2022. Government rebate programs include state Medicaid drug rebate programs and commercial rebate programs relate to contractual agreements with commercial healthcare providers, under which we pay rebates for access to and position on that provider’s patient drug formulary. Interest expense, net for the twelve months ended December 31, 2024 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.

(Gain) Loss on Foreign Currency Exchange

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

Unrealized (Gain) Loss on Digital Assets, net

Unrealized (Gain) Loss on digital assets related to unrealized (gain) losses on our digital assets held during the period. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Realized (Gain) Loss on Digital Assets, net

Realized (Gain) Loss on digital assets related to realized (gain) losses on our digital assets held during the period. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Equity and Equity method investments

Unrealized (Gain) Loss on Equity Investments, net

Unrealized (Gain) Loss on equity investments related to unrealized (gain) losses on our investment in Datavault held during the period, prior to obtaining significant influence. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Realized (Gain) Loss on Equity Investments, net

Realized (Gain) Loss on equity investments related to realized (gain) losses on our investment in Datavault held during the period, prior to obtaining significant influence. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

The Company utilizes the equity method to account for investments when the Company has the ability to exercise significant influence, but not control over the investees. In determining whether the Company has significant influence, the Company considers

its ownership levels, whether it has the right to nominate board members, and whether it has the ability to participate in the policy-making process of the investee, among other criteria.

Investments granting significant influence are generally accounted for using the equity method unless the fair value option is elected.

Unrealized (Gain) Loss on Equity Method Investments, net

Unrealized (Gain) Loss on equity method investments (or “EMI”) related to unrealized (gain) losses on our investment in Datavault accounted for using the equity method. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Realized (Gain) Loss on Equity Method Investments, net

Realized (Gain) Loss on equity method investments (or “EMI”) related to realized (gain) losses on our investment in Datavault accounted for using the equity method. See Note 5 titled “Fair Value Measurements” to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Results of Operations

The following tables summarize our results of operations for the years ended December 31, 2025, and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Changes
Statements of Operations Data:			
Net revenue	\$ 30,253	\$ 56,590	\$ (26,337)
Net operating costs and expenses:			
Cost of revenue	10,599	16,689	(6,090)
Research and development	20,710	9,641	11,069
Selling, general and administrative	266,884	119,016	147,868
Goodwill impairment	73,358	—	—
Intangible amortization	4,364	4,031	333
Legal settlements	345	(9,391)	9,736
Total net operating costs and expenses	376,260	139,986	162,916
Loss from operations	(346,007)	(83,396)	(189,253)
Other (income) expense, net:			
(Gain) loss on derivative liability	22,693	(17,378)	40,071
Change in fair value of debt and liability instruments	25,351	4,782	20,569
Loss on debt extinguishment, net	7,351	—	7,351
Interest expense, net	11,459	1,963	9,496
Loss on foreign currency exchange	(86)	45	(131)
Unrealized loss on digital assets, net	12,180	—	12,180
Realized loss on digital assets, net	30,200	—	30,200
Unrealized (gain) on equity investment, net	(2,692)	—	(2,692)
Realized (gain) on equity investments, net	(19,218)	—	(19,218)
Unrealized (gain) on equity method investments carried at fair value, net	(54,760)	—	(54,760)
Realized (gain) on equity method investments carried at fair value, net	(4,657)	—	(4,657)
Realized (gain) on securities	199	—	—
Total other (income) expense, net	28,020	(10,588)	77,356
Loss before income taxes	(374,027)	(72,808)	(266,609)
Income tax expense (benefit)	26	(1)	27
Net loss	\$ (374,053)	\$ (72,807)	\$ (266,636)

Comparison of the Years Ended December 31, 2025, and 2024:

Net Revenue

The following table summarizes net revenue by product for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Increase (Decrease)
ZTlido			
Net Revenue	\$ 25,626	\$ 52,094	\$ (26,468)
ELYXYB			
Net Revenue	3,798	4,258	(460)
GLOPERBA			
Net Revenue	151	238	(87)
Vivasor Contract Revenue			
Net Revenue	678	—	678
Total Net Revenue	<u>\$ 30,253</u>	<u>\$ 56,590</u>	<u>\$ (27,015)</u>

Net revenue for the years ended December 31, 2025 and 2024 was \$30.3 million and \$56.6 million, respectively. The decrease of \$26.3 million comprised of \$26.4 million, \$0.5 million and \$0.1 million decrease in net product sales of ZTlido, ELYXYB and GLOPERBA, respectively, with GLOPERBA sales commencing in June 2024. The decrease in net sales of ZTlido and ELYXYB was driven by a decrease in gross sales of approximately 26% and 7%, respectively, as a result of a decrease in the sales volume and a decrease in sales rebate for inflation, partially offset by an increase in sales returns and a standard industry annual price increase, effective January 1, 2025.

Cost of Revenue

The following table summarizes cost of revenue by product for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Increase (Decrease)
ZTlido			
Cost of Revenue	\$ 4,586	\$ 6,249	\$ (1,663)
Cost of Revenue - Royalties	4,432	9,854	(5,422)
Other Cost of Revenue	44	45	(1)
Total ZTlido	9,062	16,148	(7,086)
ELYXYB			
Cost of Revenue	210	181	29
Cost of Revenue - Royalties	304	341	(37)
Total ELYXYB	514	522	(8)
GLOPERBA			
Cost of Revenue	10	19	(9)
Total GLOPERBA	10	19	(9)
Vivasor Contract Revenue			
Cost of Revenue - Services	1,013	—	1,013
Total Vivasor Contract Revenue	1,013	—	—
Total Cost of Revenue	<u>\$ 10,599</u>	<u>\$ 16,689</u>	<u>\$ (7,103)</u>

Cost of revenue for the years ended December 31, 2025 and 2024 was \$10.6 million and \$16.7 million, respectively. Cost of revenue for ZTlido decreased by \$7.1 million due to decrease in gross product sales of approximately 25%, driven by decrease in sales demand.

Research and Development Expenses

The following table summarizes research and development expenses by project for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		Increase (Decrease)
	2025	2024	
SP-102			
Contracted R&D	\$ 1,429	\$ 1,160	\$ 269
Personnel	922	467	455
Other	204	57	147
Total SP-102	2,555	1,684	871
SP-103			
Contracted R&D	5,909	2,472	3,437
Personnel	1,174	1,317	(143)
Other	261	188	73
Total SP-103	7,344	3,977	3,367
SP-104			
Contracted R&D	3	50	(47)
Personnel	119	292	(173)
Other	42	—	42
Total SP-104	164	342	(178)
GLOPERBA			
Contracted R&D	385	687	(302)
Personnel	435	813	(378)
Other	643	116	527
Total GLOPERBA	1,463	1,616	(153)
ELYXYB			
Contracted R&D	352	758	(406)
Personnel	1,175	1,068	107
Other	319	196	123
Total ELYXYB	1,846	2,022	(176)
R&D Discovery Project			
Contracted R&D	1,086	—	1,086
Personnel	834	—	835
Other	5,417	—	5,417
Total Discovery Project	7,337	—	7,338
Total Research and Development Expenses	\$ 20,710	\$ 9,641	\$ 11,070

Research and development expenses for the years ended December 31, 2025, and 2024 were \$20.7 million and \$9.6 million, respectively. The increase was primarily attributed to higher development costs related to SP-102 and additional expenses related to the development of KDS2010 by Scilex Bio.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended December 31, 2025 and 2024 were \$266.9 million and \$119.0 million, respectively. The increase of approximately \$147.9 million was primarily due to a \$148.7 million increase related to issuance costs for reverse recapitalization with Denali and other financing activities, a \$18.6 million increase in advisory and financing expenses, a \$4.0 million increase in contracted services, a \$0.2 million increase in allowances for expected credit losses on accounts receivable, partially offset by a \$5.7 million decrease in rebate expense related to future shipments of the Additional Product (as defined below) under the Satisfaction Agreement, a \$1.0 million decrease in insurance costs, a \$1.3 million decrease in legal fees, a \$6.1 million decrease in personnel expense, a \$4.1 million decrease in travel expenses, a \$5.4 million decrease in marketing expenses.

Goodwill Impairment

In connection with preparing our financial statements for the year ended December 31, 2025, we evaluated the carrying value of goodwill for impairment in response to impairment indicators identified during our business combination with Vivasor. As such, we performed a quantitative goodwill impairment test on each of our newly consolidated subsidiary and as a result, we concluded that Vivasor had a carrying value that exceeded its estimated fair value. As a result, we recorded a goodwill impairment charge of \$73.4 million during the year ended December 31, 2025, which was the entire goodwill balance for Vivasor. See Note 7 to our consolidated financial statements for additional information.

Intangible Amortization Expense

Intangible amortization expense for the years ended December 31, 2025 and 2024 was \$4.4 million and \$4.0 million, respectively. The increase of \$0.4 million is related to the amortization of the Datavault acquired license (see Note 7 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 Expense

Legal settlements for the years ended December 31, 2025 and 2024 were \$0.3 million and \$(9.4 million), respectively. The increased expense in 2025 compared to 2024 is primarily due to payments received by the Company from the litigation settlement that was entered into during the first quarter of 2024. See Note 13 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, 2025 and 2024 were \$22.7 million and (\$17.4 million), respectively. The loss recognized during the year ended December 31, 2025 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, the December 2024 RDO Common Warrants, the Exchange Warrants (as defined below), September 2025 Warrants and November 2025 Warrants (each as defined below). 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.

Change in Fair Value of Debt and Liability Instruments

Change in fair value of debt and liability instruments for the years ended December 31, 2025 and 2024 was \$25.4 million and \$4.8 million, respectively. The loss recognized during the year ended December 31, 2025 was attributed to losses of \$8.4 million for the Oramed Note, \$2.4 million for the purchased revenue liability pursuant to the ZTlido Royalty Purchase Agreement, \$1.8 million for the purchased revenue liability pursuant to the Gloperba-Elyxyb Royalty Purchase Agreement, totaling \$4.4 million, a \$12.9 million in change in fair value of the Tranche B Notes and a \$0.3 million gain in change in fair value remeasurement gain related to the termination of the Tumim Purchase Agreement. The loss recognized during the year ended December 31, 2024, 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 \$28.2 million remained outstanding as of December 31, 2025. 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 \$17.5 million remained outstanding as of December 31, 2025. The Scilex-St. James Loans were received in December 2025 in the principal amount of \$22.6 million, of which the principal amount \$22.6 million remained outstanding as of December 31, 2025.

(Gain) loss on debt extinguishment, net

(Gain) loss on debt extinguishment, net for the years ended December 31, 2025 and 2024 was \$7.4 million and nil, respectively. Loss recognized during the year ended December 31, 2025 was attributed to the loss associated with the exchange of October 2024 Warrant

for the Exchange Warrants (as defined below), and exchange of April 2024 RDO Common Warrants and December 2024 RDO Common Warrants for the November 2025 Warrants (each as defined below).

Interest Expense, Net

Interest expense, net for the years ended December 31, 2025 and 2024 was \$11.5 million and \$2.0 million, respectively. Interest expense of \$11.5 million primarily consists of interest on the balances due for government and commercial rebate programs. Interest expense of \$2.0 million consists of interest related to the Revolving Facility.

Unrealized (Gain) Loss on Digital Assets, net

Unrealized loss on digital assets for the years ended December 31, 2025 and 2024 was \$12.2 million, and nil, respectively. The unrealized loss during the twelve months ended December 31, 2025, was attributed to the unrealized loss on digital assets held, which had depreciated in value.

Realized (Gain) Loss on Digital Assets, net

Realized loss on digital assets for the years ended December 31, 2025 and 2024 was \$30.2 million, and nil, respectively. The realized loss during the twelve months ended December 31, 2025, was attributed to the realized loss on digital assets sold, which had depreciated in value.

Unrealized (Gain) Loss on Equity Investments, net

Unrealized (gain) on equity investments for the year ended December 31, 2025 and 2024 was \$2.7 million and nil, respectively. The unrealized (gain) during the twelve months ended December 31, 2025, was attributed to the unrealized (gain) on Datavault investment held that had appreciated in value.

Realized (Gain) Loss on Equity Investments, net

Realized (gain) on equity investments for the year ended December 31, 2025 and 2024 was \$19.2 million and nil, respectively. The realized (gain) during the twelve months ended December 31, 2025, was attributed to the realized (gain) on Datavault investment sold that had appreciated in value.

Unrealized (Gain) Loss on Equity Method Investments, net

Unrealized (gain) on equity method investments for the year ended December 31, 2025 and 2024 was \$54.8 million and nil, respectively. The unrealized (gain) during the twelve months ended December 31, 2025 was attributed to the unrealized (gain) on Datavault investment held that had appreciated in value.

Realized (Gain) Loss on Equity Method Investments, net

Realized (gain) on equity method investments for the year ended December 31, 2025 and 2024 was \$4.7 million and nil, respectively. The realized (gain) during the twelve months ended December 31, 2025 was attributed to the realized (gain) on Datavault investment sold that had appreciated in value.

Liquidity and Capital Resources

As of December 31, 2025, we had cash and cash equivalents of approximately \$5.0 million.

We have funded our operations in the years ended December 2025 and 2024 primarily through equity and debt financings pursuant to the A&R Yorkville Purchase Agreement, and the B. Riley Purchase Agreement, together as the “Standby Equity Purchase Agreements”) with B. Riley Principal Capital II, LLC (“B. Riley”), the Sales Agreement (the “ATM Sales Agreement”) with B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the “Sales Agents”), the Oramed Note and Tranche B Notes, various registered direct offerings and private placements and the Scilex-St. James Loans, as well as deferred consideration related to the GLOPERBA license acquired from Romeg in 2022. The following table summarizes the aggregate carrying value indebtedness of these issuances as of December 31, 2025, and December 31, 2024 (in thousands):

	December 31, 2025	December 31 , 2024
Oramed Note (outstanding principal balance and paid in kind interest: \$28.2 million and \$25.0 million as of December 31, 2025 and 2024, respectively)	\$ 27,688	\$ 12,161
Tranche B Notes (outstanding principal balance: \$17.9 million and \$38.0 million as of December 31, 2025 and 2024, respectively)	17,500	23,560
Promissory Notes	3,517	—
Purchased Revenue Liability	8,400	6,800
Deferred Consideration with Romeg	2,448	2,895
Scilex-St. James Loans (outstanding principal balance: \$22.6 million and nil as of December 31, 2025 and 2024, respectively)	21,528	—
Vivasor Related Debt (outstanding principal balance: \$47.0 million and nil as of December 31, 2025 and 2024, respectively)	46,967	—
Total indebtedness	<u>\$ 128,048</u>	<u>\$ 45,416</u>

The Oramed Note

As of December 31, 2025, the fair value of the Oramed Note outstanding was \$28.2 million pursuant to the Scilex-Oramed SPA (see Note 8 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, 2025, the fair value of the Tranche B Notes outstanding was \$17.5 million pursuant to the Tranche B Securities Purchase Agreement (see Note 8 titled “*Debt*” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Promissory Notes

As of December 31, 2025, the carrying value of the Promissory Notes outstanding was \$3.5 million pursuant to the Promissory Notes (see Note 8 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, 2025, the fair value of the purchased revenue liability was \$8.4 million pursuant to the ZTlido Royalty Purchase Agreement and Gloperba-Elyxyb Royalty Purchase Agreement (see Note 8 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, 2025, we have \$2.4 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.

Vivasor Related Debt

As of December 31, 2025, the aggregated outstanding principal balance of the Vivasor-related debt was \$47.0 million pursuant to the Vivasor-related debt agreement (see Note 8 titled “*Debt*” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Scilex-St. James Loans

As of December 31, 2025, the carrying value of the Scilex-St. James Loans outstanding was \$21.5 million pursuant to the Scilex-St. James Loan Agreement (see Note 8 titled “*Debt*” and Note 16 titled “*Subsequent Events*” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

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, 2025, and 2024, Scilex Pharma made royalty payments in the amount of \$6.3 million and \$8.3 million, respectively. As of December 31, 2025, and 2024, Scilex Pharma had ending balances of accrued royalty payables of \$2.1 million and \$4.0 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, 2025, and 2024, we made royalty payments in the amount of \$0.2 million and \$0.3 million, respectively. As of December 31, 2025, and December 31, 2024, we had ending balances of accrued royalty payables of \$0.2 million and \$0.1 million.

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 each of the years ended December 31, 2025, and 2024, we made royalty payments in the amount of \$0.6 million.

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” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

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. During the year ended December 31, 2025, no sales of Common Stock had been made under the ATM Sales Agreement. During the year ended December 31, 2024, we sold 78,976 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately \$2.7 million.

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”), 168,068 shares (the “February 2024 BDO Firm Shares”) of the Common Stock, and accompanying common warrants to purchase up to an aggregate of 168,068 shares of Common Stock (the “February 2024 BDO Firm Warrants”). Each February 2024 BDO Firm Share was sold together with a February 2024 BDO Firm Warrant at a combined public offering price of \$59.50. The combined price per Firm Share and accompanying February 2024 BDO Firm Warrant paid by the Underwriters was \$54.74, which amount reflects the combined public offering price of \$59.50, 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 \$59.50 per share. The exercise price of the February 2024

BDO Common Warrants is subject to certain adjustments, including (but not limited to) 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 13,446 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 \$74.38 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 428,572 shares (the “April 2024 RDO Shares”) of Common Stock, and (ii) common warrants to purchase up to 428,572 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 \$35.00, 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 \$38.50 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 34,286 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 \$43.75 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 Commitment Closing”) and (ii) the remaining \$15 million within 60 days following the Initial Commitment 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 Commitment 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 the Tranche B Securities Purchase Agreement 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) the “Tranche B Notes”), which 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 \$38.15 per share (which was automatically reduced to \$36.40 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 214,284 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 \$38.15 per share of Common Stock (which was automatically reduced to \$36.44 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 107,142 shares of Common Stock in the aggregate. The October 2024 Noteholder Warrants issued to Oramed are initially exercisable for 107,142 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, 2024 (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 104,848 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.

Pursuant to the Tranche B Notes, commencing on January 2, 2025, we were 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, collectively 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 and then further to October 8, 2026. In consideration of such deferral, (i) SCLX JV delivered to the Tranche B Noteholders an aggregate of 142,855 shares of Common Stock held by SCLX JV, (ii) we paid an aggregate of \$1.1 million in respect of a portion of the First Amortization Payment and related make-whole interest, and (iii) we entered into the Gloperba-Elyxyb Royalty Purchase Agreement.

Oramed Warrant

Pursuant to the Tranche B Notes, we were required to make an amortization payment on October 1, 2025 (the “Second Amortization Payment”) to Oramed. On December 31, 2025, the Company entered into a commitment letter with Oramed to purchase 50,000 shares of common stock of Scilex, par value 0.0001 per share, with an exercise price of \$20.00 per share (in each case subject to adjustment for recapitalizations, stock splits, stock dividends and similar types of transactions) and a verbal commitment for Oramed to purchase an additional 50,000 shares for a total of 100,000 shares of common stock of Scilex to which Oramed deferred its right to receive this amortization payment. On February 19, 2026, the Company issued to Oramed a new warrant to purchase an aggregate of 100,000 shares of Common Stock (the “February 2026 Warrant”) at an initial exercise price of \$20.00 per share. The deferred amortization payment was made to Oramed in November 2025.

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 753,009 shares of Common Stock, (ii) pre-funded warrants to purchase up to 68,604 shares of Common Stock (the “December 2024 RDO Pre-Funded Warrants”) and (iii) common warrants to purchase up to 1,642,871 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 \$20.65 and (b) per Pre-Funded Warrant and accompanying December 2024 RDO Common Warrants was \$20.6499. 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.

Tumim Purchase Agreement

In July 2025, we entered into a common stock purchase agreement (the “Tumim Purchase Agreement”) and a related registration rights agreement (the “Tumim Registration Rights Agreement”) with Tumim Stone Capital, LLC (“Tumim”). Pursuant to the Tumim Purchase Agreement, we had the right but not the obligation, to sell, from time to time, to Tumim up to \$100.0 million in aggregate gross purchase price of shares of Common Stock in our sole discretion, subject to certain conditions and limitations, during the term of 24 months. Through December 31, 2025, there were no sales of shares of Common Stock under the Tumim Purchase Agreement.

In connection with the Tumim Purchase Agreement, we incurred an obligation to issue 150,000 shares of Common Stock (“Commitment Shares Obligation”) to Tumim. The Commitment Shares Obligation was determined to be an equity-linked contract and met all the conditions for equity classification. We recognized an amount of \$3.0 million in expense and in accrued expenses. As part of the termination, no shares were issued and instead Tumim was paid an aggregate of \$2.7 million.

During the twelve months ended December 31, 2025, there were no sales of shares of Common Stock under the Tumim Purchase Agreement. As of December 31, 2025, Tumim Purchase Agreement has been terminated.

Warrant Exchange Agreements

On July 22, 2025, the Company entered into Warrant Exchange Agreements (each, a “Warrant Exchange Agreement” and collectively, the “Warrant Exchange Agreements”) with certain holders of the Company’s then-existing Tranche B warrants (such certain holders (excluding Oramed), the “Exchanging Warrant Holders”) to purchase shares of Common Stock (such Tranche B warrants held by the Exchanging Warrant Holders, the “Existing Tranche B Warrants”). Pursuant to the Warrant Exchange Agreements, the Company and the Exchanging Warrant Holders effected a voluntary securities exchange whereby the Exchanging Warrant Holders exchanged the Existing Tranche B Warrants, which were then exercisable for an aggregate of 107,142 shares of Common Stock at an exercise price of \$36.40 per share, originally issued pursuant to the Tranche B Securities Purchase Agreement, for warrants to purchase an aggregate of 500,000 shares of Common Stock (the “Exchange Warrants”) at an exercise price of \$40.00 per share (the “Exchange Warrant Exercise Price”).

Warrant Exercise Agreement

On September 30, 2025, we entered into a Warrant Exercise Agreement (the “Warrant Exercise Agreement”) with certain holders of the December 2024 RDO Common Warrants, pursuant to which, among other things, such holders exercised the December 2024 RDO Common Warrants to purchase 179,236 shares and deferred, for a deferral fee of \$7.72 per share being exercised, their right to receive an amortization payment scheduled to be paid by us on October 1, 2025 as set forth in the amortization schedule included in the Tranche B Notes in exchange for our agreement to issue new warrants to purchase an aggregate of 275,000 shares of Common Stock (the “September 2025 Warrants”) at an exercise price of \$20.00 per share.

Warrant Inducement Agreement

On November 23, 2025, we entered into a warrant inducement agreement (the “Warrant Inducement Agreement”) with a certain institutional investor, pursuant to which the investor agreed to exercise (the “Exercise”) (i) a warrant to purchase shares of Common Stock issued to the investor on April 25, 2024, which was then exercisable for 428,572 shares and has an exercise price of \$38.50 per share (the “Existing April 2024 Warrants”) and (ii) a warrant to purchase shares of Common Stock issued to the investor on December 13, 2024, which was then exercisable for 475,824 shares and has an exercise price of \$22.72 per share (together with the Existing April 2024 Warrants, the “Existing Warrants”). As consideration for the Exercise, the Company agreed to (i) reduce the exercise price of the Existing Warrants to \$22.51 per share and (ii) issue to the investor the “November 2025 Investor Warrant”) to purchase up to an aggregate of 1,356,594 shares of Common Stock with an exercise price of \$29.00 per share (the “November 2025 Investor Warrant Exercise Price”) in a private placement pursuant to Section 4(a)(2) of the Securities Act. The November 2025 Investor Warrant shall be immediately exercisable and in certain circumstances may be exercised on a cashless basis. The November 2025 Investor Warrant shall expire five years from the date of its issuance. The November 2025 Investor Warrant Exercise Price shall be subject to adjustment for any stock split, stock dividend, stock combination, recapitalization or similar event. Further, in connection with a warrant inducement agreement and pursuant to the terms of an engagement agreement by and between the Company and StockBlock, dated as of March 22, 2024 (as amended and supplemented from time to time, the “Engagement Agreement”), the Company has agreed to issue the placement agents or their designees, warrants to purchase up to an aggregate of 72,352 shares of Common Stock (the “November 2025 Placement Agent Warrants” and, together with the November 2025 Investor Warrant, the “November 2025 Warrants”). The Placement Agent Warrants have substantially the same terms of the November 2025 Warrant, including exercise price and expiration.

