Risk Factors Comparison 2025-03-31 to 2024-03-12 Form: 10-K

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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 ~~two~~ **three** commercial products ~~(with our third~~ , **ZTlido, ELYXYB and** GLOPERBA ~~, expected to launch in the first half of 2024), ZTlido and ELYXYB~~ ; but we are currently heavily dependent on the commercial success of ZTlido, as ELYXYB ~~is~~ **and GLOPERBA are** in the initial stages of commercialization ~~and we have not yet launched GLOPERBA~~ , 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 ~~review~~ **requirements** , which may result in significant expense and limit our ability to commercialize such products. Risks Related to our Relationship with Sorrento • **Sorrento previously supported** ~~Certain of our directors and officers may~~ **many of our important corporate functions. Accordingly, our historical consolidated financial statements may not necessarily be indicative of the conditions that would** have ~~actual~~ **existed or** ~~or~~ **our results** ~~potential conflicts~~ of ~~interest because~~ **operations if we had been operated as an unaffiliated company** of ~~their positions with~~ Sorrento **, .** ~~• Our Executive Chairperson holds an~~ **and we have** ~~executive officer position at Sorrento~~ and ~~devotes time~~ **will continue** to **incur incremental costs** ~~both companies. In addition, our Executive Chairperson is the chairperson of Sorrento' s board of directors. The ongoing Chapter 11 Cases (~~ as

~~defined below) could require that such executive devotes time to such proceedings, which could cause~~ a ~~diversion of his time and~~ **stand - alone public company** ~~attention from our business and operations, and as a result could have a material adverse effect on our business and operations~~. 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. ~~• We are no longer a " controlled company " under the corporate governance rules of Nasdaq. However, during the applicable phase- in periods, we may rely on exemptions from certain corporate governance requirements, which may limit the presence of independent directors on our Board or committees of our Board.~~ We currently have ~~two~~ **three** commercial products ~~(with our third~~, **ZTlido, ELYXYB and** GLOPERBA ~~, expected to launch in the first half of 2024), ZTlido and ELYXYB~~; but we are currently heavily dependent upon ZTlido sales to generate revenue, as ELYXYB ~~is~~ **and GLOPERBA are** in the initial stages of commercialization ~~and we have not yet launched GLOPERBA~~. In February 2018, we obtained **FDA** regulatory approval for ZTlido for the relief of neuropathic pain associated with **post- herpetic neuralgia (" PHN ") in adults**, which is a form of post- shingles nerve pain, and we began commercializing ZTlido in the United States in October 2018. In late February 2023, we acquired ELYXYB, a potential first-line treatment and the only FDA- approved, ready- to- use oral solution for the acute treatment of migraine, with or without aura, in adults, in the U. S. We launched ELYXYB in April of 2023. **In June 2022, we acquired certain rights to GLOPERBA, the first and only liquid oral version of the anti- gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults. We launched GLOPERBA in June 2024.** As a result, it is difficult to evaluate our current business and predict our future prospects. We cannot assure that ZTlido ~~or~~ **,** 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 ~~and~~ **,** ELYXYB and ~~following its launch,~~ GLOPERBA ~~,~~ depends on a number of factors, including: • acceptance by physicians, major operators of clinics and patients of ZTlido ~~and~~ **,** ELYXYB ~~,~~ and ~~following its launch,~~ 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** ~~In order to~~ successfully commercialize ZTlido, ELYXYB and GLOPERBA ~~(which we expect to launch in the first half of 2024)~~, 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. Prior to March 2019, our operations were conducted through Scilex Pharma, which was formed in September 2012 and is now our wholly owned subsidiary. In March 2019, we effected a corporate reorganization and acquired Semnur, which was formed in June 2013. Since our inception, we have focused on organizing and staffing our company, business planning, raising capital, identifying potential non- opioid pain therapy candidates, undertaking preclinical studies and clinical trials of our product candidates and establishing research and development and manufacturing collaborations. Most of our revenue to date is attributable to sales of ZTlido, and we expect that sales of ZTlido will account for most of our revenue for at least the near term. Our relatively short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We will encounter risks and difficulties frequently experienced by early- stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. Our ability to execute on our business model and generate revenues depends on a number of factors including our ability to: • successfully complete ongoing ~~pre- clinical studies and~~ clinical trials and obtain regulatory approvals for our current and future product candidates; • identify new acquisition or in- licensing opportunities; • successfully identify new product candidates and advance those product candidates into pre- clinical studies and clinical trials; • raise additional funds when needed and on terms acceptable to us; • attract and retain experienced management and advisory teams; • add operational, financial and management information systems and personnel, including personnel to support clinical, ~~pre- clinical~~ manufacturing and planned future commercialization efforts and operations; • launch commercial sales of our product candidates, whether alone or in collaboration with others; • initiate and continue relationships with third- party suppliers and manufacturers and have commercial quantities of product candidates manufactured at acceptable cost and quality levels and in compliance with the FDA, and other regulatory requirements; • set acceptable prices for product candidates and obtain coverage and adequate reimbursement from third- party

payors; • achieve market acceptance of product candidates in the medical community and with third- party payors and consumers; and • maintain, expand and protect our intellectual property portfolio. If we cannot successfully execute any one of the foregoing, our business may not succeed or become profitable. Since our inception, we have incurred significant net losses, with net losses of $ **72. 8 million and $** 114. 3 ~~million, $ 23. 4 million and $ 88. 4~~ million for the years ended December 31, **2024 and** 2023 ~~, 2022 and 2021~~ , respectively. As of December 31, **2024 and** 2023 ~~and December 31, 2022~~ , we had an accumulated deficit of approximately $ **563. 1 million and $** 490. 2 ~~million and $ 375. 9~~ 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** ~~5mg~~ **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 ~~eCapital Credit Agreement may restrict the operation of our business and limit the cash available for investment in our business operations. The eCapital Credit Agreement (the " eCapital Credit Agreement "), dated as of June 27, 2023, between Scilex Pharma and eCapital Healthcare Corp. (the " ABL Lender "), provides that Scilex Pharma will be made available loans (the " Revolving Facility ") in an aggregate principal amount of up to $ 30, 000, 000, subject to certain terms and conditions, which facility cap may be increased at the request of Scilex Pharma and with the consent of the ABL Lender. Under the eCapital Credit Agreement, Scilex Pharma shall make interest payments monthly in arrears. We agreed to unconditionally guarantee the prompt, complete and full payment of Scilex Pharma' s obligations under the eCapital Credit Agreement. The payment and performance obligations under the eCapital Credit Agreement are also secured by a continuing security interest in Scilex Pharma' s accounts receivable, related deposit accounts and in the other " Collateral " as defined in the eCapital Credit Agreement. In addition, the eCapital Credit Agreement includes customary affirmative and negative covenants that will limit or restrict the ability of Scilex Pharma, subject to negotiated exceptions, to incur additional indebtedness and additional liens on its assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, enter into transactions with affiliated persons, or make investments. Pursuant to that certain Subordination Agreement (the " Subordination Agreement "), dated as of September 21, 2023, entered into by Scilex Pharma with the ABL Lender and Acquiom Agency Services LLC (the " Agent "), the parties agreed that the ABL Lender' s rights and interests under the eCapital Credit Agreement and the Agent' s rights and interests under that certain Subsidiary Guarantee (the " Subsidiary Guarantee "), dated as of September 21, 2023, entered into by us and each of our subsidiaries with Oramed Pharmaceuticals Inc. (" Oramed ") and the Agent, shall be secured by first priority liens on certain other collateral and second priority liens on the ABL Priority Collateral (as defined in the Subordination Agreement). The terms of the eCapital Credit Agreement and borrowings we may make in the future could have significant adverse consequences for our business, including: • requiring us, Scilex Pharma or our other subsidiaries to dedicate a substantial portion of cash and cash equivalents and marketable securities to the payment of interest on, and principal of, our debt, which would reduce the amounts available to fund operating expenditures, including working capital, capital expenditures and other general corporate purposes; • obligating us, Scilex Pharma or our other subsidiaries to additional negative covenants further restricting our activities; • requiring compliance with affirmative covenants, including payment and reporting covenants; • making it more difficult for us to successfully execute our business strategy, invest in our growth strategy and compete against companies who are not subject to such restrictions; • limiting our flexibility in planning for, or reacting to, changes in our business and our industry; and • placing us at a competitive disadvantage compared to our competitors that have less debt, better debt servicing options or stronger debt servicing capacity. Scilex Pharma intends to satisfy the payment obligation under the eCapital Credit Agreement with its existing cash and cash equivalents, anticipated product revenue from ZTlido, GLOPERBA and ELYXYB, and funds from external sources. However, Scilex Pharma may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under the eCapital Credit Agreement or future debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, failure to comply with the covenants under the eCapital Credit Agreement, including those outside of Scilex Pharma' s control, could result in an event of default. The events of default include, among others, a change of control of Scilex Pharma. Upon an event of default, subject to notice requirements in the case of certain events of default, the commitments and other obligations of the ABL Lender under the eCapital Credit Agreement may be terminated and all amounts outstanding under the eCapital Credit Agreement may become immediately due and payable. Scilex Pharma may not have sufficient funds or may be unable to arrange for additional financing to repay its indebtedness or to make any accelerated payments, and the ABL Lender could seek to enforce its security interests in the collateral securing such indebtedness or other remedies available to it under the eCapital Credit Agreement or as provided by applicable law. The ABL Lender could also seek to enforce the guaranty provided by us to carry out Scilex Pharma' s payment obligations. Any failure by Scilex Pharma or us to comply with the obligations under the eCapital Credit Agreement could have a negative effect on our business, financial condition and results of operations. The terms of the~~ Oramed Note **and the Tranche B Notes** place restrictions on our operating and financial flexibility. 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 ") ~~. The Oramed Note matures on March 21, 2025 and is payable in six principal installments, with the first installment in the principal amount of $ 5, 000, 000 paid on December 21, 2023, the second installment in the principal amount of $ 15, 000, 000 payable on March 21, 2024 and the next three installments each in the principal amount of $ 20, 000, 000 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) 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, ~~if~~ **since** the outstanding principal of the Oramed Note ~~has~~ **was** not ~~been~~ repaid in full on or prior to March 21, 2024, an exit fee of $ 3, 056, 250 **has been** ~~shall become fully~~ earned with respect to the Oramed Note, which shall be due and payable on the date ~~on which~~ the outstanding principal amount of the Oramed Note is paid in full. Upon the occurrence and during the continuance of an event of default under the Oramed Note, holders of more than 50 % of the aggregate unpaid principal amount of the Oramed Notes may elect to cause all outstanding amounts under the Oramed Note to accrue interest at a default rate equal to the lesser of (i) Term SOFR plus fifteen percent (15 %) or (ii) the maximum rate permitted under applicable law. Any voluntary prepayments of the Oramed Note occurring prior to the one- year anniversary of the Oramed Closing Date are required to be paid together with a make- whole amount equal to 50 % of the amount of additional interest that would accrue on the principal amount so prepaid under the Oramed Note from the date of such prepayment through and including the maturity date. **The make- whole amount was waived by Oramed for our voluntary prepayments in March 2024.** If the Oramed Note is accelerated upon an event of default, **we are** ~~the Company is~~ required to repay the principal amount of the Oramed Note at a mandatory default rate of 125 % of such principal amount (together with 100 % of accrued and unpaid interest thereon and all other amounts due in respect of the Oramed Note). The Oramed Note contains mandatory prepayment provisions requiring us and our subsidiaries to, following the earlier of (x) April 1, 2024, and (y) the date on which the Acceptable Indebtedness (as defined in the Oramed Note) is repaid in full, use 70 % of the net cash proceeds of any Cash Sweep Financing (as defined in the Oramed Note) or advance under the ELOCs (as defined in the Oramed Note) to prepay the outstanding principal amount of the Oramed Note (the " Mandatory Prepayment Sweep "). **Following each of the April 2024 RDO, the receipt of the FSF Deposit and ATM Sales Agreement (each as defined below), we made a mandatory prepayment of $ 9, 578, 835, $ 7, 000, 000 and $ 1, 760, 796, respectively, to Oramed, which equals 70 % of the net cash proceeds we received from each of the April 2024 RDO, the FSF Deposit and the sale of shares pursuant to the ATM Sales Agreement. Given such payment was not a voluntary prepayment, such prepayment did not trigger the make- whole amount under the Oramed Note. On October 8, 2024 (the " Issuance Date "), we issued and sold in a registered offering to certain institutional investors (collectively, the " Tranche B Investors ") and Oramed (together with the Investors, the " Tranche B Noteholders ") senior secured convertible notes in the aggregate principal amount of $ 50, 000, 000 (the " Tranche B Notes "), which notes will be convertible into shares of Common Stock, pursuant to that certain securities purchase agreement we entered into with the Tranche B Noteholders, dated as of October 7, 2024 (the " Tranche B Securities Purchase Agreement "). In consideration for Tranche B Notes issued to Oramed, the outstanding principal balance of the Oramed Note was reduced by $ 22, 500, 000, and an additional principal payment of an aggregate amount of $ 15, 000, 000 was made in November and December 2024. As of December 31, 2024, the outstanding principal amount, as well as the accrued interest and fees, of the Oramed Note was $ 24, 955, 634, with the remaining amount due on March 21, 2025, which maturity date was extended to December 31, 2025 pursuant to an amendment letter we entered into with Oramed, dated as of January 21, 2025. Unless earlier converted or redeemed, the Tranche B Notes mature on the two- year anniversary of the Issuance Date (the " Maturity Date "), subject to extension at the option of the holder in certain circumstances as provided therein. The Tranche B Notes bear interest at a rate of 5. 5 % per annum, payable in arrears on the first trading day of each calendar quarter, beginning January 2, 2025, payable, at our option, either in cash or in shares of Common Stock, subject to certain conditions.** The Oramed Note **and the Tranche B Notes** ~~contains~~ **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, ~~amending charter and organizational documents,~~ repaying **certain** ~~or repurchasing stock, repaying, repurchasing, or acquiring~~ indebtedness, **or declaring or** paying **any** ~~or declaring~~ cash dividends ~~, assigning~~ **or distribution** , selling ~~, transferring~~ or otherwise disposing of **any** 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, exceptions, and " baskets " set forth in the Oramed Note **and the Tranche B Notes** . The Oramed Note also contains covenants requiring **us** ~~the Company~~ to maintain a segregated bank account under specific terms and conditions, for purposes of receiving the Mandatory Prepayment Sweep, requiring SCLX Stock Acquisition JV LLC, our indirect wholly owned subsidiary (" SCLX JV "), to comply with the separateness representations and covenants in its organizational documents, and requiring our subsidiary, SCLX DRE Holdings LLC, to maintain its status as a passive holding company. The **Tranche B Notes also require us to, at the request of the holder, not more frequently than once per fiscal year, hire an independent, reputable investment bank to investigate whether any breach of the Tranche B Notes has occurred if an event constituting an event of default has occurred and is continuing or any holder reasonably believes that an event constituting an event of default has occurred or is continuing. The** Oramed Note **and the Tranche B Notes** ~~contains~~ **contain** certain customary events of default, including, without limitation, a cross- default to other specified indebtedness or any other indebtedness involving an obligation of **certain amount** ~~greater than $ 1~~ , ~~000, 000~~ **a failure in payment of principal** , as well as ~~an~~ **any bankruptcy, insolvency, reorganization** event ~~of default upon a Change of Control Transaction or Fundamental Transaction (in each case, as defined in the Oramed Note). See the risk factor titled " We may not have the ability to raise the funds necessary to settle our Convertible Debentures or the Oramed Note 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 Convertible Debentures " for additional information regarding such event of default provisions~~ . The Oramed Note also contains additional events of default with respect to certain events relating to our obligations under that certain registration rights agreement, dated as of September 21, 2023, between us and Oramed and relating to (i) the warrants to purchase up to an aggregate of 13, 000, 000 shares of Common Stock, with an exercise price of $ 0. 01 per share (the " Penny Warrants "), that we issued to Oramed pursuant to the Scilex- Oramed SPA, (ii) the warrants to purchase up to 4, 000, 000 shares of Common Stock, with an exercise price of $ 11. 50 per share (the " Transferred Warrants "), that we transferred to Oramed pursuant to the Scilex- Oramed SPA and / or (iii) the shares of Common Stock underlying the Penny Warrants or Transferred Warrants, in each case as more fully set forth in the Oramed Note. In addition, failure to comply with the covenants under the Oramed Note could result in an event of default. The events of default include, among others, a change of control of ~~the~~ **our** ~~Company~~ **company** . Upon an event of default, subject to notice requirements in the case of certain events of default, all amounts outstanding under the Oramed Note may become immediately due and payable. We may not have sufficient funds or may be unable to arrange for additional financing to repay such indebtedness or to make any accelerated payments, and Oramed could seek to enforce its security interests in the collateral securing such indebtedness or other remedies available to it under the Oramed Note or as provided by applicable law. Oramed could also seek to enforce the guaranty under the Subsidiary Guarantee entered into by us and each of our subsidiaries ~~(collectively, the " Guarantors ")~~ , dated as of September 21, 2023, to carry out our payment obligations under the Oramed Note. Any failure by us to comply with the obligations under the Oramed Note could have a negative effect on our business, financial condition and results of operations **. In addition, the Tranche B Notes prohibit us from entering into specified fundamental transactions unless the successor entity assumes all of our obligations under the Tranche B Notes under a written agreement approved by the required holders of the Tranche B Notes before the transaction is completed. Upon consummation of specified fundamental transactions, the successor entity must confirm that upon conversion or redemption of the Tranche B Notes thereafter, shares of the successor entity will be issuable upon such conversion or redemption. The holders of the Tranche B Notes also have certain redemption rights upon a fundamental transaction constituting a change of control** . Our outstanding indebtedness and any future indebtedness we may incur, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. **The Oramed Note and Tranche B Notes impose certain operating and financial covenants and any failure to comply with such covenants could result in an event of default that could adversely affect our business, financial condition and results of operations. If an event of default occurs under the Oramed Note or the Tranche B Notes (collectively, the " Existing Notes "), the holder of the Oramed Note could elect to immediately accelerate the due date of such note and, in the case of the Tranche B Notes, all of the holders thereof could require that we redeem such notes in accordance with the terms thereof, including any default interest rates, liquidated damages or similar penalties that would arise pursuant to the terms of such Existing Notes upon an event of default that is not cured within the applicable periods set forth in the Existing Notes.** We may not have **sufficient funds or may be unable to arrange for additional financing to repay our indebtedness under the Existing Notes or to make any accelerated or redemption payments, and the lenders could seek to enforce their respective security interests in the collateral securing such indebtedness or other remedies available to such lenders under the Existing Notes or as provided by applicable law. The lenders could also seek to enforce the guaranty under the Subsidiary Guarantee entered into by us and each of our subsidiaries, dated as of September 21, 2023 and amended as of October 8, 2024, to carry out our payment obligations under the Existing Notes. Any failure by us to comply with the obligations under the Existing Notes could cause our stock price to decrease significantly, result in substantial dilution or cause us to be unable to raise additional capital, which could have a material negative effect on our business, financial condition and results of operations. See the risk factor titled " We may not have** the ability to raise the funds necessary to settle ~~our Convertible Debentures or~~ 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 ~~Convertible Debentures~~ **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 convertible debentures (the " Convertible Debentures ") that we issued to YA II PN, Ltd. (" Yorkville ") pursuant to that certain securities purchase agreement, dated as of March 21, 2023, between us and Yorkville if the Convertible Debentures are not retired in connection with such change of control transaction, which will result in the full unpaid principal amount of the Convertible Debentures, together with interest and other amounts owing in respect thereof, to the date of acceleration becoming, at the election of the holders of the Convertible Debentures, immediately due and payable in cash. Similarly, 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 ~~Convertible Debentures or 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 ~~Convertible Debentures or the~~ Oramed Note **or the Tranche B Notes** . In addition, our ability to pay cash upon default of the ~~Convertible Debentures or the~~ Oramed Note **or the Tranche B Notes** may be limited by law, regulatory authority, or any agreements governing our future indebtedness. We may be required to make milestone payments to the former stockholders of Semnur in connection with our development and commercialization of SEMDEXA, which could adversely affect the overall profitability of SEMDEXA, if approved. Under the terms of the Agreement and Plan of Merger we entered into with Semnur, Sigma Merger Sub, Inc., our prior wholly owned subsidiary, Fortis Advisors LLC, solely as representative of the holders of Semnur equity (the " Semnur Equityholders "), and Sorrento, for limited purposes, we are obligated to pay the Semnur Equityholders up to an aggregate of $ 280. 0 million in contingent cash consideration based on the achievement of certain milestones. A $ 40. 0 million payment will be due upon obtaining the first approval of a new drug application by the FDA (" NDA ") of any Semnur product, which includes SEMDEXA. Additional payments will be due upon the achievement of certain cumulative net sales of Semnur products, as follows: • a $ 20. 0 million payment upon the achievement of $ 100. 0 million in cumulative net sales of a Semnur product; • a $ 20. 0 million payment upon the achievement of $ 250. 0 million in cumulative net sales of a Semnur product; • a $ 50. 0 million payment upon the achievement of $ 500. 0 million in cumulative net sales of a Semnur product; and • a $ 150. 0 million payment upon the achievement of $ 750. 0 million in cumulative net sales of a Semnur product. These milestone obligations could impose substantial additional costs on us, divert resources from other aspects of our business, and adversely affect the overall profitability of SEMDEXA, if approved. We may need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. 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, ~~2023~~ **2024** , our cash and cash equivalents were approximately $ 3. ~~9~~ **3** million and we had an accumulated deficit of approximately $ ~~490~~ **563** . ~~2~~ **1** million. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to: • the costs and expenses associated with our ongoing commercialization efforts for ZTlido, GLOPERBA and ELYXYB; • the degree of success we experience in commercializing ZTlido, GLOPERBA and ELYXYB; • the revenue generated by sales of ZTlido, GLOPERBA, ELYXYB and other products that may be approved, if any; • the scope, progress, results and costs of conducting studies and clinical trials for our product candidates, SEMDEXA, SP- 103 and SP- 104; • the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates; • the costs of manufacturing ZTlido, GLOPERBA, ELYXYB and our product candidates; • the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements; • our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement; • the extent to which ZTlido, GLOPERBA, ELYXYB or any of our product candidates, if approved for commercialization, is adopted by the physician community; • our need to expand our research and development activities; • the costs of acquiring, licensing or investing in businesses, product candidates and technologies; • the effect of competing products and product candidates and other market developments; • the number and types of future products we develop and commercialize; • any product liability or other lawsuits related to our products; • the expenses needed to attract, hire and retain skilled personnel; • the costs associated with being a public company; • our need to implement additional internal systems and infrastructure, including financial and reporting systems; • the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property- related claims; **• the costs related to servicing of our debt; • the costs of financing additional clinical, regulatory and commercial activities;** and • the extent and scope of our general and administrative expenses. Until we are able to generate significant revenue, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, government contracts or other strategic transactions. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Furthermore, any additional equity or equity- related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. If we are unsuccessful in our efforts to raise additional financing on acceptable terms, we may be required to significantly reduce or cease our operations **. 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 . 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 ~~year~~ **years** ended December 31, **2024 and** 2023, which stated that management has concluded that substantial doubt exists about our ability to continue as a going concern for one year after the date our consolidated financial statements are issued. We have negative working capital and have incurred significant operating losses and negative cash flows from operations and expect to continue incurring losses for the foreseeable future. Further, we had an accumulated deficit of approximately $ **563. 1 million as of December 31, 2024 and approximately $** 490. 2 million as of December 31, 2023 ~~and approximately $ 375. 9 million as of December 31, 2022~~ . 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 ~~and ,~~ ELYXYB ~~,~~ **and GLOPERBA** among which ELYXYB ~~is~~ **and GLOPERBA are** still in the early stages of commercialization, and are dependent upon, among other things, the success of our marketing of ZTlido ~~and ,~~ 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 ~~a~~ material ~~weakness~~ **weaknesses** in our internal control over financial reporting. If we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to timely and accurately report our financial results and such material weaknesses may result in a material misstatement of our **consolidated** financial statements. In connection with the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted ~~a~~ material ~~weakness~~ **weaknesses** . A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our **consolidated** financial statements will not be prevented or detected on a timely basis. As more fully disclosed in Item 9A **of this Annual Report on Form 10- K** , for the years ended December 31, 2022 and 2021, the material weakness identified in our internal control over financial reporting related to ineffective control activities in the areas of revenue, business combination, debt and derivative liabilities caused by a lack of sufficient accounting resources with appropriate experience and technical expertise to effectively execute controls over certain judgmental and technical accounting areas. As a result of the material weakness, we hired additional accounting personnel and are implementing remediation measures including, but not limited to, performing a comprehensive assessment of accounting and finance resource requirements and hiring other personnel with sufficient accounting expertise at our company to improve the operating effectiveness of our review controls and monitoring activities, and utilizing external accounting experts as appropriate. Any potential material misstatements were identified and corrected as audit adjustments in the applicable periods and are properly reflected in our **consolidated** financial statements included in this Annual Report on Form 10- K. We hired a new Chief Financial Officer in May 2022 at Legacy Scilex and she served as Chief Financial Officer of the Company through September 2023. In May 2023, we appointed a Chief Accounting Officer, who became our Chief Financial Officer in September 2023. In addition, we expect to hire additional personnel with accounting expertise and utilize external accounting experts. As of December 31, 2023, we have remediated the previously identified material weaknesses in our internal control over financial reporting **, and we have not identified a material weakness in our internal control over financial reporting for the year ended December 31, 2024** . If we identify additional material weaknesses or deficiencies in internal controls in the future and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of our Common Stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition. If, in the future, we identify material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes- Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes- Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our business, financial condition and results of operations could suffer. 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, ~~2023~~ **2024** , our net profits for ZTlido and SP- 103 have not exceeded five percent of net sales. Accordingly, Oishi and Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, ~~2023~~ **2024** , neither Oishi nor Itochu has exercised its right of termination. If the Product Development Agreement and the Commercial Supply Agreement are terminated, we would lose access to the intellectual property and proprietary manufacturing process upon which ZTlido and SP- 103 depend. We expect our third- party manufacturers and suppliers of both GLOPERBA ~~(which product we expect to launch in the first half of 2024)~~ 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** ~~Under the Genzyme Supply Agreement~~ , we **have purchased** ~~depend on Genzyme to fulfill~~ our clinical and commercial supply requirements for sodium hyaluronate, one of the excipients for ~~SEMDEXA~~ **SP- 102** , **solely from** ~~and we are aware of only a limited number of suppliers of the excipient.~~ Genzyme **Corporation (“** ~~has the right to terminate the~~ Genzyme **”) pursuant to a** ~~Supply~~ **supply** ~~Agreement~~ **agreement** ~~under certain circumstances~~ , **which** ~~including, but not limited to, if Genzyme decides to discontinue manufacturing the product at its facility for economic or strategic reasons and provides us with 24 months’ notice. Genzyme has notified us of its intention to terminate~~ **terminated** ~~the Genzyme Supply Agreement as it has determined to discontinue manufacturing the product at its facility, effective~~ as of May 31, 2024. ~~Although we are~~ **We anticipate that our** ~~currently~~ -- **current supply** ~~in the process~~ of ~~identifying and certifying new suppliers~~ **sodium hyaluronate will be sufficient** to ~~fulfill~~ **satisfy** our clinical and commercial supply requirements for sodium hyaluronate **for at least 12 months following our expected commercial launch of SP- 102 in 2027. Although we are currently in discussions with Sanofi S. A. (“ Sanofi ”), an affiliate of Genzyme, and are in the process of identifying and certifying new suppliers, in each case to fulfill our future supply requirements for sodium hyaluronate** , we may not be able to **reach agreement with Sanofi or** find an alternative supplier of sodium hyaluronate on commercially reasonable terms **, or at all** . Under the Lifecore Master Services Agreement, we depend on Lifecore to manufacture clinical supplies of SEMDEXA. Lifecore has the right to terminate the Lifecore Master Services Agreement under certain circumstances, including, but not limited to: (1) if we are in material breach of the agreement and fail to cure such breach within 30 days of written notice; (2) if we (a) become insolvent, (b) cease to function as a going concern, (c) become convicted of or plead guilty to a charge of violating any law relating to either party’ s business, or (d) engage in any act which materially impairs goodwill associated with SEMDEXA or materially impairs the terminating party’ s trademark or trade name; (3) if we fail to pay past due invoices upon 30 days’ written notice, or (4) if we reject or fail to respond to a major change proposed by Lifecore that does not change Semnur’ s written and approved acceptance criteria in its product specifications. In the event that Lifecore decides to terminate the Lifecore Master Services Agreement, finding an alternative manufacturer on commercially reasonable terms, or at all, may be difficult. **On June 6, 2023, Semnur entered into the Second Amendment to Lifecore Master Services Agreement with Lifecore, which extended the term of the agreement until December 31, 2028.** Under the Tulex Master Services Agreement and the statement of work with Tulex, we depend on Tulex to develop, test and manufacture clinical supplies of SP- 104. Tulex has the right to terminate the Tulex Master Services Agreement under certain circumstances, including, but not limited to: (1) if we are in material breach of the agreement or a statement of work and fail to cure such breach within 15 days after receipt of notice of such breach (or such other time period expressly stated in the applicable statement of work) or (2) in the event of our insolvency, bankruptcy, reorganization, liquidation or receivership, or a failure to remove any insolvency, bankruptcy, reorganization, liquidation or receivership proceedings within ten days from the date of institution of such proceedings. In addition, we may terminate the agreement or any statement of work (a) without cause upon 30 days prior written notice to Tulex or (b) immediately upon written notice in the event Tulex is dissolved or undergoes a change in control. In the event that the Tulex Master Services Agreement or a statement of work is terminated, we may not be able to find an alternative manufacturer and supplier on commercially reasonable terms. Additionally, the manufacturing facilities used by our third- party suppliers and manufacturers must continue to comply with FDA regulations and are subject to periodic announced or unannounced inspections. We have limited control over the ability of our third- party suppliers and manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our third- party suppliers and manufacturers fail to comply with FDA regulations, the FDA may not authorize the manufacture of our products and product candidates at these facilities, and we may be unable to find

