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): December 1, 2023

SCILEX HOLDING COMPANY
(Exact name of registrant as specified in its charter)

Delaware	**001-39852**	**92-1062542**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 one month ended November 30, 2023 and year-to-date through November 30, 2023, 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 one month ended November 30, 2023 and year-to-date through November 30, 2023.

The Company estimates that:

- ZTlido gross sales for November 2023 were in the range of $14.0 million to $15.0 million with year-to-date gross sales through November 2023 in the range of $125.0 million to $135.0 million, compared to $84.6 million for year-to-date through November 2022, representing growth in the range of approximately 48% to 60%. Projected full year gross sales for ZTlido in 2023 are estimated to be in the range of $140.0 million to $150.0 million, compared to $96.0 million in 2022, representing estimated growth in the range of approximately 46% to 56%.
- ZTlido net sales for November 2023 were in the range of $3.9 million to $4.5 million with year-to-date net sales through November 2023 in the range of $40.0 million to $43.0 million, compared to $33.9 million for year-to-date through November 2022, representing growth in the range of approximately 18% to 27%. Projected full year net sales for ZTlido in 2023 are estimated to be in the range of $44.0 million to $50.0 million, compared to $38.0 million in 2022, representing estimated growth in the range of approximately 16% to 32%.
- Total product gross sales for November 2023 were in the range of $14.0 million to $16.0 million with year-to-date total product gross sales through November 2023 in the range of $130.0 million to $140.0 million, compared to $84.6 million for year-to-date through November 2022, representing growth in the range of approximately 54% to 65%.
- Total product net sales for November 2023 were in the range of $4.0 million to $4.6 million with year-to-date total product net sales through November 2023 in the range of $41.0 million to $44.0 million, compared to $33.9 million for year-to-date through November 2022, representing growth in the range of approximately 21% to 30%.

On December 1, 2023, the Company issued a press release that included certain preliminary unaudited financial results for the one month ended November 30, 2023 and year-to-date through November 30, 2023. 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.

Exhibit Number	Description
99.1	Press Release, dated December 1, 2023.
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: December 1, 2023

FOR IMMEDIATE RELEASE

December 1, 2023

Scilex Holding Company Generates Monthly Revenue In November 2023 And Provides Certain Preliminary Unaudited Financial Results For Gross And Net Sales For The One Month Ended November 2023, And Year-To-Date Through November 30, 2023, Based On Currently Available Information

PALO ALTO, CA. December 1, 2023 /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 monthly revenue in November 2023 and provided certain preliminary unaudited financial results for gross and net sales for the one month ended November 2023 and year-to-date through November 30, 2023.

The Company estimates that:

- ZTlido gross sales for November 2023 were in the range of $14.0 million to $15.0 million with year-to-date gross sales through November 2023 in the range of $125.0 million to $135.0 million, compared to $84.6 million for year-to-date through November 2022, representing growth in the range of approximately 48% to 60%.
    - Projected full year gross sales for ZTlido in 2023 are estimated to be in the range of $140.0 million to $150.0 million, compared to $96.0 million in 2022, representing estimated growth in the range of approximately 46% to 56%.
- ZTlido net sales for November 2023 were in the range of $3.9 million to $4.5 million with year-to-date net sales through November 2023 in the range of $40.0 million to $43.0 million, compared to $33.9 million for year-to-date through November 2022, representing growth in the range of approximately 18% to 27%.
    - Projected full year net sales for ZTlido in 2023 are estimated to be in the range of $44.0 million to $50.0 million, compared to $38.0 million in 2022, representing estimated growth in the range of approximately 16% to 32%.
- Total product gross sales for November 2023 were in the range of $14.0 million to $16.0 million with year-to-date total product gross sales through November 2023 in the range of $130.0 million to $140.0 million, compared to $84.6 million for year-to-date through November 2022, representing growth in the range of approximately 54% to 65%.
- Total product net sales for November 2023 were in the range of $4.0 million to $4.6 million with year-to-date total product net sales through November 2023 in the range of $41.0 million to $44.0 million, compared to $33.9 million for year-to-date through November 2022, representing growth in the range of approximately 21% to 30%.

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, with FDA Fast Track status. 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. 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 one month ended November 30, 2023, and year-to-date through November 30, 2023, the potential impact of the successful FDA audit on Scilex's commercialization plans for ZTlido®, 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 one month ended November 30, 2023, and year-to-date through November 30, 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 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 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 registered trademark by Scilex Holding Company.

All other trademarks are the property of their respective owners.