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.

However, our ability to generate proceeds will depend on the market price of our Common Stock. In addition to the liquidity provided by revenue generating products, as of December 31, 2025, we would receive up to an aggregate of approximately \$80.0 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 \$402.50 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. If the price of our Common Stock remains below \$402.50 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 Placement Agent Warrants, Deposit Warrant, October 2024 Noteholder Warrants, October 2024 Placement Agent Warrants, December 2024 RDO Common Warrants, StockBlock Warrants, the Exchange Warrants, the September 2025 Warrants, the November 2025 Warrants and the February 2026 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,	
	2025	2024
Cash Flow Data:		
Net cash proceeds from operating activities	\$ 3,816	\$ 19,349
Net cash proceeds from (used for) investing activities	4,084	(2,675)
Net cash (used for) financing activities	(5,461)	(18,131)
Effect of exchange rate changes on cash	(760)	—
Net change in cash, cash equivalents and restricted cash	<u>\$ 1,679</u>	<u>\$ (1,457)</u>

Cash Flows from Operating Activities

Net cash provided by operating activities was \$3.8 million, for the year ended December 31, 2025 compared to net cash provided by operating activities of \$19.3 million for the same period in 2024.

Significant changes impacting net cash provided by operating activities for the year ended December 31, 2025 compared to the same period in 2024 were as follows:

- Net loss of \$374.1 million for the year ended December 31, 2025 compared to a net loss of \$72.8 million for the year ended December 31, 2024.
- A loss on derivative liability of \$22.7 million for the year ended December 31, 2025 compared to a gain of \$17.4 million for the prior year period, a difference of \$40.1 million. The change is primarily due to change in fair value of derivative liability.
- Transaction costs related to the Semnur Business Combination of \$140.0 million for the year ended December 31, 2025 and nil for the prior year period, a difference of \$140.0 million. The change is primarily due to the closing of the Semnur Business Combination that occurred in September 2025.
- A loss on digital assets of \$42.4 million for the year ended December 31, 2025 and nil for the prior year period, a difference of \$42.2 million. The change is primarily due to the digital assets held, which had depreciated in value.

- A loss on convertible debentures of \$25.4 million for the year ended December 31, 2025 compared to a \$4.8 for the prior year period, a difference of \$28.3 million. The change is primarily due to change in fair value of debt and liability instruments.
- A loss on equity method investment of \$59.4 million for the year ended December 31, 2025 and nil for the prior year period, a difference of \$446.1 million. The change is primarily due to the Datavault investment, which had depreciated in value.
- A loss on debt extinguishment of \$7.4 million for the year ended December 31, 2025 and nil for the prior year period, a difference of \$7.4 million. The change is primarily due to the loss associated with the exchange of October 2024 Warrant for the Exchange Warrants (as defined below) and exchange of April 2024 RDO Common Warrants and December 2024 RDO Common Warrants for the November 2025 Warrants (each as defined below).
- A gain on purchase of pre-funded warrants of \$– million for the year ended December 31, 2025 compared to a \$1.2 million gain for the prior year period, a difference of \$472.0 million. The change is primarily due to gain on purchase of Datavault pre-funded warrants.
- A gain on equity investment of \$21.9 million for the year ended December 31, 2025 and nil for the prior year period, a difference of \$21.9 million. The change is primarily due to the Datavault investment, which had appreciated in value.
- Other non-cash reconciling items of approximately \$33.1 million and \$38.7 million for the year ended December 31, 2025 and 2024, respectively, a difference of approximately \$5.4 million related to depreciation and amortization and non-cash operating lease cost, financing costs, allocated expense for financial instrument at fair value, in-process research and development expense and stock-based compensation and changes in operating assets and liabilities that provided \$114.0 million of cash, partially offset by our net loss of \$374.1 million, compared to 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, 2024.

Cash Flows from Investing Activities

For the year ended December 31, 2025, net cash provided by investing activities was approximately \$4.1 million and was primarily related to \$39.6 million related to sale of Datavault shares, partially offset by \$15.8 million related to purchase of Bitcoin with cash, \$9.2 million related to cash paid to settle Datavault obligation, \$1.0 million related to repayments on promissory note, \$0.6 million payments of deferred consideration for Romeg intangible asset acquisition under the Romeg License Agreement, and \$0.2 million related to purchase of Gloperba Ex-U.S. rights, in-process research and development assets.

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 6 titled “*Balance Sheet Components*” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Cash Flows from Financing Activities

For the year ended December 31, 2025, net cash used for financing activities was approximately \$5.5 million and is primarily related to the repayment of an aggregate of \$20.5 million of the Tranche B Notes, a \$2.7 million payment for the termination of the Tumim Purchase Agreement, a \$0.9 million payment of excise tax on stock repurchases, and a payment of \$27.0 million cash consideration paid in connection with Penny Warrants repurchase, an aggregate of \$3.2 million payment under the ZTlido Royalty Purchase Agreement and Gloperba-Elyxyb Royalty Purchase Agreement, \$0.1 million in payment of debt issuance costs, a \$1.7 million transaction costs paid in connection with issuance of Common Stock and exchange of April 2024 RDO Warrants and December 2024 RDO Warrants for November 2025 Warrants, \$1.0 million transaction costs paid in connection with share repurchase, partially offset by \$20.4 million in gross proceeds from the exercise of April 2024 RDO Warrants and December 2024 RDO Warrants, together, the Original Warrants, \$10.2 million in proceeds from the exercise of December 2024 Warrants, \$21.5 million in proceeds from borrowings pursuant to the Scilex-St. James Loan Agreement.

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 \$42.2 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 \$25.5 million in gross proceeds from issuance of Tranche B Notes and ZTlido Royalty Purchase Agreement, \$10.7 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.

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 "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.

There have been no material changes in our critical accounting estimates as compared to the critical accounting estimates disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, except for the accounting treatment for the cryptocurrency assets, noncontrolling interests and equity method investment as discussed in Note 1 to the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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.

Deductions from Revenues

The Company's gross product revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration represents chargebacks, rebates, sales allowances and sales returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these product revenue deductions on net sales for a reporting period.

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.

The allowance for product returns is determined based on historical return rates, product shelf life, and inventory levels within the distribution channel. This estimated rate is applied to gross sales to accrue the sales allowance. Discounts, typically 2% of sales, are offered to wholesalers for prompt payment. Upon receipt of actual product returns, the Company updates its balances accordingly, while continuing to refine its estimates based on historical trends.

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 expired, 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. The Company evaluated the Scilex-St. James Loan Agreement for embedded derivatives and identified certain features that required bifurcation because they are not clearly and closely related to the host instrument. The embedded derivatives relate to (i) default provisions that could require additional interest payments, and (ii) a provision which could require the settlement of the principal amount of the Scilex-St. James Loans through the Scilex-St. James Pledged Securities upon an uncured event of default. The Company determined that the fair value of these embedded derivatives was immaterial as of the issuance dates of the Scilex-St. James Loans and as of December 31, 2025.

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 8 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.

Goodwill Impairment

We test for goodwill impairment at the reporting unit level. We consider our reporting units for goodwill impairment testing. When evaluating goodwill for impairment, we may first assess qualitative factors to determine whether it is more likely than not the fair value of a reporting unit is less than its carrying amount. Qualitative factors include macroeconomic conditions, industry and market conditions and overall company financial performance. If, after assessing the totality of events and circumstances, we determine that it is more likely than not the fair value of the reporting unit is greater than its carrying amount, the quantitative impairment test is unnecessary. The quantitative impairment test, if necessary, involves comparing the fair value of each reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of the reporting unit. If the fair value exceeds the carrying value, we conclude that no goodwill impairment has occurred. If the carrying value exceeds the fair value, we recognize an impairment charge in an amount equal to the excess, not to exceed the carrying value of the goodwill. Determining the fair value of a reporting unit when performing a quantitative impairment test involves the use of significant estimates and assumptions to evaluate the impact of operational and economic changes on each reporting unit. We estimate the fair value using the income and market valuation approaches. We apply a market approach, which develops a value correlation based on the market capitalization of similar publicly traded companies, referred to as a multiple, to apply to the operating results of the reporting units. The primary market multiples to which we compare include revenue and earnings before interest, taxes, depreciation, and amortization. We base fair value estimates on assumptions we believe to be reasonable but that are unpredictable and inherently uncertain. Actual future results may differ from those estimates. We confirm the reasonableness of the valuation conclusions by comparing the indicated values of all the reporting units to the overall company value indicated by the stock price and outstanding shares as of the valuation date, or market capitalization.

Impairment test

During the fiscal fourth quarter of 2025, management determined that a triggering event had occurred as a result of business combination with Vivasor, and a further decrease in our stock price. Therefore, we performed an impairment test post consolidation of Vivasor, as of the last day of fiscal December 2025.

Based on the results of our year-end impairment test, we concluded that the carrying amount of goodwill for Vivasor exceeded the estimated fair value and we recorded a non-cash impairment charge of \$73.4 million, which was included in goodwill and intangible asset impairment charge on our Consolidated Statements of Operations and Comprehensive Income (Loss) for the fiscal year ended December 31, 2025. As a result of this impairment charge, \$73.4 million of the total goodwill carrying value of \$73.4 million for Vivasor was impaired. The goodwill impairment was primarily driven by company-specific factors following the acquisition, including a more challenging capital markets environment for early-stage biotechnology companies, increased cost of capital, and updated expectations regarding the timing and probability of future development and financing activities, which together resulted in a decline in the estimated fair value of the reporting unit below its carrying amount. Based on our year-end impairment test, we concluded that, other than goodwill impairment for Vivasor, the rest of the goodwill balance was not impaired. See Note 7: *Goodwill and Intangible Assets*, to our consolidated financial statements found elsewhere in this Annual Report on Form 10-K, for additional details on the 2025 goodwill impairment. There were no goodwill impairment charges recorded during fiscal 2024.

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.

None.

Item 9A. Controls and Procedures.***Evaluation of Disclosure Controls and Procedures***

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

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report 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, 2025, based on the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our ICFR was effective as of December 31, 2025.

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, 2025, that have materially affected, or are reasonably likely to materially affect, our ICFR.

Item 9B. Other Information.

During the fourth quarter ended December 31, 2025, 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 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 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 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 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 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 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 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 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 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2026 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#	<u>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).</u>
2.2	<u>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).</u>
2.3#	<u>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).</u>
2.4^#	<u>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).</u>
2.5#	<u>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).</u>
2.6#	<u>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).</u>
2.7#	<u>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).</u>
2.8#	<u>Amendment No. 1 to Agreement and Plan of Merger, dated as of April 16, 2025, by and among Denali Capital Acquisition Corp., Denali Merger Sub Inc. and Semnur Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on April 21, 2025).</u>
2.9	<u>Amendment No. 2 to Agreement and Plan of Merger, dated as of July 22, 2025, by and among Denali Capital Acquisition Corp., Denali Merger Sub Inc. and Semnur Pharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
3.1	<u>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).</u>

Exhibit Number	Description
3.2	<u>Certificate of Amendment to the Restated Certificate of Incorporation of Scilex Holding Company, filed with the Secretary of State of the State of Delaware on April 14, 2025 (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on April 15, 2025).</u>
3.3	<u>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).</u>
3.4	<u>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).</u>
3.5	<u>Certificate of Elimination 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 February 3, 2026).</u>
3.6	<u>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).</u>
4.1	<u>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).</u>
4.2	<u>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).</u>
4.3	<u>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).</u>
4.4	<u>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).</u>
4.5	<u>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).</u>
4.6	<u>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).</u>
4.7	<u>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).</u>
4.8	<u>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).</u>
4.9	<u>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).</u>
4.10	<u>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).</u>
4.11	<u>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).</u>
4.12	<u>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).</u>
4.13	<u>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).</u>
4.14	<u>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).</u>
4.15	<u>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).</u>

Exhibit Number	Description
4.16	<u>Amendment No. 1 to Common Stock Purchase Warrant, dated December 11, 2024, between Scilex Holding Company and the investor named therein (incorporated by reference to Exhibit 4.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 13, 2024).</u>
4.17	<u>Description of Securities of Scilex Holding Company (incorporated by reference to Exhibit 4.16 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 31, 2025).</u>
4.18	<u>Form of Exchange Warrant (incorporated by reference to Exhibit 10.6 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
4.19	<u>Form of September 2025 Warrant (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 1, 2025).</u>
4.20	<u>Form of November 2025 Investor Warrant (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 24, 2025).</u>
4.21	<u>Form of November 2025 Placement Agent Warrant (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 24, 2025).</u>
10.1*	<u>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).</u>
10.2*	<u>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).</u>
10.3*	<u>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).</u>
10.4*	<u>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).</u>
10.5*	<u>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).</u>
10.6*	<u>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).</u>
10.7*	<u>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).</u>
10.8*	<u>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).</u>
10.9*	<u>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).</u>
10.10*	<u>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).</u>
10.11*	<u>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).</u>
10.12*	<u>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).</u>
10.13*	<u>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).</u>

Exhibit Number	Description
10.14^	<u>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).</u>
10.15^	<u>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).</u>
10.16^	<u>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).</u>
10.17^	<u>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).</u>
10.18^	<u>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).</u>
10.19^	<u>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 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).</u>
10.20	<u>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).</u>
10.21#	<u>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).</u>
10.22	<u>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).</u>
10.23#	<u>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).</u>
10.24	<u>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).</u>
10.25^	<u>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).</u>
10.26	<u>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).</u>
10.27^	<u>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).</u>

Exhibit Number	Description
10.28^	<u>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).</u>
10.29	<u>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).</u>
10.30	<u>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).</u>
10.31#^	<u>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).</u>
10.32	<u>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).</u>
10.33^	<u>Second Amendment to Master Services Agreement, dated as of June 6, 2023, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC (incorporated by reference to Exhibit 10.33 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 31, 2025).</u>
10.34	<u>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).</u>
10.35#	<u>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).</u>
10.36#^	<u>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).</u>
10.37#^	<u>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 (incorporated by reference to Exhibit 10.37 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 31, 2025).</u>
10.38	<u>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).</u>
10.39	<u>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).</u>
10.40#	<u>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).</u>
10.41#	<u>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).</u>

Exhibit Number	Description
10.42#	<u>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).</u>
10.43	<u>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).</u>
10.44	<u>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).</u>
10.45#	<u>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).</u>
10.46	<u>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. (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).</u>
10.47#	<u>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).</u>
10.48#	<u>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).</u>
10.49#	<u>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).</u>
10.50*	<u>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).</u>
10.51*	<u>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).</u>
10.52*	<u>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).</u>
10.53	<u>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).</u>
10.54	<u>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).</u>
10.55	<u>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).</u>
10.56^	<u>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).</u>

Exhibit Number	Description
10.57#	<u>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).</u>
10.58#	<u>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).</u>
10.59#	<u>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).</u>
10.60	<u>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).</u>
10.61	<u>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).</u>
10.62	<u>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).</u>
10.63	<u>Consent and Side Letter, dated October 2, 2024, by and between Scilex Holding Company and Oramed Pharmaceuticals, Inc. (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 7, 2024).</u>
10.64#	<u>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).</u>
10.65#	<u>Purchase and Sale Agreement, dated October 8, 2024, by and among Scilex Holding Company, Scilex 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).</u>
10.66#	<u>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).</u>
10.67	<u>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).</u>
10.68	<u>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).</u>
10.69	<u>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).</u>
10.70	<u>Consent and Amendment, dated as of October 8, 2024, by and between Scilex Holding Company and Oramed Pharmaceuticals, 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 October 8, 2024).</u>
10.71	<u>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).</u>
10.72	<u>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</u>

Exhibit Number	Description
	<u>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).</u>
10.73	<u>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).</u>
10.74	<u>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).</u>
10.75	<u>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).</u>
10.76	<u>Deferral and Consent under Tranche B Senior Secured Convertible Note, dated January 2, 2025, 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 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 3, 2025)).</u>
10.77	<u>Deferral and Consent under Tranche B Senior Secured Convertible Note, dated January 2, 2025, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc., SCLX Stock Acquisition JV LLC and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 3, 2025).</u>
10.78	<u>Deferral and Consent under Tranche B Senior Secured Convertible Note, dated January 2, 2025, by and among Scilex Holding Company, 3i, LP, 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 January 3, 2025).</u>
10.79#^	<u>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 (incorporated by reference to Exhibit 10.37 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 31, 2025).</u>
10.80	<u>Amendment to Senior Secured Note, dated January 21, 2025, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc. and SCLX Stock Acquisition JV 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 January 22, 2025).</u>
10.81	<u>Purchase and Sale Agreement, dated February 28, 2025, by and among Scilex Holding Company, Scilex Pharmaceuticals Inc. and the purchasers 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 March 3, 2025).</u>
10.82	<u>Security Agreement, dated February 28, 2025, by and among Scilex Holding Company, Scilex Pharmaceuticals Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 3, 2025).</u>
10.83	<u>Subordination Agreement, dated February 28, 2025, by and among Scilex Holding Company, Scilex Pharmaceuticals Inc., Acquiom Agency Services LLC and other signatories 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 March 3, 2025).</u>
10.84	<u>License Agreement (Gloperba), dated February 28, 2025, by and between Scilex Holding Company, Scilex Pharmaceuticals Inc. and RoyaltyVest Ltd. (incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 3, 2025).</u>
10.85	<u>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).</u>

Exhibit Number	Description
10.86	<u>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).</u>
10.87	<u>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).</u>
10.88#	<u>Consent under Securities Purchase Agreement and Senior Secured Promissory Note, dated April 16, 2025, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc. and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.75 of our Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (File No. 333-276245 and 333-280882), filed with the SEC on May 7, 2025).</u>
10.89#	<u>Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated April 16, 2025, by and among Scilex Holding Company, Nomis Bay Ltd, BPY Limited and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.76 of our Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (File No. 333-276245 and 333-280882), filed with the SEC on May 7, 2025).</u>
10.90#	<u>Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated April 16, 2025, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc. and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.77 of our Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (File No. 333-276245 and 333-280882), filed with the SEC on May 7, 2025).</u>
10.91#	<u>Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated April 16, 2025, by and among Scilex Holding Company, 3i, LP and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.78 of our Post-Effective Amendment No. 1 to Form S-3 on Form S-1 (File No. 333-276245 and 333-280882), filed with the SEC on May 7, 2025).</u>
10.92	<u>Scilex Holding Company Amended and Restated Non-Employee Director Compensation Policy (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 12, 2025).</u>
10.93#	<u>Warrant Exchange Agreement, dated July 22, 2025, by and between Scilex Holding Company and Nomis Bay Ltd (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
10.94#	<u>Warrant Exchange Agreement, dated July 22, 2025, by and between Scilex Holding Company and BPY Limited (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
10.95#	<u>Warrant Exchange Agreement, dated July 22, 2025, by and between Scilex Holding Company and 3i, LP (incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
10.96^	<u>Option Agreement for the Repurchase of Warrants, dated July 22, 2025, by and between Scilex Holding Company and Oramed Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.7 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on July 23, 2025).</u>
10.97^	<u>Consulting Agreement, dated September 22, 2025, between Scilex Holding Company and Inform 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, 2025).</u>
10.98#	<u>Securities Purchase Agreement, dated September 23, 2025, by and among Scilex Holding Company, Scilex, Inc., Semnur Pharmaceuticals and Biconomy PTE.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 September 26, 2025).</u>
10.99#	<u>Securities Purchase Agreement, dated September 25, 2025, by and between Scilex Holding Company and Datavault AI Inc. (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, 2025).</u>
10.100#	<u>Warrant Exercise Agreement, dated as of September 30, 2025, by and among the Company, BYP Limited and Nomis Bay 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 October 1, 2025).</u>

Exhibit Number	Description
10.101#	<u>License Agreement, dated November 3, 2025, by and between Scilex Holding Company and Datavault AI Inc. (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 4, 2025).</u>
10.102	<u>Warrant Inducement Agreement, dated as of November 23, 2025, by and between the Company and Armistice Capital Master Fund 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 November 24, 2025).</u>
10.103	<u>Non-Recourse Loan and Securities Pledge Agreement, dated December 1, 2025, by and between Scilex Holding Company and The St. James Bank & Trust Company 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 December 5, 2025).</u>
10.104	<u>Amendment to Non-Recourse Loan and Securities Pledge Agreement, dated December 8, 2025, by and between Scilex Holding Company and The St. James Bank & Trust Company 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 December 12, 2025).</u>
10.105	<u>Non-Recourse Loan and Securities Pledge Agreement, dated December 15, 2025, by and between SCLX Stock Acquisition JV LLC and The St. James Bank & Trust Company 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 December 17, 2025).</u>
10.106	<u>Warrant Agreement, dated as of February 19, 2026, by and between the Company and Oramed Pharmaceuticals Inc. (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 20, 2026).</u>
19.1	<u>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).</u>
21.1+	<u>List of Subsidiaries of the Registrant.</u>
23.1+	<u>Consent of BPM LLP, independent registered public accounting firm.</u>
24.1+	<u>Power of Attorney (included on the signature page hereto).</u>
31.1+	<u>Certification of Henry Ji, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2+	<u>Certification of Stephen Ma, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1+	<u>Certification of Henry Ji, Principal Executive Officer, and Stephen Ma, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
97.1	<u>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).</u>
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.

