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 9, 2021

SORRENTO THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36150**	**33-0344842**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

4955 Directors Place
San Diego, CA 92121
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (858) 203-4100

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**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	SRNE	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.

On December 9, 2021, Scilex Holding Company, a majority-owned subsidiary of Sorrento Therapeutics, Inc., issued a press release announcing highly significant positive top-line results from its SP-102 (SEMDEXA™) Phase 3 Pivotal Trial C.L.E.A.R. Program, a corticosteroid injectable dexamethasone sodium phosphate viscous gel for the treatment of lumbosacral radicular pain, or sciatica. A copy of the press release is filed herewith 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.

99.1	Press Release, dated December 9, 2021.
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.

SORRENTO THERAPEUTICS, INC.

Date: December 9, 2021

By: /s/ Henry Ji, Ph.D.
Name: Henry Ji, Ph.D.
Title: Chairman of the Board, President and Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

December 9, 2021

Scilex Holding Company, a Sorrento Therapeutics, Inc. Subsidiary, Announces Highly Significant Positive Top-Line Results from its Phase 3 Non-Opioid Injectable SP-102 (SEMDEXA™) Pivotal Trial C.L.E.A.R. Program for Sciatica Pain Management Supporting the Potential Use of SP-102 as a Best-in-Class Therapy

- Scilex Holding Company, a commercial-stage, non-opioid biopharmaceutical pain management company, announces highly significant positive top-line results from its Phase 3 SP-102 (SEMDEXA™) Pivotal Trial C.L.E.A.R Program for its novel, non-opioid, corticosteroid formulation, injectable dexamethasone sodium phosphate viscous gel product for the treatment of lumbosacral radicular pain (sciatica). SP-102 (SEMDEXA™) has received Fast Track status from the FDA.

- The C.L.E.A.R. Program trial has met the primary efficacy and key secondary efficacy endpoints with highly statistical significance:

    - For the primary endpoint of change in average daily pain (as measured by the Numeric Pain Rating Scale) in the affected leg over 4 weeks following the initial injection the LS Mean (SE) group difference of -1.08 (0.17) compared to placebo with a p-value <0.001.

    - The two key secondary endpoints assessing Oswestry Disability Index (ODI) and Time to open-label repeat injection have also demonstrated highly statistically significant results for SP-102. The LS Mean (SE) group difference in ODI compared to placebo at week 4 was -6.28 (1.49) with a p-value <0.001. A Cox proportional hazard model showed significantly longer duration of initial SP-102 (SEMDEXA™) treatment compared to placebo Hazard Ratio (95% CI) 0.49 (0.36, 0.65), with a p-value <0.001.

- Scilex expects SP-102 (SEMDEXA™) to be the first FDA-approved non-opioid epidural injection for sciatica with the potential to replace the current 10 to 12 million off-label epidural steroid injections administered each year in the USA, where more than 30 million people suffer from low back and radicular pain. This population is expected to grow as the overall population ages.

PALO ALTO, Calif., December 9, 2021 (GLOBE NEWSWIRE) — Scilex Holding Company (“Scilex”), a subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”), today announced highly significant positive top-line results from its SP-102 (SEMDEXA™) Phase 3 Pivotal Trial C.L.E.A.R. Program, a corticosteroid injectable dexamethasone sodium phosphate viscous gel for the treatment of lumbosacral radicular pain, or sciatica. SP-102 (SEMDEXA™) has received Fast Track status from the FDA.

C.L.E.A.R. Trial (Corticosteroid Lumbosacral Epidural Analgesia for Radiculopathy) was designed to investigate safety and analgesic effects of a single and repeat transforaminal injections of SP-102 (SEMDEXA™) compared to placebo (saline injection). The trial enrolled 401 low back pain subjects with unilateral intervertebral disc herniation in lumbosacral spine resulting in radicular pain symptoms of moderate to severe leg pain. It is the largest known randomized well-controlled trial in sciatica using epidural steroid injections. The primary endpoint of change in average daily pain in the affected leg over 4 weeks following the initial injection had demonstrated LS Mean (SE) group difference of -1.08 (0.17) compared to placebo with a p-value <0.001.

The two key secondary endpoints assessing Oswestry Disability Index (ODI) and Time to open-label repeat injection had also demonstrated highly statistically significant results. The LS Mean (SE) group difference in ODI compared to placebo at week 4 was -6.28 (1.49) with a p-value <0.001. Following the initial 4-week observation period, subjects with moderate to severe radicular pain could receive an open-label repeat injection of SP-102 (SEMDEXA™). Between weeks 4 and 12, repeat injections were administered to 67% of subjects who initially received placebo treatment and 46% of subjects who initially received active treatment. A Cox proportional hazard model showed significantly longer duration of initial SP-102 (SEMDEXA™) treatment compared to placebo Hazard Ratio (95% CI) 0.49 (0.36, 0.65), with a p-value <0.001.

SP-102 (SEMDEXA™) demonstrated a very clean safety profile with no identified safety risks. There were no adverse events of special interest reported (paraplegia, hematoma, injection) associated with epidural steroid injections. There were no SAEs related to the drug or injection procedure.