alternative manufacturing facilities in a timely manner or at all. The failure by such third parties to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, import detention, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of our product, operating restrictions and criminal prosecutions. In addition, our product candidates may compete with other product candidates and products for access to manufacturing facilities and other supplies. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Also, prior to the approval of our product candidates, we would need to identify a contract manufacturer that could produce our products at a commercial scale and that could successfully complete FDA pre- approval inspection and inspections by other health authorities. Agreements with such manufacturers or suppliers may not be available to us at the time we would need to have that capability and capacity. If the commercial supply of our commercial products, clinical supply of our product candidates and certain of the raw materials used in our product candidates are disrupted or delayed, there can be no assurance that alternative sources can serve as adequate replacements or that supplies will be available on terms that are favorable to us, if at all. Any disruption in supply could affect the profitability of ZTlido, the commercialization of GLOPERBA and ELYXYB, and the development of SEMDEXA, SP- 103 and SP- 104. We rely on a single third- party logistics distribution provider **for ZTlido** , **ELYXYB and GLOPERBA** ~~Cardinal Health 105, which until recently had also been our only customer~~ . We currently rely on Cardinal Health 105, LLC (" Cardinal Health 105 ") as our third- party logistics distribution provider for ZTlido ~~and ,~~ 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 ~~and ,~~ 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. ~~In the years ended December 31, 2020 and 2021 and the first quarter of 2022, Cardinal Health 105 was also our only customer for ZTlido 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 discontinued our use of " title model " services provided by Cardinal Health 105 in the second quarter of 2022 and expanded our direct distribution network to national and regional distributors and pharmacies. Beginning on April 1, 2022, we began selling ZTlido directly to three large distributors, McKesson, Cardinal Health 110 and AmerisourceBergen, as well as to numerous pharmacies. We expect that Cardinal Health 105 will continue to perform other third- party logistics services for us. Any disruption in the above- mentioned distribution channel would adversely affect our business, financial condition and results of operations.~~ If we fail to achieve certain milestones in our Product Development Agreement with Itochu and Oishi, we could lose rights that are important to our business. Certain of our existing license and supply agreements impose various milestone and other obligations on us. For example, under our Product Development Agreement with Itochu and Oishi, if our total net profits for ZTlido and SP- 103 are equal to or less than five percent of our net sales of ZTlido and SP- 103 for a period of four or more consecutive quarters, Itochu and Oishi have the right to terminate the Product Development Agreement if the parties are unable to resolve the concerns after 30 days of good- faith negotiation. As of December 31, ~~2023~~ **2024** , our net profits for ZTlido and SP- 103 have not exceeded five percent of net sales. Accordingly, Oishi and ~~Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, 2023, 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 currently do not have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations (" CROs "), to conduct GCP- compliant clinical trials of our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GCP- compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount and timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GCP- compliant clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. For any violations of laws and regulations in the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement actions that may include civil penalties up to and including criminal prosecution. Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. We face the risk of potential unauthorized disclosure or infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology. Further, any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If the third parties conducting our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data

they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval or successful commercialization in a timely fashion, or at all, for the applicable product candidate. Our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. We may in the future enter into collaborations, in- licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant future revenues. Our business is substantially dependent upon the intellectual property licensed from Oishi and Itochu. In the ordinary course of our business, we may enter into collaborations, additional in- licensing arrangements (such as, for example, the Romeg **License** Agreement), joint ventures, or strategic alliances to develop proposed products and to pursue new markets. Proposing, negotiating and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all, and may not realize the anticipated benefits of any such transactions or arrangements. Additionally, with respect to current and future collaborations, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. Delays in clinical trials could result in increased costs to us and delay our ability to obtain commercial approval and generate additional revenue. Before obtaining marketing approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates for their intended indications. Clinical testing is expensive, time- consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include: • delays in obtaining regulatory authorizations to commence a clinical trial or reaching a consensus with regulatory authorities on trial design; • delays in identifying prospective clinical investigators or clinical trial sites that have necessary qualifications, interest and capacity to perform a requested protocol; • delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • delays in obtaining approval from one or more institutional review boards (" IRBs "); • IRBs refusing to approve, suspending or terminating the trial at the investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; • changes to the clinical trial protocol; • delays in recruiting suitable subjects to participate in our clinical trials; • failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements; • failure to perform in accordance with GCPs; • delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions; • delays in subjects completing participation in a trial or returning for post-treatment follow- up ~~, including, for example, as a result of reluctance to visit medical facilities as a result of COVID- 19~~ ; • clinical trial sites or subjects dropping out of a trial; • key investigators departing their clinical sites; • lack of adequate funding to continue the trial; • selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; • subjects experiencing severe or unexpected drug- related adverse effects; • imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, or for other reasons; • occurrence of serious adverse events in our trials or in trials of the same class of agents conducted by other sponsors; • changes in regulatory requirements or guidance that require amending or submitting new clinical protocols; • a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements; • any changes to our manufacturing process that may be necessary or desired; • third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials and / or not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements; • third- party contractors not performing data collection or analysis in a timely or accurate manner; or • third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by subcontractors in support of our marketing applications. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the

FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, participants being exposed to unacceptable health risks, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Our product development costs will increase if we experience delays in testing or marketing approvals. The FDA and other regulatory agencies may impose new or refined testing expectations based on experience and increased knowledge over time. In addition, if we make manufacturing or other changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. We do not know whether any of our clinical trials, including our planned clinical trials of SP- 103, SP- 104 and SEMDEXA, will begin or continue as planned, will need to be restructured or will be completed on schedule, or at all. We may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates. **Our** ~~We face potential~~ business **could be adversely affected by the effects of health pandemics or other health crises, which could cause significant** disruptions **in our operations** and ~~related risks resulting from the~~ **those of our CMOs, CROs and other third parties upon whom we rely. Health pandemics or other health crises, including** COVID- 19 ~~pandemic~~ **, have in the past and could again in the future result in a disruption of our businesses, delay our research and development programs and timelines, negatively impact our productivity and increase risks associated with cybersecurity. More specifically, these types of events may negatively impact personnel at third- party manufacturing facilities or the availability or cost of materials** , which could **disrupt our supply chain. Moreover, our clinical trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if wide- spread health crisis impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may** have ~~a material~~ **heightened exposure) may be hindered, which would** ~~adverse~~ **adversely** ~~effect~~ **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 ~~and ,~~ results of operations **and prospects** . In **addition** ~~December 2019 , a novel strain of coronavirus, or SARS- CoV- 2, was reported to have surfaced in Wuhan, China. SARS- CoV- 2 is~~ the **impact of such health** ~~virus that causes COVID- 19. The COVID- 19 outbreak has grown into a global pandemic~~ **pandemics or** ~~that has impacted countries throughout the~~ **other health crises on** ~~world. Financial markets have been experiencing extreme fluctuations that may cause a contraction in available liquidity globally as important segments of~~ the ~~credit markets react to the development. The pandemic may lead to a decline in business and consumer confidence. The global outbreak of COVID- 19 continues to rapidly evolve. As a result, businesses have closed or limited~~ operations ~~and limits have been placed on travel. We continue to monitor the potential impact~~ of the **FDA** ~~COVID- 19 outbreak, and if COVID- 19 or variants of concern continue to spread globally, including in the United States, we may experience disruptions that could severely impact the development of our~~ - **or other** ~~product candidates, including: • delays or difficulties in enrolling patients in our clinical trials as patients may be reluctant, or unable, to visit clinical sites; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators, clinical site staff and potential closure of clinical facilities; • decreases in patients seeking treatment for chronic pain; • delays in receiving approval from local~~ regulatory authorities ~~to initiate our planned clinical trials; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials; • changes in local regulations as part of a response to the COVID- 19 outbreak, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or cause us to discontinue the clinical trials altogether; • diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; • risk that participants enrolled in our clinical trials will acquire COVID- 19 while the clinical trial is ongoing, which~~ could ~~impact the results of the clinical trial, including by increasing the number of observed adverse events; • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and • interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others. The spread of COVID- 19, which has caused a broad impact globally, may materially affect the Company economically. While the potential economic impact brought by, and the duration of, COVID- 19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, which could in the future~~ negatively affect our **planned trials** ~~liquidity. In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business~~ and **approval processes** ~~the value of our Common Stock. In addition, the continued spread of COVID- 19 globally could materially and adversely impact our operations, including without limitation, our manufacturing and supply chain, sales and marketing efforts, sales of ZTlido, GLOPERBA and ELYXYB, travel and employee health and availability, which may have a material and adverse effect on our~~

~~business, financial condition and results of operations~~ . Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for our product candidates and the approval may be for a more narrow indication than we seek. We cannot commercialize our product candidates until the appropriate regulatory authorities have reviewed and approved the product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals. Even if our product candidates meet the safety and efficacy endpoints in clinical trials, the **data may not be considered sufficient by regulatory authorities, those** regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA advisory committee **is convened** , **including** if ~~convened,~~ **such advisory committee** recommends non- approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory authority policy or data requirements during the period of product development, clinical trials and the regulatory review process. Even if we receive regulatory approval, the FDA may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, **black box** warnings or a Risk Evaluation and Mitigation Strategy (“ REMS ”). The FDA may require labeling that includes **warnings and** precautions or contra- indications with respect to conditions of use, or may grant approval subject to the performance of costly post- marketing clinical trials. In addition, the FDA may not approve the labeling claims that are **considered** necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. Additionally, if the results of any clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may: • be delayed or fail in obtaining marketing approval for our product candidates; • obtain approval for indications or patient populations that are not as broad as we intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to changes in the way the products are administered; • be required to perform additional clinical trials to support approval or be subject to additional post- marketing testing requirements; • have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified REMS; • be sued and held liable for harm caused to patients; or • experience damage to our reputation. We may find it difficult to enroll or maintain patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates. Identifying and qualifying patients to participate in any clinical trials of our product candidates is critical to our success. The timing of any clinical trials depends on our ability to recruit patients and to complete required follow- up periods. If patients are unwilling to participate in our clinical trials due to negative publicity from adverse events, competitive clinical trials for similar patient populations, or for other reasons, the timeline for recruiting patients, conducting trials and potentially obtaining regulatory approval may be delayed. We may also experience delays if patients withdraw from a clinical trial or do not complete the required monitoring period. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of clinical trials altogether. Patient enrollment is affected by many factors, including: • the size and nature of the patient population; • the proximity of patients to clinical sites; • the eligibility and exclusion criteria for the trial; • the design of the clinical trial; • competing clinical trials; • the risk that enrolled patients will not complete a clinical trial; • ability to monitor patients adequately during and after treatment; • potential disruptions caused by COVID- 19 (or other similar disruptions), including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented and other factors; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; and • clinicians’ and patients’ perceptions as to the potential advantages of the product candidate in relation to other available products. The conditions for which we currently plan to evaluate our product candidates are common, but the eligibility criteria of our clinical trials limit the pool of available trial participants. For example, we experienced a delay in the enrollment of our now completed SEMDEXA Phase 3 clinical trial in sciatica due to the selective eligibility criteria in place to reduce the placebo effect and the impacts of COVID- 19, and may experience similar issues with enrollment of our other planned clinical trials **. Under the federal Food and Drug Omnibus Reform Act (the “ FDORA ”), sponsors are required to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “ pivotal study ” of a new drug product. These plans are meant to encourage enrollment of more diverse patient populations in late- stage clinical trials of FDA- regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans. Unlike most guidance documents issued by the FDA, the diversity action plan guidance, when finalized, will have the force of law. In January 2025, in response to an executive order issued by President Trump on diversity, equity and inclusion programs, the FDA removed this draft guidance from its website. The implications of this action are not yet known. If we are not able to adhere to any new requirements, our ability to conduct clinical trials may be delayed or halted** . In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to it, because some patients who have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor. We may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. The incidence and prevalence for target patient populations of our product candidates are based on estimates and third- party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected. Periodically, we make estimates regarding the incidence and prevalence of target patient populations of our product candidates based on various third- party sources and internally generated analyses and use such estimates in making decisions regarding our product development

strategy, including acquiring or in- licensing product candidates and determining indications on which to focus in preclinical studies or clinical trials. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunities will depend on, among other things, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects. We face significant competition and our competitors may discover, develop or commercialize products faster or more successfully than us. The biotechnology and pharmaceutical industries are characterized by intense competition and rapid technological advances. In addition, the competition in the pain management market, and other relevant markets, is intense. ZTlido and our product candidate, SP- 103, face and will likely face competition from other prescription patches, generic topical lidocaine patches, and OTC lidocaine patches, including Lidoderm ®, generic lidocaine patches manufactured by Mylan N. V., Teva and Par Pharmaceutical, Inc., and various OTC patches. Additionally, SP- 103, if approved, will likely compete with various opioid pain medications, NSAIDs, muscle relaxants, antidepressants and anticonvulsants particularly as we seek approval for the treatment of chronic neck pain. SEMDEXA, if approved, has the potential to become the first FDA- approved epidural steroid product for the treatment of sciatica. While there are currently no FDA approved epidural steroid injections indicated for the treatment of sciatica, we are aware of certain non- steroid product candidates in development. SEMDEXA, if approved, also will compete with various opioid pain medications, NSAIDs, muscle relaxants, antidepressants, anticonvulsants and surgical procedures. Procedures may include nerve blocks and transcutaneous electrical nerve stimulations. We may also face indirect competition from the off- label and unapproved use of branded and generic injectable steroids. While there are currently no formulations containing naltrexone in clinical development for the treatment of fibromyalgia, we are aware of certain non-opioid therapeutics currently in a late- stage phase 3 pipeline containing two 505 (b) (2) development programs. Our product candidate, SP- 104, will likely face direct competition from these candidates. We expect that the market will become increasingly competitive in the future. Many of our competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in developing product candidates and technologies, undertaking preclinical studies and clinical trials, obtaining FDA and other regulatory approvals of product candidates, formulating and manufacturing product candidates, and launching, marketing and selling product candidates. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early- stage companies or generic or biosimilar pharmaceutical manufacturers may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our commercial opportunity could be reduced or eliminated if our competitors succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make our product candidates less competitive. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business, financial condition and results of operations. The third- party payor coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for ZTlido, GLOPERBA, ELYXYB or our product candidates, if approved, could decrease our ability to generate product revenue. There is significant uncertainty related to the third- party coverage and reimbursement of existing and newly approved products. Market acceptance and sales of ZTlido, GLOPERBA, ELYXYB and our product candidates, if approved, in domestic markets will depend significantly on the availability of coverage and adequacy of reimbursement from third- party payors, including government programs (such as Medicare and Medicaid) and private payor healthcare and insurance programs. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Coverage and reimbursement for ZTlido can differ significantly from payor to payor, and we may not be able to maintain adequate coverage and reimbursement in the future. Further, obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data for the use of our products to each third- party payor separately, with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Additionally, coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Assuming that coverage is obtained for a given product, the resulting reimbursement rates might not be adequate or may require co- payments or co- insurance that patients find unacceptably high. Patients, physicians, and other healthcare providers may be less likely to prescribe, dispense or use, as applicable, any approved product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. The market for our products will depend significantly on access to third- party payors' drug formularies for which third- party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third- party payors may refuse to include a particular branded product in their

formularies or otherwise restrict patient access to a branded product when a less costly generic equivalent or other alternative is available. In addition, even if we obtain adequate levels of reimbursement, third- party payors carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Increasingly, third- party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices for products. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Furthermore, the requirements governing medical product pricing vary widely from country to country. In some foreign countries, the proposed pricing for a prescription device must be approved before it may be lawfully marketed. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Our product candidate SEMDEXA is expected to be a physician- administered injectable viscous gel and as such, separate reimbursement for the product itself may not be available. Instead, if SEMDEXA receives regulatory approval, the administering physician may be reimbursed only for providing the treatment or procedure in which SEMDEXA is used. To the extent separate coverage and reimbursement should become available for SEMDEXA, we anticipate that it will be sold to physicians on a " buy and bill " basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third-party payor, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer our product candidates, if approved, because they would have to fund the purchase of the product and then seek reimbursement, which may be lower than their purchase price, or because they do not want the additional administrative burden required to obtain reimbursement for the product. Further, the codes used by providers to bill for SEMDEXA, if approved, could also affect reimbursement. J- Codes are codes maintained by the Centers for Medicare and Medicaid Services (" CMS "), which are a component of the Healthcare Common Procedure Coding System and are typically used to report injectable drugs that ordinarily cannot be self- administered. We do not have a specific J- Code for any of our product candidates. If our product candidates are approved, we may apply for one but cannot guarantee that a J- Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J- Code is not available, physicians would need to use a non- specific miscellaneous J- Code to bill third- party payors for these physician- administered drugs. Because miscellaneous J- Codes may be used for a wide variety of products, health plans may have more difficulties determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim denials and claim errors. Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment approaches, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success. Apart from our FDA- approved products, ZTlido, GLOPERBA and ELYXYB, we currently have several product candidates that are at various stages of development. We have limited financial and management resources. As a result, we may forego or delay pursuit of opportunities with potential target indications or product candidates that later prove to have greater commercial potential than our current and planned development programs and product candidates. We strive to progress product candidates that can address unmet or underserved medical needs and favor those candidates with large market opportunities. However, our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be required to relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates. Additionally, we may pursue additional in- licenses or acquisitions of product candidates or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical testing is expensive, difficult to design and implement, and can take many years to complete, in part because it is subject to rigorous regulatory requirements. The FDA or other regulatory authorities may not agree with the proposed analysis plans or trial design for the clinical trials of our product candidates. They may also not agree with the scope of our proposed investigational plan. In addition, the outcome of our clinical trials is risky and uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials may not be predictive of the results of later- stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the pharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful. This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early and late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program,

such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve their intended objectives. A Phase 3 trial was completed for SEMDEXA for the treatment of sciatica, a Phase 2 trial **was** completed for SP- 103 **in 2023** , and multiple Phase 1 trials were completed in the first half of 2022 for SP- 104. We may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of such clinical trials in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. Our clinical trials may produce negative or inconclusive results, and, in the future, we may decide, or regulators may require us, to conduct additional clinical trials and preclinical studies in addition to those we have planned. In March 2022, we announced final results from our Phase 3 trial for SEMDEXA, which **reflect positive** results ~~reflect achievement of~~ **with respect to** primary and secondary endpoints, and we intend to use the results to support ~~an~~ **a** NDA submission seeking approval for the treatment of sciatica. ~~However~~ **In November 2023** , **we had a Type C meeting with** the FDA ~~may~~ **to discuss the requirements for filing a 505 (b) (2) NDA for SEMDEXA. In the Type C meeting, the FDA indicated that it** ~~disagree~~ **disagreed** with ~~our assumptions and require~~ us **that the clinical data we had collected was sufficient** to ~~conduct~~ **support the safety** ~~an~~ **and efficacy of SEMDEXA. The FDA provided guidance regarding expectations for the** additional **confirmatory** ~~Phase 3~~ trial ~~before submitting an~~ **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 ~~receipt of~~ regulatory ~~clearance or~~ approval and, ultimately, the commercialization of that product ~~or~~ **for the proposed** indication for use. 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. As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with ZTlido, GLOPERBA, ELYXYB and our product candidates. In the event that ZTlido, GLOPERBA or ELYXYB is identified to have undesirable side effects, a number of potentially significant negative consequences could occur. Regulatory authorities may withdraw their approval of the product or seize the product. Restrictions may be imposed on the manufacturing or marketing of ZTlido, GLOPERBA or ELYXYB or any component thereof, including the imposition of a REMS plan that may require creation of a Medication Guide outlining the risks of such side effects for distribution to patients, as well as elements to assure safe use of the product, such as a patient registry and training and certification of prescribers. Any of these events could damage our reputation and prevent us from achieving or maintaining market acceptance of ZTlido, GLOPERBA or ELYXYB. In the clinical trials we conduct with our product candidates, patients may experience changes in their health, including illnesses, injuries, discomforts or a fatal outcome. Often, it is not possible to determine whether the product candidate being studied caused or was associated with these conditions. In addition, it is possible that as we test our clinical products in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier clinical trials, as well as conditions that did not occur or went undetected in previous clinical trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large- scale, Phase 3 clinical trial. In the event that our product candidates reveal an unacceptable severity and prevalence of these or other side effects, the clinical trials could be suspended or terminated and the FDA could order us to cease further development of or deny approval of our product candidates, for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly. ZTlido, GLOPERBA, ELYXYB and our product candidates are complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or manufacturing problems that result in delays in our development or commercialization programs, limit the supply of our product candidates, or otherwise harm our business. We currently depend on contract manufacturers to conduct the manufacturing and supply activities for ZTlido, GLOPERBA, ELYXYB and our product candidates. Manufacturing these product candidates require facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers. If contaminations are discovered in our supply of ZTlido, GLOPERBA, ELYXYB or our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We may not be successful in securing additional sources at all or on a timely basis, which could materially harm our development timelines. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely. In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition and results of operations. Furthermore, our manufacturers may encounter problems hiring and retaining the experienced scientific, quality assurance, quality- control and manufacturing personnel needed to operate our complex manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in our manufacturing process could restrict our ability to meet potential future market demand for products, which could harm our business, financial condition and results of operations. Our industry

has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate key executives to accomplish our business objectives, we may experience constraints that will significantly impede our ability to raise additional capital and our ability to implement our overall business strategy. In particular, we are highly dependent upon our executive officers, including Jaisim Shah, our President and Chief Executive Officer, Henry Ji, Ph. D., our Executive Chairperson, and Stephen Ma, our Chief Financial Officer. The loss of services of these executive officers could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials and the successful commercialization of ZTlido, GLOPERBA and ELYXYB. We do not carry " key person " insurance on any of our executive officers or other employees. Competition for key executives in the biotechnology and pharmaceuticals field is intense, due to the limited number of individuals who possess the skills and experience required by our industry. Many of the pharmaceutical companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to qualified candidates than what we have to offer. In addition, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non- compete agreements with employees and require employers to rescind existing non- compete agreements, may lead to increased uncertainty in hiring and competition for talent. Further, we may experience employee turnover as a result of the ongoing " great resignation " occurring throughout the U. S. economy, which has impacted job market dynamics. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. Moreover, we conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. As such, we could have difficulty attracting and retaining experienced executives and may be required to expend significant financial resources in our recruitment and retention efforts. We may need to increase the size of our company and may not effectively manage our growth. As of December 31, ~~2023~~ **2024** , we had approximately ~~105~~ **115** full- time employees. We may need to continue to expand our managerial, operational, sales and marketing, finance and other resources in order to manage our operations, clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities, including co- promotion activities. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, including the clinical, FDA and internal regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, if any, which may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition and results of operations **. There is no assurance that we will complete the Business Combination with respect to the sale of our wholly owned subsidiary, Semnur, and / or our SP- 102 product candidate, under the terms of the Merger Agreement or otherwise and the failure to complete the Business Combination could adversely affect our stock price and future business and financial results. As previously announced, our Board authorized our management to explore ways in which to maximize the value of Semnur and SP- 102 (SEMDEXA ™), the product candidate held by Semnur, for us and our stockholders, including by way of conducting a spin- off, merger, dividend, reclassification or other similar transaction. On August 30, 2024, Semnur entered into a Merger Agreement (the " Semnur Business Combination Agreement ") with Denali Capital Acquisition Corp. (" Denali ") and Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali (" Denali Merger Sub "), in connection with a business combination (the " Business Combination "). The consummation of the Business Combination is subject to the satisfaction or waiver of a number of closing conditions of the respective parties. The completion of the Business Combination is not assured and is subject to risks, including, among others, the risk that approval of the Business Combination by Denali' s shareholders is not obtained or that other closing conditions are not satisfied. There is also no assurance the Business Combination will actually maximize the value of Semnur and / or the SP- 102 asset for us or our stockholders. In addition, we will remain liable for significant transaction costs, including legal, accounting and financial advisory fees. Furthermore, the market price of our Common Stock may reflect various market assumptions as to whether the Business Combination will occur. Consequently, the failure to complete the Business Combination could result in a significant change in the market price of our Common Stock** . Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities. Although we endeavor to obtain appropriate insurance coverage for insurable risks that we identify, we do not carry insurance for all categories of risk that our business may encounter. Insurance coverage is becoming increasingly expensive. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. We may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts to protect us against losses due to liability. While we maintain property, casualty and general liability coverage, we do not carry specific biological or hazardous waste insurance coverage and our insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or

injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. We do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition and results of operations. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. Manufacturing and marketing of ZTlido, GLOPERBA and ELYXYB and clinical testing of our product candidates may expose us to individual product liability claims, class action lawsuits or actions, and other individual or mass tort claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. In addition, physicians may misuse our products with their patients if they are not adequately trained, potentially leading to injury and increased risk of product liability. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of risks inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • loss of revenue from product sales; • decreased demand for our product candidates or products that we develop; • injury to our reputation; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • restrictions on labeling, the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; and • the inability to commercialize our product candidates. Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $ 10. 0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. Our principal executive offices are in the San Francisco Bay Area, California. Our facilities may be affected by natural or man- made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake- prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fires, floods and similar events. If our facilities are affected by a natural or man- made disaster, we may be forced to curtail our operations and / or rely on third parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all. We may seek to grow our business through acquisitions and may fail to realize the anticipated benefits of any acquisition, and acquisitions can be costly and dilutive. Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may expand our business and intellectual property portfolio through the acquisition of new businesses and technologies. We cannot assure that we will achieve anticipated benefits from any acquisition to justify the transaction. Competition within our industry for acquisitions of businesses, technologies and assets may become intense. Even if we are able to identify an acquisition that we would like to consummate, we may not be able to complete the acquisition on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions that are not ultimately consummated. Those negotiations could result in diversion of management time and significant out- of- pocket costs. The success of any acquisition depends on, among other things, our ability to combine our business with an acquired business in a manner that does not materially disrupt existing relationships and that allows us to achieve development and operational synergies. If we are unable to achieve these objectives, the anticipated benefits of an acquisition may not be realized fully, or at all, or may take longer to realize than expected. If we are obligated to make any milestone payments in connection with an acquisition or licensing agreement, such obligations could impose substantial additional costs on us and divert resources from other aspects of our business. In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses or acquire intangible assets that could result in significant future amortization expenses. As a result, an acquisition may not be accretive to our stock value or development pipeline in the near or long term. We expect to incur higher development and regulatory costs, and additional costs integrating the operations and personnel of any companies we acquire, which cannot be estimated accurately at this time. If the total costs of the integration of our companies and advancement of acquired product candidates and technologies exceed the anticipated benefits of the acquisition, our business, financial condition and results of operations could be adversely affected. International components of our business expose us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the United States. We currently collaborate with international manufacturing partners and may potentially expand our business internationally in the future. The purchase and shipment of components from international sources subjects us to U. S. and foreign governmental trade, import and export, and customs regulations and laws. Compliance with these regulations and laws is

costly and exposes us to penalties for non- compliance. Other laws and regulations that can significantly impact us include various anti- bribery laws, including the U. S. Foreign Corrupt Practices Act (the " FCPA "), as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting **. Moreover, the new administration has substantially altered prior U. S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi- lateral trade agreements and treaties with foreign countries. In addition, the new administration has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U. S. goods. It remains unclear what the new administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our products, impact our ability to sell our products outside the United States or to sell our products outside the United States at competitive prices and / or to affect the United States or global economy or certain sectors thereof and, thus, could adversely impact our business** . Conducting business internationally involves a number of risks, including: • multiple, sometimes conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti- bribery and anti- corruption laws, regulatory requirements and other governmental approvals, permits and licenses; • difficulties in enforcing our intellectual property rights and in defending against third- party threats and intellectual property enforcement actions against us, our distributors or any of our third- party suppliers; • failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries; • difficulties in managing foreign operations; • cost and availability of shipping and other means of product transportation; • foreign currency exchange rate fluctuations; • changes in duties and tariffs, license obligations and other non- tariff barriers to trade; • the imposition of new trade restrictions; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • complexities associated with managing multiple payor- reimbursement regimes or self- pay systems; • natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and • failure to comply with the FCPA, including its books and records provisions and its anti- bribery provisions, and similar anti- bribery and anti- corruption laws in other jurisdictions, for example, by failing to maintain accurate information and control over sales or distributors' activities. Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our business, financial condition and results of operations. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our research, product candidates, investigational medicines and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of non- compliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event. When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, our employees, affiliates and / or business partners may use social media for their personal use, and their activities on social media or in other forums could result in adverse publicity for us. Any negative publicity as a result of social media posts, whether or not such claims are accurate, could adversely impact us. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business, financial condition and results of operations. Our business and operations would suffer in the event of a system failure. While we have implemented and maintain security measures, our computer systems and those of our CROs and other contractors and consultants are vulnerable to **, and have experienced,** computer viruses, unauthorized access, cybersecurity attacks, and other security incidents, including as perpetrated by hackers, or as the result of natural disasters, terrorism, war, or telecommunications or electrical failures. ~~While we~~ **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 ~~not experienced any~~ **a material impact on the Company as a whole. A** material system failure or ~~a~~ security breach ~~to date~~ , if such an event were to occur, ~~it~~ could result in a material disruption of our product development programs or a loss of our trade secrets or other proprietary information. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce such data. To the extent that any disruption or security breach were to result in the loss of or damage to our data or applications, or the unauthorized disclosure of confidential or proprietary information, including personal data, we could incur material legal liability or be the subject of legal claims, suffer damage to our reputation, lose or harm our intellectual property rights, and delay the continued research, development and commercial efforts of 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 ~~and especially in 2021, 2022 and 2023 due to the impacts of the COVID- 19 pandemic~~ , including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, as well as the continued hostilities between Russia and Ukraine and, more recently, Hamas' attack against Israel and the ensuing conflict ~~. For example, an overall decrease in or loss of insurance coverage among individuals in the United States as a result of unemployment, underemployment or the repeal of certain provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2020 (the " ACA "), may decrease the demand for healthcare services and pharmaceuticals. If fewer patients seek medical care because they do not have insurance coverage, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected~~ . In addition, Russia' s invasion of Ukraine and sanctions against Russia are causing disruptions to global economic conditions. The escalation in October 2023 of the conflict between Israel and Hamas also could cause disruptions to global economic conditions and affect the stability of the Middle East region. It is not possible to predict the broader consequences of these ongoing conflicts. It is also not possible to predict with certainty these ongoing conflicts and additional adverse effects on existing U. S. macroeconomic conditions and financial markets, all of which could impact the business, financial condition, and results of operations of the Company as well as our ability to raise capital. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. In addition, the closure of any additional national or regional commercial banks could lead to further economic instability. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and price of our Common Stock, and could require us to delay or abandon clinical development plans. Our ability to effectively monitor and respond to the rapid and ~~ongoing~~ **evolving** developments and expectations relating to ~~the environmental~~ **corporate responsibility** , **corporate governance, sustainability and / or corporate involvement in** social **issues** ~~and governance matters, including related social expectations and concerns~~ , may impose unexpected costs or results in reputational or other harm that could have a material adverse effect on our business. There is an increasing focus from certain investors, employees, regulators, listing exchanges and other stakeholders concerning **factors such as** corporate responsibility ~~and~~ **, corporate governance,** sustainability **and / or corporate involvement in** ~~matters, specifically related to environmental,~~ social **issues** ~~and governance (" ESG ") factors~~ . Some investors and investor ~~advocacy~~ groups may use these factors **— either in support or opposition —** to guide **their** investment strategies and, in some cases, investors may choose not to invest in us if they believe our policies **or practices** relating to ~~corporate responsibility are inadequate~~ **these factors do not align with their expectations** . **Currently, a variety of** ~~Third~~ **third** - party providers of corporate responsibility **and sustainability** ratings ~~and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently~~ measure the performance of companies on **these factors** ~~such ESG topics~~ , and the results of these assessments are widely publicized. **Certain** ~~Investors~~ **investors** , particularly institutional investors, use these ratings to benchmark companies against their peers, and **certain** major institutional investors have publicly emphasized the importance of ~~ESG measures~~ **these factors** to their investment decisions. Topics taken into account in such assessments include, among others, **the risks faced by** companies **arising out of** ~~' efforts and impacts on~~ climate change ~~and~~ **,** human rights, **business** ethics and compliance ~~with law~~ , ~~diversity~~ and the role of companies' board of directors in ~~supervising~~ **overseeing** various sustainability ~~issues~~ **- related risks. Equally, certain investors, including institutional investors, actively reject the consideration of these matters when making their investment decisions** . In light of **certain** investors' increased focus on ~~ESG matters~~ **these factors** , if we are **, for example,** perceived as ~~lagging with~~ **deviating from our peers in** respect ~~to ESG~~ **of practices and** initiatives ~~,~~ **related to** these **factors**

~~investors may engage with us to improve ESG disclosures or performance and may also make voting decisions .~~ **we may be exposed** ~~or take other actions,~~ to ~~hold us~~ **shareholder activism** and **litigation (both in support of,** ~~our~~ **or** ~~Board accountable~~ **in opposition to, such practices and initiatives)** . In addition, there are ~~rapid~~ **rapidly evolving** ~~and ongoing~~ developments and changing expectations relating to ~~ESG matters~~ **such factors. As a result** , ~~and~~ the criteria by which our corporate responsibility **and sustainability** practices are assessed may change, which could ~~result in greater expectations of us and~~ cause us to undertake costly initiatives **or actions** to satisfy ~~such~~ new ~~criteria~~ **demands** . If we elect not to or are unable to adequately recognize and respond to such developments and **changing (and sometimes conflicting)** governmental, societal, investor and **/ or** consumer expectations relating to such **factors** ~~ESG matters~~ , we may miss corporate opportunities, become subject to additional scrutiny or incur unexpected costs. We may **also** face risk of **consumer** litigation or reputational damage in the event that our **policies** ~~corporate responsibility procedures~~ or ~~standards~~ **practices** do not meet the standards set by various constituencies. We may also face reputational damage if we are unable to achieve an acceptable ~~ESG or~~ sustainability rating from third- party rating services. A low ~~ESG or~~ sustainability rating by a third- party rating service could also result in the exclusion of our Common Stock from consideration by certain investors who may elect to invest with our competitors instead. Ongoing focus on corporate responsibility **and sustainability** matters by investors and other ~~parties~~ **stakeholders** as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, financial condition or results of operations, including the sustainability of our business over time, and could cause the market value of our Common Stock to decline. Further, our ~~emphasis on ESG issues~~ **risk management related to these factors** may not maximize short- term financial results and may yield financial results that conflict with the market' s expectations. We may in the future make business decisions ~~that may reduce our short- term financial results if we believe that the decisions are~~ consistent with our ~~ESG goals, which~~ **risk management related to these factors that** we believe **, based on considered analysis,** will **create value and** improve our financial ~~results~~ **performance** over the long- term. These decisions **, however,** may not be consistent with the short- term expectations of our stockholders and may not produce the long- term benefits that we expect, in which case our business, financial condition and results of operations could be harmed. 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, ~~2023~~ **2024** , Scilex' s net profits for ZTlido and SP- 103 have not exceeded five percent of net sales. Accordingly, Oishi and Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, ~~2023~~ **2024** , neither Oishi nor Itochu has exercised its right of termination. If the Product Development Agreement is terminated for certain reasons, such as our material breach of the agreement, our bankruptcy, or lack of economic viability, we will be required to transfer all licensed intellectual property rights, including those relating to ZTlido and SP- 103, to Oishi and Itochu or their designee, at our own cost and expense. The loss of such licenses could materially harm our business, financial condition and results of operations. 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 . ~~Pursuant~~ **, which was amended by that First Amendment** to **License and Commercialization Agreement, dated as of January 16, 2025. Under** the Romeg ~~Agreement, we have been granted (1) the right to manufacture, promote, market, distribute and sell pharmaceutical products comprising liquid formulations of colchicine for the prophylactic treatment of gout in adult humans in the United States and (2) an exclusive, transferable license~~ **License** ~~to use the trademark " GLOPERBA. " Under the Romeg~~ Agreement, among other things, Romeg granted us (1) a ~~transferable~~ license, with the right to sublicense, under the patents and know- how specified therein to (a) commercialize ~~the~~ **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; ~~and~~ (2) an exclusive ~~, transferable~~ 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** . ~~The~~ **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~~ **Royalty** ~~term~~ **Term** , but is otherwise non- exclusive ~~. The~~ **, 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 ~~royalty term~~ **Romeg U. S. Territory** begins on the **Original Signing** ~~date~~ **Date** ~~of the agreement~~ 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 ~~Romeg~~ **amendment** ~~Agreement~~ **agreement and ends on the tenth anniversary of such date** . Our ability to commercialize GLOPERBA and develop Licensed Products depends on the effectiveness and continuation of the Romeg **License** Agreement. If we lose the right to license the intellectual property rights granted by the Romeg **License** Agreement, our ability to develop GLOPERBA as well as new product candidates based on the licensed intellectual property would be harmed. The Romeg **License** Agreement imposes various development, regulatory and / or commercial diligence obligations, payments and other obligations. Romeg has the right to terminate the Romeg **License** Agreement under certain circumstances, including, among other things: (a) in the event we are in material breach of the Romeg **License** Agreement, unless we have cured any such breach within 60 days after any notice thereof was provided; (b) upon notice to us, if we fail to timely pay any milestone payment, percentage royalties or minimum quarterly royalties or fail to timely deliver the requisite quarterly report, which termination will be effective 30 days after the date of such notice, unless we have made such payment in full or delivered such quarterly report within such 30 day period; (c) immediately, if we challenge the licensed patents under any court action or proceeding or before any patent office or assist any third party to conduct any of these activities; (d) by written notice to us if sales of **the** Licensed Products do not commence or continue within specified periods agreed to by the parties; or (e) in the event of our bankruptcy or assignment for the benefit of creditors. If the Romeg **License** Agreement is terminated for certain reasons, such as our material breach of the agreement, our bankruptcy, or our failure to timely pay milestone payments, we will be required upon Romeg' s request to transfer all licensed intellectual property rights, including those relating to GLOPERBA and the Licensed Products, to Romeg or its designee, within thirty days after the termination of the Romeg **License** Agreement at a price to be agreed upon by the parties. The loss of such licenses could materially harm our business, financial condition and results of operations. Potential disputes over intellectual property rights that we have licensed may prevent or impair our ability to maintain our current licensing arrangements on acceptable terms. Licensing of intellectual property rights is of high importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • our financial or other obligations under the license agreement; • whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement; • our right to sublicense intellectual property rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, financial condition and results of operations may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences. Furthermore, if our licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of certain of our product candidates, if approved. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations. We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to ZTlido, GLOPERBA, ELYXYB and our product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States for GLOPERBA, in the United States and Canada for ELYXYB, and in the United States and other countries with respect to ZTlido and our product candidates. We seek to protect our proprietary position by filing and / or in- licensing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patents and patent applications that we own or in- license may fail to result in issued patents with claims that protect ZTlido, GLOPERBA, ELYXYB and our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our

patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover ZTlido, GLOPERBA, ELYXYB and our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following: • the U. S. Patent and Trademark Office (“ PTO ”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the non- compliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; • countries other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products; • other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position; • any successful intellectual property challenge to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop; • because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses; and • an interference proceeding can be provoked by a third party or instituted by the PTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013. The patent prosecution process is also expensive and time- consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If the patent applications we hold or in- license with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for ZTlido, GLOPERBA, ELYXYB and our product candidates, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize ZTlido, GLOPERBA, ELYXYB and our product candidates. Any such outcome could have a materially adverse effect on our business. We may not be successful in obtaining or maintaining necessary rights to product components and processes and brands for our development pipeline through acquisitions and in- licenses. Presently we have intellectual property rights, through acquisitions and licenses from third parties, related to ZTlido, SP- 103 and GLOPERBA. Because our programs for ZTlido, GLOPERBA, ELYXYB, SP- 103 and SP- 104 may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. It may also be commercially advantageous to use trademarks held by others. We may be unable to acquire or in- license proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidates. Even if we are able to obtain a license to such proprietary rights, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing and prosecution of patent and trademark applications, or to maintain the patents covering technology that we license from third parties and associated trademark registrations, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents, trademarks and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents and trademarks, or any patents and trademark registrations that may issue from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, or loss of trademark rights, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents or trademarks against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to

provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor' s rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. The licensing and acquisition of third- party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. We may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third- party may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition and results of operations could suffer. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Claims that we infringe, misappropriate, or violate the intellectual property rights of third parties may give rise to costly and lengthy litigation, and we could be prevented from selling products, forced to pay damages, and defend against litigation. Third parties may assert patent or other intellectual property infringement or misappropriation claims against us or our strategic partners, licensors or licensees with respect to ZTlido, GLOPERBA, ELYXYB and our product candidates. If ZTlido, GLOPERBA, ELYXYB or any of our product candidates, methods, processes and other technologies are alleged to infringe on or be improperly based on the proprietary rights of other parties, we could face adverse consequences. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third- party patent applications which may later result in issued patents that our product candidates or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of our valuable management and employee resources from our business. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. Any claims of patent infringement asserted by third parties would be time- consuming and could: • result in costly litigation; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law; • require us to develop non- infringing technology, which may not be possible on a cost- effective basis; • require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property; • require us to pay the attorney' s fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and / or • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all. If we are sued for patent infringement, we