April 10, 2026

Scilex Holding Company

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

April 10, 2026

By: /s/ Stephen Ma
Stephen Ma
**Chief Financial Officer, Chief Operating Officer,
Secretary and Director**
(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 Henry Ji, Ph.D. 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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Henry Ji, Ph.D.</u> Henry Ji, Ph.D.	Chief Executive Officer, President, Chairperson and Director (Principal Executive Officer)	April 10, 2026
<u>/s/ Stephen Ma</u> Stephen Ma	Chief Financial Officer, Chief Operating Officer, Secretary and Director (Principal Financial and Accounting Officer)	April 10, 2026
<u>/s/ Dorman Followwill</u> Dorman Followwill	Director	April 10, 2026
<u>/s/ Jay Chun</u> Jay Chun, M.D., Ph.D.	Director	April 10, 2026
<u>/s/ Yue Alexander Wu</u> Yue Alexander Wu, Ph.D.	Director	April 10, 2026

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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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of their operations and cash flows for each of the two years in the period ended December 31, 2025, 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 Company 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 Company’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 Company’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
April 10, 2026

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, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,955	\$ 3,272
Marketable securities	6,026	—
Accounts receivable, net	15,244	26,442
Inventory	4,789	2,436
Prepaid expenses and other current assets	7,344	9,397
Total current assets	38,358	41,547
Property and equipment, net	13,599	708
Operating lease right-of-use asset	14,818	2,225
Intangibles, net	59,088	32,453
Investments	1,000	2,420
Equity method investment, at fair value	127,040	—
Equity method investment, at fair value (pledged as collateral)	32,363	—
Digital assets	64,711	—
Goodwill	13,481	13,481
Other long-term assets	523	119
Total assets	<u>\$ 364,981</u>	<u>\$ 92,953</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 86,266	\$ 52,620
Accrued payroll	3,270	1,505
Accrued rebates and fees	231,756	162,517
Accrued expenses	66,414	2,841
Current portion of deferred consideration	407	447
Debt, current	83,262	34,876
Promissory notes	3,517	—
Purchased revenue liability, current	3,764	4,115
Current portion of operating lease liabilities	1,733	714
Other current liabilities	3,263	—
Total current liabilities	483,652	259,635
Long-term portion of deferred consideration	2,041	2,448
Debt, net of issuance costs	22,480	845
Purchased revenue liability, net of current portion	4,636	2,685
Derivative liabilities	50,599	18,303
Operating lease liabilities, net of current portion	13,151	1,523
Other long-term liabilities	174	155
Total liabilities	576,733	285,594
Commitments and contingencies (See Note 13)		
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, 2025 and December 31, 2024	—	—
Series 1, 5,000,000 shares declared as a stock dividend, not yet distributed as of December 31, 2025; and December 31, 2024	1	1
Common stock, \$0.0001 par value, 740,000,000 shares authorized; 8,491,267 shares issued and 7,033,004 shares outstanding as of December 31, 2025; 6,951,622 shares issued and 5,235,377 shares outstanding as of December 31, 2024	1	1
Additional paid-in capital	796,721	454,614
Accumulated other comprehensive income	(5,803)	6,317
Accumulated deficit	(921,786)	(563,052)
Treasury stock, at cost; 1,458,263 shares as of December 31, 2025 and 1,716,245 as of December 31, 2024	(76,915)	(90,522)
Total stockholders' deficit before noncontrolling interests	(207,781)	(192,641)
Noncontrolling interests	(3,971)	—
Total stockholders' deficit	(211,752)	(192,641)
Total liabilities and stockholders' deficit	<u>\$ 364,981</u>	<u>\$ 92,953</u>

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,	
	2025	2024
Net revenue	\$ 30,253	\$ 56,590
Net operating costs and expenses:		
Cost of revenue	10,599	16,689
Research and development	20,710	9,641
Selling, general and administrative	266,884	119,016
Goodwill impairment	73,358	—
Intangible amortization	4,364	4,031
Legal settlements	345	(9,391)
Total net operating costs and expenses	376,260	139,986
Loss from operations	(346,007)	(83,396)
Other (income) expense, net:		
(Gain) loss on derivative liability	22,693	(17,378)
Change in fair value of debt and liability instruments	25,351	4,782
Interest expense, net	11,459	1,963
Loss on foreign currency exchange	(86)	45
Loss on debt extinguishment, net	7,351	—
Unrealized loss on digital assets, net	12,180	—
Realized loss on digital assets, net	30,200	—
Unrealized (gain) on equity investment, net	(2,692)	—
Realized (gain) on equity investments, net	(19,218)	—
Unrealized (gain) on equity method investments carried at fair value, net	(54,760)	—
Realized (gain) on equity method investments carried at fair value, net	(4,657)	—
Realized (gain) on securities	199	—
Total other (income) expense, net	28,020	(10,588)
Loss before income taxes	(374,027)	(72,808)
Income tax expense (benefit)	26	(1)
Net loss	(374,053)	(72,807)
Net loss attributable to noncontrolling interests	(15,319)	—
Net loss attributable to common stockholders before deemed dividend	(358,734)	(72,807)
Deemed dividend	(43,753)	—
Net loss attributable to common stockholders	<u>\$ (402,487)</u>	<u>\$ (72,807)</u>
Net loss per share attributable to common stockholders — basic	<u>\$ (36.48)</u>	<u>\$ (7.24)</u>
Net loss per share attributable to common stockholders — diluted	<u>\$ (36.48)</u>	<u>\$ (8.05)</u>
Weighted average number of shares during the period — basic	<u>11,034</u>	<u>10,061</u>
Weighted average number of shares during the period — diluted	<u>11,034</u>	<u>10,145</u>
Comprehensive loss:		
Net loss attributable to common stockholders	\$ (358,734)	\$ (72,807)
Other comprehensive income:		
Foreign currency translation adjustment	(756)	—
Changes in fair value attributable to instrument-specific credit risk	(11,364)	6,317
Total other comprehensive income	(12,120)	6,317
Comprehensive loss attributable to common stockholders	<u>\$ (370,854)</u>	<u>\$ (66,490)</u>

See accompanying notes to audited consolidated financial statements

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

	Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock		Noncontrolling Interest	Stockholders' Equity (Deficit)	
	Shares	Amount	Shares	Amount	Paid-in Capital			Shares	Amount			
Balance, December 31, 2023	29,057	\$ —	4,574	\$ —	1	\$ 407,828	\$ —	\$ (490,245)	1,716	\$ (90,522)	\$ —	\$ (172,938)
Shares issued under the Standby Equity Purchase Agreements and under the ATM Sales Agreement	—	—	81	—	2,671	—	—	—	—	—	—	2,671
Shares issued under the February 2024 BDO	—	—	168	—	3,769	—	—	—	—	—	—	3,769
Shares issued under the April 2024 RDO	—	—	429	—	5,919	—	—	—	—	—	—	5,919
April 2024 RDO Placement Agent Warrants and February 2024 BDO Representative Warrants	—	—	—	—	956	—	—	—	—	—	—	956
Retainer shares issued	—	—	286	—	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	—	—	63	—	3,792	—	—	—	—	—	—	3,792
Conversion of Tranche B Notes into common stock	—	—	263	—	9,256	—	—	—	—	—	—	9,256
Shares issued under December 2024 RDO	—	—	753	—	328	—	—	—	—	—	—	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	—	—	321	—	2,311	—	—	—	—	—	—	2,311
Shares issued under ESPP	—	—	10	—	246	—	—	—	—	—	—	246
Stock options exercised	—	—	4	—	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	6,952	1	454,614	6,317	(563,052)	1,716	(90,522)	—	—	(192,641)
Treasury Stock transferred to Tranche B Investors for Tranche B Notes deferral	—	—	—	—	(5,353)	—	—	(143)	7,535	—	—	2,182
Treasury Stock paid for Gloperba Ex-US License	—	—	—	—	(808)	—	—	(22)	1,174	—	—	366
Treasury Stock transferred to Oramed for the Oramed Note maturity extension	—	—	—	—	(3,523)	—	—	(93)	4,898	—	—	1,375
Acquisition of controlling interest in Scilex Bio	—	—	—	—	1,816	—	—	—	—	1,944	—	3,760

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, 2025

☐ 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
(State or Other Jurisdiction of
Incorporation or Organization)
960 San Antonio Road
Palo Alto, CA
(Address of Principal Executive Offices)

92-1062542
(I.R.S. Employer
Identification No.)

94303
(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 \$402.50 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 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, 2025 (the last trading day of the registrant’s second fiscal quarter of 2025), as reported on the Nasdaq Capital Market, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$32.4 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 April 2, 2026, the registrant had 8,491,267 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 2026 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant’s fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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

	Preferred Stock		Common Stock		Additional	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock		Noncontrolling Interest	Stockholders' Equity (Deficit)	
	Shares	Amount	Shares	Amount	Paid-in Capital			Shares	Amount			
Balance, December 31, 2023	29,057	\$ —	4,574	\$ —	1	\$ 407,828	\$ —	\$ (490,245)	1,716	\$ (90,522)	\$ —	\$ (172,938)
Shares issued under the Standby Equity Purchase Agreements and under the ATM Sales Agreement	—	—	81	—	2,671	—	—	—	—	—	—	2,671
Shares issued under the February 2024 BDO	—	—	168	—	3,769	—	—	—	—	—	—	3,769
Shares issued under the April 2024 RDO	—	—	429	—	5,919	—	—	—	—	—	—	5,919
April 2024 RDO Placement Agent Warrants and February 2024 BDO Representative Warrants	—	—	—	—	956	—	—	—	—	—	—	956
Retainer shares issued	—	—	286	—	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	—	—	63	—	3,792	—	—	—	—	—	—	3,792
Conversion of Tranche B Notes into common stock	—	—	263	—	9,256	—	—	—	—	—	—	9,256
Shares issued under December 2024 RDO	—	—	753	—	328	—	—	—	—	—	—	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	—	—	321	—	2,311	—	—	—	—	—	—	2,311
Shares issued under ESPP	—	—	10	—	246	—	—	—	—	—	—	246
Stock options exercised	—	—	4	—	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	6,952	1	454,614	6,317	(563,052)	1,716	(90,522)	—	—	(192,641)
Treasury Stock transferred to Tranche B Investors for Tranche B Notes deferral	—	—	—	—	(5,353)	—	—	(143)	7,535	—	—	2,182
Treasury Stock paid for Gloperba Ex-US License	—	—	—	—	(808)	—	—	(22)	1,174	—	—	366
Treasury Stock transferred to Oramed for the Oramed Note maturity extension	—	—	—	—	(3,523)	—	—	(93)	4,898	—	—	1,375
Acquisition of controlling interest in Scilex Bio	—	—	—	—	1,816	—	—	—	—	1,944	—	3,760

Reverse recapitalization - Semnur Business Combination	—	—	—	—	127,245	—	—	—	—	(1,716)	125,529
Sale of 12.5 million New Semnur Common	—	—	—	—	200,685	—	—	—	—	(685)	200,000
Exercise of April 2024 and December 2024 RDO warrants and issuance of November 2025 Warrants	—	—	905	—	19,767	—	—	—	—	—	19,767
Exercise of December 2024 RDO Warrants in exchange for Tranche B Notes deferral	—	—	179	—	3,527	—	—	—	—	—	3,527
Non-Controlling interest in Vivasor net assets at date of acquisition	—	—	—	—	—	—	—	—	—	11,805	11,805
Issuance of common stock upon exercise of December 2024 RDO Warrants	—	—	450	—	10,237	—	—	—	—	—	10,237
Payments in lieu of fractional shares or Reverse Stock Split	—	—	—	—	(1)	—	—	—	—	—	(1)
Option fee and repurchase of Penny Warrants	—	—	—	—	(27,000)	—	—	—	—	—	(27,000)
Shares issued under ESPP	—	—	5	—	23	—	—	—	—	—	23
Stock-based compensation	—	—	—	—	15,492	—	—	—	—	—	15,492
Other comprehensive income	—	—	—	—	—	(12,120)	—	—	—	—	(12,120)
Net loss	—	—	—	—	—	—	(358,734)	—	—	(15,319)	(374,053)
Balance, December 31, 2025	<u>34,057</u>	<u>\$ 1</u>	<u>8,491</u>	<u>\$ 1</u>	<u>\$ 796,721</u>	<u>\$ (5,803)</u>	<u>\$ (921,786)</u>	<u>1,458</u>	<u>\$ (76,915)</u>	<u>\$ (3,971)</u>	<u>\$ (211,752)</u>

See accompanying notes to audited consolidated financial statements

Reverse recapitalization - Semnur Business Combination	—	—	—	—	127,245	—	—	—	—	(1,716)	125,529
Sale of 12.5 million New Semnur Common	—	—	—	—	200,685	—	—	—	—	(685)	200,000
Exercise of April 2024 and December 2024 RDO warrants and issuance of November 2025 Warrants	—	—	905	—	19,767	—	—	—	—	—	19,767
Exercise of December 2024 RDO Warrants in exchange for Tranche B Notes deferral	—	—	179	—	3,527	—	—	—	—	—	3,527
Non-Controlling interest in Vivasor net assets at date of acquisition	—	—	—	—	—	—	—	—	—	11,805	11,805
Issuance of common stock upon exercise of December 2024 RDO Warrants	—	—	450	—	10,237	—	—	—	—	—	10,237
Payments in lieu of fractional shares or Reverse Stock Split	—	—	—	—	(1)	—	—	—	—	—	(1)
Option fee and repurchase of Penny Warrants	—	—	—	—	(27,000)	—	—	—	—	—	(27,000)
Shares issued under ESPP	—	—	5	—	23	—	—	—	—	—	23
Stock-based compensation	—	—	—	—	15,492	—	—	—	—	—	15,492
Other comprehensive income	—	—	—	—	—	(12,120)	—	—	—	—	(12,120)
Net loss	—	—	—	—	—	—	(358,734)	—	—	(15,319)	(374,053)
Balance, December 31, 2025	<u>34,057</u>	<u>\$ 1</u>	<u>8,491</u>	<u>\$ 1</u>	<u>\$ 796,721</u>	<u>\$ (5,803)</u>	<u>\$ (921,786)</u>	<u>1,458</u>	<u>\$ (76,915)</u>	<u>\$ (3,971)</u>	<u>\$ (211,752)</u>

See accompanying notes to audited consolidated financial statements

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

	Year Ended December 31,	
	2025	2024
Operating activities		
Net loss including noncontrolling interest	\$ (374,053)	\$ (72,807)
Adjustments to reconcile net loss to net cash proceeds from operating activities:		
Depreciation and amortization	4,623	4,046
Amortization of debt issuance costs and debt discount	409	316
Non-cash operating lease cost	812	718
Stock-based compensation	15,492	15,689
Fair value of Gloperba-Elyxyb RPA liability expensed	500	—
Fair value of treasury Stock expensed - Tranche B and Oramed Note	3,557	—
Fair value of September 2025 warrants expensed - Tranche B modification	3,091	—
(Gain) loss on derivative liability	22,693	(17,378)
Loss on extinguishment of derivative liability	7,350	—
Goodwill impairment	73,358	—
Financing costs and allocated expense for financial instruments at fair value	—	17,297
In-process research and development expense	5,426	—
Transaction costs expensed related to Semnur Business Combination	140,000	—
Change in fair value of debt and liability instruments	25,351	4,782
Change in fair value of equity investments	(2,692)	—
Change in fair value of digital assets	12,180	—
Change in fair value of equity method investment, net	(54,759)	—
Realized (gain) loss on investment, net	(19,218)	—
Realized (gain) loss on digital assets, net	30,200	—
Realized (gain) loss on equity method investment, net	(4,657)	—
Realized Gains & Losses on Securities	199	—
Allowances for expected credit losses	—	1,186
Other	(13)	661
Changes in operating assets and liabilities:		
Accounts receivables, net	13,837	(6,267)
Inventory	1,799	1,462
Prepaid expenses and other	3,300	(479)
Other long-term assets	(3)	(30)
Accounts payable	13,121	7,419
Accrued payroll	(1,095)	(1,176)
Accrued expenses	14,601	(8,167)
Accrued rebates and fees	69,239	72,859
Operating lease liability	(857)	(758)
Other long-term liabilities	25	(24)
Net cash proceeds from operating activities	3,816	19,349
Investing activities		
Acquisition consideration paid in cash for Romeg intangible asset acquisition	(600)	(600)
Purchase of equity securities	—	(2,000)
Cash paid for in-process research and development, net	(200)	(75)
Cash paid to settle Datavault Obligation	(9,230)	—
Purchases of Bitcoin with cash	(15,837)	—
Purchase of property and equipment	(133)	—
Exercise of prefunded warrant	(27)	—
Purchase of preferred shares of Vivator	(9,000)	—
Sale of Datavault AI Inc. shares for cash, net	39,606	—
Repayments on promissory note	(962)	—
Payment made for PA OPS investment	(1,000)	—
Vivator Cash Acquired	1,517	—
Purchase of convertible promissory note from Denali	(50)	—
Net cash proceeds from (used for) investing activities	4,084	(2,675)
Financing activities		
Proceeds from issuance of shares under Standby Equity Purchase Agreements and ATM Sales Agreement	—	2,671
Proceeds from issuance of Revolving Facility	—	95,438
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)
Repayment of Oramed Note	—	(64,200)
Cash consideration paid in connection with warrant repurchase	—	(300)
Cash assumed in Semnur Business Combination	35	—
Repayment of Convertible Debentures	—	(4,375)
Repayment of Tranche B Notes	(20,532)	(3,283)
Payments of debt issuance costs	(71)	(4,172)
Cash consideration paid in connection with the repurchase of Penny Warrants	(27,000)	—

Payments on purchased revenue liability	(3,179)	—
Transaction costs paid in connection with share repurchase	(996)	—
Proceeds from exercise of April 2024 RDO Warrants and December 2024 RDO Warrants	20,358	—
Transaction costs paid in connection with issuance of common stock and exchange of April 2024 RDO Warrants and December 2024 RDO Warrants for November 2025 Warrants	(1,745)	—
Payments for the termination of Tumim Purchase Agreement	(2,700)	—
Proceeds from issuance of Scilex-St. James Loans	21,528	—
Excise tax paid in connection with share repurchase	(860)	(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 exercise of December 2024 RDO Warrants for Common Stock	10,237	—
Proceeds from stock options and warrants exercised and ESPP	23	2,113
Payments for Vivasor debt	(558)	—
Payments in lieu of fractional shares for Reverse Stock Split	(1)	—
Net cash (used for) financing activities	(5,461)	(18,131)
Effect of exchange rate changes on cash	(756)	—
Net change in cash and cash equivalents	1,683	(1,457)
Cash, cash equivalents and restricted cash at beginning of period	3,272	4,729
Cash, cash equivalents and restricted cash at end of period	\$ 4,955	\$ 3,272
Supplemental disclosure:		
Cash paid for interest	\$ 935	\$ 1,561
Non-cash investing and financing activities		
Issuance costs related to direct offerings included in accrued expenses and account payables	\$ —	\$ 1,845
Net liabilities assumed in Semnur Business Combination	\$ 12,822	\$ —
Derecognition of Scilex's equity investment in Denali in connection with Semnur Business Combination	\$ 2,470	\$ —
Exercise of December 2024 RDO Warrants in exchange for settlement of Tranche B Notes principal and interest	\$ 2,689	\$ —
Purchase of equity investment in Datavault AI Inc in exchange for Bitcoin	\$ 8,069	\$ —
Bitcoin acquired in exchange for shares of Semnur Stock	\$ 200,000	\$ —
Additions to intangible assets included in accrued expenses	\$ 1,000	\$ —
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
Datavault Licenses acquired but not yet paid	\$ 30,000	\$ —
Purchase of Bitcoin in exchange for Scilex-St. James Loans	\$ 9,395	\$ —
Excise tax in connection with share repurchase included in accrued expenses	\$ —	\$ 860
Purchase and exercise of prefunded warrant for Datavault shares in exchange for Bitcoin	\$ 110,043	\$ —
Issuance of warrants as financing costs in connection with issuance of common stock and exchange of liability classified instruments	\$ 862	\$ —
Vivasor debt forgiveness	\$ (2,469)	\$ —
Vivasor net assets consolidated	\$ —	\$ —
Net impact of the issuance of November 2025 Warrants and exchange of liability classified instruments	\$ 6,248	\$ —

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 consolidated 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 eight subsidiaries, of which the following five are wholly owned: Scilex Inc. (“Legacy Scilex”), Scilex Pharmaceuticals Inc. (“Scilex Pharma”), SCLX DRE Holdings LLC, and SCLX Stock Acquisition JV LLC (“SCLX JV”), Scilex BVI Limited (“Scilex BVI”); and the following three subsidiaries are controlled by Scilex: Scilex Bio, Inc. (“Scilex Bio”) and Semnur Pharmaceuticals, Inc. (“Semnur”) and Vivasor Holding Company (“Vivasor”). The business combination with Vivasor started in December 2025. 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. In January 2025, the Company received approval from Health Canada’s Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for ELYXYB for the acute treatment of migraine with or without aura in Canada and in-licensed the rights to commercialize GLOPERBA outside the U.S.

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 initiated a second Phase 3 study (“SP-102” or “SEMDEXA”) in September 2025, 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”), 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. 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, ELYXYB and GLOPERBA.

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 consolidated financial statements include 100% of the accounts of the wholly owned and majority owned subsidiaries as well as a variable interest entity for which the Company is the primary beneficiary. The proportion of profit and loss and changes in equity allocated to the shareholders of the Company and the non-controlling interests are determined on the basis of existing ownership interest. All intercompany balances and transactions have been eliminated.

The Company consolidates those entities in which it has a direct or indirect controlling financial interest based on either the variable interest model (the “VIE model”) or the voting interest model (the “VOE model”). Variable interest entities (“VIEs”) are entities that, by design, either lack sufficient equity to permit the entity to finance its activities without additional subordinated financial support from other parties, or have equity investors that do not

have the ability to make significant decisions relating to the entity's operations through voting rights, or do not have the obligation to absorb the expected losses, or do not have the right to receive the residual returns of the entity.

The Company consolidates its VIEs under the VIE model if the Company is considered the primary beneficiary due to (i) the power to direct activities of the VIE that most significantly impact the entity's economic performance; and (ii) the obligation to absorb losses of the entity or the right to receive benefits from the entity that could potentially be significant to the VIE. If the Company is not deemed to be the primary beneficiary in a VIE, the Company accounts for the investment or other variable interests in a VIE in accordance with the applicable GAAP.

Upon the occurrence of certain significant events, as required by the VIE model, the Company reassesses whether a legal entity in which the Company is involved is a VIE. The reassessment process considers whether the Company has acquired or divested the power to direct the activities of the VIE through changes in governing documents or other circumstances. The reassessment also considers whether the Company has acquired or disposed of a financial interest that could be significant to the VIE, or whether an interest in the VIE has become significant or is no longer significant. The consolidation status of the entities with which the Company is involved may change as a result of such reassessments. Changes in consolidation status are applied prospectively, with assets and liabilities of a newly consolidated VIE initially recorded at fair value.

Reverse Stock Split

On April 3, 2025, the Board of Directors of the Company (the "Board") approved a reverse stock split of the Common Stock at a ratio of 1-for-35 (the "Reverse Stock Split"), which was effected on April 15, 2025. As a result of the Reverse Stock Split, every 35 shares of pre-Reverse Stock Split Common Stock was combined into one share of post-Reverse Stock Split Common Stock, without any change in par value per share. No fractional shares were issued as a result of the Reverse Stock Split, as fractional shares of Common Stock were rounded down to the nearest whole share. Stockholders who would have otherwise received a fractional share of Common Stock pursuant to the Reverse Stock Split, received cash-in-lieu of the fractional share. All Common Stock amounts and references have been retroactively adjusted for all figures presented to reflect the Reverse Stock Split unless specifically stated otherwise. The Company also adjusted the amounts for shares of Common Stock reserved for issuance upon the exercise of outstanding warrants, outstanding stock options and shares reserved under the Company's stock-based compensation plans, except for the outstanding Penny Warrants and the Deposit Warrant (each as defined below), which do not contain antidilution provisions and therefore were not adjusted in connection with the Reverse Stock Split, to the extent they were outstanding at the time of the Reverse Stock Split. As a result, a deemed dividend of \$43.8 million was recognized, representing the increase in value to Penny Warrant holders. The Company has an accumulated deficit, as a result, the deemed dividend was not recorded as a reduction in additional paid-in capital, resulting in a net impact of zero to additional paid-in capital in the accompanying consolidated balance sheet. The non-cash deemed dividend has been included as an increase to the net loss allocated to common shareholders, and thus increase the net loss per share for both basic and diluted net loss per share.

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, the fair value of assets acquired and liabilities assumed in acquisitions, and the noncontrolling interests recognized in acquisitions. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

Customer and Supplier Concentration Risk

The Company had four and three customers during the years ended December 31, 2025 and 2024, respectively, each of which individually generated 10% or more of the Company's total revenue. These customers accounted for 98% and 86% of the Company's revenue for the years ended December 31, 2025 and 2024, respectively, individually ranging from 12% to 33% and 23% to 34%, respectively. As of December 31, 2025 and 2024, four and three customers represented 96% and 95% of the Company's outstanding accounts receivable, respectively, individually ranging between 10% and 35% and 30% and 33% for respective periods. Additionally, during the years ended December 31, 2025 and 2024, the Company purchased ZTlido, ELYXYB and GLOPERBA inventories from its sole supplier, Itochu Chemical Frontier Corporation ("Itochu"), 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, 2025 and 2024, the Company had allowances for expected credit losses of nil and \$1.2 million, respectively.

Digital Assets

In September 2025, the Company adopted a cryptocurrency treasury strategy and began acquiring Bitcoin. We account for all digital assets held as crypto assets, a subset of indefinite-lived intangible assets in accordance with ASC 350-60, Intangibles - Goodwill and Other - Crypto Assets. We have ownership of and control over our digital assets and are held in custody accounts and are not considered cash equivalents. The digital assets are initially recorded at cost on a first-in, first-out basis and are subsequently remeasured on the consolidated balance sheets at fair value at each reporting period.

We determine and record the fair value of our digital assets in accordance with ASC 820, Fair Value Measurement ("ASC 820"), based on quoted prices on the active exchange(s) that we have determined is the principal market for such assets (Level I inputs). Realized and unrealized gains and losses are recorded to Other (income) expense, net in our consolidated statement of operations and comprehensive loss.

Noncontrolling Interests

The Company consolidates entities in which it has a controlling financial interest, including variable interest entities (VIEs) where it is the primary beneficiary. Noncontrolling interests represent the portion of equity in consolidated subsidiaries not attributable to the Company and are presented separately in the consolidated balance sheets and statements of operations and comprehensive loss. Profit or loss and changes in equity attributable to noncontrolling interests are allocated based on ownership percentages as well as the preferential rights and obligations associated with the respective equity class of noncontrolling interests.

