Semnur Pharmaceuticals, Inc., a Wholly Owned Subsidiary of Scilex Holding Company, and Denali Capital Acquisition Corp. (Nasdaq: DECA) Enter into a Letter of Intent for a Proposed Business Combination

Jul 2, 2024

- Semnur Pharmaceuticals, Inc. (“Semnur”), a wholly owned subsidiary of Scilex Holding Company (Nasdaq: SCLX, “Scilex”), and Denali Capital Acquisition Corp. (Nasdaq: DECA) (“SPAC”) announce signing of a letter of intent for a proposed business combination, which provides for a pre-transaction equity value of Semnur of up to $2.0 billion, subject to adjustment based on third-party fairness opinion, with expected cash on hand at closing of up to $40 million depending on the number of SPAC shares that are redeemed prior to the completion of the business combination.

- The proposed business combination would create a publicly traded biopharma company and further provide investment into Semnur for the development of a non-opioid product, SP-102 (10 mg injectable dexamethasone sodium phosphate viscous gel), or SEMDEXA™, a Phase 3 novel non-opioid, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, with FDA Fast Track status.

- Anticipated proceeds from the proposed business combination are expected to fund Semnur’s lead program, SP-102, and a final Phase 3 study in connection with a potential New Drug Application filing with the FDA.

- Scilex is expected to be the majority holder of the combined company following completion of the proposed business combination.

- As previously disclosed, the Board of Directors of Scilex approved a resolution to authorize a potential dividend of up to 10% of the Scilex’s ownership interest in Semnur in connection with certain transactions, including a merger, subject to the registration of Semnur’s common stock (or such securities, property or other assets into which or for which such stock may be exchanged or converted in such a transaction) with the Securities and Exchange Commission (“SEC”).

PALO ALTO, Calif., July 02, 2024 (GLOBE NEWSWIRE) -- Semnur Pharmaceuticals, Inc. (“Semnur”), a wholly owned subsidiary of Scilex Holding Company (Nasdaq: SCLX, “Scilex”), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, and Denali Capital Acquisition Corp., a Cayman Islands corporation and special purpose acquisition company (Nasdaq: DECA, “SPAC”), today announced the signing of a letter of intent for a proposed business combination, which provides for a pre-transaction equity value of Semnur up to $2.0 billion, subject to adjustment based on third-party fairness opinion, with expected gross proceeds of up to $40 million depending on the number of SPAC shares that are redeemed prior to the completion of the business combination.

Semnur is a clinical-late stage specialty pharmaceutical company focused on the development and commercialization of a novel non-opioid pain therapies. Semnur’s lead program, SP-102 (SEMDEXA™), is the first non-opioid novel injectable corticosteroid gel formulation for patients with moderate to severe chronic radicular pain/sciatica, containing no preservatives, surfactants, solvents, or particulates. If approved by the FDA, SP-102 (SEMDEXA™) will be available in a pre-filled syringe formulation and will be administered as an epidural injection for the treatment of sciatica. SP-102 completed a Phase 3 trial, meeting primary and important key secondary endpoints, with SP-102 (SEMDEXA™) treatment decreasing pain intensity for over a month in sciatica patients and resulting in statistically significant and clinically meaningful improvement in the disability index score while maintaining safety comparable to placebo. The Phase 3 topline data result was presented at the American Society of Interventional Pain (ASIPP) conference in Las Vegas in May 2022 in an oral presentation by Dr. Nebojsa Nick Knezevic, M.D., Ph.D., Professor of Anesthesiology and Surgery, College of Medicine, University of Illinois at Chicago, President of the Illinois Society of Interventional Pain Physicians, Director-at-Large of the North American Society of Neuromodulation, Vice-Chair for Research and Education, Advocate Illinois Masonic Medical Center, Department of Anesthesiology and Pain Management. This Phase 3 study represents a potential significant improvement in treatment of adult patients with lumbosacral radicular pain (sciatica), who struggle with the clinical consequences of no currently FDA approved therapies, suboptimal formulations of corticosteroids used off-label and/or excess pain and disability. Download the presentation by clicking here.

The results of the pivotal registration trial of SP-102 (SEMDEXA™) was published in PAIN, the official journal of the International Association for the Study of Pain, which features original research on the nature, mechanisms and treatment of pain. Download the publication by clicking here.