would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do either. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management' s time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non- infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because: • some patent applications in the United States may be maintained in secrecy until the patents are issued; • patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived; • pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates; • identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims; • patent applications in the United States are typically not published until 18 months after the priority date; and • publications in the scientific literature often lag behind actual discoveries. Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. Numerous third- party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U. S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Even if we were to prevail, any litigation or administrative proceeding could be costly and time- consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our strategic partners or licensees, we or our strategic partners or licensees may be forced to stop or delay developing, manufacturing or selling technologies, product candidates or potential products that are claimed to infringe a third party' s intellectual property unless that party grants us or our strategic partners' or licensees' rights to use its intellectual property. Ultimately, we may be unable to develop some of our product candidates or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent infringement claims, which could severely harm our business, financial condition and results of operations. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming and divert the time and attention of our management and key personnel. For example, on June 22, 2022, we filed a complaint against Aveva and Apotex in the U. S. District Court for the Southern District of Florida alleging infringement of certain Orange Book patents covering ZTlido. See the section of this Annual Report on Form 10- K titled " Business — Legal Proceedings " for additional information regarding such proceedings. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability

to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our business, financial condition and results of operations. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. Any of the foregoing may have a material adverse effect on our business, financial condition and results of operations. If our intellectual property rights are invalidated or circumvented, our business, financial condition and results of operations will be adversely affected. Our long- term success depends on our ability to continually discover, develop and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new product candidates to the market and for commercialization. Intellectual property protection varies throughout the world and is subject to change over time. In the United States, for small molecule drug products, such as ZTlido, GLOPERBA and ELYXYB, the Hatch- Waxman Act provides generic companies powerful incentives to seek to invalidate our pharmaceutical patents. As a result, we expect that our U. S. patents on major pharmaceutical products will be routinely challenged, and there can be no assurance that our patents will be upheld. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a distraction to management and other employees. We face generic manufacturer challenges to our patents outside the United States as well. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay damages for past infringement or royalties on future sales. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition and our business, financial condition and results of operations may be adversely affected. We have registered trademarks with the PTO for the mark " ZTlido, " " SCILEX, " " ELYXYB, " and " RESPONSIBLE BY DESIGN, " and we have filed trademark applications for the marks " SEMNUR PHARMACEUTICALS **, " " SCILEX BIO,** " and " SEMDEXA " in the United States. We also have trademark registrations for ZTlido in the UK and Greece and we have a pending trademark application for ZTlido in China. In China, we ~~are~~ **were** involved in an ongoing dispute regarding third- party trademarks for ZTlido filed in the name of 秦皇島恆駿商貿有限公司 (Qinhuangdao Hengjun Trading Co., Ltd.) **. The China National Intellectual Property Administration issued a decision in our favor in February 2025, which has now become final** . Our trademarks or trade names may be challenged, infringed, diluted, tarnished, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, dilution or tarnishment claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity. Therefore, obtaining and enforcing biotechnology and pharmaceutical patents is costly, time- consuming and inherently uncertain. In addition, the America Invents Act (the " AIA "), which was passed in September 2011, resulted in significant changes to the U. S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a " first- to- invent " to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the PTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from

promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the PTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in PTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a PTO proceeding sufficient for the PTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the PTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. We may become involved in opposition, interference, derivation, inter partes review, post- grant review, or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in- licensed patent rights, allow third parties to commercialize ZTlido, GLOPERBA, ELYXYB and our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the PTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future ~~. For example, the Biden administration recently indicated its support for a proposal at the World Trade Organization to waive patent rights with respect to COVID- 19 vaccines~~ . Any waiver of our patent or other intellectual property protection by the U. S. and other foreign governments could have a material adverse effect on our competitive position, business, financial condition and results of operations. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but, the complexity and uncertainty of European patent laws has also increased in recent years. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (" UPC "). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The PTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. For example, periodic maintenance fees on any issued patent are due to be paid to the PTO and other foreign patent agencies in several stages over the lifetime of the patent. The PTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. If we or any of our licensors fail to maintain the patents or patent applications covering ZTlido, GLOPERBA, ELYXYB and our product candidates, our competitors may be able to enter the market, which would have an adverse effect on our business, financial condition and results of operations. Confidentiality agreements with employees may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete. To help protect our proprietary know- how and our inventions for which patents may be unobtainable or difficult to obtain, or prior to seeking patent protection, we rely on trade secret protection and confidentiality agreements. To this end, we require all our employees to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements typically limit the rights of the third parties to use or disclose our confidential information. We also typically obtain agreements from these parties that provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, current or former employees may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential

information. For example, on March 12, 2021, we filed the Former Employee Action, as described under the section titled " Legal Proceedings " of this Annual Report on Form 10- K. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business, financial condition and results of operations. Enforcing a claim that a third party obtained illegally, and is using, trade secrets and / or confidential know- how is expensive, time- consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. If any of our trade secrets, know- how or other proprietary information is disclosed, the value of our trade secrets, know- how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. Moreover, our third- party licensing partners may retain rights in some of our proprietary or joint trade secrets, know- how, patented inventions or other proprietary information, including rights to sublicense and rights of publication, which may adversely impact our ability to obtain patents and protect trade secrets, know- how or other proprietary information. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, as well as our academic partners. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. We may also be subject to claims that patents and applications that we may file to protect inventions of our employees or consultants are rightfully owned by their former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. An inability to incorporate such technologies or features would have a material adverse effect on our business, financial condition and results of operations and may prevent us from successfully commercializing ZTlido, GLOPERBA, ELYXYB and our product candidates, if approved. Moreover, any such litigation or the threat of such litigation may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize ZTlido, GLOPERBA, ELYXYB and our product candidates, if approved. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self- executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, individuals executing agreements with us may have preexisting or competing obligations to a third party. Our position as a relatively small company may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against infringement claims by third parties. Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that ZTlido, GLOPERBA, ELYXYB or any of our product candidates infringes or misappropriates third- party intellectual property rights. However, we may seek to use various post- grant administrative proceedings, including procedures created under the AIA, to invalidate potentially overly- broad third- party rights. Even if we can defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. In the course of the ongoing litigation or any future additional litigation to which we may be subject, we may not be able to protect our intellectual property at a reasonable cost, or at all. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal, contractual or intellectual property rights, which could have a significant adverse effect on our business, financial condition and results of operations. Third- party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including PTO administrative proceedings, such as inter partes reviews, post- grant reviews, and reexamination proceedings before the PTO or oppositions and revocations and other comparable proceedings in foreign jurisdictions. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the development and / or commercialization of ZTlido, GLOPERBA, ELYXYB or our product candidates may give rise to claims of infringement of the patent rights of others. Despite safe harbor provisions for products prior to commercial launch, third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents, of which we are currently unaware, with claims to materials, formulations, methods of doing research, methods of manufacture or methods for treatment related to the use or manufacture of ZTlido, GLOPERBA, ELYXYB or our product candidates. Because patent applications can take many years to issue, there may be currently pending unpublished patent applications which may later result in issued patents that ZTlido, GLOPERBA, ELYXYB or our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that the use of our technologies infringes these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing

process of ZTlido, GLOPERBA, ELYXYB or any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize ZTlido, GLOPERBA and ELYXYB, or develop and commercialize one or more of our product candidates. For example, Takeda filed the GLOPERBA Patent Litigation against us **and Scilex Pharma** on November 6, 2023, alleging that our filing with the FDA of an application for approval of a proposed revision to the product label for our GLOPERBA product infringed the Colcrys Patents. Takeda **sought** ~~is seeking~~ 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** ~~filing of the complaint subjects~~ **subject** ~~us~~ to ~~a 30- month stay, preventing us from selling GLOPERBA under a revised~~ **review** ~~label (but not from selling GLOPERBA under its current label)~~ **by the Federal Trade Commission and the U. S. Department of Justice, neither of which objected** during ~~that time~~ **the review period** . ~~The stay could last as long as until~~ **After the expiration of the review period, the U. S. District Court for the District of Delaware entered a final consent judgment on** May ~~6~~ **3** , ~~2026~~ **2024** ~~, unless the litigation is resolved before that time~~ . See the section of this Annual Report on Form 10- K titled " Business – Legal Proceedings " for additional information regarding such proceedings. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, cease marketing ZTlido, GLOPERBA or ELYXYB, or developing our product candidates, limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of ZTlido, GLOPERBA or ELYXYB or our product candidates, if approved. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further commercialize ZTlido, GLOPERBA or ELYXYB, or develop and commercialize one or more of our product candidates, which could harm our business, financial condition and results of operations significantly. **If we do not obtain patent term extension and data exclusivity for any of our product candidates we are developing or may develop, our business may be materially harmed. Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended; the extension cannot extend the total patent term beyond 14 years from approval; and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.** We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. We may not be able to protect our intellectual property rights throughout the world. The requirements for

patentability and the patent enforcement differ in many countries. Filing, prosecuting and defending patents on ZTlido, GLOPERBA, ELYXYB and all of our product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement in some countries is not as strong as that in the United States. These products may compete with ZTlido, GLOPERBA, ELYXYB or our product candidates, if approved, in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. The ongoing conflict in Ukraine and related sanctions could significantly devalue our Ukrainian and Russian patent applications. Russian decrees may significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals and methods of treatment of the human body, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. Furthermore, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition and results of operations. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and inventions agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, in 2010, the FDA, as part of its Transparency Initiative, recommended steps that the FDA could take to increase transparency, including with respect to making additional information publicly available on a routine basis, which may include information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA' s disclosure policies may change in the future, if at all. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Competitors and other third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Our reliance on third parties may require us to share our trade secrets, which

increases the possibility that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to help manufacture and supply our products and product candidates, and we expect to collaborate with third parties on the continuing development of future product candidates, we must, at times, share trade secrets with them. We also expect to conduct research and development programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs, research institutions and / or investigators. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including, material transfer agreements, consulting agreements, confidentiality agreements or other similar agreements with our advisors, contractors, service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business, financial condition and results of operations. In addition, these agreements typically restrict the ability of our advisors, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition and results of operations. Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example: • Others may be able to make products that are similar to ZTlido, GLOPERBA, ELYXYB or our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; • We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; • We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions; • Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • Our pending patent applications may not lead to issued patents; • Issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; • Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • We may not develop additional proprietary technologies that are patentable; and • The patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, financial condition and results of operations. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for PTA. If we or our partners, collaborators, licensees or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and results of operations. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect ZTlido, GLOPERBA, ELYXYB and our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. If these changes were to occur, they could have a material adverse effect on our ability to generate revenue. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will / will not be viewed in the future and whether patent expiration dates may be impacted. Similarly, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the

uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the PTO or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post- issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize ZTlido, GLOPERBA, ELYXYB and our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and potentially licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of ZTlido, GLOPERBA, ELYXYB or our product candidates. Generally, patents are granted a term of 20 years from the earliest claimed non- provisional filing date. In certain instances, patent term can be adjusted and increased to recapture a portion of delay incurred by the PTO in examining the patent application. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. 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, ~~we believe that~~ **following our March 2022 announcement of** the ~~data~~ **final results** from our Phase 3 ~~CLEAR~~ trial ~~will be~~ **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. ~~However~~ **In the Type C meeting** , the FDA ~~has~~ **indicated that it** disagreed **with us that the clinical data we had collected was sufficient to support the safety** and ~~has issued~~ **efficacy of SEMDEXA. The FDA provided** guidance ~~requiring~~ **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 ~~conduct an additional clinical study~~ **be able to satisfy the requirements** for **a 505** ~~the purpose of collecting additional safety data before we are able to submit the NDA, even though we believe the data from the CLEAR trial are adequate~~ (**b** ~~see the section titled " Business — The Company — Our Product Candidates " for additional information~~) **(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. ~~Other than an NDA submitted~~ **We have limited experience submitting applications** for **marketing authorization to** ~~ZTlido in the United States, which was approved by~~ the FDA ~~in February 2018, we have not previously submitted an NDA to the FDA for any product candidate~~ , 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. ~~In~~ **With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Furthermore, the U. S. Supreme Court' s June 2024 decision in Loper Bright Enterprises v. Raimondo, which overturned the long- standing Chevron doctrine that required courts to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes, could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. The Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed. Moreover, in** order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Approval of a product candidate by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, the clinical trials conducted in one country, and the data generated therefrom, may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. If we do not receive regulatory approvals for our product candidates, our business, financial condition and results of operations will be substantially harmed. If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. For our product candidates SEMDEXA, SP-103 and SP- 104, we may seek FDA approval through the Section 505 (b) (2) regulatory pathway. The Hatch- Waxman Act added Section 505 (b) (2) to the Federal Food, Drug and Cosmetic Act (the " FDCA "). Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2) allows an NDA we submit to the FDA to rely in part on data in the public domain or the FDA' s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of data that we would need to generate in order to obtain FDA approval. If the FDA does not agree that the Section 505 (b) (2) regulatory pathway is acceptable as we anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. Even if FDA accepts our plan to pursue the Section 505 (b) (2) regulatory pathway, we cannot assure that our product candidates will receive the requisite approvals for commercialization. In addition, the pharmaceutical industry is highly competitive, and Section 505 (b) (2) NDAs are subject to special requirements designed to protect the patent and market exclusivity rights of sponsors of previously approved drugs that are referenced in a Section 505 (b) (2) NDA. These requirements may give rise to patent litigation against us and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. Further, a manufacturer of an approved product may file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. FDA imposes strict requirements on such petitions in part to dissuade companies from improperly using these petitions to delay approval of competing drug products. Nonetheless, if successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505 (b) (2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval. 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. ~~These~~ **Other** requirements include submissions of safety and other post- marketing information and reports, registration and listing **, product tracking and tracing** , as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. The future discovery of previously unknown problems with a product, including adverse events of unanticipated type, severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • investigation or additional study obligations; • communications to prescribers or patients about specific information or issues; • restrictions on the

marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; • fines, warning or untitled letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; • product seizure or detention, or refusal to permit the import or export of products; and • injunctions or the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation. The FDA' s and other regulatory authorities' policies may change, and additional laws or government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our ability to generate revenue and achieve or sustain profitability. Changes in law or government regulations may also alter the competitive landscape, potentially to our disadvantage. Certain manufacturers in the market in which we compete distribute certain products without completing the FDA approval process. For example, we believe certain lidocaine topical patches, plaster or poultice products marketed OTC and without FDA approval, require approval and compete inappropriately with ZTlido. In December 2018, we filed a citizen' s petition asking the FDA to clarify its requirements and take enforcement action against such products. Furthermore, we believe the labeling and marketing of certain OTC lidocaine patches products are false and deceptive, which could cause significant damages to our business and a diminution of goodwill in our intellectual property. In addition, on March 7, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the " CARES Act ") was signed into law, which included statutory provisions reforming FDA' s mechanisms for regulating OTC drugs. Under the CARES Act, the FDA considers a drug to be generally recognized as safe and effective (" GRASE ") if it meets certain requirements, including items such as the active ingredient, indication for use, dosage, route of administration, and labeling set forth in the OTC monograph and related rulemakings. Historically, the FDA was required to establish, revise, and amend an OTC monograph by notice- and- comment rulemaking, which was lengthy and resource-intensive. The CARES Act replaces the rulemaking process with a final administrative order process. Administrative orders may be initiated by the FDA or at the request of a drug manufacturer or any other person. After a period for public comment on the administrative order, the FDA is able to issue a final administrative order, rather than a regulation, permitting the drug to be marketed over the counter. **In 2023, the FDA has posted a final administrative order for external analgesic drug products for OTC human use.** As this process is much more streamlined and less burdensome, this may benefit the manufacturers of lidocaine topical patches to obtain GRASE status from the FDA and thereby legally market these products over- the- counter and compete with ZTlido. The FDA ultimately denied our citizen' s petition in light of the new administrative order process under the CARES Act for considering OTC drug products. In February 2021, we filed a complaint against Sanofi and Hisamitsu, certain manufacturers of OTC lidocaine patches, to seek an award of damages and the entry of injunctive relief enjoining further dissemination of false and deceptive advertisement concerning claims about their lidocaine patches. On January 26 and February 2, 2024, Scilex Pharma entered into two separate settlement agreements and mutual releases with the two manufacturers that resolve the Action. The terms of those agreements are confidential. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U. S. administration may impact our business and industry. Namely, recent U. S. administrations have taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA' s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA' s ability to exercise its regulatory authority. If these executive actions impose constraints on FDA' s ability to engage in oversight and implementation activities in the normal course, our business, financial condition and results of operations may be negatively affected. **In addition, three decisions from the U. S. Supreme Court in June and July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned a regulatory agency' s ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and other agency regulations, policies, and decisions may become subject to increasing legal challenges, delays and changes.** A fast track product ~~designation, breakthrough therapy~~ designation or other designation to facilitate product candidate development may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval. A product sponsor may apply for fast track designation from the FDA if a product is intended for the treatment of a serious or life- threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition. The FDA has broad discretion whether or not to grant this designation. We have received fast track designation for SEMDEXA for the treatment of sciatica and SP- 103 for the treatment of chronic neck pain. Even though SEMDEXA and SP- 103 have received fast track designation, we may not experience a faster process, review or approval compared to conventional FDA procedures. A fast track designation does not expedite clinical trials, or mean that regulatory requirements are less stringent or provide assurance of ultimate marketing approval by the FDA. Instead, fast track

designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review of individual sections of an NDA submitted to the FDA as they become finalized. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program. The FDA may also withdraw any fast track designation at any time. Changes in funding for the FDA could hinder its ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business, financial condition and results of operations. The ability of the FDA to review and approve new products **and conduct other regulatory activities** can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other regulatory authorities may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business, financial condition and results of operations. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities in 2020. **Additionally, the new administration recently announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations.** If a prolonged government shutdown occurs, ~~or~~ if **funding for the FDA or other federal agencies (including their workforce) is reduced or if future** global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, financial condition and results of operations. Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business. We and our collaborators are subject to federal, state and foreign data protection laws and regulations. In the United States, such laws may include, but are not limited to, U. S. state personal data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the FTC Act, each of which govern the collection, use, disclosure and protection of health- related and other personal information. Although we are not subject to HIPAA, as we are neither a Covered Entity nor Business Associate (as such terms are defined in HIPAA), we may have access to very sensitive data regarding patients who participate in, or whose tissue samples or other biospecimens are used in, our clinical trials. The maintenance of this data imposes upon us administrative and financial burdens and litigation risks. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data that are subject to HIPAA and other privacy, data security and consumer protection laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a Covered Entity in a manner that is not authorized by HIPAA, and we may be subject to other civil and / or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. Our ability to use or disclose information may be limited by the scope of an authorization signed by clinical trial subjects or the terms of the contract that we enter into with providers or other data sources. Furthermore, U. S. state laws and regulations relating to data privacy and security and consumer protection are constantly evolving. For example, the CCPA, which went into effect on January 1, 2020, created new individual privacy rights for California consumers and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA has been amended by the CPRA, which largely took effect on January 1, 2023. The CPRA also created a new state agency, the CPPA, vested with authority to implement and, along with the California Attorney General, enforce the CCPA **. Further, Washington' s My Health My Data Act, taking effect July 1, 2024, imposes requirements specific to consumer health data** . Several other states have enacted or are considering similar state consumer privacy laws. The state privacy laws vary from each other in many ways, which may complicate compliance efforts. The effects on our business of the state privacy laws and general consumer protection authorities are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to so comply. Privacy laws and regulations are constantly evolving and there are a number of legislative proposals at both the state and federal levels that could impose new obligations or limitations in areas affecting our business. The FTC also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may be result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. International data protection laws, including the EU' s and UK' s GDPR, may also apply to health- related and other personal information obtained outside of the United States. The GDPR imposes several data protection requirements in the EU, as well as fines for violations that can reach up to the greater of € 20 million or 4 % of annual global revenue. The regulation imposes numerous requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information, including the right to access, correct and delete their data. Compliance with international data protection

laws and regulations could require us to take on more onerous obligations in our contracts, increase our compliance costs, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We cannot guarantee that we are or will be in compliance with all applicable international regulations as they are enforced now or as they evolve. Claims that we have violated individual privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend against and could result in adverse publicity that could harm our business, financial condition, and results of operations. Our business **may be impacted by actions of the new U. S. administration, including executive orders, policies, new legislation and judicial decisions. The impact of the new U. S. administration is currently unknown. However, actions of the administration may cause us to change our business operations, with an unknown impact to our stakeholders, including patients, healthcare providers and employees. Failure to comply with new administration actions could expose us to litigation or other government actions. There can be no assurance that our compliance with new administration actions will provide sufficient mitigation. Our business** involves the use of hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third- party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements, which could have a material adverse effect on our business, financial condition and results of operations. We are exposed to the risk of fraud, illegal activity or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by employees could include intentional, reckless and / or negligent conduct that fails to comply with the laws and regulations of the FDA, EU Member States, EMA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with federal and state health- care fraud and abuse laws and regulations, comply with laws and regulations, including, but not limited to the FCPA and internal policies restricting payments to government agencies and representatives, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission **or contracting** , customer incentive programs and other business arrangements. Misconduct by employees, independent contractors, consultants, commercial partners and vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations ~~or~~ **,** 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 ~~law~~ **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** ~~may be~~ used in the calculation of reimbursement and / or discounts on marketed products paid by government healthcare programs. Participation in these programs and compliance with the applicable requirements may result in potentially significant discounts on products subject to reimbursement under federal healthcare programs and increased infrastructure costs, and may potentially limit a drug manufacturer' s ability to offer certain marketplace discounts **. Additionally, if it is determined by the government, which could include a government agency such as CMS, Health Resources and Services Administration (" HRSA "), the VA, or by the Office of Inspector General (" OIG ") or Department of Justice (" DOJ "), that the Statutory Price Reporting was incorrect, causing the government to essentially pay more than they should through the reimbursement and / or discount, the manufacturer may be subject to significant False Claims Act investigations, civil monetary penalties and / or additional fines** ; • the Prescription Drug Marketing Act, which restricts the manner in which manufacturers may disseminate complimentary drug samples to healthcare practitioners, requires physical and accounting controls, and establishes penalties for improper sample distribution; and • state law equivalents of each of the above federal laws, such as licensing, anti- kickback, false claims, consumer protection and unfair competition laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing information and marketing expenditures, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. In addition, our current and future research and development of our product candidates outside the United States, and any future sales of our product or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business practices and arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, exclusion from government- funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition and results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business, financial condition and results of operations. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted off- label uses of ZTlido, GLOPERBA, ELYXYB, or our product candidates, if approved, or if we are found to have improperly engaged in pre- approval promotion prior to the approval of such product candidates, we may become subject to

significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as ZTlido, GLOPERBA, ELYXYB, and our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. Physicians may use our products, and our product candidates if they receive marketing approval, for their patients in a manner that is inconsistent with the approved labels, if the physicians believe in their professional medical judgment they could be used in such manner. However, if we are found to have promoted any of our products for any off- label uses, the federal government could levy civil, criminal and / or administrative penalties, and seek fines against us. The FDA, Department of Justice or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement **or corporate mentorship** , or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of ZTlido, GLOPERBA, ELYXYB, or our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations. Healthcare reform measures could hinder or prevent our product candidates' commercial success. There have been, and we expect there will continue to be, a number of legislative and regulatory changes to health care systems in the United States and abroad that could impact our ability to sell our products profitably. The United States government and other governments have shown significant interest in pursuing healthcare reform. For example, in 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. Healthcare reform measures like the ACA may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third- party payors. Since its enactment, there have been ongoing efforts to modify the ACA and its implementing regulations. For example, tax legislation enacted at the end of 2017 included provisions that, effective January 1, 2019, eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage, or the so- called " individual mandate. " It is unclear how healthcare reform measures enacted by Congress or implemented by the ~~Biden~~ **Trump** administration or efforts, if any, to modify the ACA or its implementing regulations, or portions thereof, will impact our business. Litigation and legislation over the ACA and other healthcare reform measures are likely to continue, with unpredictable and uncertain results. Further, additional legislative changes to and regulatory changes under or related to the ACA remain possible. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of, on average, 2 % per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through May 31, 2022, due to the COVID- 19 pandemic. The law provides for 1 % Medicare sequestration in the second quarter of 2022 and allows the full 2 % sequestration thereafter until 2030. To offset the temporary suspension during the COVID- 19 pandemic, in 2030, the sequestration will be 2. 25 % for the first half of the year, and 3 % in the second half of the year. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs, as addressed further in the risk factor below titled " If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs applicable to our product or product candidates, if approved, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and future prospects. " While any proposed measures may require authorization through additional legislation to become effective, Congress and ~~the Biden~~ **recent presidential** ~~administration~~ **administrations** have each indicated **an intent** ~~that it will continue~~ to seek new legislative and / or administrative measures to control drug costs. We expect that additional U. S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal health care programs and commercial payers will pay for healthcare products and services, which could result in reduced demand for ZTlido, GLOPERBA, ELYXYB and our product candidates, if approved, or additional pricing pressures. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally- mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition and results of operations. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third- party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These or other reforms could reduce the ultimate demand for ZTlido, GLOPERBA, ELYXYB and our product candidates, if approved, or put pressure on our product pricing. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, ZTlido, GLOPERBA and / or ELYXYB may lose any regulatory approval that may

have been obtained and we may not achieve or sustain profitability. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies and the courts. Such interpretation can change and evolve over time. In the case of Medicaid pricing data, if a manufacturer becomes aware that its reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, the manufacturer is obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an overage or underage in rebate liability for past quarters. Price recalculations also may affect the ceiling price at which a manufacturer is required to offer its products under the 340B program. A failure to comply with reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively affect financial results. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes under the ACA to the Medicaid Drug Rebate Program. The final regulation has increased and will continue to increase costs and the complexity of compliance, has been and will continue to be time- consuming to implement, and could have a material adverse effect on the results of operations, particularly if CMS challenges the approach a manufacturer has taken in the implementation of the final regulation. Other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program may have a similar impact. **In addition, potential policy changes by the new administration may introduce additional uncertainty for our business, including changes to the level of scrutiny applied by the Health Resources and Services Administration (“ HRSA ”) to enforce non- compliance with the 340B program, new price restrictions on products we sell to Medicaid, Medicare or other government purchasers, or other regulatory changes impacting reimbursement or competitive dynamics in multisource markets. Any such policy shifts could significantly impact our business and operations.** Manufacturers have obligations to report the average sales price for certain of drugs to the Medicare program as a part of the agreement to participate in the Medicaid Drug Rebate program. For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for products and the resulting Medicare payment rate, and could negatively affect results of operations. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologics, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single- dose containers or single- use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10 % of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 ~~percent~~ **%** 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. ~~The Health Resources and Services Administration (“~~ 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. ~~The~~ **In recent years, two** U. S. ~~Court~~ **Courts** of Appeals for the Third Circuit **and District of Columbia Circuits** (the “ Third Circuit ” **and “ D. C. Circuit, ” respectively**) **have** ruled ~~in January 2023~~ 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 availability to the hospital’ s own pharmacy, and one contract pharmacy~~ . The Third Circuit also upheld the ADR rules. ~~Two~~ **One** other ~~cases~~ **case** ~~are~~ **is** pending ~~, one~~ in the U. S. Court of Appeals for the Seventh Circuit ~~and~~ **. Various states have also enacted laws prohibiting manufacturers from placing conditions** ~~one~~ **on** ~~in~~ **covered entities’ use of contract pharmacies. There is ongoing litigation over** ~~the~~ **these state laws** ~~U. S. Court of Appeals for the District of Columbia Circuit~~ . 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 ~~percent~~ **%** of the discount that was due. Furthermore, the Inflation Reduction Act of 2022 (the “ IRA ”), PL 117- 169, seeks to limit manufacturers’ price increases for drugs reimbursed by Medicare, to not more than the rate of inflation, at least where those increases would otherwise affect payments under Medicare. Under the provisions, beginning in October 2022, if a manufacturer increases the price of a drug

reimbursed under Medicare by more than the rate of inflation (as measured by the consumer price index), the manufacturer must pay rebates to the federal government, equal to the amount by which the increase exceeds the rate of inflation in the relevant period. Congress could also enact additional changes that affect our overall rebate liability and the information we report to the government as part of price reporting calculations. The IRA also requires the U. S. Department of Health and Human Services (" HHS ") to negotiate prices for a limited number of single- source brand- name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). The number of drugs affected is limited to ten Part D drugs for 2026, another fifteen Part D drugs for 2027, another fifteen Part D and Part B drugs for 2028, and another twenty Part D and Part B drugs for 2029 and later years. On August 29, 2023, HHS announced the list of the ten drugs for which negotiations will occur. Drugs that are less than 9 years (for small- molecule drugs) or 13 years (for biological products) from their FDA approval or licensure date are excluded from the negotiation process. Small biotech drugs, defined as those which account for 1 % or less of Part D or Part B spending and account for 80 % or more of spending under each part on that manufacturer' s drugs, are also excluded until 2029. CMS has issued initial guidance on the implementation of the provisions. Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract- based requirements under the VA Federal Supply Schedule and / or Tricare programs can subject a manufacturer to civil monetary penalties. These programs and contract- based obligations also contain extensive disclosure and certification requirements. If a manufacturer overcharges the government in connection with its arrangements with Federal Supply Schedule or Tricare, the manufacturer may be required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and / or response to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and future prospects. We will need to obtain prior FDA authorization for any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business, financial condition and results of operations. Any brand names we intend to use for our product candidates will require authorization from the FDA regardless of whether we have secured a formal trademark registration from the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner, or at all, which would limit our ability to successfully commercialize our product candidates. We are subject to the U. S. Foreign Corrupt Practices Act and other anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition and results of operations. Our operations are subject to certain anti- corruption laws, including the FCPA, and other anti- corruption laws that apply in countries where we conduct business, including performing clinical trials. The FCPA and other anti- corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to foreign government officials or other persons to obtain or retain business or gain some other business advantage. We, our commercial partners and our affiliates operate in a number of jurisdictions that pose a risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti- corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anti- corruption laws, including the FCPA or other legal requirements, such as trade control laws. Any investigation of potential violations of the FCPA, other anti- corruption laws or trade control laws by U. S., European Union or other authorities could have an adverse impact on our reputation, our business, financial condition and results of operations. Furthermore, should we be found not to be in compliance with the FCPA, other anti- corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, financial condition and results of operations. We **may in the future conduct clinical trials for current or future product candidates outside the U. S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We expect to conduct clinical trials internationally in the future. The acceptance of data from clinical trials conducted outside the U. S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U. S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials** are subject to ~~recently enacted state~~ **the applicable local** laws ~~in California that require gender and diversity quotas for boards~~ of ~~directors of public companies headquartered in California. In September 2018, California enacted Senator Bill 826 (" SB 826 "), which generally requires public companies with principal executive offices in California to have at least two female directors on its board of directors if the company has at least five directors, and at least three~~ -- **the foreign**

jurisdictions where ~~female directors on its board of directors if~~ the ~~company has at least six directors. SB 826 has been challenged in legal proceedings and on May 13, 2022, the Superior Court of California for the County of Los Angeles entered an order striking down SB 826, holding that the statute violates the Equal Protection Clause of the California Constitution. The California Secretary of State has appealed the order and such appeal is currently pending. On September 16, 2022, the appellate court ruled to temporarily stay enforcement of the trial~~ **trials** ~~court's order, which prevented the California Secretary of State from collecting diversity data on corporate disclosure forms pursuant to SB 826, pending a further order of the appellate court. On December 1, 2022, the appellate court vacated the temporary stay order and on February 3, 2023, a record on appeal was filed and such appeal is currently pending. To the extent that this ruling of the appellate court permits the Secretary of State of California to collect and report diversity data, we may be required to comply with additional disclosure requirements. However, ultimate enforceability of SB 826 remains uncertain. Additionally, on September 30, 2020, California enacted Assembly Bill 979 ("AB 979"), which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities". A director from an "underrepresented community" means a director who self- identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California was required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities. On April 1, 2022, the Superior Court of California for the County of Los Angeles entered an order striking down AB 979, holding that the statute violates the Equal Protection Clause of the California Constitution. On June 6, 2022, a notice of appeal was filed. On September 16, 2022, the appellate court ruled to temporarily stay enforcement of the trial court's order, which prevented the California Secretary of State from collecting diversity data on corporate disclosure forms pursuant to AB 979, pending a further order of the appellate court. On December 1, 2022, the appellate court vacated the temporary stay order and on February 3, 2023, a record on appeal was filed and such appeal is currently pending. To the extent that this ruling of the appellate court permits the Secretary of State of California to collect and report diversity data, we may be required to comply with additional disclosure requirements. In June 2023, the federal district court for the Eastern District of California granted the plaintiffs a summary judgment and determined that AB 979 was unconstitutional on its face. The Eastern District of California's decision is currently on appeal. Litigation regarding AB 979 will continue. We cannot assure that we can recruit, attract and / or retain qualified members of our Board and meet gender and diversity quotas under Nasdaq Listing Rules or any California law that may become applicable to the Company, which may expose us to financial penalties and adversely affect our reputation. Mr. Jaisim Shah, Dr. Henry Ji, Mr. Dorman Followwill, Mr. David Lemus and Dr. Alexander Wu serve on our Board. Mr. Jaisim Shah and Dr. Henry Ji, who~~ are **conducted** ~~our executive officers, are also members of the board of directors of Sorrento (and in the case of Dr. Henry Ji, the positions of President, Chief Executive Officer and Chairman of the board of directors of Sorrento). While our Board has determined that Mr. Dorman Followwill, Mr. David Lemus and Dr. Alexander Wu are "independent directors" within the meaning of applicable regulatory and stock exchange requirements in the United States, each of Mr. David Lemus, Mr. Dorman Followwill and Dr. Alexander Wu have served, and continue to serve, as directors of Sorrento (and in the case of Mr. Dorman Followwill, the Lead Independent Director of Sorrento). In May 2022, pursuant to a bill of sale and assignment and assumption agreement (the "Bill of Sale"), Sorrento sold, conveyed, assigned and transferred to us all of its rights, title and interest in and to the delayed burst release low dose naltrexone formulation asset and intellectual property rights that it had previously acquired from Aardvark. When Sorrento had previously purchased such assets from Aardvark, it also purchased shares of Aardvark's Series B Preferred Stock, resulting in Sorrento holding approximately 9. 4 % of Aardvark's ownership interest as of December 31, 2023. Also as part of such investment, Dr. Henry Ji joined the board of directors of Aardvark in May 2021. We may enter into commercial arrangements with Aardvark in the future and Sorrento and Aardvark may also enter into more commercial arrangements in the future. Due to the interrelated nature of Sorrento and Aardvark with us as a result of the foregoing overlapping relationships, conflicts of interest may arise with respect to transactions involving business dealings between us and Aardvark and between us and Sorrento. Service as an overlapping director or officer of Sorrento and / or Aardvark and us could create, or appear to create, conflicts of interest with respect to matters involving or affecting more than one of the companies to which such directors or officers owe fiduciary duties. For example, these matters could relate to potential acquisitions of businesses or products, the development and ownership of technologies and product candidates, the sale of products, markets and other matters in which our best interest and the best interests of our stockholders may conflict with the best interests of Sorrento or Aardvark and their respective stockholders. In particular, it is possible that we may be precluded from participating in certain business opportunities that we might otherwise have participated in as those opportunities may be presented to Aardvark or Sorrento because such directors may deem such opportunities to have a greater benefit to Aardvark or Sorrento than to us. In addition, we, Sorrento and Aardvark may disagree regarding the interpretation of certain terms in the Aardvark Asset Purchase Agreement or the Bill of Sale. Conflicts could also arise in any renegotiation or extension of these agreements. From time to time, Aardvark, Sorrento or their respective affiliates may enter into additional transactions with us or our subsidiaries or affiliates. In an effort to balance their conflicting interests, our directors or officers may approve terms equally favorable to Aardvark, Sorrento and us as opposed to negotiating terms more favorable to us but adverse to Sorrento or Aardvark. In addition, such directors and officers may own shares of Sorrento or Aardvark common stock, options to purchase shares of Sorrento or Aardvark common stock or other Sorrento or Aardvark equity awards. These individuals' holdings of such common stock, options or other equity awards of Sorrento or Aardvark may be significant for some of these persons compared to these persons' total assets. Their ownership of any Sorrento or Aardvark equity or equity awards creates, or may create the appearance of, conflicts of interest when these directors and officers are faced with decisions that could have different implications for Sorrento or Aardvark than the decisions~~