Datavault Investment

On September 25, 2025, we entered into a Securities Purchase Agreement (the "Datavault SPA") with Datavault AI Inc., a Delaware corporation ("Datavault"), pursuant to which Datavault agreed to issue and sell, and we agreed to purchase, 15.0 million shares (the "Datavault Shares") of common stock of Datavault ("Datavault Common Stock") in the initial closing which occurred on September 26, 2025 (the "Initial Datavault Closing" and the date of such closing, the "Initial Datavault Closing Date") and a pre-funded warrant (the "Datavault Pre-Funded Warrant") to

purchase 263,914,094 shares of Datavault Common Stock in a subsequent closing (the “Subsequent Datavault Closing”), for an aggregate purchase price of \$150 million in Bitcoin (“BTC”) (based on the spot exchange rate for BTC as published by Coinbase.com at 8:00 p.m. (New York City time) on the trading day immediately prior to the date of the Initial Datavault Closing Date, or September 25, 2025. (such rate, the “Spot Exchange Rate”)). On November 25, 2025, the Subsequent Datavault Closing was consummated with us transferring an amount of BTC (based on the Spot Exchange Rate) in satisfaction of the payment of the remainder of the aggregate purchase price to Datavault and Datavault issuing the Datavault Pre-Funded Warrant to us. Also on November 25, 2025, following the Subsequent Datavault Closing, we exercised the Datavault Pre-Funded Warrant in full for an aggregate exercise price of approximately \$26.4 thousand, paid in cash. The Company has the ability to nominate two out of nine board seats, and holds approximately 37% of Datavault’s outstanding voting shares as of December 31, 2025, and the Company believes it is able to exercise significant influence over Datavault. As such, following the exercise of the Datavault Pre-Funded Warrants, the Company accounts for its investment in Datavault under the equity method under Accounting Standards Codification (“ASC”) 323, Investments - Equity Method and Joint Venture as of this date.

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. Equity method investment and digital assets are also recorded at fair value in our consolidated balance sheets.

The valuation of the derivative warrant liability for the Private Warrants, the February 2024 BDO Firm Warrants, the Deposit Warrant, the October 2024 Noteholder Warrants, the December 2024 RDO Common Warrants the Exchange Warrants, the September 2025 Warrants and the November 2025 Warrants (each as defined below) is outlined in Note 5, utilizing the Black-Scholes option pricing model. The Company has chosen the fair value option for the Oramed Note, FSF Deposit, and Tranche B Notes (each as defined below), with the valuation methodologies detailed in Note 8. 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, Restricted Cash and Marketable Securities

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. The Company considers marketable securities as current investments if the maturity date is less than or equal to one year from the balance sheet date. The Company considers marketable securities as non-current investments if the maturity date is in excess of one year from the balance sheet date.

Restricted cash as of December 31, 2025 and December 31, 2024 is nil, 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, 2025 and 2024.

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, 2025 and 2024, the Company recorded nil and \$1.2 million, allowances for credit losses on its accounts receivable, respectively. As of December 31, 2025 and 2024, allowances for prompt payment discounts were \$0.4 million and \$0.6 million, respectively.

Inventory

The Company determines inventory cost on a first-in, first-out basis, with the exception of the Vivasor entity which determines inventory cost using the average cost method. 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, 2025 and 2024, the Company's inventory was composed of equal parts of raw material and finished goods.

Property and Equipment, Net

Property and equipment are carried at cost less accumulated depreciation. Property and equipment for the Vivasor entity was fair valued on the date of the acquisition under acquisition accounting. 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 two 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.

Valuation of Purchased In-Process Research and Development, Goodwill, and Other Intangible Assets

When we acquire another company, the purchase price is allocated, as applicable, between in-process research and development, other identifiable intangible assets, tangible assets, liabilities assumed and goodwill as required by generally accepted accounting principles in the U.S. Purchased in-process research and development is defined as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to in-process research and development and other intangible assets requires us to make significant estimates. The amount of the purchase price allocated to purchased in-process research and development and other intangible assets is determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present values. The discount rate used is determined at the time of the acquisition in accordance with accepted valuation methods. For purchased in-process research and development, these methodologies include consideration of the risk of the project not achieving commercial feasibility.

Goodwill represents the excess of the aggregate purchase price over the fair value of net assets, including in-process research and development, of the acquired businesses, net of the fair value of liabilities assumed. Goodwill is tested for impairment annually, or more frequently if changes in circumstance or the occurrence of events suggest an impairment exists. The test for impairment requires us to make several estimates about fair value, most of which are based on projected future cash flows. Our estimates associated with the goodwill impairment tests are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value amounts, including projected future cash flows.

The purchase price allocation in connection with the purchase of Vivasor is preliminary and subject to adjustment. As the Company continues to evaluate the fair value of assets acquired, including in-process research and development (IPR&D), adjustments may result in a reallocation between goodwill and identified intangible assets.

Any such measurement period adjustments will be recorded in accordance with ASC 805, with corresponding offsets to goodwill, and will be finalized no later than one year from the acquisition date.

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 FASB 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.

Debt assumed in connection with the Vivasor, Business Combination was recorded at fair value at the acquisition date. Subsequent to initial recognition, such debt is carried at amortized cost, with any difference between fair value and contractual amounts accreted or amortized to interest expense over the remaining term of the instrument using the effective interest method.

The Oramed Note, FSF Deposit, Tranche B Notes

The Company has elected the fair value option to account for the FSF Deposit and the Tranche B Notes (each as defined in Note 2 "*Liquidity and Going Concern*" below) and the Oramed Note (as defined in Note 5 "*Fair Value Measurements*" below) that were issued in June 2024, October 2024, and September 2023, respectively, as discussed further in Note 8. 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 12.35% and 6.67% for the years ended December 31, 2025 and 2024, respectively.

Scilex-St. James Loans

The Company accounted for Scilex-St. James Loans using amortized cost model. Transaction fees paid to the lender are treated as debt discounts which are recorded as reduction to the principal of the notes. The debt discounts are

amortized over the contractual term of the notes, using the effective interest method, and recorded as interest expense in the consolidated statements of operations and comprehensive loss.

Purchased Revenue Liability

The purchased revenue liability is associated with the Purchase and Sale Agreement that the Company entered into in October 2024 with certain institutional investors (collectively, the “ZTlido Royalty Investors”) and Oramed (the “ZTlido Royalty Purchase Agreement”) and the Purchase and Sale Agreement that the Company entered into in February 2025 with certain institutional investors (collectively, the “Gloperba-Elyxyb Royalty Investors”) and Oramed (the “Gloperba-Elyxyb Royalty Purchase Agreement”, and together with the ZTlido Royalty Purchase Agreement, the “Royalty Purchase Agreements”) (Note 8). The Company elected the fair value option to account for the purchased revenue liability (as described in Note 5 “Fair Value Measurements” below). The Company recorded the these Royalty Purchase Agreements 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, 2025 and 2024, 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 primarily 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, 2025 and 2024 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.

Deductions from Revenues

The Company's gross product revenues are subject to a variety of deductions, which generally are estimated and recorded in the same period that the revenues are recognized. Such variable consideration represents chargebacks, rebates, sales allowances and sales returns. These deductions represent estimates of the related obligations and, as such, knowledge and judgment are required when estimating the impact of these product revenue deductions on net sales for a reporting period.

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.

The allowance for product returns is determined based on historical return rates, product shelf life, and inventory levels within the distribution channel. This estimated rate is applied to gross sales to accrue the sales allowance.

Discounts

Discounts, typically 2% of sales, are offered to wholesalers for prompt payment. Upon receipt of actual product returns, the Company updates its balances accordingly, while continuing to refine its estimates based on historical trends.

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 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. We adopted this ASU for our 2025 annual period prospectively. See Note 14 for the revised disclosures consistent with the new standard.

In December 2023, the FASB issued ASU No. 2023-08, *Intangibles—Goodwill and Other—Crypto Assets (Subtopic 350-60): Accounting for and Disclosure of Crypto Assets*. The amendments in ASU No. 2023-08 are intended to improve the accounting for certain crypto assets by requiring an entity to measure those crypto assets at fair value each reporting period with changes in fair value recognized in net income. The amendments also improve the information provided to investors about an entity's crypto asset holdings by requiring disclosure about significant holdings, contractual sale restrictions, and changes during the reporting period. The amendments are effective for all entities for fiscal years beginning after December 15, 2024, including interim periods within those fiscal years. We adopted ASU 2023-08 in 2025, and it did not have a material impact on the Company's financial statements when adopted, as the Company did not hold any crypto assets as of the adoption date. During the third quarter of 2025, the Company began holding crypto assets, which are accounted for in accordance with ASU 2023-08. See Note 6 for related disclosures.

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.

In July 2025, the FASB issued ASU No. 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. The amendments in this update provide a practical expedient permitting an entity to assume that conditions at the balance sheet date remain unchanged over the life of the asset when estimating expected credit losses for current classified accounts receivable and contract assets. This update is effective for annual periods beginning after December 15, 2025, including interim periods within those fiscal years. Adoption of this ASU can be applied prospectively for reporting periods after its effective date. Early adoption is permitted. The Company is currently evaluating the provisions of this ASU and do not expect this ASU to have a material impact 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 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, 2025, no sales of Common Stock had been made under the ATM Sales Agreement. As of December 31, 2024, the Company sold 78,976 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately \$2.7 million.

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 Commitment 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 Commitment 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 (the "Deposit Warrant"), with an exercise price of \$1.20 per share. The exercise price and number of shares of Common Stock issuable upon the exercise of the Deposit Warrant may be subject to certain adjustments in the event of any stock dividend, stock split, recapitalization, reorganization or similar transaction, as described in the Deposit Warrant. 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. 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 7, 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”, and 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 \$36.40 per share. In exchange for the issuance of the Tranche B Notes to the Tranche B Investors, the Company has received an aggregate amount in cash of \$22,500,000, excluding fees and expenses payable by the Company. In consideration for the Tranche B Notes issued to Oramed, the Company has received from Oramed an exchange and reduction of the principal balance under the Oramed Note (as defined below) of \$22,500,000.

On December 1, 2025, the Company entered into a Non-Recourse Loan and Securities Pledge Agreement (the “Scilex-St. James Loan Agreement”) to issue loans (the “Scilex-St. James Loans”) with St. James Bank & Trust Company Ltd., a corporation existing under the laws of the Bahamas (“St. James”), in up to an aggregate principal amount of \$50.0 million, which may be advanced in one or more tranches. The Scilex-St. James Loans are non-recourse loans, which are collateralized by the shares of Datavault common stock held by the Company, wherein St. James will act as the custodian over these collateralized shares.

On December 8, 2025, the Company and St. James executed an amendment to the “Scilex-St. James Loan Agreement (the “Scilex-St. James Loan Amendment”). The Scilex-St. James Loan Amendment, among other things, increased the maximum amount borrowable under the Scilex-St. James Loan Agreement from \$50.0 million to \$100.0 million, and increased the number of shares of Datavault common stock collateralizing the Scilex-St. James Loans to 85,838,800 shares.

On December 19, 2025, (the “Initial Scilex-St. James Loan Closing Date”), St. James funded \$10.0 million of principal of the Scilex-St. James Loans (the “Scilex-St. James Loan Tranche 1”), net of a \$0.8 million financing fees, collateralized by 17,361,111 shares of Datavault Common Stock, at a collateral price per share of \$0.96. The Company has received proceeds of the Scilex-St. James Loan Tranche 1 and aggregate amount of \$9.2 million in cash, excluding fees and expenses payable by the Company.

On December 22, 2025 (the “Scilex-St. James Tranche 2 Closing Date”), St. James funded and the Company received in cash \$12.6 million of principal of the Scilex-St. James Loans (the “Scilex-St. James Tranche 2”), collateralized by 21,841,689 shares of Datavault Common Stock, excluding fees and expenses payable by the Company.

As of December 31, 2025, the Company’s negative working capital was \$445.3 million, including cash and cash equivalents of approximately \$5.0 million. During the year ended December 31, 2025, the Company had operating losses of \$346.0 million and cash flows outflows from operations of \$3.8 million. The Company had an accumulated deficit of \$921.8 million as of December 31, 2025.

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 and ELYXYB are 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

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, 2025 and December 31, 2024, the contingent consideration associated with the Development Milestone Payment was \$0.2 million, recorded in the other long-term liabilities.

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 each of December 31, 2025 and 2024, the Company had ending balances of accrued royalty payables of \$0.2 million, which was recorded as accrued expenses under current liabilities on the consolidated balance sheets. During the years ended December 31, 2025 and 2024, the Company made royalty payments in the amount of \$0.2 million and \$0.3 million, respectively. As of December 31, 2025, a regulatory milestone payment of \$1.0 million had been accrued.

Semnur Business Combination Agreement and Sponsor Interest Purchase Agreement

On August 30, 2024, Semnur entered into an agreement and plan of merger (as may be amended or restated from time to time in accordance with its terms, including by Amendment No. 1 thereto, dated as of April 16, 2025 (“Amendment No.1”), the “Semnur Business Combination Agreement”) with Denali and Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali (“Denali Merger Sub”). On July 22, 2025, Semnur entered into Amendment No. 2 to the Semnur Business Combination Agreement with Denali and Denali Merger Sub (“Amendment No. 2”). Amendment No. 2 amends the Semnur Business Combination Agreement to, among other things, modify the definitions of the “Exchange Ratio” and “Merger Consideration” to facilitate the issuance of additional shares of common stock of Semnur prior to the closing of the Semnur Business Combination in connection with any potential private placement financing or for issuance to advisors and other service providers for services rendered and maintain the 1.25-to-1 exchange ratio.

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 Semnur Common Stock 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. Pursuant to Amendment No. 1, among other things, the parties agreed to (i) modify certain covenants of the parties to address the potential delisting of the Denali ordinary shares and warrants from the Nasdaq Capital Market, (ii) extend the Outside Date (as defined in Amendment No. 1) to September 30, 2025, and (iii) require Denali to amend its organizational documents to extend the period of time within which Denali can complete a business combination to December 11, 2025, or such other date that is mutually agreed to by Semnur and Denali.

In connection with the execution and delivery of the Semnur Business Combination Agreement, 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, of Denali (the “Purchased Interests”) that were 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) 8,571 shares of Common Stock. Pursuant to the SIPA, the Company paid the Cash Consideration and has agreed to issue Common Stock to the Sponsor contingent upon and following the occurrence of the Semnur Business Combination. The Purchased Interests converted automatically, on a one-for-one basis, into one New Semnur Common Share upon the closing of the Semnur Business Combination pursuant to the terms of the Semnur Business Combination Agreement. On September 22, 2025, the requirement to deliver the shares was discharged pursuant to that certain Satisfaction and Discharge Agreement by and among the Company, Sponsor and Semnur.

As of December 31, 2025, and December 31, 2024, the Company had deferred offering costs of approximately nil and \$6.0 million, respectively, related to the Semnur Business Combination. Because the transaction was completed without cash consideration, these costs were recognized as an expense in the Company’s consolidated statements of operations upon closing.

Vivasor Business Combination

On December 5, 2025 (the “VHC Transaction Date”), the Company entered into a Share Transfer Agreement with EAR SPV LLC, a Delaware corporation (“EAR SPV”) and Vivasor Holding Company (“VHC”), a privately held biotechnology company, pursuant to which, among other things, EAR SPV agreed to sell, and the Company agreed to buy, all 6,101,468 shares of VHC’s Series A-1 Preferred Stock, par value \$0.00001 per share, held by EAR SPV, for an aggregate purchase price of \$9.0 million (“VHC Business Combination”).

The Company evaluated VHC under the VIE model in accordance with ASC 810 and concluded that VHC is a VIE because it lacked sufficient equity at risk to finance its activities without additional subordinated support. Due to the Company's power to direct key activities through its eligible majority board representation and its significant economic exposure through its 30.8% equity interest, it was determined that the Company was the primary beneficiary of VHC. As a result, the Company consolidated VHC as of the VHC Transaction Date. The Company will reassess its primary beneficiary status and VIE conclusion for VHC upon the occurrence of any reconsideration events.

The Company accounted for the transaction as a business combination using the acquisition method of accounting in accordance with ASC 805. The identifiable assets acquired and liabilities assumed of VHC were recorded at their estimated fair values as of the VHC Transaction Date. Any excess of the purchase consideration over the fair value of net identifiable assets acquired was recorded as goodwill. Acquisition-related expenses were not material for the year ended December 31, 2025.

The purchase price allocation is preliminary and subject to adjustment. As the Company continues to evaluate the fair value of assets acquired, including in-process research and development ("IPR&D"), fair value of inventory and receivables, adjustments may result in a reallocation between goodwill and identified tangible and intangible assets. Any such measurement period adjustments will be recorded in accordance with ASC 805, with corresponding offsets to goodwill, and will be finalized no later than one year from the acquisition date.

The fair value estimates for the assets acquired and liabilities assumed were based upon valuations using information known and knowable as of the date of this filing. Changes to these assumptions and estimates could cause an impact to the valuation of assets acquired including goodwill. The Company is in the process of finalizing the purchase price allocation. Accordingly, the allocation of the purchase price to the assets acquired and liabilities assumed is preliminary and subject to adjustment during the measurement period, which may not exceed one year from the VHC Transaction Date.

The fair value of the total purchase consideration for the VHC Business Combination was \$71.3 million, subject to purchase price adjustment and was comprised of the following (in thousands):

Purchase Consideration	Fair Value	
Cash consideration	\$	9,000
Upside consideration – Aardvark shares claw back		3,111
Debt assumed (short-term and long-term)		47,415
69.2% noncontrolling interest in VHC		11,805
Total purchase consideration	\$	71,331

The purchase consideration includes the cash paid for the equity interest in VHC, the fair value of debt assumed at acquisition, the upside consideration payable to Sorrento Therapeutics, Inc. ("Sorrento") based on a percentage of proceeds from the Aardvark Therapeutics, Inc. ("Aardvark") equity investment, and the fair value of the noncontrolling interests. The 69.2% noncontrolling interest in VHC was measured at fair value using an option pricing model backsolve methodology with a discount for lack of control of 23.1%. The 7.0% noncontrolling interest relates to Sorrento's retained interest in certain VHC subsidiaries pursuant to the Asset Purchase Agreement dated March 8, 2024 between Sorrento and VHC.

The preliminary allocation of the VHC Business Combination purchase consideration to the estimated fair value of the net assets acquired and liabilities assumed at the VHC Transaction Date was as follows (in thousands):

Liabilities presented below exclude assumed debt and upside consideration, which are presented as components of the purchase consideration above.

	Fair Value
Assets acquired:	
Cash and cash equivalents	\$ 1,517
Marketable securities	6,223
Accounts receivable	5,122
Prepaid expenses and other current assets	1,234
Inventory	4,135
Property, plant and equipment	13,023
Right-of-use assets	13,405
Other long-term assets	404
Total assets acquired	45,063
Liabilities assumed:	
Accounts payable	17,587
Accrued expenses	14,802
Operating lease liabilities	13,405
Other current liabilities	1,296
Total liabilities assumed	47,090
Total identifiable net liabilities	-2,027
Goodwill	73,358
Total purchase consideration	\$ 71,331

Goodwill of \$73.4 million represents the excess of the purchase consideration over the fair value of the net identifiable assets acquired and liabilities assumed. Goodwill is primarily attributable to the assembled workforce, expected synergies from combining the operations of VHC with those of the Company, and the platform VHC provides for the Company's strategy to pursue in-license opportunities in the biotechnology industry. Goodwill recognized in the transaction is not deductible for income tax purposes. As of December 31, 2025, based on the results of both qualitative and quantitative goodwill impairment tests performed, the Company concluded that the carrying amount of the goodwill associated with the VHC Business Combination was impaired, and therefore recognized a total goodwill impairment charge of \$73.4 million for the year then ended (see Note 7).

Goodwill will not be amortized but will be tested for impairment at least annually or more frequently if events or changes in circumstances indicate that it may be impaired.

Property, plant and equipment was valued at \$13.0 million using a combination of the cost and market approaches, resulting in a net step-down of \$1.1 million from historical net book value. Marketable securities of \$6.2 million represent the Company's indirect interest in publicly traded shares of Aardvark, measured at the closing market price as of the VHC Transaction Date. Debt assumed of \$47.4 million was measured at fair value using discounted cash flow analyses reflecting the Company's incremental borrowing rate, which resulted in a fair value reduction of \$13.2 million from book value.

The Company elected to apply pushdown accounting in accordance with ASC 805-50, recording the fair value adjustments at the VHC entity level.

For the twelve months ended December 31, 2025, net loss from Vivasor attributable to the noncontrolling interest was \$11.8 million.

Consulting Agreement — Acea Therapeutics, Inc.

Acea Therapeutics, Inc. ("Acea Therapeutics") is a biopharmaceutical company in which Henry Ji, Ph.D., the Executive Chairperson of the Board of Directors of the Company and a subsidiary of Vivasor, holds a greater than 50% ownership interest. As a result of Dr. Ji's position as Executive Chairperson of the Company and his greater than 50% ownership interest in Acea Therapeutics, Acea Therapeutics is considered a related party of the Company for purposes of ASC 850, Related Party Disclosures, and Item 404 of Regulation S-K.

During the year ended December 31, 2025, the Company engaged Acea Therapeutics to provide regulatory strategy

consulting services in connection with the Company's development and commercialization activities in the People's Republic of China. The consulting services provided by Acea Therapeutics included advisory support with respect to the regulatory processes, submissions, and related strategic guidance required for the Company's product candidates under the National Medical Products Administration ("NMPA") and other applicable Chinese regulatory authorities.

During the year ended December 31, 2025, the Company paid an aggregate of \$5.6 million in consulting fees to Acea Therapeutics under this arrangement. All fees were paid in full during the fiscal year ended December 31, 2025.

4. License Agreements

GLOPERBA License Agreement

On June 14, 2022, 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 upfront 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 22,267 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 each of the years ended December 31, 2025, and 2024, the Company made royalty payments in the amount of \$0.6 million. No contingent consideration was recognized as a liability or included in the fair value of the assets as of December 31, 2025 or December 31, 2024.

Gloperba Rest of World License Agreement

On February 28, 2025 (the "Gloperba 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) together, 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 the Gloperba Product for commercialization of the Gloperba Products in the United States in the Field, and (ii) worldwide, to develop and manufacture the Gloperba Product for commercialization in the United States in the Field. 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 Gloperba 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 Gloperba 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 Gloperba Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the “Gloperba License Term”).

Elyxyb Rest of World License Agreement

On February 28, 2025 (the “Elyxyb Effective Date”), the Company entered into a License Agreement (the “Elyxyb License Agreement”) with Scilex Pharma and the Licensee with respect to (i) services, compositions, products, dosages and formulations comprising Elyxyb 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 Elyxyb APA, 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) together, the “Elyxyb Product”).

Under the Elyxyb License Agreement, the Company granted to the Licensee during the Elyxyb License Term (as defined below) a worldwide, exclusive, non-transferable (except in connection with a permitted assignment of the Elyxyb 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 Elyxyb Products, in all cases solely for commercialization of the Elyxyb 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 Elyxyb 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 Elyxyb Product for commercialization of Elyxyb Products in the United States in the Field, and (ii) worldwide, to develop and

manufacture Elyxyb Product for commercialization in the United States in the Field. Each of the Licensee and the Company will receive 50% of the Canadian Net Revenue (as defined therein) generated based on the Licensee's sale of the Elyxyb 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 Canadian Net Revenue on a quarterly basis.

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

Promptly after the Elyxyb Effective Date, the Company is required to (i) facilitate an introduction between the Licensee and CPL as of the Elyxyb Effective Date, and (ii) use reasonable efforts to cause CPL to accept a direct engagement with the Licensee for the manufacturing or supply of the Elyxyb Product in finished dosage form. In addition, the Company agreed to appoint the Licensee as its exclusive distributor of the Elyxyb Product in the entire world other than the United States during the Elyxyb License Term. The term of the Elyxyb License Agreement commences on the Elyxyb Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the "Elyxyb License Term").

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 Koseido Co., Ltd. ("Oishi") and Itochu, as amended, and (ii) the associated Commercial Supply Agreement, dated February 16, 2017, among 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 that certain Rest of World License Term Sheet the 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 Licensors 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 Licensors Territory in the Field (as defined therein), and (ii) worldwide, to develop and manufacture Lido Product for commercialization in the Licensors Territory in the Field. 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 Licensors Territory.