“We are very pleased with the positive outcome and are looking forward to receive a complete data set to further evaluate and characterize efficacy and safety of SP-102 (SEMDEXA™). These top-line results are very remarkable. They will impact greatly the pain management community and will enable us to proceed with our plans for registering SP-102 (SEMDEXA™) with the FDA for the treatment of subacute lumbosacral radicular pain. We plan to present the results from the Phase 3 C.L.E.A.R trial at upcoming scientific conferences and submit for publication in a peer reviewed journal,” said Dmitri Lissin, MD, Chief Medical Officer of Scilex.

Scilex intends to use the results from this pivotal Phase 3 trial to discuss with the FDA in 2022 a licensure application and Breakthrough Designation Status for the high unmet need sciatica indication for which no treatments have been approved in the U.S.

Scilex has extensive clinical and pre-clinical data (including multiple Phase 2 clinical trials) with the novel viscous gel formulation of SP-102 (SEMDEXA™), which was designed to provide extended non-opioid pain relief for sciatica patients. Scilex expects to present the robust data collected over the course of the company's multi-year clinical development program to the FDA as part of a New Drug Application (NDA).

SP-102 (SEMDEXA™) is the first non-opioid novel injectable corticosteroid gel formulation product in development for the treatment of lumbar radicular pain, and it contains no preservatives, surfactants, solvents, or particulates. If approved by the FDA, the SP-102 (SEMDEXA™) formulation will be available in a pre-filled syringe and will be administered by epidural injection. Based on preclinical and clinical studies, it extends the residency time at the site of injection and does not show the safety concerns that led the FDA to warn against using other injectable steroid formulations by the epidural route of administration.

More than 40% of U.S. opioid prescriptions are for the treatment of chronic low back pain (CLBP)[9-11] despite the fact that opioids are associated with serious and potentially life-threatening side effects and have not demonstrated efficacy in the treatment of CLBP.[11,12,13] In 2018, more than 67,000 drug overdose deaths occurred in the United States[14] of which almost 47,000 (70%) were opioid-related. Over 70% of the 70,630 deaths in 2019 involved an opioid.[15] Provisional data release by the Centers for Disease Control and Prevention showed drug overdose deaths rose by nearly 29% over a 12-month period ending in April 2021, to an estimated 100,306. [16]

"We are anxiously awaiting a new injectable gel formulation of dexamethasone and submission of this data to the FDA for the treatment of radicular pain based on the results of a large, randomized, placebo-controlled, multi-center trial. If approved by the FDA, SP-102 (SEMDEXA™) would be the first corticosteroid with an indication for epidural administration in the U.S. and world, and providing meaningful, extended pain relief. SP-102 (SEMDEXA™) would be a welcome addition to the armamentarium of interventional pain physicians, providing a non-surgical, non-opioid alternative for a condition affecting millions of people," said Dr. Steven P. Cohen, Chief of Pain Medicine and Professor of Anesthesiology & Critical Care Medicine, Neurology, Physical Medicine & Rehabilitation, and Psychiatry & Behavioral Sciences at the Johns Hopkins School of Medicine, and a Professor of Anesthesiology and Physical Medicine & Rehabilitation at Walter Reed National Military Medical Center, Uniformed Services University of the Health Sciences.

"We are very pleased to have achieved this important milestone and would like to commend the experienced investigators and advisors of the C.L.E.A.R. trial for their persistence and diligence in enrolling sciatica patients through the COVID-19 pandemic and enabling Scilex to achieve a landmark milestone. These highly significant positive clinical results for the pivotal SP-102 (SEMDEXA™) Phase 3 trial may provide encouraging news for the many millions of people worldwide who are confronting painful radicular pain (sciatica) and we look forward to sharing complete Phase 3 results next year. We believe that SP-102 (SEMDEXA™) could be the first FDA-approved epidural steroid gel injection product for patients suffering from this common, very painful condition," said Jaisim Shah, President and Chief Executive Officer of Scilex.

By 2022, the overall estimated number of epidural steroid injection (ESI) procedures in the U.S. is expected to be 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 Consulting. Despite widespread utilization of ESIs, concerns persist in the market about particulate and solution steroids and potential side effect and safety concerns (e.g., stroke) from current off-label use. Opioid prescriptions account for about 40% of the chronic back 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] As a result, a significant unmet medical need exists within the market for a novel, non-particulate ESI formulation that demonstrates safety and effectiveness in controlled clinical trial evaluations.[7]

In the U.S., more than 30 million people suffer from low back and radicular pain. This population is 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]

Chronic pain affects 116 million Americans and costs the U.S. as much as $635 billion each year, according to a recent report from the Institute of Medicine (IOM) that called for changes in how chronic pain is managed[6] and nearly 30 million patients suffer from lower back pain in the U.S.[8] Government agencies, physicians, patients, and payers are looking for alternatives to opioids to reduce the risk of dependency or addiction, and serious side effects (such as respiratory depression and constipation), while still offering potent solutions for people living with chronic pain.