~~have for us. Any potential conflict that qualifies as a " related party transaction " (as defined in Item 404 of Regulation S- K under the Securities Act) is subject to review by our audit committee in accordance with our related person transaction policy~~ . There can be no assurance that the ~~terms of~~ **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 ~~transactions will~~ **data, it would result in the need for additional trials, which could** be **costly and time- consuming, and which** ~~as favorable to us or our stockholders as would be the case where there are no overlapping officers or directors. Sorrento previously supported many~~ **may** ~~of~~ **result in current** ~~our~~ **or** ~~important corporate functions. Accordingly,~~ **future product candidates that we may develop being delayed** ~~our~~ **or** ~~historical financial statements may~~ not **receiving approval** ~~necessarily be indicative of the conditions that would have existed or~~ **for commercialization in the applicable jurisdiction** ~~our results of operations if we had been operated as an unaffiliated company of Sorrento, and we have and will continue to incur incremental costs as a stand- alone public company~~ . We have completed the process of replicating and replacing certain functions, systems and infrastructure previously provided by Sorrento **(our former controlling stockholder)** prior to and subsequent to the Business Combination. We currently have no shared services or other intercompany arrangements ~~other than as it relates to our continued access to and usage of Sorrento' s software consolidation system for financial reporting purposes~~ . We have made and continue to make investments and hire additional employees to operate without access to Sorrento' s operational and administrative infrastructure. These functions, systems and infrastructure are costly to implement. Historically, Sorrento performed or supported many important corporate functions for us. Our **consolidated** financial statements for the fiscal years ended December 31, 2023, 2022 and 2021 reflect charges for these services on an allocation basis. As a result, such **consolidated** financial statements may not be reflective of conditions that would have existed or what our results of operations would have been had we been a stand- alone public company and no longer a majority- owned subsidiary of Sorrento during such periods. We have incurred significant costs to replace the services and resources that are no longer provided by Sorrento. We are also incurring additional costs as a stand- alone public company. As a stand- alone public company, our total costs related to certain support functions may differ from the costs that were historically allocated to us from Sorrento. As we now operate separately from Sorrento, if we are not able to maintain adequate systems and business functions, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline. ~~Our Executive Chairperson holds an executive officer position at Sorrento and devotes time to both companies. In addition, our Executive Chairperson is the chairperson of Sorrento' s board of directors. The ongoing Chapter 11 Cases could require that such executive devotes time to such proceedings, which could cause a diversion of his time and attention from our business and operations, and as a result could have a material adverse effect on our business and operations. Dr. Henry Ji is our Executive Chairperson and also serves as President, Chief Executive Officer and Chairman of the board of directors of Sorrento. The amount of time that Dr. Ji devotes to us varies day- to- day and week- to- week depending on the then current needs and demands of each company' s business, transactions each company may be evaluating, and other corporate matters. On February 13, 2023, Sorrento and Sorrento' s wholly owned direct subsidiary, Scintilla Pharmaceuticals, Inc. (" Scintilla " and together with Sorrento, the " Debtors "), commenced voluntary proceedings under Chapter 11 of the United States Bankruptcy Code (the " Bankruptcy Code ") in the United States Bankruptcy Court for the Southern District of Texas (the " Bankruptcy Court "). The Debtors' Chapter 11 proceedings are jointly administered under the caption In re Sorrento Therapeutics, Inc., et al., Case Number 23- 90085 (DRJ) (the " Chapter 11 Cases "). So long as the proceedings related to the Chapter 11 Cases continue, Dr. Ji may be required to devote additional time and effort dealing with the reorganization of Sorrento instead of focusing on our business operations. Such diversion of management attention could have a material adverse effect on our business and operations.~~ The market price of our Common Stock may fluctuate significantly, and investors in our Common Stock may lose all or a part of their investment. The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, from November 11, 2022 (the first trading day following the closing of the Business Combination) to March ~~7~~ **25** , ~~2024~~ **2025** , our closing stock price ranged from $ 0. ~~95~~ **23** to $ 14. 80. The market price of our Common Stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as: • our ability to commercialize ZTlido, GLOPERBA, ELYXYB or our product candidates, if approved; • legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for ZTlido, GLOPERBA, ELYXYB or our product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or stockholder litigation ~~; • our relationship with Sorrento; • Sorrento' s voluntary proceedings under Chapter 11 of the United States Bankruptcy Code~~ ; • extension of the lock- up restriction by court order in the Chapter 11 Cases on the 76, 000, 000 shares of our Common Stock that were previously distributed by Sorrento to Sorrento equityholders as a dividend; • announcements of the introduction of new products by our company and our competitors; • issuances of debt or equity securities; • market conditions and trends in the pharmaceutical and biotechnology sectors; • overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; • trading volume of our Common Stock; • ineffectiveness of our internal controls; and • other events or factors, many of which are beyond our control. See the risk factor below titled " If our operations and performance do not meet the expectations of investors or securities analysts, the market price of our securities may decline " for more factors affecting the trading price of our securities. The realization of any of the above risks or any of a broad range of other risks, including those described in these " Risk Factors, " could have a dramatic and material adverse impact on the market price of our Common Stock. The equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our Common Stock. Further, price volatility of our Common Stock might worsen if the trading volume of our Common Stock is low **. Although we have had periods of high- volume daily trading in our Common Stock, generally our stock is thinly**

traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction . If an active trading market for our Common Stock does not continue, the price of our Common Stock may be more volatile and it may be more difficult and time consuming to complete a transaction in our Common Stock, which could have an adverse effect on the realized price of our Common Stock. In addition, an adverse development in the market price for our Common Stock could negatively affect our ability to issue new equity to fund our activities. 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: • 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; • 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; • 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; • 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; • compliance with our contractual obligations; • sales of our Common Stock by us or our stockholders in the future; • publication of research reports about the Company or its industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • ~~failure to effectively integrate the operations of Semnur; •~~ general political and economic conditions, including the wars in Ukraine and Israel; • effects of natural or man- made catastrophic events; • effects of public health crises, pandemics and epidemics ~~, such as the COVID- 19 pandemic~~ ; and • other events or factors, many of which are beyond our control, such as the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions. Further, the global equity markets in general have recently experienced extreme price and volume fluctuations, including as a result of the COVID- 19 pandemic, economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions that may be unrelated to our operating performance. Continued market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of our Common Stock. Price volatility of our Common Stock might worsen if the trading volume of our Common Stock is low. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against the Company, could cause us to incur substantial costs and divert management' s attention and resources from our business. The realization of any of the above risks or any of a broad range of other risks, including those described in these " Risk Factors ", could have a dramatic and material adverse impact on the market price of our Common Stock. We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future **and there is no assurance that we will complete the previously declared stock dividend** . Any return on investment may be limited to the capital appreciation, if any, of our Common Stock. We have not paid cash dividends on our Common Stock and we do not anticipate paying cash dividends on our Common Stock in the foreseeable future. Should we decide in the future to do so, as a holding company, our ability to pay dividends on our capital stock and meet other obligations depends upon the receipt of dividends or other payments from our operating subsidiaries, including Legacy Scilex. In addition, our ability to pay dividends may be limited by covenants in future outstanding indebtedness that we or our subsidiaries may incur. Since we do not intend to pay **cash** dividends, a stockholder' s ability to receive a return on such stockholder' s investment will depend on any future appreciation in the market value of our Common Stock. There is no guarantee that our Common Stock will appreciate or even maintain the price at which our stockholders have purchased it. **In October 2024, the Board declared a stock dividend (the " Dividend ") consisting of an aggregate of 5, 000, 000 shares (the " Dividend Stock ") of Series 1 Mandatory Exchangeable Preferred Stock, par value $ 0. 0001 per share, to record holders of certain of our securities as of the close of business on November 7, 2024 (which date was subsequently changed to April 11, 2025) (the " Record Date "). Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Mandatory Exchangeable Preferred Stock (the " Certificate of Designation ") previously filed with the Secretary of State of the State of Delaware, designating the Dividend Stock, if the Dividend Stock is distributed, the holders of thereof may become entitled to a pro rata portion of the number of shares that represents the lesser of (a) 10 % of the shares of common stock, par value $ 0. 00001 per share (the " Semnur Common Stock "), of Semnur (or such other securities into which or for which such stock may be exchanged or converted), held by us as of immediately prior to the Effective Date (as defined in the Semnur Business Combination Agreement) (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction) and (b) that number of shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) equal to $ 200, 000, 000 divided by the closing price of such Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) on any national securities exchange on which such shares are listed on the date that is 10 trading days prior to the Determination Date (as defined below), which shares shall be paid from the shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) held by us as of immediately prior to**

the Effective Time (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction). For purposes of the Certificate of Designation, (a) " Effective Time " means the effective time of the Business Combination (as defined below) as determined under the terms of the Semnur Business Combination Agreement, (b) " Determination Date " means, if the Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) is listed for, and trading on, any national securities exchange, the date that is 15 trading days following the Registration Date, (c) " Registration Date " means the earlier of (i) the Effective Time, at which time the shares of Semnur Common Stock (or such other securities into which or for which such stock has been exchanged or converted) are registered under the Exchange Act and (ii) the time at which the Registration Statement is declared effective by the SEC and (d) " Registration Statement " means a registration statement, whether under the Exchange Act or the Securities Act, that is filed by Semnur or any successor thereto or affiliate thereof with respect to the registration of the Semnur Common Stock or any securities into which or for which such stock may be exchanged or converted. The Board has the right to change the Record Date and the right to revoke the Dividend at any time prior to the payment date therefor. There can be no assurance that the Board will not revoke the Dividend or that, even if such Dividend is paid, the conditions for the mandatory exchange set forth in the Certificate of Designations will ever occur (including that the Registration Date shall have occurred on or before 11: 59 p. m. Eastern time on October 28, 2025). Future sales, or the perception of future sales, of a substantial number of shares of our Common Stock may cause the price of our Common Stock to decline. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our Common Stock, the trading price of our Common Stock could decline and it could impair our ability to raise capital through the sale of additional equity securities. On December 30, 2022, Sorrento announced that its board of directors authorized Sorrento to dividend to Sorrento ~~equityholders~~ **equity holders** of record as of January 9, 2023 an aggregate of 76, 000, 000 shares of our Common Stock that were held by Sorrento (the " Dividend Shares "). **As of** ~~Such shares were initially subject to a lock- up restriction prohibiting the sale, pledge or other -- the date on transfer until May 11, 2023. Such lock- up restriction was extended to March 31, 2024 by court order in the Chapter 11 Cases. On March 8, 2024, in connection with the Chapter 11 Cases, the Bankruptcy Court approved a motion with respect to the sale of certain assets of Sorrento to Vivasor, Inc. (an affiliate of Dr. Henry Ji, Ph. D., our Executive Chairperson) (the " Sorrento Asset Sale "),~~ which ~~sale is expected to close on or before March 17, 2024 (any such date of closing, the " Asset Closing Date "). In connection with the Sorrento Asset Sale, Sorrento is required to file a motion with the Bankruptcy Court to extend the application of trading and other restrictions to the transfer of the Dividend Shares under the automatic stay previously granted by the Bankruptcy Court through the two month period following the Asset Closing Date and Sorrento is required to use commercially reasonable efforts to obtain approval of such motion. As of the filing of~~ this Annual Report on Form 10- K **was filed with the SEC** , such ~~motion~~ **shares are subject to a lock- up restriction prohibiting the sale, pledge** ~~for -~~ **or other transfer until April 14, 2025** ~~extension has not yet been filed or approved~~ . As the restrictions on resale end, the market price of shares of our Common Stock could drop significantly if the holders of these shares of Common Stock sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of Common Stock or other securities. Our operating results may fluctuate significantly. We expect our operating results to be subject to quarterly, and possibly annual, fluctuations. Our net loss and other operating results will be affected by numerous factors, including: • variations in the level of expenses related to our development programs; • the addition or termination of clinical trials; • any intellectual property infringement lawsuit in which we may become involved; • regulatory developments affecting ZTlido, GLOPERBA, ELYXYB or our product candidates, regulatory approvals of our product candidates, and the level of underlying demand for such products and purchasing patterns; • our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and • the effect on pharmaceutical purchases and prices of the timing during which patients who purchase our product satisfy their deductibles under the reimbursement requirements of their health providers' plans. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our Common Stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our Common Stock to fluctuate substantially. Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail. On March 10, 2023, the Federal Deposit Insurance Corporation (the " FDIC ") announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation and on March 12, 2023, Signature Bank was closed by the New York State Department of Financial Services and the FDIC was named receiver. Although we do not maintain any bank accounts with Silicon Valley Bank or Signature Bank, we regularly maintain cash balances at third- party financial institutions in excess of the FDIC insurance limit. Any failure of a depository institution to return any of our deposits, or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our stock, our stock price and trading volume could decline. The trading market for our Common Stock will be influenced by the research and reports that industry or securities analysts publish about the Company or our business. We may never obtain research coverage by securities and industry analysts. Since we became public through a merger, securities analysts of major brokerage firms may not provide coverage of the Company since there is no incentive to brokerage firms to recommend the purchase of our Common Stock. If no or few securities or industry analysts commence coverage of the Company, the trading price for our capital stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover it issues an adverse opinion regarding the Company, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, we could lose visibility in the

financial markets, which in turn could cause our stock price or trading volume to decline. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to ZTlido or our product candidates. We may issue additional equity securities to fund future expansion and pursuant to equity incentive or employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as our Common Stock or, alternatively, may have dividend, liquidation or other preferences to our Common Stock. The issuance of additional equity securities, whether upon conversion of the ~~Convertible Debentures~~ **Tranche B Notes** into Common Stock ~~or pursuant to the Amended and Restated Standby Equity Purchase Agreement, dated as of February 8, 2023, between us and Yorkville (the " A & R Yorkville Purchase Agreement ") (pursuant to each of which we may also sell up to $ 500 million of shares of our Common Stock, or an aggregate of $ 1. 0 billion, as more fully described elsewhere in this Annual Report on Form 10- K), the Sales Agreement, dated as of December 22, 2023, between us and B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H. C. Wainwright & Co., LLC (pursuant to which we may sell up to $ 170 million of shares of our Common Stock) (the " ATM Sales Agreement ")~~ 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 ~~20~~ **24** , ~~167~~ **426** , ~~587~~ **545 shares of Common Stock** (which number of shares accounts for the **automatic** annual increase on January 1, ~~2024~~ **2025)** ~~and the increase of 10~~ , ~~000~~ **5** , ~~000~~ **970, 115** shares **of Common Stock** ~~authorized for issuance thereunder that was approved by our stockholders on May 4, 2023), 4, 476, 601~~ (which number of shares accounts for the annual increase on January 1, ~~2024~~ **2025**) and 1, 400, 000 shares of our Common Stock have been reserved for future issuance under the Equity Incentive Plan, the ESPP and the Inducement Plan, respectively. In addition, the Equity Incentive Plan and ESPP provide for annual automatic increases in the number of shares reserved thereunder, in each case, beginning on January 1, 2023. As a result of such annual increases, our stockholders may experience additional dilution, which could cause the price of our Common Stock to fall. Pursuant to the Amended and Restated Registration Rights Agreement, dated as of November 10, 2022, by and among us, Vickers Venture Fund VI Pte Ltd, Vickers Venture Fund VI (Plan) Pte Ltd, Sorrento Therapeutics, Inc. and certain security holders set forth on the signature pages thereto (the " Registration Rights Agreement "), which was entered into in connection with the Business Combination, certain stockholders of Vickers and Legacy Scilex can each demand that we register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, we are required to file and maintain an effective registration statement under the Securities Act covering such securities and certain of our other securities. We have filed a registration statement on Form S- 1 (File No. 333- 268603) which was initially declared effective by the SEC on December 27, 2022, in order to satisfy these obligations. The registration of these securities will permit the public sale of such securities, subject to certain contractual restrictions imposed by the Registration Rights Agreement and the Merger Agreement. The presence of these additional shares of our Common Stock trading in the public market may have an adverse effect on the market price of our securities. If we raise additional funds through collaboration, licensing or other similar arrangements, we may have to relinquish valuable rights to ZTlido, GLOPERBA, ELYXYB or our product candidates, or grant licenses on terms unfavorable to **us** ~~the Company~~ . If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product candidates **. Our failure to meet the continued listing standards of Nasdaq could result in a delisting of our Common Stock. On November 1, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our shares of Common Stock, has been below $ 1. 00 per share for 30 consecutive business days, we no longer comply with the minimum bid price requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550 (a) (2) requires listed securities to maintain a minimum bid price of $ 1. 00 per share (the " Minimum Bid Price Requirement "), and Nasdaq Listing Rule 5810 (c) (3) (A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive business days. Pursuant to Nasdaq Listing Rule 5810 (c) (3) (A), we have been provided an initial compliance period of 180 calendar days, or until April 30, 2025, to regain compliance with the Minimum Bid Price Requirement. If we do not regain compliance with the Minimum Bid Price Requirement by April 30, 2025, we may be afforded a second 180 calendar day grace period. To qualify, we would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement. In addition, we would be required to provide written notice of our intention to cure the minimum bid price deficiency during this second 180- day compliance period by effecting a reverse stock split, if necessary. If it appears to the Staff of Nasdaq that we will not be able to cure the deficiency in connection with the Minimum Bid Price Requirement, or if we are otherwise not eligible for the additional compliance period, and we do not regain compliance by April 30, 2025 for the Minimum Bid Price Requirement, Nasdaq will provide written notification to us that our shares of Common Stock are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules. If Nasdaq determines to delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, some or all of the following may occur, each of which could have a material adverse effect on our stockholders: • causing our shares of Common Stock to be transferred to a more limited market than Nasdaq, which could affect the market price, trading volume, liquidity and resale price of such shares; • causing an event of default under our existing debt instruments; • reducing the number of investors, including institutional investors, willing to hold or acquire our Common Stock, which could**