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").

Datavault License Agreement

On November 3, 2025, the Company entered into a license agreement with Datavault (the “Datavault License Agreement”).

Under the Datavault License Agreement, among other things, Datavault granted the Company a worldwide, exclusive, non-transferable license, with the right to sublicense, under the patents and know-how specified therein to among other things, research, develop, make, have made, use, sell, have sold, offer for sale, import, export, register, market, promote, advertise, commercialize and distribute the Proprietary Materials (as defined in the Datavault License Agreement), including a suite of patents related to Datavault’s data platforms and any products created therefrom within the Target Market (as defined below).

With respect to the foregoing, “Target Market” shall mean industries including biotechnology, biopharmaceutical, genetic, diagnostic, and data-related industries, and any markets relating to the generation, use, storage, analysis, tokenization, and exchange of DNA, genetic, diagnostic, and therapeutic data or materials.

The Datavault License Agreement expires upon the expiry of the patents underlying the Proprietary Materials, at which point the license shall become perpetual, irrevocable, non-exclusive and royalty-free. The Datavault License Agreement is subject to earlier termination if, among other things: (i) either party ceases to exist or becomes insolvent, (ii) either party commits a material breach of the Datavault License Agreement, (iii) the Company fails to make any required payment to Datavault that is not cured within 15 days, or (iv) the Company does not achieve and maintain annual royalty payments to Datavault of a minimum of \$1,000,000 after 24 months following the date of the Datavault License Agreement.

As consideration for the license under the Datavault License Agreement, the Company agreed to pay Datavault (a) a non-refundable license fee of \$10.0 million, payable in four equal installments of \$2,500,000 on or before the last day of each fiscal quarter, beginning on December 31, 2025, (b) subject to achievement of certain net sales for the Licensed Product (as defined therein), up to an aggregate of \$2,550,000,000, and (c) a five-percent (5%) royalty on net sales of the Product (as defined therein) during the applicable royalty term under the Datavault License Agreement.

The Datavault License Agreement contains customary reciprocal indemnification obligations for Datavault and the Company and customary representations and warranties.

The Company has not recognized any sales relating to the Licensed Product. Accordingly, the Company has not recognized any additional liabilities under the Datavault License Agreement, other than the \$10.0 million license fee, all of which remains payable as of December 31, 2025.

Vivator Datavault License Agreement

On December 20, 2025, Vivator, Inc. entered into a license agreement with Datavault (the “Vivator-Datavault License Agreement”).

Pursuant to the Vivator-Datavault License Agreement, Datavault granted the Company a worldwide, exclusive, non-transferable license, with the right to sublicense, under certain patents and know-how to, among other things, research, develop, make, have made, use, sell, have sold, offer for sale, import, export, market, promote, commercialize and distribute products incorporating the licensed technology (the “Vivator Licensed Product”) within a defined target market.

The “Vivator Target Market” includes medical imaging and scanning applications, including magnetic resonance imaging (MRI), computed tomography (CT), X-ray (radiography), positron emission tomography (PET), mammography, fluoroscopy, nuclear medicine and three-dimensional scanning technologies utilizing high-performance computing, including quantum-based scanning technologies.

The Vivator-Datavault License Agreement continues for the life of the patents underlying the licensed technology, after which the license becomes fully paid-up, perpetual, irrevocable and royalty-free. The Vivator-Datavault License Agreement is subject to earlier termination upon the occurrence of certain customary events, including (i) insolvency of either party, (ii) an uncured material breach and (iii) failure by the Company to make required payments when due, subject to applicable cure periods.

As consideration for the license, Vivasor, Inc. agreed to pay Datavault (i) a non-refundable license fee of \$20.0 million, payable within 120 days of the invoice date, (ii) sales-based milestone payments of up to an aggregate of \$2.55 billion upon achievement of specified net sales thresholds, and (iii) a royalty equal to five percent (5%) of net sales of Licensed Products.

The Vivasor-Datavault License Agreement contains customary reciprocal indemnification obligations for Datavault and Vivasor and customary representations and warranties.

The Company has not recognized any sales relating to the Vivasor Licensed Product. Accordingly, the Company has not recognized any liabilities under the Vivasor-Datavault License Agreement, other than the \$20.0 million license fee, all of which remains payable as of December 31, 2025.

5. 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, 2025			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Equity method investment, at fair value	\$ 159,403	\$ 159,403	\$ —	\$ —
Marketable securities	6,026	6,026	—	—
Digital assets	64,711	64,711	—	—
Total assets	<u>\$ 230,140</u>	<u>\$ 230,140</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities				
Oramed Note	\$ 27,688	\$ —	\$ —	\$ 27,688
Tranche B Notes	17,500	—	—	17,500
Purchased revenue liability	8,400	—	—	8,400
Derivative liabilities	50,599	—	—	50,599
Contingent consideration short-term	3,013	3,013	—	—
Other long-term liabilities	174	—	—	174
Total liabilities measured at fair value	<u>\$ 107,374</u>	<u>\$ 3,013</u>	<u>\$ —</u>	<u>\$ 104,361</u>
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	<u>\$ 60,979</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 60,979</u>

Equity method investment

As described in Note 1 above and Note 6 below, upon the additional closing under the Datavault SPA, the Company accounted for investment in Datavault Common Stock in accordance with the equity method. The Company

determines the fair value of its Datavault investment by taking the publicly available share price as of the balance sheet date multiplied by the number of shares the Company holds. There are no non-observable inputs in determining the fair value.

Digital assets

As of December 31, 2025, the Company determines the fair value of its digital asset investment by taking the averages of publicly available price of Bitcoin on multiple platform as of the balance sheet date multiplied by the number of Bitcoin the Company holds. There are no non-observable inputs in determining the fair value.

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 8). 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, 2025 and 2024 was determined to be \$27.7 million and \$12.2 million, respectively, by applying a discount rate of 21.00% and 128.82%, respectively. For the years ended December 31, 2025 and 2024, the Company recorded a loss of \$8.4 million and \$3.6 million in change in fair value of the Oramed Note, respectively. For the years ended December 31, 2025 and 2024, the change in fair value due to instrument-specific credit risk recorded as a component of other comprehensive income was \$7.1 million and \$6.3 million, 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 8).

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 8). 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, 2025 and 2024, was determined to be \$17.5 million and \$23.6 million. For the year ended December 31, 2025 and 2024, the Company recorded a loss of \$12.9 million and a gain of \$6.6 million in change in fair value of the Tranche B Notes in the consolidated statement of operations. For the year ended December 31, 2025 and 2024, the change in fair value due to instrument-specific credit risk recorded as a component of other comprehensive income was \$4.3 million and nil, respectively.

Purchased Revenue Liability

In October 2024, the Company entered into the ZTlido Royalty Purchase Agreement with the “ZTlido Royalty Investors” and Oramed (see Note 8). In February 2025, the Company also entered into “the Gloperba-Elyxyb Royalty Purchase Agreement”) with the “Gloperba-Elyxyb Royalty Investors” and Oramed (see Note 8). 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 aggregate fair value of both agreements as of December 31, 2025 and 2024, was determined to be \$8.4 million and \$6.8 million, respectively. For the year ended December 31, 2025 and 2024, the Company recorded a loss of \$4.4 million and \$0.9 million, respectively, in change in fair value of the purchased revenue liability in the consolidated statement of operations.

Derivative Liabilities

As of December 31, 2025, the following warrants to purchase Common Stock that are included in derivative liabilities were outstanding: 1,000,000 Private Warrants, which are currently exercisable for an aggregate of up to 28,572 shares of Common Stock February 2024 BDO Firm Warrants, which are currently exercisable for an aggregate of up to 108,686 shares of Common Stock, 3,250,000 Deposit Warrant, which are currently exercisable for an aggregate of up to 3,250,000 shares of Common Stock, 3,750,000 October 2024 Noteholder Warrants, which are currently exercisable for an aggregate of up to 107,142 shares of Common Stock, and 18,809,454 December 2024 RDO Common Warrants, which are currently exercisable for an aggregate of up to 537,298 shares of Common Stock, 500,000 Exchange Warrants, 275,000 September 2025 Warrants and 1,356,594 November 2025 Warrants. As of December 31, 2025, the fair value of derivative warrant liabilities related to these warrants was \$50.6 million.

The Company recorded a loss of \$22.7 million for the year ended December 31, 2025, attributed to warrant liabilities consisting of the Private Warrants, the February 2024 BDO Firm Warrants, the April 2024 RDO Common Warrants, Deposit Warrant, the October 2024 Noteholder Warrants, December 2024 RDO Common Warrants, the Exchange Warrants, the September 2025 Warrants and November 2025 Warrants (each as defined below). 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.

The Company evaluated the Scilex-St. James Loans for embedded derivatives and identified certain features that required bifurcation because they are not clearly and closely related to the host instrument. The embedded derivatives relate to (i) default provisions that could require additional interest payments, and (ii) a provision which could require the settlement of the principal amount of the Notes through the Pledged Securities upon an uncured event of default. The Company determined that the fair value of these embedded derivatives was immaterial as of the issuance dates of the Notes and as of December 31, 2025.

The following table includes a summary of the derivative liabilities measured at fair value during the years ended December 31, 2025 and 2024 (in thousands):

	Fair Value
Ending Balance as of December 31, 2024	\$ 18,303
Change in fair value measurement	22,693
Issuance of September 2025 Warrants	3,091
Issuance of November 2025 Warrants	6,248
Tranche B deferral modification	(839)
Change in fair value related to the October 2024 Noteholder Warrants exchanged for Exchange Warrants	1,103
Ending Balance as of December 31, 2025	\$ 50,599

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 10).

A summary of the inputs used in valuing the derivative warrant liabilities as of December 31, 2025 is as follows:

	Private Warrants	February 2024 BDO Firm Warrants	Deposit Warrant	October 2024 Noteholder Warrants	December 2024 RDO Common Warrants (5yr)	December 2024 RDO Common Warrants (2.5yr)	Exchange Warrants	September 2025 Warrants	November 2025 Warrants
Exercise price	\$ 402.50	\$ 59.50	\$ 1.20	\$ 36.40	\$ 22.72	\$ 22.72	\$ 40.00	\$ 20.00	\$ 29.00
Term, in years	1.86	3.18	3.47	3.77	3.95	1.45	3.77	3.95	4.90
Volatility	98.0%	81.0%	76.0%	79.0%	78.0%	93.0%	79.0%	74.0%	80.0%
Risk-free rate	3.44%	3.53%	3.56%	3.59%	3.60%	3.45%	3.59%	3.60%	3.69%
Dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

A summary of the inputs used in valuing the derivative warrant liabilities as of December 31, 2024 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)
Exercise price	\$ 402.50	\$ 59.50	\$ 38.50	\$ 1.20	\$ 36.40	\$ 22.72	\$ 22.72
Term, in years	2.86	418.00	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%

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 9.2%. As of December 31, 2025 and 2024, 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, 2025 and 2024.

6. Balance Sheet Components

Investment

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 \$15,063.70, with the remaining \$164,936.30 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 drawdown 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 "Denali 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 Denali 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. On September 22, 2025, the Company's majority owned subsidiary Semnur completed the Semnur Business Combination Agreement (see Note 3). Pursuant to the Semnur Business Combination, Legacy Semnur assumed all liabilities of Denali, including writing off its \$2,000,000 cash consideration investment in Denali and its existing promissory notes and its liability for its deferred underwriting costs associated with the Semnur Business Combination. Simultaneously upon the closing of the Semnur Business Combination, the agreements for these existing liabilities were terminated and new promissory notes and discharge payment agreements were signed with the holders (see Note 8).

PA OPS Investment Agreement

In August 2025, Scilex Bio entered into an Investment Commitment Agreement (the "Investment Agreement") with PA OPS Investor LLC ("Investor LLC"). Pursuant to the terms of the agreement, the Company committed to providing \$2.5 million (the "Committed Amount") in future funding, contingent upon Investor LLC successfully identifying and acquiring an appropriate target company ("Target") for investment using the Committed Amount by December 31, 2025. Although the arrangement was legally structured as if the Investor LLC had extended a \$2,500,000 loan (the "Loan") to Scilex at an annual interest rate of 4.03%, no cash was exchanged between the Investor LLC and the Company on Day 1. Accordingly, the Company concluded that, in substance, the transaction does not represent a loan. In August 2025, the LLC acquired the Target which consists of certain assets of a nursing home. However, as the Company is yet to provide the full funding of the Committed Amount, the Company has no ownership interest in the LLC or in the nursing home as of December 31, 2025. On December 31, 2025, the Company made \$1.0 million in cash (the "Funding") payment to Investor LLC out of the Committed Amount of \$2.5 million, this funding was treated as a partial repayment of the Loan, therefore, no equity ownership was granted to Scilex, as the Target has already been acquired, the Funding is no longer subject to a refund. The Company recorded the Funding in equity investment in the Company balance sheet at cost, net of any impairment, as the Funding was provided close to the balance sheet date, there were no indicators of impairment as of December 31, 2025.

Equity Method Investments, at fair value

Datavault Securities Purchase Agreement

On September 25, 2025, the Company entered into the Datavault SPA with Datavault, pursuant to which Datavault agreed to issue and sell, and the Company agreed to purchase, 15.0 million shares of Datavault Common Stock and the Datavault Pre-Funded Warrant to purchase 263,914,094 shares of Datavault Common Stock for an aggregate purchase price of \$150.0 million.

On the Initial Datavault Closing Date, the Company acquired 15,000,000 shares of Datavault Common Stock at a purchase price of \$0.5378 per share, for an aggregate consideration of approximately \$8.1 million, which was settled in Bitcoin and accounted for as an equity investment in equity securities.

On November 25, 2025, the Company exercised the Datavault Pre-Funded Warrant in full for an aggregate exercise price of approximately \$26.4 thousand to purchase 263,914,094 shares of Datavault Common Stock (such shares, the "Datavault Pre-Funded Warrant Shares") in exchange for an aggregate of approximately \$141.9 million, to be

settled in Bitcoin. The exercise of the Datavault Pre-Funded Warrant increased the Company's percentage ownership in Datavault to approximately 48.0% and provided the Company with the right to nominate two of the nine members of the board of directors. Although no appointments have been made, the Company has determined that it has obtained the ability to exercise significant influence over its investment. Therefore, the Company began accounting for its investment under the equity method of accounting and elected to apply the fair value option, with changes in the fair value recognized in unrealized gains and losses on equity investment in the period in which they occur. The fair value option has been elected as the Company believes it best reflects the underlying economics of this investment.

During the months of October 2025 and prior to the Company exercise of Datavault Pre-Funded Warrant in November 2025, the Company sold a total of 13,389,235 shares of Datavault Common Stock for gross proceeds of \$26.4 million, which resulted in realized gains in the amount of \$19.2 million accounted for using equity investment. After the Company exercised of Datavault Pre-Funded Warrant in November 2025, the Company sold a total of 21,079,599 shares of Datavault Common Stock for gross proceeds of \$13.6 million, which resulted in realized gains in the amount of \$4.7 million accounted for using equity method investment.

There have been no transactions between the Company and Datavault other than those arising from the Datavault License Agreements (see Note 4 for more details) and purchases of Bitcoin from Datavault during the year amounting to \$25.2 million (See Below Digital Assets for more details).

The fair value measurement of the Company's investment in Datavault is based on quoted prices in an active market and valued at the closing price reported at the end of each period and thus represents a Level 1 measurement on the fair value hierarchy. The Company recognized a \$19.2 million loss accounted for using equity security investment measured at fair value. Upon exercise of the Datavault Pre-funded Warrants on November 25, 2025, the Company recognized \$4.7 million gain using equity method, for the year ended December 31, 2025.

As of December 31, 2025 and 2024, the carrying value of the Company investment in Datavault's common stock is \$159.4 million and nil, and is recorded in non-current Equity method investment in the consolidated balance sheets.

The Company's ownership of Datavault Common Stock was approximately 37% and nil as of December 31, 2025 and December 31, 2024, respectively.

Summarized Financial Information

The following is a summary of financial data for investments accounted for under the equity method of accounting (in thousands):

<i>Balance Sheets</i>			
Balance Sheet			
Datavault AI Inc.			
		December 31,	December 31,
		2025	2024
	ASSETS		
Current assets:		\$ 142,873	\$ 6,439
Total assets		<u>\$ 274,704</u>	<u>\$ 100,625</u>
	LIABILITIES		
Current liabilities:		\$ 26,881	\$ 4,113
Total liabilities		<u>\$ 36,730</u>	<u>\$ 14,899</u>
<i>Statement of Operations</i>			
Income Statement			
Datavault AI Inc.			
		December 31,	
		2025	2024
Loss from operations		\$ 32,475	\$ 21,138
Net loss		<u>\$ 78,994</u>	<u>\$ 51,409</u>

Digital Assets

On September 23, 2025, the Company entered into a securities agreement with Biconomy PTE Ltd (“Biconomy”), pursuant to which the Company sold to Biconomy an aggregate of 12,500,000 Semnur Common Shares held by the Company for proceeds of \$200.0 million in Bitcoin. As noted above, the Company used \$150.0 million to purchase stock on Datavault payable in Bitcoin. During the twelve month ended December 31, 2025, the Company purchased Bitcoin from Datavault amounting to \$25.1 million.

The table below summarizes the amounts shown on our consolidated balance sheet as of December 31, 2025 (in thousands except units of digital assets):

	December 31, 2025		
	Units	Cost Basis	Fair Value
Bitcoin	737	\$ 76,891	\$ 64,711
Total Digital assets	737	\$ 76,891	\$ 64,711

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

	Year ended December 31, 2025
Bitcoin	
Additions	\$ 225,233
Disposition	(148,340)
Unrealized loss on digital assets	(12,182)
Ending balance at fair value	\$ 64,711

The Company recorded a \$30.2 million realized gain for the year ended December 31, 2025 upon dispositions.

Property and Equipment, Net

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

	December 31, 2025	December 31, 2024
Construction in progress	\$ 909	\$ 689
Furniture	139	17
Computers and equipment	75	16
Leasehold improvements	3,746	50
Machinery and lab equipment	8,192	—
Land and Buildings	859	—
Property and equipment, gross	13,920	772
Less: Accumulated depreciation	(321)	(64)
Property and equipment, net	\$ 13,599	\$ 708

The Company recognized depreciation expense of \$258.9 thousand and \$14.0 thousand for the years ended December 31, 2025 and 2024, respectively.

Accrued Expenses

Accrued expenses consists of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued professional service fees	\$ 356	\$ 667
Accrued sales and marketing costs	—	876
Accrued research and development costs	13,058	315
Accrued tax payable	50	876
Accrued advisor fees related to Semnur business Combination	14,000	—
Accrued Datavault licenses	30,000	—
Accrued interests	6,862	—
Accrued others	2,088	107
Accrued expenses	<u>\$ 66,414</u>	<u>\$ 2,841</u>

Accrued Rebates and Fees

Gross-to-Net Revenue Adjustments

Gross revenue is directly impacted by the Company's gross-to-net revenue adjustments for sales rebates, discounts, coupons, fees, returns, and chargebacks.

For the year ended December 31, 2025 and 2024, gross revenue was \$125.8 million and \$167.4 million, respectively, while net revenue was \$30.3 million and \$56.6 million, respectively. The gross-to-net revenue adjustment of approximately \$96.3 million and \$110.8 million for the years ended December 31, 2025 and 2024, respectively, was primarily attributable to the following:

	December 31, 2025	December 31, 2024
Gross-to-Net Revenue Adjustments		
Sales rebates	\$ (67,755)	\$ (77,364)
Service fees	(12,900)	(16,753)
Estimated sales returns, discounts, co-payment assistance and coupon	(9,881)	(9,154)
Chargebacks	(5,726)	(7,577)
Total	<u>\$ (96,262)</u>	<u>\$ (110,848)</u>

The accruals for Medicare, Medicaid and related state program and contractual rebates, chargebacks, sales allowances and sales returns and cash discounts are as follows:

	December 31, 2025	December 31, 2024
Other current liabilities:		
Accrued rebates	\$ 220,693	\$ 152,920
Other accruals	11,063	9,597
Total accrued rebates and fees	<u>\$ 231,756</u>	<u>\$ 162,517</u>

As of December 31, 2025, the Company's accrued rebates and fees liability was \$231.8 million, compared to \$162.5 million as of December 31, 2024. The increase of approximately \$69.3 million year-over-year was mainly due to the fact that the Company made only limited disbursements to counterparties during 2025 as its focus was to deploy its cash resources to repay Company debt. The rebates balance of \$220.7 million primarily consists of government disbursements (Medicare and Medicaid) and commercial insurance disbursements. The other accrual balance of \$11.1 million consists of service fees, returns, and coupons. Year-over-year the accrued rebates balance increased by approximately \$67.8 million while the other accrual and fees balance increased by approximately \$1.5 million.

7. Goodwill and Intangible Assets

As of December 31, 2025 and 2024, the Company had recorded goodwill of \$13.5 million. During Q4 2025, the Company recorded a goodwill impairment loss of \$73.4 million, attributable to business combination with Vivator in December 2025. At December 31, 2025, based on the results of both qualitative and quantitative impairment tests performed, the Company concluded that the carrying amount of the goodwill associated with the Vivator Business Combination exceeded its fair value, thereby resulting in a full write-off of the associated goodwill balance. No goodwill impairment was recognized for the year ended December 31, 2024.

Amortization of the intangible assets that have finite useful lives is generally recorded on a straight-line basis over their useful lives, ranging from 5.8 to 12.4 years. A summary of the Company's identifiable intangible assets as of December 31, 2025 and 2024 is as follows (in thousands):

December 31, 2025			
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Patent rights	\$ 32,630	19,946	\$ 12,684
Acquired technology	22,940	10,650	12,289
Acquired licenses	35,711	1,596	34,115
Assembled workforce	500	500	—
Total intangible assets	<u>\$ 91,781</u>	<u>\$ 32,692</u>	<u>\$ 59,088</u>

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	<u>\$ 60,781</u>	<u>\$ 28,328</u>	<u>\$ 32,453</u>

As of December 31, 2025, the weighted average remaining life for identifiable intangible assets was 7.5 years. Aggregate amortization expense was \$4.3 million and \$4.0 million for the years ended December 31, 2025 and 2024, respectively. Patent rights, acquired technology and acquired licenses are amortized over a 15-year period, other than Datavault acquired licenses, which are amortized over a 7-year period. Assembled workforce is amortized over a five-year period.

Estimated future amortization expense related to intangible assets as of December 31, 2025 is as follows (in thousands):

	Amount
2026	\$ 8,368
2027	\$ 8,368
2028	\$ 8,368
2029	\$ 8,368
2030	\$ 8,368
Thereafter	\$ 17,248
Total	<u>\$ 59,088</u>

8. Debt

Scilex-St. James Loan Agreement and Amendment

On December 1, 2025, the Company entered into the Scilex-St. James Loan Agreement with St. James, pursuant to which St. James agreed to loan the Company an aggregate principal amount of up to \$50 million in one or more tranches. The timing and amount of any particular tranche of the Scilex-St. James Loans shall be determined at the

sole discretion of St. James and St. James shall notify the Company in advance of its intention to fund a particular tranche.

The Scilex-St. James Loans will accrue interest at the rate of the 12-month Secured Overnight Financing Rate plus 2.0% per annum, with such interest due and payable on the earlier of Maturity Date and the date of an event of default. The “Maturity Date” of the Scilex-St. James Loans is the fourth anniversary of the closing date of the first tranche of the Scilex-St. James Loans and may be extended by up to 12 months at the request of the Company. The Company is also required to pay a fee of 0.25% of the principal amount of each tranche.

Pursuant to the terms of the Scilex-St. James Loan Agreement, the Company agreed to pledge approximately 39,202,800 shares of common stock of Datavault held by Scilex (the “Scilex-St. James Pledged Securities”) in favor of St. James as security for the Company’s satisfaction of its obligations thereunder. The Scilex-St. James Pledged Securities are held in a securities account that the Company has opened with St. James.