Based on the independent market research conducted by Syneos Health Consulting (“Syneos”), with the substantial intent in

utilization for SP-102 (SEMDEXA™) with peak sales potential projected to be up to $3.6 billion annually 5 years post launch.[7]

In the U.S., more than 30 million people live with low back and radicular pain, with this population expected to grow as the overall population ages.[1,2] Many patients experience moderate to severe pain with intolerance of and/or inadequate response to current analgesic therapies such as opioids and nonsteroidal anti-inflammatory drugs (NSAIDs).[3,4] There is a great need for highly effective analgesic medications to provide patient relief without the toxicity and tolerability challenges of NSAIDs and opioids.[2] Opioid prescriptions account for about 40% of the chronic pain market and carry a well-known risk of abuse and misuse, underscoring the need for alternate pain therapies without the medical and societal challenges.[2,5]

The overall estimated number of epidural steroid injection (ESI) procedures in the U.S. is approximately 12.1 million across all Medicare and private coverage patients, with lumbar radiculopathy/sciatica procedures comprising approximately 88% of all ESIs administered, according to a proprietary study by Syneos Health. Despite widespread utilization of ESIs, concerns persist in the market about particulate steroids and potential side effects and safety concerns (e.g., stroke) from current off-label use. As a result, a significant unmet medical need exists within the market for a potent, non-particulate ESI formulation that demonstrates safety and effectiveness in controlled clinical trial evaluations.[6]

“This is an important milestone in our path towards unlocking the value of SP-102 (SEMDEXA™), a treatment for lumbar radicular pain or sciatica, that we have been passionately working on over the years. I want to take a moment to thank our team for their incredible work and our established track record with collaborations and execution of the comprehensive development program to date. We look forward to closing the proposed business combination as soon as reasonably practicable and look forward to collaborating with the Denali team in this exciting next chapter”, said Jaisim Shah, Chief Executive Officer and President of Scilex.

“Semnur has a strong management team with deep scientific and operational experience in neurology and pain management and an exciting late-stage asset in SP-102 (SEMDEXA™), which has already shown significant clinical benefit in high unmet need area of lumbar radicular pain or sciatica where no products are approved for treatment to date. We are excited about the potential for SP-102 (SEMDEXA™) which has been granted Fast Track Status from the FDA impacting diseases such as Sciatica, Chronic Neck Pain, Lumbar Spinal Stenosis, and Spondylolisthesis. The talented team has done a tremendous job of creating value in a timely and capital efficient manner and we look forward to working together with them to advance their promising product to the next level”, said Lei Huang, CEO of Denali Capital Acquisition Corp.

Terms of Letter of Intent

Completion of the proposed transaction is subject to the negotiation of a definitive merger agreement (the “Merger Agreement”), approval by the SPAC’s and Scilex’s boards of directors, satisfaction of the conditions negotiated in the proposed Merger Agreement and approval of the proposed transaction by the SPAC’s shareholders. There can be no assurance that a Merger Agreement will be entered into or that the proposed transaction will be consummated. Further, readers are cautioned that those portions of the letter of intent that describe the proposed transaction, including the consideration to be issued therein, are subject to change.

The letter of intent contemplates the combined company (the “Combined Company”) changing its name to Semnur Pharmaceuticals, Inc. and being led by Scilex and Semnur’s current management team. Assuming execution of the proposed Merger Agreement and consummation of the proposed transaction, the Combined Company expects to capitalize on Semnur’s product candidate, SP-102 (injectable dexamethasone sodium phosphate viscous gel product containing 10 mg dexamethasone), or SEMDEXA™.

Assuming the SPAC and Semnur enter into the proposed Merger Agreement in the near term, the parties anticipate seeking approval from the SPAC’s shareholders in the second half of 2024.

Contingent upon execution of the Merger Agreement, the SPAC would file a registration statement on Form S-4 with the SEC, which would include a proxy statement/prospectus, and each party would file other documents regarding the proposed transaction with the SEC.

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.

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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 chronic neck pain and for which Scilex has recently completed a Phase 2 trial in 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.

About Semnur Pharmaceuticals, Inc.

Semnur Pharmaceuticals, Inc. 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, 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.

About Denali Capital Acquisition Corp.

Denali Capital Acquisition Corp. is a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities.

