Scilex Holding Company Generates Record Monthly Revenue In August 2023 And Provides Certain Preliminary Unaudited Financial Results For Gross And Net Sales For The One Month Ended August 2023, And Year-To-Date As Of August 31 2023, Based On Currently Available Information

September 11, 2023 1:00 PM EDT

PALO ALTO, Calif., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, “Scilex”), a majority-owned subsidiary of Sorrento Therapeutics, Inc. (OTC: SRNEQ), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, announces record revenue for the month of August 2023 and is providing certain preliminary unaudited financial results for the month ended August 31, 2023, and year-to-date as of August 31, 2023, based on currently available information.

Scilex estimates that:

- ZTlido gross sales for (i) August 2023 were in the range of $13.0 million to $14.0 million, compared to $10.1 million in August 2022, representing growth in the range of 29% to 39%; and (ii) year-to-date August 2023 were in the range of $87.2 million to $91.3 million, compared to $56.3 million for year-to-date August 2022, representing growth in the range of 55% to 62%.

- ZTlido net sales for (i) August 2023 were in the range of $4.4 million to $4.8 million, compared to $4.0 million in August 2022, representing growth in the range of 10% to 20%; and (ii) year-to-date August 2023 were in the range of $26.2 million to $32.0 million, compared to $21.3 million for year-to-date August 2022, representing growth in the range of 23% to 50%.

- Total product gross sales for (i) August 2023 were in the range of $13.4 million to $14.6 million, compared to $10.1 million in August 2022, representing growth in the range of 33% to 44%; and (ii) year-to-date August 2023 were in the range of $89.3 million to $93.7 million, compared to $56.3 million for year-to-date August 2022, representing growth in the range of 59% to 66%.

- Total product net sales for (i) August 2023 were in the range of $4.5 million to $4.9 million, compared to $4.0 million in August 2022, representing growth in the range of 13% to 23%; and (ii) year-to-date August 2023 were in the range of $26.3 million to $32.2 million, compared to $21.3 million for year-to-date August 2022, representing growth in the range of 23% to 51%.

This preliminary financial data has been prepared by and is the responsibility of Scilex. Scilex has not fully completed its review of these preliminary financial results for the one month ended August 31, 2023, and year-to-date as of August 31, 2023. Scilex’s independent auditor has not reviewed or audited these preliminary estimated financial results. Scilex’s actual results may differ materially from these preliminary financial results, and may be outside the estimated ranges.

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 is pending official minutes in writing from 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® in the

fourth quarter of 2023 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 acute low back pain, with FDA Fast Track status; 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 2023. For further information regarding the SP-102 Phase 3 efficacy trial, see NCT identifier NCT03372161 – Corticosteroid Lumbar Epidural Analgesia for Radiculopathy – Full Text View – ClinicalTrials.gov.

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 Scilex's preliminary unaudited financial results for the one month ended August 31, 2023, and year-to-date as of August 31, 2023, Scilex's plans to commercialize Gloperba ® in the fourth quarter of 2023, 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 one month ended August 31, 2023, and year-to-date as of August 31, 2023 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 the ongoing COVID-19 pandemic; 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 results of the Phase 2 trial for SP-103 or Phase 1 trials for 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.

Contacts:

Investors and Media
Scilex Holding Company
960 San Antonio Road
Palo Alto, CA 94303
Office: (650) 516-4310

Email: investorrelations@scilexholding.com

Website: www.scilexholding.com

SEMDEXA™ (SP-102) is a trademark owned by Semnur 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 trademark by Scilex Holding Company.

All other trademarks are the property of their respective owners.

© 2023 Scilex Holding Company All Rights Reserved.

Source: Scilex Holding Company