The Scilex-St. James Loan Agreement contains certain events of default, including, without limitation: a decrease in the closing price of the Scilex-St. James Pledged Securities of more than 20%, provided that such decrease is not cured within three days by delivering additional securities into the securities account or depositing cash into a bank account with St. James as security for the Scilex-St. James Loans; a decrease in the average trading volume of the Scilex-St. James Pledged Securities for any three consecutive trading days of more than 20% relative to the average trading volume of the 30 trading day period immediately preceding the closing of a tranche of the Scilex-St. James Loans; or the Scilex-St. James Pledged Securities are delisted from the national securities exchange on which they are currently listed. If an event of default occurs and is not cured within the specified cure period under the terms of the Scilex-St. James Loan Agreement, then St. James has certain remedies under the Scilex-St. James Loan Agreement, in addition to any remedies provided at law or in equity, including, without limitation, the interest rate of the Scilex-St. James Loans will increase by an additional 5.0% per annum and the Scilex-St. James Loan Agreement will terminate automatically with St. James entitled to foreclose upon or otherwise dispose of the Scilex-St. James Pledged Securities.

The Scilex-St. James Loan Agreement also contains positive and negative covenants, representations and warranties and indemnification provisions that are customary for transactions of this type.

On December 8, 2025, the Company and St. James entered into an amendment to the Scilex-St. James Loan Agreement (the “Scilex-St. James Loan Amendment”) pursuant to which the total aggregate principal amount available under the Scilex-St. James Loan Agreement was increased to \$100.0 million. Additionally, the amount of Scilex-St. James Pledged Securities was increased to 85,838,800 shares of common stock of Datavault. All other terms of the Scilex-St. James Loan Agreement will continue in full force and effect unamended.

On December 19, 2025, the Company borrowed a principal amount of \$10.0 million (i.e., the Scilex-St. James Loan Tranche 1), which was collateralized by 17,361,111 shares of the Scilex-St. James Pledged Securities. Net proceeds were \$9.2 million after transaction fees paid to the lender. The net proceeds were paid directly to a vendor of its equity method investee Datavault to settle the investee’s obligation (the “Datavault Obligation”) on the same day.

On December 31, 2025, in exchange for the settlement of the Datavault Obligation, Datavault repaid the Company \$9.4 million, which was settled in Bitcoin.

On December 22, 2025, the Company borrowed an additional principal amount of \$12.6 million (i.e., Scilex-St. James Loan Tranche 2) which was collateralized by 21,841,689 shares of the Scilex-St. James Pledged Securities. On December 26, 2025, the fair value of the Scilex-St. James Pledged Securities declined, requiring the Company to provide an additional 7,116,816 shares of the Scilex-St. James Pledged Securities.

As of December 31, 2025, the Company received from the original Scilex-St. James Loan Agreement, the first and second tranche, an aggregate of \$22.6 million and pledged 49,628,160 shares of common stock of Datavault. The remained available for borrowing under the Scilex-St. James Loan Agreement was \$18.0 million, based on the fair value of the Scilex-St. James Pledge Securities and subject to customary covenant conditions as of December 31, 2025.

The principal amounts under both the Scilex-St. James Loan Tranche 1 and the Scilex-St. James Loan Tranche 2 are due in full on December 19, 2029. Voluntary prepayments may be made 20 months after the closing date without penalty. Interest under both tranches accrues at a fixed per-annum rate of 5.46%, which equals to the 12-month Term SOFR plus 2%, payable upon maturity.

The Company evaluated the Scilex-St. James Loan Agreement for embedded derivatives and identified certain features that required bifurcation because they are not clearly and closely related to the host instrument. The embedded derivatives relate to (i) default provisions that could require additional interest payments, and (ii) a provision which could require the settlement of the principal amount of the Notes through the Scilex-St. James Pledged Securities upon an uncured event of default. The Company determined that the fair value of these embedded derivatives was immaterial as of the issuance dates of the Scilex-St. James Loans and as of December 31, 2025.

SCLX JV-St. James Loan Agreement

On December 15, 2025, SCLX JV entered into a Non-Recourse Loan and Securities Pledge Agreement (the “SCLX JV-St. James Loan Agreement”) with St. James, pursuant to which St. James agreed to loan SCLX JV an aggregate principal amount of up to \$100.0 million in one or more tranches (the “SCLX JV-St. James Loan”). The timing and amount of any particular tranche of the SCLX JV-St. James Loan shall be determined at the sole discretion of St. James and St. James shall notify SCLX JV in advance of its intention to fund a particular tranche.

The SCLX JV-St. James Loan will accrue interest at the rate of the 12-month Secured Overnight Financing Rate, with such interest due and payable on the earlier of Maturity Date and the date of an event of default. The “Maturity Date” of the SCLX JV-St. James Loan is the eighth anniversary of the closing date of the first tranche of the SCLX JV-St. James Loan and may be extended by up to 12 months at the request of SCLX JV. SCLX JV is also required to pay a fee of 0.25% of the principal amount of each tranche.

Pursuant to the terms of the SCLX JV-St. James Loan Agreement, SCLX JV agreed to pledge such number of shares of common stock of the Company currently held by SCLX JV equal to 70% of the aggregate principal amount of the SCLX JV-St. James Loan, calculated in accordance with the terms set forth in the SCLX JV-St. James Loan Agreement (the “SCLX JV-St. James Pledged Securities”), and together with the Scilex-St. James Pledged Securities, the “St. James Pledged Securities” in favor of St. James as security for SCLX JV’s satisfaction of its obligations thereunder. The SCLX JV-St. James Pledged Securities will be held in a securities account that SCLX JV or its affiliates will open with St. James.

The SCLX JV-St. James Loan Agreement contains certain events of default, including, without limitation: a decrease in the closing price of the SCLX JV-St. James Pledged Securities of more than 20%, provided that such decrease is not cured within three days by delivering additional securities into the securities account or depositing cash into a bank account with St. James as security for the SCLX JV-St. James Loan; a decrease in the average trading volume of the SCLX JV-St. James Pledged Securities for any three consecutive trading days of more than 20% relative to the average trading volume of the 30 trading day period immediately preceding the closing of a tranche of the SCLX JV-St. James Loan; or the SCLX JV-St. James Pledged Securities are delisted from the national securities exchange on which they are currently listed. If an event of default occurs and is not cured within the specified cure period under the terms of the SCLX JV-St. James Loan Agreement, then St. James has certain remedies under the SCLX JV-St. James Loan Agreement, in addition to any remedies provided at law or in equity, including, without limitation, that the interest rate of the SCLX JV-St. James Loan will increase by an additional 5.0% per annum and the SCLX JV-St. James Loan Agreement will terminate automatically with St. James entitled to foreclose upon or otherwise dispose of the SCLX JV-St. James Pledged Securities.

As of December 31, 2025, no amounts were outstanding under the SCLX JV-St. James Loan Agreement.

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 10), 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, which are currently exercisable for an aggregate of up to 114,286 shares of Common Stock) 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. In consideration of such extension, SCLX JV agreed to deliver to Oramed an aggregate of 92,857 shares of Common Stock held by SCLX JV, with a fair value of \$1.4 million on the date of delivery, which was recorded as financing costs within the selling, general and administrative expenses in the Company’s consolidated statements of operations.

On July 22, 2025, the Company entered into an option agreement (the “Option Agreement”) with Oramed. Pursuant to the Option Agreement, Oramed granted an option (the “Option”) to the Company to repurchase certain Penny Warrants, held by Oramed, in two tranches (the “Warrant Repurchase”) for an aggregate purchase price of \$27.0 million (the “Warrant Repurchase Amount”), subject to the terms and conditions set forth therein. In consideration of the Option, the Company agreed to pay \$1.5 million (the “Option Payment Amount”) to Oramed in two equal installments, occurring on or before August 8, 2025, and December 16, 2025, respectively. Provided that the Company has made the applicable option payment on or before such dates, the Company shall be entitled to purchase the Penny Warrants as follows: (i) on or before September 30, 2025, it may repurchase 3,130,000 Penny Warrants for \$13.0 million, and (ii) on or before December 31, 2025, it may repurchase 3,370,000 Penny Warrants for \$14.0 million. Additionally, if the Company effects the Warrant Repurchase and has paid the Option Payment Amount and the Warrant Repurchase Amount in full, then the maturity date of the Oramed Note shall be extended to March 31, 2026, and any make-whole payment due thereunder upon prepayment shall be waived. The modification of the terms of the Oramed Note was accounted for as debt extinguishment and the Option was determined to be an embedded feature of the Oramed Note and was reflected into the remeasurement of Oramed Note liability as of December 31, 2025.

In September 2025 and December 2025, the Company fully exercised its option purchasing an aggregate of 6,500,000 Penny Warrants. As Oramed is a shareholder, the Company accounted for the excess fair value over the repurchase price as a deemed contribution from Oramed, which was recorded within Additional Paid-in Capital.

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, 2025 and 2024, the fair value of the Oramed Note was \$27.7 million and \$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, 2025
Ending Balance as of December 31, 2024	\$ 12,161
Change in fair value of Oramed Note – recorded in the consolidated statements of operations	8,413
Change in fair value of Oramed Notes - due to instrument-specific credit risk recorded as a component of other comprehensive income	7,114
Ending Balance as of December 31, 2025	<u>\$ 27,688</u>

Aggregate principal for the Company’s outstanding debt was \$28.2 million as of December 31, 2025.

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 Commitment 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 Commitment 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, 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 Commitment 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 Commitment 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 Commitment 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 Commitment 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.

Tranche B Notes

On October 7, 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 current conversion price equal to \$36.40 per share and (ii) warrants (the "October 2024 Noteholder Warrants") to purchase up to 214,284 shares of Common Stock directly to the Tranche B Noteholders.

In exchange for the issuance of the Tranche B Notes to the Tranche B Investors, the Company has received an aggregate amount in cash of \$22,500,000, excluding fees and expenses payable by the Company. In consideration for the Tranche B Notes issued to Oramed, the Company has received from 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 a current exercise price equal to \$36.40 per share and will expire five years from the issuance date. The October 2024 Noteholder Warrants issued to the Tranche B Investors are initially exercisable for 107,142 shares of Common Stock in the aggregate. The October 2024 Noteholder Warrants issued to Oramed are initially exercisable for 107,142 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 (together, the "October 2024 Placement Agents") or their respective designees, (i) 62,794 shares of Common Stock (the "October 2024 Placement Agent Shares") and (ii) warrants to purchase up to 104,848 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 October 2024 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 for \$5.0 million of the aggregate purchase price for the ZTlido Purchased Receivables (as defined below) 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 within the change in fair value of debt and liability instruments in the consolidated statements of operations during the year ended December 31, 2024.

Pursuant to the Tranche B Notes, commencing on January 2, 2025, the Company was 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, collectively 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, and then further to October 8, 2026. In consideration of such deferral, (i) SCLX JV delivered to the Tranche B Noteholders an aggregate of 142,855 shares of Common Stock held by SCLX JV, with a fair value of \$2.2 million on the date of delivery, which was recorded as financing costs within the selling, general and administrative expenses in the Company’s consolidated statements of operations, (ii) the Company paid an aggregate of \$1.1 million in respect of a portion of the First Amortization Payment and related make-whole interest, and (iii) the Company entered into the Gloperba-Elyxyb Royalty Purchase Agreement (as described below).

On July 22, 2025, the Company entered into Warrant Exchange Agreements (each, a “Warrant Exchange Agreement” and collectively, the “Warrant Exchange Agreements”) with certain holders of the Company’s then-existing Tranche B warrants (such certain holders (excluding Oramed), the “Exchanging Warrant Holders”) to purchase shares of Common Stock (such Tranche B warrants held by the Exchanging Warrant Holders, the “Existing Tranche B Warrants”). Pursuant to the Warrant Exchange Agreements, the Company and the Exchanging Warrant Holders, in reliance on Section 3(a)(9) of the Securities Act, effected a voluntary securities exchange whereby the Exchanging Warrant Holders exchanged the Existing Tranche B Warrants, which are currently exercisable for an aggregate of 107,142 shares of Common Stock at an exercise price of \$36.40 per share, originally issued pursuant to the Tranche B Securities Purchase Agreement, for warrants to purchase an aggregate of 500,000 shares of Common Stock (the “Exchange Warrants”) at an exercise price of \$40.00 per share (the “Exchange Warrant Exercise Price”). The Exchange Warrants shall be immediately exercisable, but may only be exercised on a cash basis on or after the earlier of (i) the date that is 90 days following the Closing Date (as defined in the Warrant Exchange Agreements), and (ii) the initial date after the date of the Warrant Exchange Agreements that a registration statement is effective and available for the issuance of the shares of Common Stock underlying the Exchange Warrants to the holders of the Exchange Warrants (or the resale of shares of Common Stock underlying the Exchange Warrants); provided, however, the Exchange Warrants may only be exercised on a cashless basis if there is no registration statement to cover the issuance of the shares of Common Stock underlying the Exchange Warrants or the resale of such shares. The Exchange Warrants shall have an expiration date of October 8, 2029. The Company recognized a loss in the amount of \$1.1 million in relation to this exchange transaction. As of December 31, 2025, there were 500,000 Exchange Warrants outstanding.

The terms of the Exchange Warrants are generally identical to the terms of the Existing Tranche B Warrants, other than with respect to the number of shares issuable upon exercise thereof and the Exchange Warrant Exercise Price and certain other matters. The Exchange Warrant Exercise Price of the Exchange Warrants is subject to adjustment for any stock split, stock dividend, stock combination, recapitalization or similar event. The Exchange Warrant Exercise Price is also subject to full-ratchet adjustment (down to the Exchange Warrant Exercise Price Floor (as defined below)) in connection with a subsequent offering at a per share price less than the exercise price then in effect. The Exchange Warrants also permit a voluntary adjustment to the Exchange Warrant Exercise Price, subject to certain conditions set forth therein, including compliance with the Nasdaq Listing Rules and having obtained the prior written consent of the required holders as described therein. The Exchange Warrant Exercise Price cannot be lower than \$36.40 per share (as adjusted for stock splits, stock dividends, stock combinations, recapitalizations and similar events, the “Exchange Warrant Exercise Price Floor”), unless shareholder approval is obtained to allow the Exchange Warrants to be exercised at a price lower than the Exchange Warrant Exercise Price Floor in accordance with the Nasdaq Listing Rules. The Company is under no obligation to seek or obtain such shareholder approval.

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, 2025
Beginning Balance as of December 31, 2024	\$ 23,560
Repayment of Tranche B Notes principal and interest	(23,221)
Change in fair value of Tranche B Notes	12,911
Change in fair value of Tranche B Notes - due to instrument-specific credit risk recorded as a component of other comprehensive income	4,250
Ending Balance as of December 31, 2025	<u>\$ 17,500</u>

Aggregate principal for the Company's outstanding debt was \$17.9 million as of December 31, 2025.

Promissory Notes

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

Immediately prior to the closing of the Semnur Business Combination, Denali, Sponsor and the Company entered a Satisfaction and Discharge of Indebtedness Agreement, pursuant to which the Sponsor received \$1.1 million in cash and a promissory note from Denali for \$0.8 million (the "Sponsor Note"). The Sponsor Note shall be payable in six monthly installments of \$134.0 thousand beginning on October 1, 2025, and ending on March 1, 2026.

Immediately prior to the closing of the Semnur Business Combination, Denali and FutureTech Capital LLC ("FutureTech") entered a Satisfaction and Discharge of Indebtedness Agreement, pursuant to which FutureTech received \$340.0 thousand in cash and a promissory note from Denali for \$1.0 million (the "FutureTech Note"). The FutureTech Note shall be payable in six monthly installments of \$170.0 thousand beginning on October 1, 2025, and ending on March 1, 2026.

At closing of the Semnur Business Combination, Denali, the Denali underwriters and the Company entered Satisfaction and Discharge of Indebtedness Agreements, pursuant to which the Denali underwriters received \$350.0 thousand in cash and promissory notes from Denali for a total of \$2.7 million (the "Denali Underwriter Notes"). The Denali Underwriter Notes shall be payable in nine monthly installments of \$300.0 thousand beginning on October 1, 2025, and ending on June 1, 2026, with the last monthly payment being \$250 thousand.

As of December 31, 2025, the Company had total current promissory notes of \$3.5 million, all which are due in less than a year.

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

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

Out of the outstanding promissory notes, the Company did not make certain scheduled installment payments during the fourth quarter of 2025 on the Sponsor Note (monthly installments of \$134 thousand) and the Denali Underwriter Note for U.S. Tiger Securities, Inc. (monthly installments of \$150 thousand). As of December 31, 2025, the Sponsor Note had an outstanding principal balance of \$0.8 million and accrued interest of approximately \$20 thousand at 10% per annum (calculated monthly). The Company has not received a notice of default and expects to make the payments in April 2026.

ACEA Hangzhou-Agilent Bio Loan Agreement

In connection with the Company's acquisition of 30.1% of the outstanding shares of Vivasor (see Note 3), the Company includes in its consolidated financial statements a loan agreement entered into on August 15, 2018 between Hangzhou ACEA Pharmaceutical Research Co., Ltd ("ACEA Hangzhou"), a subsidiary of Vivasor, and Aisen Biological (Hangzhou) Co., Ltd. ("Aisen"), pursuant to which Aisen provided 194.6 million in Chinese Yuan ("RMB") in funding to ACEA Hangzhou over multiple years from 2013 through 2018 (the "Agilent Loan Agreement"). Aisen was subsequently acquired by Agilent Technologies, Inc. on November 18, 2018, through which the loan agreement was assumed by Agilent Technologies, Inc.

The Agilent Loan Agreement documents cumulative advances made by Aisen to ACEA Hangzhou in the following amounts (denominated in RMB): 2013 – RMB 9.0 million; 2014 – RMB 10.8 million; 2015 – RMB 19.5 million; 2016 – RMB 38.9 million; 2017 – RMB 73.0 million; and 2018 – RMB 43.4 million. The proceeds of the loan are designated for the ACEA Hangzhou's operating activities, and ACEA Hangzhou is restricted from changing the use of funds without Aisen's consent.

The contractual term of each loan tranche is ten years from the date of funding. Each loan tranche bears interest at an annual rate beginning in the sixth year following each advance. The Agilent Loan Agreement provides for a five-year interest-free period from the date of each loan tranche, after which interest accrues at an annual rate of 5.39%. Interest is calculated and settled on an annual basis, with settlement occurring by December 31 of each applicable year. Based on the contractual repayment schedule, initial interest payments begin in years ranging from 2019 through 2024 depending on the year of the original advance, with principal repayments due between 2023 and 2028.

The Agilent Loan Agreement includes customary provisions permitting Aisen to monitor the ACEA Hangzhou's operations, financial condition, and use of proceeds, including the right to request financial information and participate in significant financing, restructuring, or liquidation events.

During the year ended December 31, 2018, ACEA Hangzhou repaid RMB 10 million, which repaid the full amount of the 2013 loan tranche and RMB 1 million of the 2014 loan tranche. ACEA Hangzhou has not repaid any other principal balances outstanding with Aisen through the year ended December 31, 2025.

Aisen retains the right to demand early repayment of all or part of the outstanding loan balance, which is outside of the control of the Company. Therefore, the entire loan balance outstanding has been presented within current liabilities.

As part of purchase accounting for the Acquisition, the Company recorded the assumed loan, including accrued interest of \$4.6 million, at its estimated fair value of \$25.7 million as of December 5, 2025. The fair value was determined using a discounted cash flow approach that reflects the contractual repayment terms, including the interest-free period, and a market-based discount rate commensurate with the credit risk of the borrower. The difference between the contractual principal amount of \$30.7 million as of December 5, 2025 and the initial fair value resulted in a discount of \$5.0 million, which is being accreted to interest expense over the remaining term of each tranche using the effective interest method. For any tranches that were past due, these will be accreted and paid in the next 12 months.

As of December 31, 2025, the carrying amount of the loan was \$21.5 million, net of an unamortized discount of \$4.8 million. The accrued interest balance was \$4.7 million as of December 31, 2025, and is presented separately under the accrued expenses caption. For the year ended December 31, 2025, the Company recognized interest expense of \$0.3 million related to the Agilent Loan Agreement, which includes \$0.2 million of non-cash accretion of the discount recognized at the acquisition date. For the period from the acquisition date to December 31, 2025, the Company recognized foreign currency transaction loss of \$0.2 million related to the remeasurement of the RMB-denominated loan.

Other Vivasor Borrowings

Vivasor entity contains multiple financing arrangements with various lenders that are each individually immaterial. These borrowings have substantially similar economic characteristics, including denomination in RMB, interest rates ranging from 0% - 6.00% and maturities between currently due to 2030.

As part of purchase accounting for the acquisition of Vivasor, the Company recorded the assumed other borrowings, including accrued interest of \$1.9 million, at their estimated fair value of \$21.7 million as of December 5, 2025. The

fair value was determined using a discounted cash flow approach that reflects the contractual repayment terms, including the interest-free periods, and market-based discount rates commensurate with the credit risk of the borrower. The difference between the contractual principal and accrued interest amounts of \$25.1 million and the initial fair values resulted in a discount of \$3.4 million, which is being accreted to interest expense over the remaining term of the borrowings using the effective interest method. For any financing arrangements that were past due, these will be accreted and paid in the next 12 months.

During the period from the acquisition date to December 31, 2025, the Company negotiated non-cash settlement of certain debt obligations resulting in a decrease to the debt balance of \$2.6 million. Non-cash settlements primarily consisted of the provision of services to certain counterparties in satisfaction of outstanding obligations and the issuance of equity. The Company evaluated these transactions to determine whether they represented modifications or extinguishments of debt. To the extent such arrangements resulted in the legal release of the Company's obligations, the associated liabilities were derecognized. There was no gain recognized with the settlement and extinguishment of these borrowings as the fair value.

As of December 31, 2025, the carrying amount of the borrowings was \$17.5 million, net of unamortized discounts of \$3.2 million. The accrued interest balance was \$2.1 million as of December 31, 2025, and is presented separately in accrued expenses. For the period from the acquisition date to December 31, 2025, the Company recognized interest expense of \$0.7 million related to the other borrowings, which includes \$0.3 million of non-cash accretion of the discount recognized at the acquisition date. For the period from the acquisition date to December 31, 2025, the Company recognized foreign currency transaction loss of \$0.1 million related to the remeasurement of the RMB-denominated loans.

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 ZTlido 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, 2025 and 2024, the fair value of the ZTlido Royalty Purchase Agreement was \$6.1 million and \$6.8 million, respectively, 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 related to ZTlido Royalty Purchase Agreement during the year ended December 31, 2025 (in thousands):

	December 31, 2025
Ending Balance as of December 31, 2024	\$ 6,800
Repayment of purchased revenue liability	(3,139)
Change in fair value of purchased revenue liability	2,439
Ending Balance as of December 31, 2025	<u>\$ 6,100</u>

Gloperba-Elyxyb Royalty Purchase Agreement

On February 28, 2025 (the “Gloperba-Elyxyb Closing Date”), the Company entered into the Gloperba-Elyxyb Royalty Purchase Agreement with 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 transferred 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 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 Gloperba-Elyxyb Purchased Receivables to which each Gloperba-Elyxyb RPA Purchaser is entitled during the Gloperba-Elyxyb Payment Term.

The Company elected the fair value option for the Gloperba-Elyxyb Royalty Purchase Agreement and records the changes in the fair value within the consolidated statements of operations at the end of each reporting period. As of each of February 28, 2025, and December 31, 2025, the fair value of the Gloperba-Elyxyb Royalty Purchase Agreement was \$0.5 million and \$2.3 million, recorded as a purchased revenue liability on the consolidated balance sheet.

