Scilex Holding Company Chief Executive Officer and President Issues Letter to Stockholders Highlighting 2023 Accomplishments and Outlook for 2024

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PALO ALTO, Calif., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex” or “Company”), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, today issued a letter from Jaisim Shah, its Chief Executive Officer and President, to its stockholders highlighting the Company’s accomplishments in 2023 and its forward outlook for 2024.

A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER AND PRESIDENT

Dear Scilex Holding Company Stockholders,

I would like to express my deepest gratitude for your unwavering support, patience, and invaluable feedback throughout the transformative year in 2023. It is our hope that this communication serves as both a reflection on Scilex’s significant strides in the past year and an insightful preview into the challenges and opportunities that lie ahead in 2024.

Our guiding principle has always been and remains a patient-first approach, which drives our mission to meet the increasing global demand for more effective and safer non-opioid pain management solutions. Through rigorous research and development, we believe we are on the cusp of establishing Scilex as the preeminent name in commercial non-opioid pain management, specifically targeting the unmet needs in both acute and chronic pain sectors with our innovative and leading therapies. We've not only responded to the global demand for safer, more effective pain relief solutions but also made substantial progress in demonstrating the rapid onset and enhanced safety of our products.

The unmet need in pain management is not just a medical challenge; it's a societal imperative. Every day, countless individuals grapple with pain, yet are left with limited options due to the risks associated with opioid treatments. At Scilex, we recognize our vital role in addressing this unmet need. Our efforts are concentrated on pioneering non-opioid alternatives that are not just innovative but also aim to re-define the standards of safety and accessibility in pain management.

As we continue to navigate the complexities of the pharmaceutical landscape, your role as stockholders in this journey is invaluable. Thank you for being an integral part of our mission and for your unwavering belief in our vision. Together, we are not just witnessing, but actively shaping, a pivotal chapter in healthcare history.

2023 Accomplishments

We accomplished all of the goals that we set out at the beginning of 2023, including:

- Built on our late 2022 transformation into an independent publicly traded company listed in Nasdaq under the ticker symbol “SCLX” with three FDA approved non-opioid agents to address acute and chronic pain.
- Continuous growth for ZTlido®. ZTlido® gross sales for the fiscal year ended December 31, 2023 were in the range of $145.0 million to $150.0 million, compared to $96.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 51% to 56%. ZTlido® net sales for the fiscal year ended December 31, 2023 were in the range of $46.0 million to $52.0 million, compared to $38.0 million for the fiscal year ended December 31, 2022, representing growth in the range of approximately 21% to 37%.
- ZTlido® profile being viewed as a leading prescription lidocaine patch by pain specialists. Based on the independent market research conducted by Syneos Health Consulting (“Syneos”), with the new campaign, health care providers (HCPs) report increased awareness and substantial intent to utilize for ZTlido® with peak sales potential projected to reach over $500 million in the next 6 years in the U.S.
- Expanded the market for ZTlido® by entering into a territory distribution agreement for the commercialization of ZTlido® in the Middle East and North Africa (MENA) with $105 Million minimum multi-year purchase commitment.
- Successfully completed a Good Manufacturing Practices (GMP) inspection by the U.S. Food and Drug Administration (“FDA”) of the enhanced 250kg manufacturing facility in Japan, which assures increased capacity to meet the rapidly growing demand for ZTlido®.
- Issued two new patents by the U.S. Patent and Trademark Office: (a) Patent No. 11,786,455, titled “Non-aqueous Patch”, which covers a non-aqueous lidocaine patch with certain specifications, as well as a method of relieving pain through the application of a non-aqueous lidocaine-containing patch, and (b) Patent No. 11,793,766, titled “Non-aqueous Patch for the Relief of Pain”, which covers a method of relieving pain through the application of a lidocaine-containing patch. These two new patents further strengthen the Company’s intellectual property position and coverage for ZTlido®, and will not expire until 2031. These two new issued patents will be listed in the FDA’s Orange Book in connection with ZTlido®.
- Continued to add ZTlido® as a preferred agent to the Medicaid Preferred Drug List (PDL) in a number of U.S. States.
- ZTlido® was recognized as the most prescribed non-opioid branded pain treatment by pain specialists, according to Prescription Data from Symphony Health.
- Acquired rights to ELYXYB® (celecoxib oral solution) in the U.S. and Canada, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults, and successfully launched ELYXYB® in the U.S. in April 2023.
- Launched major pharmacy initiative with two leading national pharmacy chains to stock ELYXYB® in most of their

stores throughout the U.S.

