Scilex Holding Company Announces Receipt of Notice from Nasdaq

November 22, 2024 11:00 AM EST

PALO ALTO, Calif., Nov. 22, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, "Scilex" or the "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 reported that it received a notice (the "Notice") on November 21, 2024 from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") advising the Company that it was not in compliance with Nasdaq's continued listing requirements under the Nasdaq Listing Rule 5250(c)(1) (the "Listing Rule") as a result of its failure to file its Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Q3 Form 10-Q") in a timely manner.

Under Nasdaq rules, the Company has 60 calendar days from receipt of the Notice or until January 20, 2025, to submit a plan to regain compliance with the Listing Rule. If Nasdaq accepts the Company's 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.

In response to the Notice, the Company intends to file the Q3 Form 10-Q as soon as possible in order to regain compliance with the Listing Rule. However, if the Company does not submit the Q3 Form 10-Q by January 20, 2025, the Company will submit a plan by such date to Nasdaq that outlines, as definitively as possible, the steps the Company will take to promptly file the Q3 Form 10-Q.

For more information on Scilex Holding Company, refer to www.scilexholding.com.

For more information on Scilex Holding Company Sustainability Report, refer to www.scilexholding.com/investors/sustainability.

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.com.

For more information on ELYXYB®, including Full Prescribing Information, refer to www.elyxyb.com.

For more information on Gloperba®, including Full Prescribing Information, refer to www.gloperba.com.

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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 targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with acute and chronic pain and are dedicated to advancing and improving patient outcomes. Scilex's commercial products include: (i) ZTlido ® (lidocaine topical system) 1.8%, a prescription lidocaine topical product approved by the U.S. Food and Drug Administration (the "FDA") for the relief of neuropathic pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain; (ii) ELYXYB®, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults; and (iii) Gloperba®, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults.

In addition, Scilex has three product candidates: (i) SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) ("SEMDEXA ™" or "SP-102"), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, for which Scilex has completed a Phase 3 study and was granted Fast Track status from the FDA in 2017; (ii) SP-103 (lidocaine topical system) 5.4%, ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of acute pain and for which Scilex has recently completed a Phase 2 trial in acute low back pain. SP-103 has been granted Fast Track status from the FDA in low back pain; and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022.

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 relating to the filing of the Q3 Form 10-Q and the Company's ability to regain compliance with the Nasdaq continued listing standards, and the Company's development and commercialization plans.

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: risks related to the engagement by the Audit Committee of the Company's Board of Directors of a new independent registered public accounting firm, including the timing thereof, the Company's ability to file the Q3 Form 10-Q; risks related to the Company's ability to regain compliance with the Nasdaq continued listing standards and to maintain the listing of the Company's securities thereon; the risk of litigation or other actions arising from the failure to timely file the Q3 Form 10-Q or any subsequent SEC filing; risks associated with the unpredictability of trading markets; general economic, political and business conditions; 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 and studies for SP-102, SP-103 or SP-104 may not be successful or reflect positive outcomes; risks that the prior results of the clinical and investigator-initiated 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 described in Scilex's most recent periodic reports filed with the Securities and Exchange Commission, including Scilex's Annual Report on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q that the Company has filed or may file, including the risk factors set forth in those filings. 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 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 Scilex Holding Company to use the registered trademark.

ELYXYB® is a registered trademark owned by Scilex Holding Company.

All other trademarks are the property of their respective owners.

Source: Scilex Holding Company