

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): March 22, 2024

SCILEX HOLDING COMPANY

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39852
(Commission
File Number)

92-1062542
(IRS Employer
Identification No.)

960 San Antonio Road, Palo Alto, California, 94303
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (650) 516-4310

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.0001 per share	SCLX	The Nasdaq Stock Market LLC
Warrants to purchase one share of common stock, each at an exercise price of \$11.50 per share	SCLXW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

As previously disclosed by Scilex Holding Company (the “Company”), on November 6, 2023, Takeda Pharmaceuticals U.S.A., Inc. and Takeda Pharmaceutical Company Ltd. (together, “Takeda”) filed a complaint (the “Action”) against the Company and Scilex Pharmaceuticals Inc., the Company’s wholly owned subsidiary (“Scilex Pharma”, together with the Company, “Scilex”), in the U.S. District Court for the District of Delaware (the “District Court”) alleging that Scilex’s filing with the U.S. Food and Drug Administration (the “FDA”) of an application for approval of a proposed revision to the product label for Scilex’s GLOPERBA® product infringed certain Orange Book listed patents covering Takeda’s colchicine product, Colcrys®. Takeda sought an order that the effective date of any FDA approval of Scilex’s labeling revision be no earlier than the expiration date of the asserted patents listed in the Orange Book, and such further and other relief as the court may deem appropriate. On March 7, 2024, Scilex entered into a Settlement Agreement (the "Settlement Agreement") with Takeda to resolve the Action and entered into a License Agreement with Takeda in connection with the granting of a non-exclusive license by Takeda to the Company and its affiliates of certain patents owned by Takeda. The terms of those agreements are confidential. The Settlement Agreement is subject to approval by the District Court, the Federal Trade Commission and the U.S. Department of Justice.

On March 20, 2024, the Company issued a press release announcing the settlement of the Action. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated March 20, 2024.
104	Cover Page Interactive Data File, formatted in Inline Extensible Business Reporting Language (iXBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SCILEX HOLDING COMPANY

By: /s/ Jaisim Shah

Name: Jaisim Shah

Title: Chief Executive Officer and President

Date: March 22, 2024



FOR IMMEDIATE RELEASE

March 20, 2024

Scilex Holding Company Announces a Settlement Agreement with Takeda Pharmaceuticals to Resolve the Paragraph IV Patent Infringement Lawsuit Relating to Scilex's Filing of a sNDA with the FDA Seeking to Expand the Label for its FDA-Approved Liquid Colchicine Product, Gloperba®

PALO ALTO, CA. March 20, 2024 /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 announced that the Company and its wholly owned subsidiary, Scilex Pharmaceuticals Inc. (“Scilex Pharma”, together with the Company, the “Scilex Parties”), have entered into a Settlement Agreement (the “Settlement Agreement”) with Takeda Pharmaceuticals U.S.A., Inc. and Takeda Pharmaceuticals Company LTD. (collectively “Takeda”) to resolve the Paragraph IV patent infringement lawsuit that Takeda filed against the Scilex Parties in federal district court in Delaware in November 2023. That litigation arose from Scilex’s filing of a sNDA with the FDA seeking to expand the label for its FDA-approved liquid colchicine product, Gloperba®, a preventive treatment for gout. As part of the Settlement Agreement, the Scilex Parties entered into a License Agreement with Takeda granting the Company and its affiliates a non-exclusive license to certain patents owned by Takeda. The terms of those agreements are confidential. The Settlement Agreement is subject to approval by the district court, and by both the Federal Trade Commission and the U.S. Department of Justice, as is required in Paragraph IV patent case settlements.

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

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

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

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



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, expected to launch in the first half of 2024.

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 has 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 chronic neck pain and for which Scilex has recently completed a Phase 2 trial in low back pain. SP-103 has 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 and a Phase 2 clinical trial is expected to commence 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 estimates for the gout treatment market and affected patient population, estimates for potential demand for Gloperba[®], estimates for the launch pricing of Gloperba[®], the belief that Scilex is well-positioned to market and distribute Gloperba[®], Scilex's expectations for Gloperba[®] to be the first liquid oral version of colchicine formulation allowing providers to prescribe precision dosing, Scilex's expectations for Gloperba[®] to last more than 30 days in patients who are treated with doses lower than 0.6 mg, Scilex's expectation to launch Gloperba[®] in the first half of 2024, each parties' releases of claims arising from the captioned patent infringement lawsuit, the granting of the non-exclusive license and FDA's approval for the modification of the Gloperba[®] label and plans to initiate a Phase 2 clinical trial in 2024 for SP-104.

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 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 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, 2022 and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, 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.

Contacts:

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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 use the registered trademark by Scilex Holding Company.

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

All other trademarks are the property of their respective owners.

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