- Expanded access to ELYXYB® by the execution of the first ELYXYB® insurance coverage agreement with one of the top three national Pharmacy Benefit Manager's for its Medicare population.
- Filed a New Drug Submission (NDS) with Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the approval of ELYXYB® for acute treatment of migraine with or without aura in Canada.
- Continued preparing for the potential launch of Gloperba® in 2024. Scilex is well-positioned to market and distribute Gloperba®. Scilex has a direct distribution network to national and regional wholesalers and pharmacies throughout the U.S., and an experienced commercial and managed care team that has successfully launched and grown market access for ZTlido® (lidocaine topical system) to more than 225 million covered lives in the U.S. as well as successfully launching ELYXYB® (celecoxib oral solution) in the U.S.
- Completed SP-103 (lidocaine topical system) 5.4%, Triple Strength Formulation of ZTlido®, Phase 2 trial which achieved its objectives to evaluate the safety and efficacy of SP-103 in subjects with moderate to severe acute lower back pain (LBP).
- Held positive Type C meeting with the FDA and reached agreement on path forward to file a New Drug Application (NDA) for SP-102 (SEMDEXA™) in lumbosacral radicular pain (Sciatica). Scilex is planning to commence an open-label multi-center safety and efficacy trial in the first half of 2024 in which it will seek to enroll approximately 700 patients with moderate-to-severe Lumbosacral Radicular Pain (LRP) requiring an epidural steroid injection. SP-102 (SEMDEXA™) is expected to be administered in up to 3 injections during a 6-month observation period. Completion of enrollment in the trial is projected to occur in 2025.
- Repurchased all of the shares of Scilex common stock and preferred stock and warrants previously owned by our former parent company, Sorrento Therapeutics, Inc.

Outlook for 2024

The lessons learned from the challenges we faced as a company in 2023 have positioned us for incredible opportunities in 2024, as the team has laid the foundation for the execution of a commercially appealing strategy which will transform how Scilex is viewed on the world stage. We are determined to continue to expand our pain management products and product candidates and mark a major milestone in our strategy to build a robust offering of novel, non-opioid treatments to improve patient care along the acute and chronic pain pathway. Importantly, ZTlido®, ELYXYB®, and Gloperba® will enhance our topline, and we believe will provide meaningful synergies that we expect to drive substantial near- and long-term accretion to our cash flows and earnings. Despite the challenges that remain ahead, we are setting ambitious goals for the Company in 2024, including:

1. Expected launch of Gloperba®. Gloperba® is the first line therapy and first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults. Gout is a painful arthritic disorder affecting an estimated 9.2 million people in the United States.(1) As gout cases increase every year, treatment requirements increase. The gout treatment market is projected to reach $2.0 billion in the U.S. by 2028 with a well-defined area of unmet need.(2)

2. Seek FDA approval for the modification of Gloperba® label to address unmet medical needs and to provide specific dosing guidance to patients with renal impairment.

3. Continue to grow our gross sales with a goal of exceeding $200 million.

4. Seek FDA approval of ELYXYB® in acute pain in the U.S. ELYXYB®, a rapid onset and ready to use formulation of Celecoxib, delivers a first line non-opioid therapeutic alternative to habit-forming opioids and acetaminophen, the leading cause of acute liver failure in the U.S.(3) DelveInsight estimates there were approximately 100 million cases of acute pain in the United States and that the total acute pain market in the U.S. was approximately $3 billion in 2021.(4)

5. Continue to develop our novel clinical pipeline with the goal of launching another product from one of our pipeline molecules within 24 months. We will utilize existing data to advance our clinical research program, and work with leading researchers to get the best possible data for assessment by regulators.

