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 10, 2024

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 7.01. Regulation FD Disclosure.

On December 10, 2024, Scilex Holding Company (the "Company") issued press releases announcing the signing of (i) a binding term sheet with IPMC Company ("IPMC"), the representative company of the Bio Open Innovation Consortium, to create a joint venture arrangement (the "JV") involving the formation of a new entity for the sole purpose of globally developing and commercializing a potential novel oral central nervous system ("CNS") compound, KDS2010, a Phase 2, novel oral tablet for the treatment of obesity and neurodegenerative diseases, including Alzheimer's disease; and (ii) a binding term sheet with NeuroBiogen Company ("NB"), pursuant to which NB will grant the JV worldwide rights, with rights to sublicense, for all indications of KDS2010. Copies of the press releases are furnished herewith as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as 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 10, 2024.
99.2	Press Release, dated December 10, 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: December 10, 2024

Exhibit 99.1

FOR IMMEDIATE RELEASE

December 10, 2024

Scilex Holding Company Enters into a Binding Term Sheet for a Joint Venture with IPMC and Bio Open Innovation Consortium to Develop and Commercialize a Phase 2 Clinical Stage, Potential Best-In-Class Novel Oral Tablet for the Treatment of Obesity and Neurodegenerative Diseases Including Alzheimer's Disease

- The joint venture, Scilex Bio ("Scilex Bio JV"), will have global development and commercialization rights for a Phase 2 clinical stage, potential best-in-class novel oral tablet, KDS2010, for the treatment of obesity and neurodegenerative diseases including Alzheimer's disease.
- KDS2010 has shown promising preclinical results with a novel mechanism (controls GABA levels in astrocytes) that acts reversibly and selectively inhibits MAO-B enzymes and presents a potential innovative new treatment addressing several cardiometabolic and neurodegenerative disorders.
- KDS2010 pharmacokinetics, lack of food effect, safety and dose selection have been characterized in Single Ascending Dose and Multiple Ascending Dose Phase 1 clinical trials with 88 healthy young adults and elderly subjects, demonstrating favorable safety and tolerability profile in adults and elderly and adequate pharmacokinetics for once-daily dosing.
- Selective inhibition of astrocytic GABA is a molecular target for treating obesity. KDS2010 is being evaluated in a Phase 2 clinical trial as an obesity treatment, which inhibits astrocytic GABA in lateral hypothalamic area (LHA), a brain nucleus which regulates food intake and energy balance. KDS2010 facilitates fat thermogenesis and reduces weight gain without affecting food intake in mice. This new treatment may be a more effective and safer alternative to existing obesity treatments, which are known to cause vomiting, potential muscle loss, nausea, and inducing resistance to GLP-1 treatment after stopping medication.
- Scilex will plan to announce scientific data on the novel mechanism of actions of KDS2010 published in prestigious scientific journals.
- Pursuant to the terms of the binding term sheet, Scilex will own controlling interest of Scilex Bio JV upon contribution of $50 million of Semnur Pharmaceuticals, Inc. ("Semnur") common stock owned by Scilex, which is expected to be publicly traded on Nasdaq during Q1-2025 and IPMC will own 40% of the JV upon contribution of the exclusive, perpetual and worldwide rights to the KDS2010 compound for all indications.

- As millions seek access to weight loss drugs, IQVIA experts at Institute for Data Science see a vast opportunity in weight loss drugs with annual global sales forecasts for the emerging obesity drug treatments to about $150 billion by the early 2030s. Global spending on obesity medication totaled $24 billion last year, IQVIA estimated in a 5-year outlook that sales could reach $131 billion by 2028.[1]

- Per Health Care analyst reports 2023[2], Alzheimer's global drug market size is expected to rise above $15 billion by 2030 in the eight major markets, as new drugs show promise and are being launched with FDA approval to slow cognitive decline.

PALO ALTO, CALIFORNIA – December 10, 2024 (GLOBE NEWSWIRE) – Scilex Holding Company (Nasdaq: SCLX, "Scilex" or "Company") and IPMC Company, a representative company of the Bio Innovation Consortium ("BOIC"), which holds the exclusive rights to NeuroBiogen Company's ("NB") KDS2010 global license, today announced a binding term sheet to create a commercial joint venture, Scilex Bio, to develop and commercialize a next-generation reversible MAO-B Inhibitor, a novel inhibitor of aberrant GABA production in reactive astrocytes for the treatment of obesity and neurodegenerative diseases including Alzheimer's disease.

IPMC, a private biopharmaceutical company, represents the BOIC, an innovative consortium committed to establishing 'Open Innovation' as a transformative paradigm in biohealth research, development, and commercialization.