Important Information and Where to Find It

This press release relates to a proposed transaction between Semnur and the SPAC and does not contain all the information that should be considered concerning the potential business combination and is not intended to form the basis of any investment decision or any other decision in respect of the potential business combination. This press release does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. In connection with the transaction described herein, contingent upon execution of the proposed Merger Agreement, the SPAC would file relevant materials with the SEC, including a registration statement on Form S-4, which will include a proxy statement/prospectus. **Investors and security holders of the SPAC are urged to read these materials (including any amendments or supplements thereto) and any other relevant documents in connection with the transaction that the SPAC files with the SEC when, and if, they become available because they will contain important information about the SPAC, Semnur and the proposed transaction.** The preliminary proxy statement/prospectus, the definitive proxy statement/prospectus and other relevant materials in connection with the transaction (when and if they become available), and any other documents filed by the SPAC with the SEC, may be obtained free of charge at the SEC's website (www.sec.gov). The documents filed by the SPAC with the SEC also may be obtained free of charge upon written request to:

Denali Capital Acquisition Corp.
437 Madison Avenue, 27th Floor
New York, NY 10022

Participants in the Solicitation

If the parties execute the proposed Merger Agreement, the SPAC and its directors and executive officers may be deemed participants in the solicitation of proxies from the SPAC's shareholders with respect to the proposed business combination. Information about the SPAC's directors and executive officers and a description of their interests in the SPAC will be included in the proxy statement/prospectus for the proposed transaction and would be available at the SEC's website (www.sec.gov). Additional information regarding the interests of such participants will be contained in the proxy statement/prospectus for the proposed transaction when available.

Semnur and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the shareholders of the SPAC in connection with the proposed business combination. Information about Semnur's directors and executive officers and information regarding their interests in the proposed transaction will be included in the proxy statement/prospectus for the proposed transaction.

Non-Solicitation

This press release is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the potential transaction and shall not constitute an offer to sell or a solicitation of an offer to buy the securities of the SPAC, the Combined Company or Semnur, nor shall there be any sale of any such securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such state or jurisdiction. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended.

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 the SPAC 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 SPAC, Scilex and its subsidiaries, including but not limited to Semnur, statements regarding the proposed business combination between Semnur and SPAC, including the estimated timing for seeking approval from the SPAC's shareholders in the second half of 2024, the potential listing of the Combined Company's common stock on Nasdaq, the expectation that the SPAC will file a registration statement on Form S-4 with the SEC, which would include a proxy statement/prospectus, the estimated or anticipated future results and benefits of the Combined Company following the proposed business combination, including the likelihood and ability of the parties to successfully consummate the proposed business combination, future opportunities for the Combined Company, Semnur and the Combined Company's proposed business strategies, the expected cash resources of the Combined Company, the expected uses thereof, the estimated pre-transaction equity valuation of Semnur and the expected gross proceeds from the proposed business combination, estimated peak sales for SP-102, estimated patient population with low back and radicular pain in the U.S., the estimated number of ESI procedures in the U.S., and the Company's development and commercialization plans. Although each of the SPAC and Scilex and its subsidiaries believes that it has a reasonable basis for each forward-looking statement contained in this press release, each of the SPAC and 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. In addition, there will be risks and uncertainties described in the proxy statement/prospectus included in the registration statement on Form S-4 relating to the proposed transaction, which is expected to be filed by the SPAC with the SEC, and described in other documents filed by the SPAC or Scilex from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Neither the SPAC nor Scilex and its subsidiaries can assure you that the forward-looking statements in this communication will prove to be accurate.

Risks and uncertainties that could cause actual results of Scilex and the SPAC to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: Semnur and the SPAC not being able to enter into the Merger Agreement for the proposed business combination; the inability of the parties to consummate any proposed business combination transaction for any reason, including any failure to meet applicable closing conditions; changes in the structure, timing and completion of the proposed transaction between the SPAC and Semnur; the SPAC's ability to continue its listing on the Nasdaq Capital Market until closing of the proposed transaction; the Combined Company's ability to list its securities on Nasdaq after closing of the proposed transaction; the ability of the parties to achieve the benefits of the proposed transaction, including future financial and operating results of the Combined Company; the ability of the parties to realize the expected synergies from the proposed transaction; risks related to the outcome of any legal proceedings that may be instituted against the parties following the announcement of the proposed business combination; 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 and the SPAC's most recent periodic reports filed with the Securities and Exchange Commission, including their Annual Reports on Form 10-K for the year ended December 31, 2023 and subsequent Quarterly Reports on Form 10-Q that the Company and SPAC have respectively 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 and the SPAC undertakes no obligation to update any forward-looking statement in this press release except as may be required by law.

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References

(1) Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 76 & 80
(2) Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 40
(3) Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 62
(4) Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 62
(5) Decisions Resources Group. Chronic Pain: Disease Landscape and Forecast. 2016; 8
(6) Proprietary Syneos SP-102 Sciatica Internal Report March 2021
(7) Syneos Health Consulting January 2020 and March 2021 market research and analysis

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.

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