6. Initiation of ELYXYB® pediatric study for migraine.

7. Finalize plan with FDA for Phase 2/3 study for SP-103 in acute pain.

8. Initiation of SP-102 chemistry, manufacturing and controls (CMC) activities for commercial scale manufacturing for NDA filing in the U.S.

9. File ZTlido® applications in ex-US markets. We will work to launch our product and develop a distribution network in Middle East to serve the new ZTlido® market there, while continuing to support our clinical trials and other potential customers around the world.

10. Prepare for the next major international change affecting the demand for non-opioid therapeutics and be ready to capitalize on that change.

11. Continue to enhance our product portfolio by in-licensing and out-licensing commercial products.

12. Continue to enhance stockholder value and optimize our capitalization structure.

As we look beyond our immediate goals, it's important to recognize the foundational beliefs that have guided the creation and growth of our company:

1. True stability comes from revenue generating products that not only meet significant medical needs but also have a strong commercialization track record.

2. The pace at which a company moves from development to commercialization is a key determinant of success. By focusing on projects with a higher likelihood of market entry, a firm can not only innovate but also realize quicker returns and greater market impact.

3. In an era marked by the opioid crisis, there is a vital need for timely and effective non-opioid solutions. Companies that respond to such urgent needs, especially in pain management, are not just making a business move; they are addressing a critical societal imperative recognized by both regulators and healthcare providers.

There are many challenges that we have to overcome before our goals can become reality, but as a leading non-opioid therapeutics company, we know that we have a valuable and important role to play as a supplier for our patients. Our focus is on fostering robust relationships with all stakeholders – including patients, neurologists, pain specialists, rheumatologists, distributors, and clinic health care professionals. This collaboration is key to ensuring that prescribers have access to our comprehensive portfolio of non-opioid drugs, with the ultimate aim of significantly improving patient lives.

In closing, my heartfelt thanks go to the remarkable team at Scilex. Your unwavering dedication, creativity, and resilience are the driving forces behind our success. To our partners, our stockholders, and our dedicated board members: thank you for your confidence in us as we continue to forge ahead with our mission.

Best Regards,

Jaisim Shah
Chief Executive Officer and President
Scilex Holding Company

About Scilex Holding Company

Scilex Holding Company is an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. Scilex is uncompromising in its focus to become the global pain management leader committed to social, environmental, economic, and ethical principles to responsibly develop pharmaceutical products to maximize quality of life. Results from the Phase III Pivotal Trial C.L.E.A.R. Program for SEMDEXA™, its novel, non-opioid product for the treatment of lumbosacral radicular pain (sciatica), were announced in March 2022. Scilex participated in the type C meeting for purposes of pre-NDA discussion with the FDA and reached agreement on a path forward to file an NDA for SP-102 (SEMDEXA™) in Lumbosacral Radicular Pain (Sciatica) with the FDA. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with moderate to severe pain. Scilex launched its first commercial product ZTlido® in October 2018, in-licensed a commercial product Gloperba® in June 2022, and launched its third FDA-approved product Elyxyb® in April 2023. It is also developing its late-stage pipeline, which includes a pivotal Phase 3 candidate, and one Phase 2 and one Phase 1 candidate. Its commercial product, ZTlido® (lidocaine topical system) 1.8%, or ZTlido®, is a prescription lidocaine topical product approved by the U.S. Food and Drug Administration for the relief of pain associated with post-herpetic neuralgia, which is a form of post-shingles nerve pain. Scilex in-licensed the exclusive right to commercialize Gloperba® (colchicine USP) oral solution, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. Scilex in-licensed the exclusive rights to commercialize Elyxyb® (celecoxib oral solution) in the U.S. and Canada, the only FDA-approved ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. Scilex launched Elyxyb® in April 2023, and is planning to commercialize Gloperba® by 2024, and is well-positioned to market and distribute those products. Scilex's three product candidates are SP-102 (injectable dexamethasone sodium phosphate viscous gel product containing 10 mg dexamethasone), or SEMDEXA™, a Phase 3, novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, with FDA Fast Track status; SP-103 (lidocaine topical system) 5.4%, a Phase 2 study, triple-strength formulation of ZTlido®, for the treatment of chronic neck pain. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute low back pain associated with muscle spasms. SP-103 was safe and well-tolerated. Increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. SP-103 received FDA Fast Track status in low back pain. We will continue to analyze the SP-103 Phase 2 trial data along with a recently completed investigator study of ZTlido in patients with chronic neck pain which also has showed promising top-line efficacy and safety results. Scilex is planning to initiate Phase 2/3 trial in chronic neck pain in 2024; and SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia that has completed multiple Phase 1 trial programs and is expected to initiate Phase 2 trials in 2024.