negatively impact our ability to raise equity; • decreasing the amount of news and analyst coverage relating to us; • reducing the availability of information concerning the trading prices and volume of our Common Stock • limiting our ability to issue additional securities, obtain additional financing or pursue strategic restructuring, refinancing or other transactions; and • impacting our reputation and, as a consequence, our business and operations. On November 21, 2024, we received a letter (the " Nasdaq Notice ") from Nasdaq advising us that we were not in compliance with Nasdaq' s continued listing requirements under the Nasdaq Listing Rule 5250 (c) (1) (the " Listing Rule ") as a result of our failure to file the Quarterly Report on Form 10- Q for the quarter ended September 30, 2024 (the " Q3 Form 10- Q ") in a timely manner. The Listing Rule requires listed companies to timely file all required periodic reports (the " Timely Reporting Requirement ") with the SEC Under Nasdaq rules, we have 60 calendar days from receipt of the Nasdaq Notice, or until January 20, 2025, to submit a plan to regain compliance with the Listing Rule. If Nasdaq accepts our plan, then Nasdaq may grant an exception of up to 180 calendar days from the due date of the Q3 Form 10- Q, or until May 19, 2025, to regain compliance. We regained compliance with the Listing Rule by filing the Q3 Form 10- Q on January 17, 2025. We and / or our directors and officers may be subject to litigation or other actions as a result of or relating to our internal investigation and our failure to timely file the Q3 Form 10- Q with the SEC and an unfavorable outcome with respect to such matters could harm our business, financial condition and results of operations. As previously disclosed, the audit committee of the Board (the " Audit Committee ") recently commenced an investigation with the assistance of independent counsel with respect to an evaluation of the following contracts: (i) the Commitment Side Letter entered into with FSF 33433 LLC (a copy of which was filed with the SEC as an exhibit to our Current Report on Form 8- K filed on June 12, 2024), (ii) a distribution agreement entered into with Endeavor Distribution LLC (" Endeavor ") in June 2024, and (iii) the Satisfaction Agreement entered into with FSF 33433 LLC and Endeavor (a copy of which was filed with the SEC as an exhibit to our Current Report on Form 8- K filed on September 18, 2024). The investigation relates to the accounting treatment of such contracts and related matters. Failure to comply with applicable laws or regulations, as interpreted and applied, or our reporting obligations with the SEC could have a material adverse effect on our reputation, the price of its securities and its business, financial condition and results of operations. We cannot predict the outcome of the above- referenced matters. Our management may be required to devote significant time and attention to these matters. An unfavorable outcome could have a material adverse impact on our financial position, results of operations or liquidity or the market for its securities, and could subject we and / or our directors and officers to litigation or other actions from third parties or regulatory bodies related to the above- referenced matters. As a result of our failure to timely file the Q3 Form 10- Q, we are currently ineligible to file new short form registration statements on Form S- 3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all. Form S- 3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Exchange Act. In addition, Form S- 3 enables eligible issuers to conduct primary offerings " off the shelf " under Rule 415 of the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S- 1. The ability to register securities for resale may also be limited as a result of the loss of Form S- 3 eligibility. As a result of our failure to timely file the Q3 Form 10- Q, we are currently ineligible to file new short form registration statements on Form S- 3, which may impair our ability to raise necessary capital to repay our debt obligations as they become due, pursue acquisition and development opportunities, and execute our business strategy. If we seek to access the capital markets through a registered offering during the period of time that we are unable to use a registration statement on Form S- 3, we may experience delays in the offering process due to SEC review of a registration statement on Form S- 1, experience downward pressure on our share price given that we will have to disclose the offering prior to formal commencement, and incur increased offering and transaction costs. If we are unable to raise capital through a registered offering, we would be required to conduct financing transactions on a private placement basis, subject to pricing, size and other limitations for equity raises under Nasdaq rules, or seek other sources of capital, which are not guaranteed. The foregoing limitations on our financing approaches could impair our ability to raise capital on terms favorable to us, in a timely manner or at all, which could have a material adverse effect on our results of operations, liquidity and financial position. Assuming we continue to timely file our required Exchange Act reports, the earliest we would regain the ability to use Form S- 3 is February 1, 2026 . We have in the past and may in the future be subject to short selling strategies that may drive down the market price of our Common Stock. Short sellers have in the past and may attempt in the future to drive down the market price of our Common Stock. Short selling is the practice of selling securities that the seller does not own but may have borrowed with the intention of buying identical securities back at a later date. The short seller hopes to profit from a decline in the value of the securities between the time the securities are borrowed and the time they are replaced. As it is in the short seller' s best interests for the price of the stock to decline, many short sellers (sometimes known as " disclosed shorts ") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog (" blogging ") have allowed many disclosed shorts to publicly attack a company' s credibility, strategy and veracity by means of so- called " research reports " that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market. Further, these short seller publications are not regulated by any governmental, self- regulatory organization or other official authority in the U. S. and they are not subject to certification

requirements imposed by the SEC. Accordingly, the opinions they express may be based on distortions, omissions or fabrications. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and / or defend themselves, including stockholder suits against the company that may be prompted by such allegations. We may in the future be the subject of stockholder suits that we believe were prompted by allegations made by short sellers. Our ability to use our net operating loss and tax credit carryforwards may be subject to limitation. Generally, a change of more than 50 % in the ownership of a company' s stock, by value, over a three- year period constitutes an ownership change for U. S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. We have experienced a corporate reorganization in the past, some ownership changes as a result of the Business Combination and may experience some subsequent changes in the future in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carryforwards to offset U. S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for the Company. The TCJA, as amended by the CARES Act, includes changes to U. S. federal tax rates and the rules governing net operating loss (" NOL ") carryforwards. The TCJA, as modified by the CARES Act, limits a taxpayer' s ability to utilize NOL carryforwards to 80 % of taxable income (as calculated before taking the NOLs, and certain other tax attributes, into account) for taxable years beginning after December 31, 2020. In addition, NOLs arising in tax years ending after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely. NOLs generated in tax years beginning before January 1, 2021 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two- year carryback and 20- year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward / carryback periods, as well as the new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future. If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Common Stock. The preparation of **consolidated** financial statements in conformity with U. S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our ~~combined~~ 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, 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. ~~Previously, Sorrento beneficially owned, in the aggregate, more than 50 % of the combined voting power for the election of our Board. However, on September 21, 2023, in connection with the Seilex- Oramed SPA, we and Sorrento entered into and consummated the transactions contemplated by that certain Stock Purchase Agreement (the " Sorrento SPA "), dated as of such date, pursuant to which, among other things, we purchased from Sorrento (i) 60, 068, 585 shares of Common Stock, (ii) 29, 057, 097 shares of Series A Preferred Stock, and (iii) warrants exercisable for 4, 490, 617 shares of Common Stock, each with an exercise price of $ 11. 50 (which constitutes the entirety of the holdings of our capital stock that was held by Sorrento, other than the 1, 917, 210 additional shares of Common Stock held by Sorrento in abeyance for the benefit of certain holders of warrants to purchase shares of common stock of Sorrento) ((i) through (iii) collectively, the " Purchased Securities ", and such transactions, the " Equity Repurchase Transaction "). As a result of the consummation of the Equity Repurchase~~

~~Transaction, Sorrento no longer controls a majority of the voting power of our outstanding capital stock and at such time we ceased to be a " controlled company " within the meaning of Nasdaq' s corporate governance standards. As a result, we are subject to additional corporate governance requirements, including the requirements that (i) a majority of our Board consists of independent directors, (ii) our Board has a compensation committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities and (iii) director nominees must be selected or recommended for the board' s selection, either by independent directors constituting a majority of the board' s independent directors in a vote in which only independent directors participate, or a nominating and corporate governance committee comprised solely of independent directors with a written charter addressing the committee' s purpose and responsibilities. Nasdaq Listing Rules provide for phase- in periods for these requirements (including that each such committee consist of a majority of independent directors within 90 days of no longer being a " controlled company "), but we must be fully compliant with the requirements within one year of the date on which we cease to be a " controlled company. " As of December 31, 2023, a majority of the directors on our Board are independent, and each of the directors serving on our audit, nominating and corporate governance and compensation committees are independent. We also adopted formal written charters for each of our audit, nominating and corporate governance, and our compensation committees at the closing of the Business Combination. While as of December 31, 2023, we are in compliance with the additional Nasdaq corporate governance requirements listed above, we may be unable to retain the number of independent directors needed to comply with such rules during the transition period. Moreover, until we are fully subject to these requirements, our stockholders will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq.~~ 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 ~~a~~ material ~~weakness~~ **weaknesses** in our internal control over financial reporting. ~~Any~~ **If we experience additional** material ~~weakness~~ **weaknesses** ~~may cause us to~~ **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 ~~or~~ **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. ~~Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our Common Stock. If we fail to satisfy Nasdaq' s continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our Common Stock. Such a delisting would likely have a negative effect on the price of our Common Stock and would impair a stockholder' s ability to sell or purchase our Common Stock when a stockholder wishes to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements.~~ Comprehensive U. S. federal income tax reform could adversely affect the Company. Changes to tax laws, which changes may have retroactive application, could adversely affect the Company or holders of our Common Stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. The TCJA, which was enacted in 2017, included changes to U. S. federal tax rates, imposed significant additional limitations on the deductibility of interest, allowed for the expensing of capital expenditures, and put into effect the migration from a " worldwide " system of taxation to a modified territorial system. On March 27, 2020, then- President Trump signed into law the CARES Act, which included certain changes in tax law (including to the TCJA) intended to stimulate the U. S. economy in light of the COVID- 19 pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. On August 16, 2022, **former** President Biden signed the IRA into law, which contained certain tax measures, including a corporate alternative minimum tax of 15 % on some large corporations, an excise tax of 1 % on certain corporate stock buy- backs, and an excise tax with respect to certain drug sales for failing to offer a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. **Many provisions of the TCJA expire at the end of 2025 or are modified beginning in 2026. The U. S. Congress and the current administration have indicated that they intend to pursue legislation in 2025 to make permanent the 2017 TCJA provisions but there is no guarantee that this initiative will be successful.** Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. The impact of these tax reforms on holders of our Common Stock is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock. Our Warrants are exercisable for our Common Stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. As of December 31, ~~2023~~ **2024** , outstanding SPAC Warrants (as defined below) to purchase an aggregate of ~~10~~ **6** , 958, 309 shares of our Common Stock are exercisable in accordance with the terms of the Warrant Agreement **(the " Warrant Agreement "), dated as of January 6, 2021, between Continental Stock Transfer & Trust Company, as warrant agent, and Vickers,** governing those securities. The exercise price of these SPAC Warrants is $ 11. 50 ~~per share. As of December 31, 2023, none of the outstanding Penny Warrants to purchase an aggregate of 13, 000, 000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 0. 01~~ per share. " SPAC Warrants " means (i) the redeemable warrants that were included in the Units (each of which consisted of one Vickers ordinary share and one- half of one redeemable warrant) that entitle the holder of each whole warrant to purchase one Vickers ordinary share at a price of $ 11. 50 per share (the " Public Warrants "), and (ii) the 6, 840, 000 warrants sold in a private placement to Vickers Venture Fund VI Pte Ltd and Vickers Venture Fund VI (Plan) Pte Ltd consummated on January 11, 2021 (of which 2, 736, 000 were subsequently forfeited and 3, 104, 000 were transferred to Sorrento, in each case in connection with the Business Combination) (the " Private Warrants "). **As of December 31, 2024, (i) outstanding Penny Warrants to purchase an aggregate of 6, 500, 000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 0. 01 per share, (ii) outstanding February 2024 BDO Firm Warrants to purchase an aggregate of 3, 803, 447 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 1. 70 per share; (iii) outstanding February 2024 BDO Representative Warrants to purchase an aggregate of 470, 588 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 2. 125 per share; (iv) outstanding Deposit Warrant to purchase an aggregate of 3, 250, 000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 1. 20 per share, (v) outstanding April 2024 RDO Common Warrants to purchase an aggregate of 15, 000, 000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 1. 10 per share and (vi) outstanding April 2024 RDO Placement Agent Warrants to purchase an aggregate of 1, 200, 000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $ 1. 25 per share. On October 8, 2024, we issued the October 2024 Noteholder Warrants to purchase an aggregate of 7, 500, 000 shares of Common Stock, which are exercisable as of the date of this Annual Report on Form 10- K. On the same date, we also issued the October Placement Agent Warrants to purchase an aggregate of 3, 669, 724 shares of Common Stock, which will become exercisable 180 days following the date of issuance. The exercise price of both the October 2024 Noteholder Warrants and the October 2024 Placement Agent Warrants was initially $ 1. 09 per share (which was automatically reduced to $ 1. 04 per share of Common Stock subsequent to the December 2024 RDO in accordance with the terms of such warrants). On December 13, 2024, we issued the December 2024 RDO Pre-Funded Warrants to purchase an aggregate of 2, 401, 132 shares of Common Stock, which have been fully exercised as of the date of this Annual Report on Form 10- K. On the same date, we also issued the December 2024 RDO Common**

Warrants to purchase an aggregate of 57, 512, 958 shares of Common Stock and the StockBlock Warrants to purchase an aggregate of 4, 601, 036 shares of Common Stock, which will become exercisable 180 days following the date of issuance. The exercise price of both the December 2024 RDO Common Warrants and the StockBlock Warrants is $ 0. 649 per share and $ 0. 7375 per share, respectively. To the extent the SPAC Warrants, the Penny Warrants, the February 2024 BDO Firm Warrants, the February 2024 BDO Representative Warrants, the Deposit Warrant, the Fee Warrant, the April 2024 RDO Common Warrants, the April 2024 RDO Placement Agent Warrants, the October 2024 Noteholder Warrants, the October 2024 Placement Agent Warrants, the December 2024 RDO Common Warrants and / or the StockBlock Warrants (collectively, the " Warrants " **)** ~~means the SPAC Warrants and the Penny Warrants. To the extent the Penny Warrants become exercisable and such Penny Warrants and / or the SPAC Warrants~~ are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the holders of our Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market, or the fact that such Warrants may be exercised, could adversely affect the prevailing market prices of our Common Stock. With respect to the SPAC Warrants, there is no guarantee that the SPAC Warrants will ever be in the money prior to their expiration, and as such, the SPAC Warrants may expire worthless. See below risk factor, " The SPAC Warrants may never be in the money, they may expire worthless and the terms of the SPAC Warrants may be amended in a manner adverse to a holder if holders of a majority of the then- outstanding SPAC Warrants approve of such amendment. " **The SPAC Warrants may never be in the money, they may expire worthless and the terms of the SPAC Warrants may be amended in a manner adverse to a holder if holders of a majority of the then- outstanding SPAC Warrants approve of such amendment. In addition, almost all of the other warrants to purchase shares of our Common Stock are out- of- the money and may also expire worthless.** As of December 31, ~~2023~~ **2024**, the exercise price for our SPAC Warrants is $ 11. 50 per share of Common Stock. On March ~~7~~ **25**, ~~2024~~ **2025**, the closing price of our Common Stock on the Nasdaq Capital Market was $ ~~1~~ **0**. ~~39~~ **25**. If the price of our shares of Common Stock remains below $ 11. 50 per share, which is the exercise price of our SPAC Warrants, we believe our warrant holders will be unlikely to cash exercise their SPAC Warrants, resulting in little or no cash proceeds to us. There is no guarantee that our SPAC Warrants will be in the money prior to their expiration and, as such, our SPAC Warrants may expire worthless. **The** ~~In addition, the~~ SPAC Warrants were issued in registered form under the Warrant Agreement ~~between Continental, as warrant agent, and Vickers~~. The Warrant Agreement provides that the terms of the SPAC Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of a majority of the then- outstanding SPAC Warrants to make any change that adversely affects the interests of the registered holders of SPAC Warrants. Accordingly, we may amend the terms of the SPAC Warrants in a manner adverse to a holder if holders of a majority of the then- outstanding SPAC Warrants approve of such amendment. Although our ability to amend the terms of the SPAC Warrants with the consent of majority of the then- outstanding SPAC Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the SPAC Warrants, convert the SPAC Warrants into cash, shorten the exercise period, or decrease the number of shares of our Common Stock purchasable upon exercise of a SPAC Warrant **. In addition, other than the SPAC Warrants discussed above and the Penny Warrants, as of December 31, 2024, we had other warrants to purchase shares of our Common Stock (with exercise prices ranging from $ 0. 6490 to $ 2. 125) issued and outstanding. As noted above, on March 25, 2025, the closing price of our Common Stock on the Nasdaq Capital Market was $ 0. 25. If the price of our shares of Common Stock remains below the foregoing exercise prices of such other warrants, we believe the holders of such warrants will be unlikely to cash exercise such warrants, resulting in little or no cash proceeds to us. There is no guarantee that our other warrants will be in the money prior to their expiration and, as such, those other warrants may expire worthless** . We may redeem any unexpired SPAC Warrants prior to their exercise at a time that is disadvantageous to you, thereby making the SPAC Warrants worthless. We have the ability to redeem outstanding SPAC Warrants (other than Private Warrants still held by the initial purchasers thereof) at any time after they become exercisable and prior to their expiration, at a price of $ 0. 01 per SPAC Warrant, provided that the closing price of our Common Stock equals or exceeds $ 18. 00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on each of the 20 trading days within any 30- trading- day period commencing after the SPAC Warrants become exercisable and ending on the third trading day prior to the date on which notice of redemption is given. If and when the SPAC Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding SPAC Warrants could force the holders thereof to: (i) exercise such SPAC Warrants and pay the exercise price therefor at a time when it may be disadvantageous for a holder to do so; (ii) sell such SPAC Warrants at the then- current market price when a holder might otherwise wish to hold such SPAC Warrants; or (iii) accept the nominal redemption price that, at the time the outstanding SPAC Warrants are called for redemption, is likely to be substantially less than the market value of such Warrants. In addition, we may redeem the SPAC Warrants (other than Private Warrants still held by the initial purchasers thereof) at any time after they become exercisable and prior to their expiration for a number of shares of our Common Stock determined based on the fair market value of our Common Stock. The value received upon exercise of the SPAC Warrants (1) may be less than the value the holders would have received if they had exercised their SPAC Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the SPAC Warrants. ~~113~~