	December 31, 2025
Beginning Balance as of February 28, 2025	\$ 500
Repayment of purchased revenue liability	(41)
Change in fair value of purchased revenue liability	1,841
Ending Balance as of December 31, 2025	<u>\$ 2,300</u>

The following table shows the outstanding principal balance of the Company's debt, by contractual maturity, as of December 31, 2025 (in thousands):

Due in 2026	\$ 76,229
Due in 2027	10,855
Due in 2028	6,626
Due in 2029	847
Due in 2030 and thereafter	6,239
Total principal payments	<u>\$ 100,796</u>

9. Sorrento Stock Purchase Agreement and Equity line of credit

Sorrento Stock Purchase Agreement

On September 21, 2023, the Company entered into that certain Stock Purchase Agreement (the “Sorrento SPA”) with Sorrento Therapeutics, Inc. (“Sorrento”), the Company’s then-controlling stockholder, pursuant to which the Company purchased from Sorrento (i) 1,716,245 shares of Common Stock, (ii) 29,057,097 shares of Series A Preferred Stock, par value \$0.0001 per share (the “Series A Preferred Stock”), and (iii) 1,386,617 Public Warrants (as defined below), which are currently exercisable for an aggregate of up to 39,617 shares of Common Stock and 3,104,000 Private Warrants (collectively, the “Purchased Securities”), which are currently exercisable for an aggregate of up to 88,685 shares of Common Stock. As a result, Sorrento no longer holds a majority of the voting power of the Company’s outstanding capital stock entitled to vote. 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 8), 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 composed of a credit bid for all amounts of principal and accrued but unpaid interest outstanding under the Junior DIP Facility in an aggregate principal amount of \$20.0 million, 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 the equity interests in SCLX JV. Holdco and SCLX JV are parties to the Security Agreement and Subsidiary Guarantee (see Note 8).

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 was classified in permanent equity and did not have any bifurcated features. Therefore, the repurchase of the Series A Preferred Stock by the Company was treated as a redemption of shares, with the excess of the redemption price paid over the carrying value of the shares treated 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 \$3,000 of the Series A Preferred Stock, with \$52.3 million in excess amount allocated as the reduction in additional paid-in capital. Although considered redeemed for accounting purposes, the shares of Series A Preferred Stock remain outstanding as they are 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 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 may be subject to certain adjustments in the event of any stock dividend, stock split, recapitalization, reorganization or similar transaction, as described in the Penny Warrants. 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 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 of Common Stock for the Company to settle the exercise of the warrants in shares of Common Stock. 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.

On July 22, 2025, the Company entered into the Option Agreement with Oramed, pursuant to which the Company fully exercised its’ repurchase option and holds Penny Warrants. See Note 9 for the additional discussion of the Option Agreement and the Warrant Repurchase.

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, 2025 and December 31, 2024, the Company made a total of \$0.9 million and 0.5 million payments for the excise tax, respectively. As of December 31, 2025, the remaining balance of the excise tax liability recorded as accrued expenses was \$33.5 thousand.

Equity Line of Credit

On July 22, 2025, the Company entered into that certain common stock purchase agreement (the “Tumim Purchase Agreement”), by and between the Company and Tumim Stone Capital, LLC (“Tumim”), the Company had the right, but not the obligation, to sell to the Tumim up to the lesser of: (a) \$100,000,000 of newly issued shares of Common Stock (“Commitment Amount”) and (b) the Exchange Cap (as defined below), from time to time, at the Company’s sole discretion (each such sale, a “VWAP Purchase”) by delivering an irrevocable written notice to Tumim (each such notice, a “VWAP Purchase Notice”). The Company was permitted to deliver a VWAP Purchase Notice to Tumim during the period commencing on the Commencement Date (as defined in the Tumim Purchase Agreement) and the date that would have been the first day of the month following the 24-month anniversary of the date on which the initial Tumim Registration Statement (as defined below) would have been declared effective by the SEC, subject to the terms and conditions set forth therein, and unless the Tumim Purchase Agreement was earlier terminated in accordance with its terms.

Tumim’s purchases of shares of Common Stock under the Tumim Purchase Agreement, if any, would have been subject to certain limitations, including that Tumim may not purchase shares that would result in it (together with its affiliates) owning more than 4.99% (or, at the election of Tumim, 9.99%) of the then-issued and outstanding shares of Common Stock. In addition, unless stockholder approval of a waiver of the Exchange Cap (as defined below) was

obtained, the Company shall not issue or sell any shares of Common Stock pursuant to the Tumim Purchase Agreement, if, after giving effect thereto, the aggregate number of shares of Common Stock that would have been issued pursuant to the Tumim Purchase Agreement and the transactions contemplated thereby would exceed 1,390,443 (representing 19.99% of the number of shares of Common Stock issued and outstanding immediately prior to the execution of the Tumim Purchase Agreement) (such maximum number of shares, the “Exchange Cap”). However, the Exchange Cap shall not be applicable for any purposes of the Tumim Purchase Agreement and the transactions contemplated thereby, to the extent that (and only for so long as) the average price of all applicable sales of Common Stock under the Tumim Purchase Agreement equaled or exceeded \$8.09, which is the Minimum Price (as defined in the Tumim Purchase Agreement). The Company was under no obligation to seek stockholder approval of a waiver of the Exchange Cap.

As consideration for Tumim’s commitment to purchase shares of Common Stock, the Company was required to issue 150,000 shares of Common Stock to Tumim as a commitment fee (the “Commitment Shares”) upon effectiveness of the Tumim Registration Statement (as defined below).

In connection with the transactions contemplated by, and concurrently with the execution of, the Tumim Purchase Agreement, the Company and Tumim also entered into a Registration Rights Agreement, dated as of July 22, 2025 (the “Tumim Registration Rights Agreement”), pursuant to which the Company agreed to file with the SEC one or more registration statements (each, a “Tumim Registration Statement”), to register under the Securities Act the offer and resale by Tumim of all of the shares that may have been issued by the Company to Tumim from time to time under the Tumim Purchase Agreement, including the Commitment Shares. Tumim’s obligation to purchase shares of Common Stock pursuant to the Tumim Purchase Agreement was subject to such a Tumim Registration Statement being filed with the SEC and declared effective.

On October 30, 2025 the Company and Tumim entered into a termination agreement (the “Termination Agreement”), pursuant to which each of the Tumim Purchase Agreement and the Tumim Registration Rights Agreement (together, the “Original Agreements”) shall terminate upon payment in full of an aggregate of \$2.7 million by the Company to Tumim in lieu of the issuance of the Commitment Shares with \$500,000 to be paid on or before each of October 31, 2025 and November 14, 2025 and the remaining \$1.7 million to be paid on or before December 15, 2025. The Company fully paid the \$2.7 million in October 2025, November 2025 and December 2025, respectively. As of December 31, 2025, pursuant to the Termination Agreement, the Original Agreements are terminated.

10. 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 a post reverse split exercise price of \$402.50 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 \$630.00 per share post reverse split price 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 9). On September 20, 2024, the Company repurchased 4,000,000 of the SPAC Warrants (which were exercisable for an aggregate of up to 114,286 shares of Common Stock) held by Oramed (refer to Note 8). Following the repurchase, these warrants were cancelled.

As of December 31, 2025 and 2024, there were Public Warrants issued and outstanding and exercisable for an aggregate of up to 156,115 and 156,220 shares of Common Stock, respectively.

As of each of December 31, 2025 and 2024, there were 1,000,000 Private Warrants outstanding, which are currently exercisable for an aggregate of up to 28,572 shares of Common Stock.

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, 2025 and 2024, 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, 2025 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.

On February 2, 2026, the Board approved revocation of the declaration of the Dividend (the “Dividend Revocation”). No shares of Series 1 Mandatory Exchangeable Preferred Stock had ever been issued or outstanding as of such date as the Spin-off Dividend (as defined in the Certificate of Designation) did not occur by the Preferred Stock End Date (as defined in the Certificate of Designation).

On February 3, 2026, in connection with the Dividend Revocation, the Company filed a Certificate of Elimination of Series 1 Mandatory Exchangeable Preferred Stock (the “Certificate of Elimination”) with the Secretary of State of the State of Delaware. The Certificate of Elimination, which became effective immediately upon filing, eliminated the previously designated 5,000,000 shares of Series 1 Mandatory Exchangeable Preferred Stock and caused such shares to resume their status as undesignated shares of preferred stock of the Company. No shares of Series 1 Mandatory Exchangeable Preferred Stock were issued or outstanding upon the filing of the Certificate of Elimination.

Treasury Stock

As of December 31, 2025 and 2024, there were 1,458,263 and 1,716,245, respectively, shares of Treasury Stock.

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.

For the year ended December 31, 2025 no sales of Common Stock had been made under the ATM Sales Agreement. For the year ended December 31, 2024, the Company sold 78,976 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately \$2.7 million.

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 the “February 2024 BDO” 108,686 shares of the “February 2024 BDO Firm Shares” and accompanying February 2024 BDO Firm Warrants to purchase up to an aggregate of 108,686 shares of Common Stock. 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 February 2024 BDO Firm Share and accompanying February 2024 BDO Firm Warrant paid by the underwriters was \$54.74, which amount reflects the combined public offering price of \$59.50, less underwriting discounts and commissions. Subject to certain ownership limitations, the Common Warrants are immediately exercisable, set to expire five years later, with an exercise price of \$59.50 per share, subject to adjustments. Additionally, the Company issued the “February 2024 BDO Representative Warrants” to the underwriters, allowing them to purchase up to 13,446 shares of Common Stock, with these warrants being immediately exercisable at \$74.38 per share, representing 125% of the combined public offering price per February 2024 BDO 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 5) 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 50,421 shares of Common Stock in cash at an amended exercise price of \$20.65 per share. During the year ended December 31, 2025 and 2024, there were nil and 59,397 February 2024 BDO Firm Warrants exercised for total net proceeds of nil and approximately \$1.6 million, including the amended February 2024 BDO Firm Warrants. As of December 31, 2025 and 2024, there were 3,803,447 February 2024 BDO Firm Warrants, which are currently exercisable for an aggregate of up to 108,686 shares of Common Stock outstanding and 470,588 February 2024 BDO Representative Warrants, which are currently exercisable for an aggregate of up to 13,446 shares of our Common Stock 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 428,572 shares of Common Stock (the “April 2024 RDO Shares”), and (ii) common warrants to purchase up to 428,572 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 \$35.00, 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 \$38.50 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 “April 2024 RDO Placement Agents”) in connection with the April 2024 RDO. As compensation for such placement agent services, the Company paid the April 2024 RDO 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 April 2024 RDO 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 April 2024 RDO Placement Agents or their respective designees common warrants, substantially in the form of the April 2024 RDO Common Warrants, to purchase up to 34,286 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 \$43.75 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 5) 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.

On November 23, 2025, in connection with the November 2025 Warrant Inducement Agreement (as defined below), the investor agreed to exercise the April 2024 RDO Common Warrants in exchange for the November 2025 Warrants.

As of December 31, 2025, there were no April 2024 RDO Common Warrants outstanding. As of December 31, 2024, there were 15,000,000 April 2024 RDO Common Warrants outstanding, which were exercisable for an aggregate of up to 428,572 shares of Common Stock. As of each of December 31, 2025 and 2024, there were 1,200,000 April 2024 RDO Placement Agent Warrants outstanding, which are currently exercisable for an aggregate of up to 34,286 shares of Common Stock.

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 753,009 shares of Common Stock, (ii) pre-funded warrants to purchase up to 68,604 shares of Common Stock (the “December 2024 RDO Pre-Funded Warrants”) and (iii) common warrants to purchase up to 1,642,871 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 \$20.65 and (b) per December 2024 RDO Pre-Funded Warrant and accompanying December 2024 RDO Common Warrants was \$20.6499. 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 5) 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.

On November 23, 2025, in connection with the November 2025 Warrant Inducement Agreement (as defined below), one of the investors exercised the December 2024 RDO Common Warrants in exchange for the November 2025 Warrants.

As of December 31, 2025 and 2024, there were December 2024 RDO Common Warrants outstanding, which are exercisable for an aggregate of up to 537,298 and 1,642,871 shares of Common Stock, respectively, and StockBlock Warrants outstanding which are exercisable for an aggregate of up to 131,472 shares of Common Stock.

Warrant Exercise Agreement

On September 30, 2025, the Company entered into a Warrant Exercise Agreement (the “Warrant Exercise Agreement”) with certain holders (the “Existing Warrant Holders”) of the Company’s existing warrants to purchase shares of the Company’s common stock, par value \$0.0001 per share (the “Common Stock”) at an exercise price of \$22.72 per share originally issued pursuant to that certain Securities Purchase Agreement, dated December 11, 2024, by and among the Company and the investors named therein (the “Existing December 2024 Warrants”). Pursuant to the Warrant Exercise Agreements, the Existing Warrant Holders will exercise in full the Existing December 2024 Warrants for an aggregate of 179,236 shares of Common Stock and defer, for a deferral fee of \$7.72 per share being exercised (the “Deferral Fee”), their right to receive an amortization payment scheduled to be paid by the Company on October 1, 2025, as set forth in the amortization schedule included in the Tranche B Notes issued to each Existing Warrant Holder and Oramed pursuant to that certain Securities Purchase Agreement, dated as of October 7, 2024, by and among the Company and the investors party thereto (including the Existing Warrant Holders) in exchange for the Company’s agreement to issue new warrants to purchase an aggregate of 275,000 shares of Common Stock (the “September 2025 Warrants”) at an exercise price of \$20.00 per share as described below. The aggregate gross proceeds from the exercise of the Existing December 2024 Warrants, net of the Deferral Fee, is approximately \$2.7 million.

The Company has agreed to use an aggregate of \$2.5 million of the gross proceeds from the warrant exercises in connection with the repayment of such aggregate amounts outstanding under the Tranche B Notes, and the remaining proceeds from the exercise of the Existing December 2024 Warrants for general corporate purposes.

The September 2025 Warrants are immediately exercisable upon issuance. The issuance of the September 2025 Warrants was made pursuant to an exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), and Rule 506(b) of Regulation D as promulgated thereunder by the United States Securities and Exchange Commission (the “SEC”). The Company has agreed to file as soon as practicable (and in any event within 30 calendar days of the date of the Warrant Exercise Agreement) a registration statement on Form S-3 (or Form S-1 if Form S-3 is not available to the Company) registering under the Securities Act, the resale by the Existing Warrant Holders of the shares of Common Stock issuable upon exercise of the of the September 2025 Warrants or to include such shares of Common Stock in any other registration statement on Form S-3 filed by the Company. Accordingly, on December 16, 2025, the Company filed a registration statement on Form S-1. The September 2025 Warrants shall have an expiration date of December 13, 2029.

The Exercise Price of the September 2025 Warrants is subject to adjustment for any stock split, stock dividend, stock combination, recapitalization or similar event and is also subject to adjustment in connection with certain subsequent offerings at a per share price less than the exercise price of the September 2025 Warrants then in effect.

A holder of a September 2025 Warrant shall not have the right to exercise any portion of a September 2025 Warrant to the extent that, after giving effect to such exercise, the holder (together with certain related parties) would beneficially own in excess of 4.99% (the “Maximum Percentage”) of shares of Common Stock outstanding immediately after giving effect to such exercise. The Maximum Percentage may be raised or lowered to any other percentage not in excess of 9.99%, at the option of the holder, except that any increase will only be effective upon 61 days’ prior notice to the Company.

The September 2025 Warrants prohibit the Company from entering into specified fundamental transactions unless the successor entity (subject to certain exceptions) assumes all of the Company’s obligations under the September 2025 Warrants under a written agreement before the transaction is completed. Upon specified corporate events, a September 2025 Warrant holder will thereafter have the right to receive upon an exercise such shares, securities, cash, assets or any other property whatsoever which the holder would have been entitled to receive upon the

happening of the applicable corporate event had the September 2025 Warrant been exercised immediately prior to the applicable corporate event. When there is a transaction involving specified changes of control, holders of September 2025 Warrants will have the right to force the Company to repurchase such holder's September 2025 Warrant for a purchase price in cash equal to the Black Scholes value, as calculated under the September 2025 Warrants, of the then unexercised portion of the September 2025 Warrant.

As of December 31, 2025, there were September 2025 Warrants outstanding, which are exercisable for an aggregate of up to 275,000 shares of Common Stock.

Warrant Inducement Agreement

On November 23, 2025, the Company entered into a Warrant Inducement Agreement (the "Warrant Inducement Agreement") with an investor, pursuant to which the investor agreed to exercise all of their outstanding April 2024 RDO Common Warrants and December 2024 RDO Common Warrants (collectively, the "Original Warrants") in exchange for (i) a reduction in the exercise prices from \$38.50 per share and \$22.72 per share, respectively, to \$22.51 per share, and (ii) the issuance of a new unregistered warrant (the "November 2025 Investor Warrant").

Because the amendments to the exercise price of the April 2024 RDO Common Warrants and December 2024 RDO Common Warrants resulted in an exercise price equal to the fair value of the Common Stock, the Company concluded that the substance of the transaction was an exchange of the Original Warrants for the November 2025 Investor Warrants as an inducement for the issuance of 904,396 shares of Common Stock at a purchase price equal to their fair value. The impact of the warrant exchange, calculated as the difference between the fair value of the November 2025 Investor Warrants and the fair value of the Original Warrants resulted in a loss amounting to \$6.3 million, which the Company recorded within the "Loss on settlement of liability classified instruments" in the statement of operations and comprehensive loss. Upon the exercise of the Original Warrants, the Company received in cash \$18.6 million, net of issuance costs.

The November 2025 Investor Warrants to purchase 1,356,594 shares of Common Stock have an exercise price of \$29.00 per share, may be exercised on a cashless basis under certain circumstances, and have an expiration date of November 25, 2030. The Company accounted for November 2025 Investor Warrants as liability classified instruments.

As of December 31, 2025, there were 1,356,594 shares of November 2025 Investor Warrants and 72,352 shares of November 2025 Placement Agent Warrants outstanding with an exercise price of \$29.00 per share, may be exercised on a cashless basis under certain circumstances, which are exercisable for an aggregate of 1,428,946 shares of Common Stock and have an expiration date of November 25, 2030.

Repricing Options

On December 11, 2025 (the "Repricing Date"), the Company's stockholders approved a one-time repricing (the "Option Repricing") of certain outstanding stock options held by 14 of the Company's current employees. The per-share exercise price of these options was reduced to \$16.80, the closing price of the Company's common stock on the Nasdaq Capital Market on the Repricing Date (the "Repricing").

The Option Repricing applied to certain stock options granted under the Company's 2022 Equity Incentive Plan, as amended (the "Plan"). This included stock options with an original exercise price of \$282.80 per share, representing an aggregate of 289,405 shares of common stock (the "Eligible Options"). The Eligible Options were held by certain current employees, executive officers, and non-employee directors as of the Repricing Date. Only options with an exercise price of \$282.80 per share immediately prior to the Repricing were eligible to participate.

Except for the modification to the exercise price, the Eligible Options continue to be subject to their original terms and conditions, including the number of shares underlying the options, vesting schedules, and expiration dates.

The Option Repricing resulted in total incremental stock-based compensation expense of \$2.4 million, which was calculated using the Black-Scholes option-pricing model. For the year ended December 31, 2025, the Company recognized incremental stock-based compensation expense of \$1.7 million related to repriced options. As of December 31, 2025, there is \$0.7 million of unrecognized incremental stock-based compensation expense related to

the Option Repricing, which will be recognized over the remaining service period of approximately 1 year.

11. 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. However, the 2017 Stock Option Plan will continue to govern outstanding awards granted thereunder.

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, 2025, a total of 1,059,347 shares of Common Stock were available and have been reserved for future issuance under 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 40,000 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, 2025 and 2024.

As of December 31, 2025, options to purchase 1,503,907 shares of Common Stock were outstanding under all equity incentive plans.

The following table summarizes stock option activity during the year ended December 31, 2025 (shares in thousands):

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life, in years	Aggregate Intrinsic Value
Outstanding as of December 31, 2024	1,028	\$ 138.23	6.4	\$ —
Granted	803	16.62	—	—
Forfeited/Cancelled	(327)	261.03	—	—
Outstanding as of December 31, 2025	1,504	\$ 46.59	6.8	\$ 5
Vested and expected to vest as of December 31, 2025	1,504	46.59	6.8	5
Exercisable as of December 31, 2025	898	\$ 58.52	5.3	\$ 1

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, 2025 and 2024 was \$11.57 and \$23.49 per share, respectively. No options were exercised during the year ended December 31, 2025. The total intrinsic values of options exercised during the year ended December 31, 2024 were \$47.3 thousand. 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 \$15.5 million and \$15.7 million for the years ended December 31, 2025 and 2024, respectively.

The total unrecognized compensation costs related to unvested employee and non-employee stock option grants as of December 31, 2025 were \$20.0 million, which the Company expects to recognize over a weighted-average period of approximately 3.1 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, 2025, the total number of shares of Common Stock that may be issued under the ESPP shall not exceed 170,575, which was increased from 127,903 shares as a result of automatic annual increase on January 1, 2025.

Total stock-based compensation recorded as operating expense for the ESPP was \$0.1 million and \$0.2 million for the years ended December 31, 2025 and 2024, respectively.

There were 5,497 and 334,326 shares of Common Stock issued under the ESPP during the years ended December 31, 2025 and 2024, 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, 2025
Stock options:	
Expected dividend yield	0.00%
Expected volatility	72.54% - 99.1%
Risk-free interest rate	3.55% - 4.17%
Term of options (in years)	6.25
Employee stock purchase plan:	
Expected dividend yield	0.00%
Expected volatility	112.87%
Risk-free interest rate	4.31%
Expected life (in years)	0.49

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, 2025, 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 \$0.4 million and \$0.6 million for the years ended December 31, 2025 and 2024, 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 114,286 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 285,714 shares of Common Stock to the same law firm.

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

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, 2025, it was not probable that any of the Retainer Shares would be applied against any outstanding legal fees.

12. Variable Interest Entities

Vivasor Business Combination

On December 5, 2025 (the “VHC Transaction Date”), the Company entered into a Share Transfer Agreement with EAR SPV LLC, a Delaware corporation (“EAR SPV”) and Vivasor Holding Company (“VHC”), a privately held biotechnology company, pursuant to which, among other things, EAR SPV agreed to sell, and the Company agreed to buy, all 6,101,468 shares of VHC’s Series A-1 Preferred Stock, par value \$0.00001 per share, held by EAR SPV, for an aggregate purchase price of \$9.0 million (“VHC Business Combination”).

The Company evaluated VHC under the VIE model in accordance with ASC 810 and concluded that VHC is a VIE because it lacked sufficient equity at risk to finance its activities without additional subordinated support (see Note 3). Due to the Company’s power to direct key activities through its eligible majority board representation and its significant economic exposure through its 30.8% equity interest, it was determined that the Company was the primary beneficiary of VHC. As a result, the Company consolidated VHC as of the VHC Transaction Date. The Company will reassess its primary beneficiary status and VIE conclusion for VHC upon the occurrence of any reconsideration events.

Scilex Bio, Inc. Acquisition

On April 17, 2025, the Company established a majority and controlling interest in Scilex Bio, a newly formed legal entity created to develop and commercialize KDS2010, a next-generation reversible MAO-B Inhibitor, a novel inhibitor of aberrant GABA production in reactive astrocytes for the treatment of obesity and neurodegenerative diseases including Alzheimer’s disease in the United States. At formation, the Company contributed 5,000,000 shares of common stock, par value \$0.00001 per share, of Semnur (the “Semnur Common Stock”) to Scilex Bio in exchange for a 60% equity interest. IPMC Company (“IPMC”) made certain representations to Scilex Bio regarding its rights in certain license and commercialization rights to KDS2010 and agreed to contribute such rights to Scilex Bio in exchange for a 40% equity interest.

The Company evaluated Scilex Bio under the variable interest entity (“VIE”) model in accordance with ASC 810 and concluded that Scilex Bio is a VIE because it lacked sufficient equity at risk to finance its activities without additional subordinated support. Due to the Company’s power to direct key activities through its majority board representation and its significant economic exposure through its 60% equity interest, it was determined that the Company was the primary beneficiary of Scilex Bio. As a result, the Company consolidated Scilex Bio beginning on the formation date.

The Company further concluded that Scilex Bio did not meet the definition of a business under ASC 805, *Business Combinations*. Therefore, the transaction was accounted for as an asset acquisition under ASC 805-50. As the shares of Semnur Common Stock were contributed by the Company (the parent) to an entity under common control, they were recorded at their historical carrying value of \$0 in the consolidated financial statements. The KDS2010 license rights contributed by IPMC were recorded at 40% of their estimated fair value of \$9.4 million for \$4.9 million and immediately expensed as in-process research and development (“IPR&D”) in accordance with ASC 730, *Research and Development*, as the contributed IP had no alternative future use. A current liability of \$1.1 million was also recognized for the initial upfront payment due under the licensing arrangement (further discussed below).