Scilex Holding Company is headquartered in Palo Alto, California.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting concerning the matters discussed in this press release contain forward-looking statements related to Scilex and its subsidiaries under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the Company's preliminary unaudited financial results for the fiscal year ended December 31, 2023, the Company's outlook, goals and expectations for 2024, projected figures for ZTlido peak sales in the next six years, the Company's ongoing preparations for the expected launch of Gloperba in 2024, the Company's plans to commence an open label trial for SP-102 and the anticipated enrollment timing and figures, projections and goals for the Company's gross sales figures, the status of any ongoing discussions with the FDA and other regulators, the Company's plans for launching other pipeline products and plans to file ZTlido applications in ex-U.S. markets, the timing of the FDA's review process and whether the FDA approves the sNDA for ELYXYB, ELYXYB's potential to further expand Scilex's non-opioid portfolio and its potential to address high unmet needs in treating acute pain, the potential market size and the size of the patient population for acute pain in the U.S., Scilex's plans to initiate a Phase 2/3 trial in chronic neck pain in 2024 and plans to initiate Phase 2 trials in 2024 for SP-104, Scilex's belief that it is well positioned to continue its growth over the next several years, Scilex's long-term objectives and commercialization plans, Scilex's potential to attract new capital, future opportunities for Scilex, Scilex's future business strategies, the expected cash resources of Scilex and the expected uses thereof; Scilex's current and prospective product candidates, planned clinical trials and preclinical activities and potential product approvals, as well as the potential for market acceptance of any approved products and the related market opportunity; statements regarding ZTlido®, Gloperba®, ELYXYB®, SP-102 (SEMDEXA™), SP-103 or SP-104, if approved by the FDA; Scilex's development and commercialization plans; and Scilex's products, technologies and prospects.

Risks and uncertainties that could cause Scilex's actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: the risk that Scilex's actual unaudited financial results for the fiscal year ended December 31, 2023, and any projections or estimates for sales figures may differ from those set forth in this press release, risks associated with the unpredictability of trading markets and whether a market will be established for Scilex's common stock; general economic, political and business conditions; risks related to COVID-19 (and other similar disruptions); the risk that the potential product candidates that Scilex develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; risks relating to uncertainty regarding the regulatory pathway for Scilex's product candidates; the risk that Scilex will be unable to successfully market or gain market acceptance of its product candidates; the risk that Scilex's product candidates may not be beneficial to patients or successfully commercialized; the risk that Scilex has overestimated the size of the target patient population, their willingness to try new therapies and the willingness of physicians to prescribe these therapies; risks that the outcome of the trials for SP-102, SP-103 or SP-104 may not be successful; risks that the prior results of the clinical trials of SP-102 (SEMDEXA™), SP-103 or SP-104 may not be replicated; regulatory and intellectual property risks; and other risks and uncertainties indicated from time to time and other risks set forth in Scilex's filings with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Scilex undertakes no obligation to update any forward-looking statement in this press release except as may be required by law.

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SEMDEXA™ (SP-102) is a trademark owned bySemnur Pharmaceuticals, Inc., a wholly-owned subsidiary of Scilex Holding Company. A proprietary name review by the FDA is planned.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company.

Gloperba® is the subject of an exclusive, transferable license to use the registered trademark by Scilex Holding Company.

ELYXYB® is the subject of an exclusive, transferable license to use the registered trademark by Scilex Holding Company.

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