Scilex is dedicated to the development and commercialization of non-opioid pain management products for treatment of acute and chronic pain. Scilex's commercial product ZTLIDO® (lidocaine topical system) 1.8%, a non-opioid prescription lidocaine topical product approved by the FDA for the relief of pain associated with postherpetic neuralgia, shows continued sales growth of 35% year over year despite the continued impact of the COVID-19 pandemic. SP-102 (SEMDEXA™) is the first non-opioid novel injectable corticosteroid gel formulation product in Phase 3 development for the treatment of lumbar radicular pain, 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. Based on preclinical and clinical studies to date, SP-102 (SEMDEXA™) extends the residency time at the site of injection and has not demonstrated the safety concerns that led the FDA to warn against using other injectable steroid formulations by the epidural route of administration.

About Sorrento Therapeutics

Sorrento is a clinical and commercial stage biopharmaceutical company developing new therapies to treat cancer, pain (non-opioid treatments), autoimmune disease and COVID-19. Sorrento's multimodal, multipronged approach to fighting cancer is made possible by its extensive immuno-oncology platforms, including key assets such as fully human antibodies ("G-MAB™ library"), immuno-cellular therapies ("DAR-T™"), antibody-drug conjugates ("ADCs"), and oncolytic virus ("Seprehvec™"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including Abivertinib, COVI-AMG™, COVISHIELD™, COVI-MSC™ and COVIDROPS™; and diagnostic test solutions, including COVITRACK™, COVISTIX™.

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule, resiniferatoxin ("RTX"), and SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (SEMDEXA™), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, and to commercialize ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a Phase IB trial for intractable pain associated with cancer and a Phase 1B trial in osteoarthritis patients. SEMDEXA is in a pivotal Phase 3 trial for the treatment of lumbosacral radicular pain, or sciatica. ZTlido® was approved by the FDA on February 28, 2018.

For more information visit www.sorrentotherapeutics.com.

About Scilex Holding

Scilex Holding Company (Scilex) a subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE), is dedicated to the development and commercialization of non-opioid pain management products for treatment of acute and chronic pain. Scilex is uncompromising in our 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. 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 in October 2018 and is 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 best-in-class prescription lidocaine topical product approved by the U.S. Food and Drug Administration for the relief of pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain. 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%, or SP-103, a Phase 2, next-generation, triple-strength formulation of ZTlido®, for the treatment of low back pain, and SP-104, 4.5 mg Delayed Burst Release Low Dose Naltrexone Hydrochloride (DBR-LDN) Capsule, for the treatment of chronic pain, fibromyalgia in multiple Phase 1 programs to be initiated this year. For further information regarding the SP-102 Phase 3 efficacy trial, see NCT identifier NCT03372161 - Corticosteroid Lumbar Epidural Analgesia for Radiculopathy - Full Text View - ClinicalTrials.gov.

On December 6, 2021, Scilex announced entering into a letter of intent for a proposed business combination with Vickers Vantage Corp. I (Nasdaq: VCKA) ("SPAC").

Scilex Holding Company is headquartered in Palo Alto, California, with operations in both Palo Alto and San Diego, California. For further information please visit www.scilexpharma.com.

About Vickers Vantage Corp. I

Vickers Vantage Corp. I 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 references a proposed transaction between Scilex and the SPAC. 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 for the business combination (the "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, Scilex 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:

Vickers Vantage Corp. I
85 Broad Street, 16th Floor
New York, NY 10004

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.

Scilex 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 Scilex'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, Scilex or the combined company (the "Combined Company"), 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 Sorrento Therapeutics, Inc. and its subsidiaries, including but not limited to Scilex, 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 proposed business combination between Scilex and the SPAC, including the timing of such business combination, the potential listing of the Combined Company's common stock on Nasdaq and the anticipated Nasdaq stock ticker symbol for such shares, 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, the timing of the completion of the proposed business combination, Scilex's and the Combined Company's proposed business strategies, the expected cash resources of the Combined Company, the expected uses thereof; Scilex's expectation that SP-102 (SEMDEXA™) would be the first FDA-approved non-opioid epidural injection for sciatica; Scilex's intent to use the results from the pivotal Phase 3 trial to discuss with the FDA a licensure application and Breakthrough Designation Status for sciatica and to support a New Drug Application, as well as the timing of a proposed NDA filing for SP-102; statements regarding SP-102 (SEMDEXA™), if approved by the FDA; Scilex's development and commercialization plans; and Sorrento's products, technologies and prospects and Scilex's products, technologies and prospects, including the potential for Scilex's product candidates to be best-in-class therapies. Risks and uncertainties that could cause Sorrento's and Scilex's actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to, Scilex 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 Scilex; 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; general economic, political and business conditions; risks related to the ongoing COVID-19 pandemic risks that the prior results of the clinical trials of SP-102 (SEMDEXA™) may not be replicated; regulatory and intellectual property risks and other risks set forth in Sorrento's and the SPAC'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 we undertake no obligation to update any forward-looking statement in this press release except as may be required by law.

Media and Investor Relations

Contact: Jaisim Shah, CEO of Scilex Holding Company

Email: jshah@scilexpharma.com

Website: www.sorrentotherapeutics.com and www.scilexpharma.com

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