"The partnership between IPMC and Scilex spans almost a decade. At the 2017 IPMC International Conference in Seoul, leaders from both companies pledged to undertake a bold challenge for the next century, dedicated to upholding the dignity of human life. Since then, we have been deeply impressed by Scilex's efforts in advancing multiple non-opioid pain management programs, addressing areas of significant unmet medical needs in the U.S. and beyond. We believe Scilex is uniquely positioned to unlock the potential of KDS2010, offering hope to individuals suffering from neurodegenerative and cardiometabolic diseases. This potential milestone represents a significant advancement in fulfilling the vision of our bold challenge," said Youngwoo Jang, President of IPMC.

"We are thrilled to partner with IPMC and BOIC to advance KDS2010, a promising oral therapy targeting some of the most pressing global health challenges, including obesity and neurodegenerative diseases, which affect over a billion people globally. By leveraging IPMC's groundbreaking work on KDS2010 and Scilex's strengths in development and commercialization, we believe this novel oral therapy may redefine treatment standards, offering a safer and more convenient solution for patients with obesity and other CNS diseases," said Jaisim Shah, President and Chief Executive Officer of Scilex.

"KDS2010 has the potential to significantly advance treatment options for obesity and neurodegenerative diseases, areas where current therapies often fall short. With its innovative mechanism and favorable safety profile, this small molecule offers a unique opportunity to deliver

better outcomes for patients. We are eager to bring this groundbreaking therapy to market," said Dr. Jay Chun, M.D., Ph.D., board member of Scilex.

The formation and organizational structure of Scilex Bio JV is subject to negotiation of definitive agreements between Scilex and IMPC, with operations of Scilex Bio JV expected to commence during Q1-2025.

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

For more information on Semnur Pharmaceuticals, refer to www.semnurpharma.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.

About Scilex Holding Company

Scilex Holding Company is an innovative revenue-generating company focused on acquiring, developing and commercializing the treatment for neurodegenerative and cardiometabolic diseases, and 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 is 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.

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

About Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. (“Semnur”) is a clinical, late-stage specialty pharmaceutical company focused on the development and commercialization of novel non-opioid pain therapies. Semnur’s lead program, SP-102 (SEMDEXA™), is the first non-opioid novel gel formulation administered epidurally in development for patients with moderate to severe chronic radicular pain/sciatica.

Semnur Pharmaceuticals, Inc. is headquartered in Palo Alto, California.

For more information on Semnur Pharmaceuticals, refer to www.semnurpharma.com

About IPMC

IPMC is a private biopharmaceutical company, represents the BOIC, an innovative consortium committed to establishing 'Open Innovation' as a transformative paradigm in biohealth research, development, and commercialization.

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 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements Scilex and its subsidiaries, including but not limited to Semnur, statements regarding the terms of the potential joint venture transaction, statements regarding KDS2010 and the potential efficacy and preclinical results, the potential for KDS2010 to be an innovative new treatment for obesity and Alzheimer’s disease benefitting people living with neurodegenerative and cardiometabolic diseases, the potential market size and growth opportunity for the weight loss and Alzheimer’s global drug market, the timing of formation and operations of Scilex Bio JV , the expectation that Semnur common stock will be publicly traded on Nasdaq during Q1-2025, statements regarding the Company’s outlook, goals and expectations for 2024, and the Company’s development and commercialization plans. Although Scilex and its subsidiaries believe that they have a reasonable basis for each forward-looking statement contained in this press release Scilex and its subsidiaries caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain.

Risks and uncertainties that could cause actual results of Scilex to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: the inability of the parties to complete the joint venture transaction, changes in timing of the proposed joint venture transaction and the ability of the parties to achieve the benefits of the proposed joint venture transaction 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 SEC, including the 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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Email: investorrelations@scilexholding.com

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References

a. www.reuters.com/business/healthcare-pharmaceuticals/weight-loss-drug-forecasts-jump-150-billion-supply-grows-2024-05-28/

b. www.ihealthcareanalyst.com/global-alzheimers-disease-market/

c. https://idf.org/news/one-billion-people-globally-estimated-to-be-living-with-obesity-by-2030/

# # #

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.

Scilex Bio™ is a trademark owned by Scilex Holding Company.

All other trademarks are the property of their respective owners.

