

**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): April 16, 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 2.02. Results of Operations and Financial Condition.

Scilex Holding Company (the “Company”) is providing certain preliminary unaudited financial results for the quarter ended March 31, 2024 based on currently available information. The Company’s independent auditor has not reviewed or audited these preliminary estimated financial results. The Company’s actual results may differ materially from these preliminary financial results, and may be outside the estimated ranges. This preliminary financial data has been prepared by and is the responsibility of the Company. The Company has not fully completed its review of these preliminary financial results for the quarter ended March 31, 2024. The Company estimates that:

- ZTlido gross sales for the first quarter of 2024 were in the range of \$34.0 million to \$38.0 million, compared to \$27.5 million for the first quarter of 2023, representing growth in the range of approximately 24% to 38%.
- ZTlido net sales for the first quarter of 2024 were in the range of \$12.0 million to \$13.0 million, compared to \$10.6 million for the first quarter of 2023, representing growth in the range of approximately 13% to 23%.

On April 16, 2024, the Company issued a press release that included certain preliminary unaudited financial results for the quarter ended March 31, 2024. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 2.02 by reference.

In accordance with General Instructions B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated April 16, 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 & President

Date: April 16, 2024



FOR IMMEDIATE RELEASE

April 16, 2024

Scilex Holding Company Provides Certain Preliminary Unaudited Financial Results For Gross and Net Sales for ZTlido® for the First Quarter 2024; Implements Planned 2024 Commercial Ramp for Additional Opioid Sparing Product and Reduction of R&D and Other Administrative Expenses

PALO ALTO, CALIFORNIA – April 16, 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 provided certain preliminary unaudited financial results for gross and net sales for ZTlido® for the quarter ended March 31, 2024, and proposed plans to reduce research and development and other administrative expenses in 2024.

The Company estimates that:

- ZTlido gross sales for the first quarter of 2024 were in the range of \$34.0 million to \$38.0 million, compared to \$27.5 million for the first quarter of 2023, representing growth in the range of approximately 24% to 38%.
- ZTlido net sales for the first quarter of 2024 were in the range of \$12.0 million to \$13.0 million, compared to \$10.6 million for the first quarter of 2023, representing growth in the range of approximately 13% to 23%.

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 quarter ended March 31, 2024. 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.

"We believe the non-opioid pain management prescription market is adopting our products rapidly and should be reflected in continued sales growth, both within the traditional neuropathic pain and migraine non-opioid market and from the additional potential launch of our new gout prophylaxis product, Gloperba® expected to launch in the first half of 2024. Scilex also plans to reduce R&D and other administrative expenses and to focus on its late-stage pipeline programs such as SP-102. This will enable us to invest in expanding the commercial and production activity for our products. Our intention is to drive value creation and ensure we remain ahead of rising demand for our non-opioid products."

Scilex has been working with its co-pay savings card adjudicators to resolve the recent breakdown of processing of insurance claims by Change Healthcare, following a cyber-attack on Change Healthcare. Scilex is aware of the impact this disruption has had on its patients and customers and has worked diligently to resolve the issue. As of today, co-pay savings card processing for ZTlido® has been restored to normal operations.

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

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.



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.

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 quarter ended March 31, 2024, the Company's outlook, goals and expectations for 2024, Scilex's planned reductions of R&D and other administrative expenses and the impact thereof on the Company's commercial and production activity, the Company's expected double-digit growth, Scilex's expectation to launch Gloperba® in the first half of 2024 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, 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.

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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