Additionally, the Company recorded \$1.9 million in additional paid-in capital as a capital contribution. For the twelve months ended December 31, 2025, net loss from Scilex Bio attributable to the noncontrolling interest was \$2.1 million.

As of December 31, 2025, Scilex Bio had not commenced revenue-generating operations and remains focused on early-stage development efforts for KDS2010. The Company will reassess its primary beneficiary status and the VIE conclusion for Scilex Bio upon the occurrence of any reconsideration events.

In connection with the formation of Scilex Bio, on April 17, 2025, the entity entered into a license agreement with IPMC and NeuroBioGen Company (“NBG”), under which it obtained exclusive rights to develop and commercialize KDS2010 globally, except for Korea. Under the terms of the agreement, Scilex Bio may be required to make aggregate payments of up to KRW 6.5 trillion (approximately \$4.8 billion) to NBG, consisting of an upfront fee of KRW 1.5 billion (approximately \$1.1 million), and KRW 68.5 billion (approximately \$50.7 million) contingent upon the achievement of specified development, regulatory and commercial milestones. Scilex Bio is also required to pay royalties equal to 5% of net sales of licensed products, payable quarterly until the expiration of the last-to-expire licensed patent. Aggregate payments to NBG are capped at KRW 6.5 trillion (approximately \$4.8 billion). As of December 31, 2025, only the first tranche of the upfront fee (KRW 1.5 billion or approximately \$1.1 million) had become payable, subject to the satisfaction of certain obligations on the part of NBG, and was recorded as a current liability.

Semnur

On September 22, 2025, the Company’s majority owned subsidiary Semnur completed the Semnur Business Combination Agreement (see Note 3). Semnur is the Company’s majority owned clinical late-stage pharmaceutical company focused on the development and commercialization of SEMDEXA.

The Semnur Business Combination was accounted for as a reverse recapitalization. Because the Company controlled Semnur before the Business Combination and also controls Semnur following the Semnur Business Combination, Denali was treated as the “acquired” company for financial reporting purposes. Accordingly, the Semnur Business Combination was treated as the equivalent of Semnur issuing stock for the net assets of Denali, accompanied by a

recapitalization whereby the net assets of Denali will be stated at historical cost and no goodwill or other intangible assets are recorded.

Due to the changes in ownership structure related to the above transactions, the Company reevaluated Semnur under the VIE model in accordance with ASC 810. The Company concluded that Semnur is a VIE because it lacked sufficient equity at risk to finance its activities without additional subordinated support. Due to the Company's power to direct key activities through its majority board representation and its significant economic exposure, it was determined that the Company was the primary beneficiary of Semnur. As a result, the Company continues to consolidate Semnur and records the interest that the Company does not own as noncontrolling interest in the consolidated financial statements.

The Company's consolidated balance sheet at December 31, 2025 includes balances for Semnur of \$20.0 thousand for cash and cash equivalents, \$0.8 million property and equipment, net, \$5.9 million accounts payable, \$0.7 million accrued expenses, and \$3.5 million note payable. For the twelve months ended December 31, 2025, net loss from Semnur attributable to the noncontrolling interest was \$1.4 million.

13. Commitments and Contingencies

Securities Purchase Agreement (the "PIPE SPA")

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

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

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, 2025 and 2024, Scilex Pharma made royalty payments in the amount of \$6.3 million and \$8.3 million, respectively. As of December 31, 2025 and 2024, Scilex Pharma had ending balances of accrued royalty payables of \$2.1 million and \$4.0 million, respectively. Total royalty expense recorded within cost of revenue was \$4.4 million and \$9.9 million for the years ended December 31, 2025 and 2024, 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.

Sales Operations Services

In November 2014, Scilex Pharma entered into a project agreement with a vendor, pursuant to which the vendor has agreed to perform certain services in accordance with written work orders, which was subsequently superseded by a new project agreement entered into in May 2025 (the "Project Agreement"). In connection with the detailing services, the Project Agreement provides that the vendor will provide Scilex Pharma with full-time sales representatives who shall detail the Product by making calls pursuant to a call plan on targets. In connection with the sales operation services, the vendor will provide certain services required for the initial implementation and ongoing operation of the sales force.

In May 2025, Scilex Pharma and the vendor entered into a work order in which the parties agreed to convert substantially all of the sales representatives allocated under the Project Agreement to become employees of the vendor. The work order shall be in effect and remain in effect until the thirty-six months anniversary of the Deployment Date, as set forth in accordance with the terms of the Project Agreement, which is June 3, 2025, or until terminated in accordance with the terms of the Project Agreement or unless extended as provided therein (the "Term"). The Term may be extended for additional periods of one (1) year (each, an "Additional Term") upon the mutual written agreement of the parties not less than sixty (60) days before the end of the Term or any Additional Term. Scilex Pharma paid a one-time implementation fee of \$72 thousand associated with the operational setup and the recruiting of the sales representatives and will pay fixed monthly fee of \$1.2 million for year one and \$1.3 million for each of year two and year three.

Pursuant to the terms set forth in the Project Agreement, either party may terminate this work order without cause upon ninety (90) days prior written notice to the other party; provided, however, that such termination by Scilex Pharma may not occur prior to the twelve (12) month anniversary of the Deployment Date.

PA OPS Investment Agreement

In August 2025, Scilex Bio entered into an Investment Commitment Agreement (the "Investment Agreement") with PA OPS Investor LLC ("Investor LLC"). Pursuant to the terms of the agreement, the Company committed to providing \$2.5 million (the "Committed Amount") in future funding, contingent upon Investor LLC successfully identifying and acquiring an appropriate target company ("Target") for investment using the Committed Amount by December 31, 2025. Although the arrangement was legally structured as if the Investor LLC had extended a \$2,500,000 loan (the "Loan") to Scilex at an annual interest rate of 4.03%, no cash was exchanged between the Investor LLC and the Company on Day 1. Accordingly, the Company concluded that, in substance, the transaction does not represent a loan. In August 2025, the LLC acquired the Target which consists of certain assets of a nursing home. However, as the Company is yet to provide the full funding of the Committed Amount, the Company has no ownership interest in the LLC or in the nursing home as of December 31, 2025. On December 31, 2025, the Company made \$1.0 million in cash (the "Funding") payment to Investor LLC out of the the Committed Amount of \$2.5 million, this funding was treated as a partial repayment of the Loan, therefore, no equity ownership was granted to Scilex, as the Target has already been acquired, the Funding is no longer subject to a refund. The Company consider the consolidation models provided in ASC 810 to determine if the Company should consolidate Investor LLC as of December 31, 2025 and concluded that the Funding meets the definition of a VIE but are not in scope of ASC 810, as the Company has not yet received any equity ownership in the Investor LLC, does not hold a board seat, does not have the power to direct Investor LLC's significant activities and it does not have an obligation to absorb any of the VIE's losses, or rights to receive any benefits from the VIE, further, the Company assess and concludes it does not meet the definition of a derivative under ASC 815. As of December 31, 2025, the Company

accounted for the Funding as an equity security under ASC 321 as it provides the Company with the right to acquire equity ownership in the future at a fixed price through the payment of the remaining Committed Amount. The Company recorded the Funding in equity investment in the Company balance sheet at cost, net of any impairment, as the Funding was provided close to the balance sheet date, there were no indicators of impairment as of December 31, 2025.

Litigation

In the normal course of business, the Company may be named as a defendant in one or more lawsuits. Other than the following three 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. The Company evaluates each matter and assesses its potential financial exposure. If the potential loss from a legal proceeding is considered probable and the amount can be reasonably estimated, the Company records an accrual for the estimated loss. Because the outcome of legal proceedings is inherently uncertain, significant judgment is required in assessing the likelihood of a loss and whether the amount is reasonably estimable. The Company's assessments and any recorded accruals are based on information available at the time of evaluation. As additional information becomes available, the Company re-evaluates its estimates and may adjust recorded liabilities accordingly.

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 requested further briefing on the remedies solely as to the remaining defendant, Mr. Mack. The parties filed further briefing and then presented oral argument on November 15, 2024. The Court's issued its decision on damages as to Mr. Mack on July 31, 2025, crediting Mr. Mack for settlement amounts previously paid to Plaintiffs by Virpax, on the count for which Mr. Mack was found liable, and assessing costs against Mr. Mack for one-third of Plaintiffs' attorneys fees. On April 2, 2026, the Court entered an order awarding Plaintiffs more than \$5.3 million in attorneys fees to be paid by Mr. Mack. The parties are awaiting the entry of final judgment.

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. Aveva received FDA approval for any generic version of ZTlido on March 25, 2025. 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. Briefing by the parties has been completed. Oral argument is scheduled for May 11, 2026.

Former Employees Litigation

On November 3, 2023, four former employees of the Company filed a complaint in California Superior Court in San Diego County, consisting of claims for back compensation that they allege were promised but not paid to them. The Company investigated those claims, conducted and responded to discovery, and vigorously contested this lawsuit. The parties concluded a settlement of all claims on June 2, 2025, the terms of which are confidential.

Sorrento Equity Holders Litigation

On April 3, 2026, a complaint was filed in the United States District Court for the Southern District of California captioned Mevi et al. v. Ji et al., Case No. 3:26-cv-02113-DMS-DEB. The plaintiffs are former equity holders of Sorrento and have named as defendants, among others, the Company and Semnur. The complaint alleges, among other things, wrongful conduct relating to Sorrento’s bankruptcy proceedings and subsequent transactions involving Sorrento’s assets, and asserts claims including aiding and abetting breach of fiduciary duty and violation of California Penal Code Section 496. The complaint seeks unspecified compensatory damages, treble damages, disgorgement, punitive damages, attorneys’ fees, costs, and other relief. The Company intends to defend the action vigorously. At this time, the Company cannot predict the outcome of this matter or reasonably estimate the possible loss or range of loss, if any.

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, 2025, the Company’s leases have remaining lease terms of approximately 10.2 years. The terms of the Company’s leases, ranging from 1 to 13 years, include extension options that were 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, 2025, the Company has no finance leases.

Lease expense was \$1.2 million and \$1.0 million for the years ended December 31, 2025 and December 31, 2024, 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,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases (in thousands)	\$ (1,139)	\$ (1,042)
Weighted average remaining lease term in years — operating leases	10.2	2.8
Weighted average discount rate — operating leases	11.1%	11.0%

Approximate future minimum lease payments under operating leases were as follows (in thousands):

Year Ended December 31,	Amount
2026	\$ 3,624
2027	\$ 3,023
2028	\$ 2,101
2029	\$ 2,080
2030	\$ 2,154
Thereafter	\$ 17,340
Total lease payments	30,322
Less imputed interest	15,438
Total lease liabilities	14,884
Less current portion of lease liability	1,733
Lease liability, net of current portion	\$ 13,151

14. Income Taxes

The components of the provision (benefit) expense were as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Current income tax (benefit) expense:		
Federal	\$ —	\$ —
State	26	(1)
Foreign	0	—
Total current income tax (benefit) expense	26	(1)
Deferred income tax benefit:		
Federal	12,786	(16,279)
State	1,076	(2,803)
Foreign	(295)	—
Total deferred income tax benefit	13,567	(19,082)
Changes in tax rate	—	2,155
Changes in valuation allowance	(13,567)	16,927
Total income tax (benefit) expense from continuing operations	\$ 26	\$ (1)

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, 2025 (in thousands):

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures the reconciliation of taxes at the federal statutory rate to our provision for (benefit from) income taxes for the year ended December 31, 2025 was as follows (in thousands, except for percentages):

	Year Ended December 31, 2025	
	Amount	Percentage
U.S. federal statutory tax rate	\$ (78,545)	21.00%
Foreign tax effects		
Statutory tax rate difference between Foreign and United States	\$ 110	-0.02%
Other	\$ —	0%
State taxes, net of federal benefit	\$ 22	-0.01%
Tax credits	\$ 254	-0.09%
Changes in valuation allowances	\$ (11,327)	3.76%
Nontaxable or nondeductible items		0%
Gain on sale of Semnur 12.5Mn shares	\$ 38,424	-12.49%
Gain or Loss on Derivative Liability	\$ 4,766	-1.60%
Revaluation of Oramed notes & Tranch B Notes	\$ 5,805	-1.95%
Despac Issuance Cost	\$ 8,820	-2.97%
Consulting & Legal expenses related to Cryptos	\$ 3,878	-1.30%
Goodwill impairment	\$ 15,392	0%
Other	\$ 12,427	-4.47%
Changes in unrecognized tax benefits	\$ —	0%
Other adjustments	\$ —	0%
Provision for income tax	<u>\$ 26</u>	<u>0%</u>

The reconciliation of taxes at the federal statutory rate to the provision for (benefit from) income taxes for the year ended December 31, 2024 in accordance with the guidance prior to the adoption of ASU 2023-09 was as follows (in thousands):

	Year Ended December 31, 2024
Income tax benefit at federal statutory rate	\$ (15,290)
Valuation allowance	18,559
Compensation expense	2,772
Acquisition related charges	485
Prior year true-up and carryback	(1,182)
State, net of federal tax benefit	(2,705)
Change in fair value of Convertible Debentures	(4,449)
Change in tax rates	2,155
Other	(346)
Income tax (benefit) expense	<u>\$ (1)</u>

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures cash paid for income taxes, net of refunds, during the year ended December 31, 2025 was as follows (in thousands)

Federal	\$ —
State	21
Foreign	—
Total cash paid for income taxes, net of refunds	<u>\$ 21</u>

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, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards		
US	\$ 86,748	\$ 85,226
Foreign	9,514	—
Total Net operating loss carryforwards	96,262	85,226
Debt related interest	14,567	16,228
Capitalized research and development	1,821	5,228
Tax credit carryforwards	3,960	4,415
Stock-based compensation	1,326	1,157
Accrued expense and reserves	2,541	1,812
Purchased revenue liability	1,888	1,754
Operating lease liabilities	2,674	577
Outside basis difference - investment in subsidiaries	704	—
Investment in digital asset	2,702	—
Other	353	303
Total deferred tax assets	128,798	116,700
Less valuation allowance	(111,385)	(113,703)
Total deferred tax assets	17,413	2,997
Deferred tax liabilities:		
Intangible assets	(1,842)	(2,423)
Investment in Datavault shares - equity method investment	(12,911)	—
Operating lease right-of-use assets	(2,660)	(574)
Total deferred tax liabilities	(17,413)	(2,997)
Net deferred tax liabilities	\$ —	\$ —

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 \$111.4 million against its deferred tax assets as of December 31, 2025. Realization of the deferred tax assets will be primarily dependent upon the Company's ability to generate sufficient taxable income prior to the expiration of its net operating losses. The valuation allowance is \$113.7 million as of December 31, 2024, and \$111.4 million as of December 31, 2025. The valuation allowance decreases by \$2.3 million during the year ended December 31, 2025.

As of December 31, 2025, the Company had a federal net operating loss carryforward of approximately \$345.8 million, of which approximately \$14.7 million will begin to expire in 2033 for federal tax purposes, and approximately \$331.1 million in federal net operating losses carryforward can be carried forward indefinitely. While these federal net operating loss ("NOL") do not expire, the Tax Cuts & Jobs Act of 2017 limits the amount of federal net operating loss utilized each year after December 31, 2017, to 80% of taxable income. As of December 31, 2025, the Company has a state net operating loss carryforward of approximately \$250.5 million.

As of December 31, 2025, the Company had a foreign net operating loss carryforward of approximately \$38.1 million for the Vivasor China entities.

As of December 31, 2025, the Company had federal research and development income tax credits of \$3.4 million which will begin to expire in 2033. As of December 31, 2025, the Company had California research and development income tax credits of \$1.9 million that have an indefinite life and will not expire.

Pursuant to Internal Revenue Code Section 38, a corporation's ability to utilize its NOL and tax credit carryforwards may be subject to annual limitations in the event of an ownership change, as defined under Section 382.

The Company has not performed a Section 382 ownership change analysis for periods subsequent to December 31, 2022. Management has been advised to undertake a Section 382 study for the period from 2023 through 2025; such analysis is currently in progress.

Utilization of pre-2020 NOLs has been carried out in accordance with the limitations established in the prior study performed.

The Company is subject to taxation in U.S. federal and state tax jurisdictions. The Company has incurred net operating losses since inception. Accordingly, all tax years remain open to examination by taxing authorities to the extent of net operating losses carried forward and utilized in future periods. Upon utilization, the statute of limitations will remain open for examination for three years from the date of utilization. There are no active tax examinations as of December 31, 2025.

During the year ended December 31, 2025, Semnur ceased to be a member of the consolidated federal income tax group of the Company due to a reduction in ownership below the threshold required under Internal Revenue Code Section 1504.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows for the years ended December 31, 2025 and 2024 (in thousands):

	2025	2024
Gross unrecognized tax benefits at the beginning of the year	\$ 1,198	\$ 1,071
Increase related to prior year tax positions	(127)	—
Increase related to current year tax positions	—	127
Gross unrecognized tax benefits at the end of the year	<u>\$ 1,071</u>	<u>\$ 1,198</u>

As of December 31, 2025 and 2024, the Company had \$1.1 million and \$1.2 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, 2025 and 2024.

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

15. Net Loss Per Share

The following table sets forth the reconciliation of basic and diluted loss per share for the years ended December 31, 2025 and 2024 (in thousands except per share data):

	Year Ended December 31,	
	2025	2024
Net loss	\$ (374,053)	\$ (72,807)
Net loss attributable to noncontrolling interest	\$ (15,319)	\$ —
Deemed dividend for anti-dilution adjustments to Oramed Penny Warrants upon reverse stock-split	(43,753)	—
Net loss for basic loss per share available to common stockholders	\$ (402,487)	\$ (72,807)
Reversal of mark-to-market adjustment for liability classified warrants	—	(8,895)
Net loss for diluted loss per share available to common stockholders	\$ (402,487)	\$ (81,702)
Weighted average number of shares outstanding	5,350	3,561
Weighted average Common Stock warrants exercisable for nominal consideration	5,684	6,500
Weighted average number of shares, basic	11,034	10,061
Effect of dilutive securities	—	84
Weighted average number of shares, diluted	11,034	10,145
Loss per share		
Basic	\$ (36.48)	\$ (7.24)
Diluted	\$ (36.48)	\$ (8.05)

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), therefore are included in the computation for basic and diluted net income per share once 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, 2025	December 31, 2024
Stock options	1,503,907	1,027,977
Public Warrants	156,115	156,220
February 2024 BDO Firm Warrants	108,686	108,686
February 2024 BDO Representative Warrants	13,446	13,446
April 2024 RDO Placement Agent Warrants	34,286	34,286
Retainer Shares	399,999	399,999
Private Warrants	28,572	28,572
Shares Issuable pursuant to the ESPP	576	2,204
Shares issuable under the SIPA	8,571	8,571
Deposit Warrants	3,250,000	—
October 2024 Noteholder Warrants	107,142	—
October 2024 Placement Agent Warrants	104,848	104,848
December 2024 RDO Common Warrants	537,298	1,642,871
StockBlock Warrants	131,472	131,472
Shares issuable under Tranche B Notes	493,004	1,158,617
Exchange Warrants	500,000	—
September 2025 Warrants	275,000	—
November 2025 Warrants	1,356,594	—
November 2025 Placement Agent Warrants	72,352	—
Total	9,081,868	4,817,769

16. Subsequent Events

Oramed Debt Extension

On March 29, 2026, the Company entered into Oramed debt extension agreement with Oramed to extend the final payment due under Oramed note and the April 1, 2026 amortization payment due under Tranche B note to April 20, 2026.

Litigation

Scilex-St. James Loan Lawsuit

On March 11, 2026, the Company filed a complaint against Marc Wade, The St. James Bank & Trust Company Ltd., Omega & Corinth Group Ltd., certain associates thereof (collectively, the “Wade Defendants”), and Bank of New York Mellon Corporation (“BNY”) in the United States District Court for the Central District of California. The complaint asserts five causes of action: (1) federal securities fraud (against all defendants); (2) state securities fraud (against the Wade Defendants); (3) fraudulent inducement (against the Wade Defendants); (4) unlawful conversion (against all defendants); and (5) negligence (against BNY). The Company seeks money damages in excess of \$100 million, punitive damages, pre- and post- judgment interest, disgorgement of profits, and attorney fees.

Sorrento Equity Holders Litigation

On April 3, 2026, a complaint was filed in the United States District Court for the Southern District of California captioned Mevi et al. v. Ji et al., Case No. 3:26-cv-02113-DMS-DEB. The plaintiffs are former equity holders of Sorrento and have named as defendants, among others, the Company and Semnur. The complaint alleges, among other things, wrongful conduct relating to Sorrento’s bankruptcy proceedings and subsequent transactions involving Sorrento’s assets, and asserts claims including aiding and abetting breach of fiduciary duty and violation of California Penal Code Section 496. The complaint seeks unspecified compensatory damages, treble damages, disgorgement, punitive damages, attorneys’ fees, costs, and other relief. The Company intends to defend the action

vigorously. At this time, the Company cannot predict the outcome of this matter or reasonably estimate the possible loss or range of loss, if any.

Warrant Agreement

On February 19, 2026, the Company entered into a Warrant Agreement (the “Oramed Warrant Agreement”) with Oramed. Pursuant to the Oramed Warrant Agreement, Oramed deferred its right to receive an amortization payment scheduled to be paid by the Company on October 1, 2025, as set forth in the amortization schedule included in the Tranche B Notes in exchange for the Company’s agreement to issue a new warrant to purchase an aggregate of 100,000 shares of Common Stock (the “February 2026 Warrant”) at an initial exercise price of \$20.00 per share (the “Exercise Price”) as described below. The deferred amortization payment was made to Oramed in November 2025.

The February 2026 Warrant is immediately exercisable upon issuance. The issuance of the February 2026 Warrant was made pursuant to an exemption from registration provided by Section 4(a)(2) of the Securities Act, and Rule 506(b) of Regulation D as promulgated thereunder by the SEC. The Company has agreed to file as soon as practicable (and in any event within the later of (i) 30 calendar days following the date of the Oramed Warrant Agreement, (ii) 10 days following the date of the filing with the SEC of the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, and (iii) March 31, 2026) a registration statement on Form S-3 (or Form S-1 if Form S-3 is not available to the Company) registering under the Securities Act the resale by Oramed of the shares of Common Stock issuable upon exercise of the February 2026 Warrant or to include such shares of Common Stock in any other registration statement on Form S-3 filed by the Company. The February 2026 Warrant shall have an expiration date of December 13, 2029.

Quantum Scan Holdings Investment

The Company entered into a convertible promissory note, dated January 29, 2026, (the “Q Scan Note”), with Quantum Scan Holdings, Inc. (“Q Scan”). Pursuant to the Q Scan Note, the Company loaned Q Scan an aggregate of \$20 million. The Q Scan Note shall be due upon request of the Company on or after October 29, 2026, and would commence accruing interest at a rate of 3.66% per annum commencing on April 29, 2026. The Q Scan Note contains customary representations and warranties of the Company and Q Scan and customary covenants of Q Scan. As of December 31, 2025, the Company prepaid \$2.5 million for services related to these transactions in November 2025.

The Company and Q Scan entered into a common stock purchase agreement, dated January 29, 2026, the “Q Scan Stock Purchase Agreement”). Pursuant to the Q Scan Stock Purchase Agreement, Q Scan agreed to sell to the Company, and the Company agreed to purchase from Q Scan, an aggregate of 193,021,436 shares of common stock of Q Scan (the “Q Scan Stock Purchase”) for an aggregate purchase price of approximately \$27.5 million. The closing of the Q Scan Stock Purchase shall occur within five business days of written notice delivered by Q Scan to the Company. The Q Scan Stock Purchase Agreement contains customary representations, warranties and covenants of the Company and Q Scan.

PA OPS Investor LLC Investment

In January 2026, the Company and the Investor LLC reached an agreement to extend the Letter commitment period from December 31, 2025 to April 30, 2026. As such, the Company now has until April 30, 2026, to fund the remaining Commitment Amount of \$1,500,000.