Exhibit 99.2

FOR IMMEDIATE RELEASE

December 10, 2024

NeuroBiogen Company and Scilex Bio, a Controlling Interest of Joint Venture by Scilex Holding Company enter into Binding Term Sheet for Worldwide License, Along with the Rights to Sublicense for All of KDS2010 indications. Binding Term Sheet Includes Collaboration for Development and Commercialization of Novel Oral Tablet KDS2010 in Ongoing Phase 2 CardioMetabolic and Neurodegenerative Diseases

- Collaboration leverages NeuroBiogen's research and development of novel oral tablet KDS2010 and Scilex's commercial and development expertise in central nervous system (CNS) and primary care diseases.
- Novel oral tablet KDS2010, a recently synthesized potent, selective, and reversible MAO-B inhibitor will be the collaboration's lead product candidate, targeting the fast growing $150 billion weight loss and Alzheimer's disease markets.[1,2]
- NeuroBiogen will grant Scilex Bio the worldwide license rights along with the rights to sublicense for all KDS2010 indications.
- Scilex Bio to advance KDS2010 in two ongoing Phase 2 clinical trials in obesity and Alzheimer's disease in the U.S. and globally with our strategic partner.

PALO ALTO, CALIFORNIA and SEOUL, SOUTH KOREA – December 10, 2024 (GLOBE NEWSWIRE) – Scilex Bio, a controlling interest of joint venture by Scilex Holding Company (Nasdaq: SCLX, "Scilex" or "Company") today announced the signing of a binding term sheet with NeuroBiogen ("NB") to grant Scilex Bio an exclusive worldwide license to the franchise KDS2010 drug candidate to develop and commercialize in metabolic diseases (including obesity and type 2 diabetes) and neurodegenerative diseases, including Alzheimer's, Parkinson's and other CNS diseases. The lead program in the proposed joint venture is an oral tablet product candidate that is currently in Phase 2 trials in obesity and Alzheimer's disease indications. The term sheet provides that NeuroBiogen will grant Scilex Bio the worldwide license rights along with the rights to sublicense for all KDS2010 indications.

“We are excited to build upon the strong innovative work performed by NeuroBiogen, a highly regarded company with broad expertise in pharmaceutical research and development. The advancement of effective oral therapy for treating highly unmet medical needs in cardiometabolic and neurodegenerative diseases has been a major goal for the pharmaceutical industry and the impressive results from NeuroBiogen suggest they have a very promising therapy. We believe Scilex’s developmental experience and commercial presence uniquely positions us to move this molecule forward with the goal of offering a full portfolio of treatment options to patients struggling with obesity, acute and chronic pain management and neurodegenerative diseases,” said Jaisim Shah, Chief Executive Officer and President of Scilex.

“We are excited to partner with Scilex who we believe is the emerging leader in the development and commercialization of the non-opioid therapies in pain management and neurological defined diseases. We believe Scilex Bio will be the ideal partner because of Scilex’s extensive experience in clinical development with a network of clinical trial sites and investigators, combined with successful commercialization of promising CNS products,” said Dr. Kim Sangwook, CEO of NeuroBiogen Company.

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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.

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About NeuroBiogen

NeuroBiogen prioritizes its research and development efforts to develop innovative new medicine to treat patients who suffer from degenerative brain diseases and central nervous system diseases. By developing innovative drugs through the efficacy verification and clinical progress of the new drug candidates (KDS2010/SeReMABI), it will continue the journey to a global company to contribute to human health.

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 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 Scilex and its subsidiaries, including but not limited to, statements regarding the terms of the potential licensing

transaction, statements regarding KDS2010 and the potential efficacy and preclinical results, the potential for KDS2010 to be an innovative new treatment for obesity and Alzheimer's disease benefitting people living with neurodegenerative and cardiometabolic diseases, the potential market size and growth opportunity for the weight loss and Alzheimer's global drug market, the Company's outlook, goals and expectations for 2024, and the Company's development and commercialization plans. Although each of Scilex and its subsidiaries believes that it has a reasonable basis for each forward-looking statement contained in this press release, each of Scilex and its subsidiaries caution you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain.

Risks and uncertainties that could cause actual results of Scilex to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: the inability of the parties to consummate the licensing transaction for any reason, including any failure to satisfy or waive any closing conditions; changes in the structure, timing and completion of the proposed transaction between Scilex and NeuroBiogen; the ability of the parties to achieve the benefits of the proposed licensing transaction, risks related to the outcome of any legal proceedings that may be instituted against the parties following the announcement of the proposed licensing transaction; risks associated with the unpredictability of trading markets; general economic, political and business conditions; the risk that the potential product candidates that Scilex or Scilex Bio 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 and Scilex Bio's product candidates; the risk that Scilex and Scilex Bio 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 SEC, including its Annual Reports 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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a. www.reuters.com/business/healthcare-pharmaceuticals/weight-loss-drug-forecasts-jump-150-billion-supply-grows-2024-05-28/

b. www.ihealthcareanalyst.com/global-alzheimers-disease-market/

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