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, 2020

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, 2020, Sorrento Therapeutics, Inc. issued a press release announcing that it received clearance from the U.S. Food and Drug Administration to proceed with Phase 1 clinical trials for COVI-AMG (STI-2020) in healthy volunteers and COVID-19 patients with mild symptoms. 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) Exhibit.

99.1	Press Release, dated December 9, 2020.
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, 2020

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 9th, 2020

SORRENTO RECEIVES US FDA CLEARANCE TO PROCEED WITH PHASE 1 CLINICAL TRIALS FOR STI-2020 (COVI-AMG) IN HEALTHY VOLUNTEERS AND IN NEWLY DIAGNOSED COVID-19 PATIENTS

- FDA has granted clearance for the commencement of Phase 1 clinical trials of STI-2020 (COVI-AMG™) in healthy volunteers and COVID-19 patients with mild symptoms.
- STI-2020, a monoclonal antibody, has been engineered for ultra-high potency, which potentially translates to a smaller IV volume required to administer an effective dose.
- In preclinical studies, STI-2020 demonstrated strong or stronger affinities to multiple antibody drug-resistant SARS-CoV-2 variants.
- Outpatient trials are expected to enroll quickly and will be followed by pivotal trials to potentially support an EUA (Emergency Use Authorization) submission.

SAN DIEGO, December 9, 2020 (GLOBE NEWSWIRE) -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced today FDA acceptance of its Investigational New Drug (IND) application for its Phase 1 clinical trials for intravenous (IV) STI-2020 (COVI-AMG). The trials will evaluate the safety, pharmacokinetics and efficacy of a single injection of STI-2020 in healthy volunteers and outpatient COVID-19 patients with mild symptoms.

Sorrento previously announced that STI-2020 demonstrated a complete neutralizing effect at a very low dose in preclinical studies and high potency that may potentially enable rapid deployment and availability to patients. Sorrento has initiated cGMP manufacturing to produce up to 100,000 doses in anticipation of a potential EUA.

The FDA has been requesting that IND sponsors evaluate SARS-CoV-2 neutralizing antibodies in development for activity against antibody drug-resistant SARS-CoV-2 variants, including the E484K, F490S, Q493R and S494P mutations. Sorrento has evaluated the binding activity of STI-2020 against all of these variants in preclinical studies and the binding affinity of STI-2020 against each of the variants is similar to or better than that observed for wild-type SARS-CoV-2. In addition, STI-2020 demonstrated similarly strong binding affinities to the currently dominant D614G variant and the mink-associated N439K variant as compared to that for wild-type SARS-CoV-2.

To expedite development toward a potential EUA submission, Sorrento is planning on initiating dosing in a healthy population. "Since COVI-AMG comes in a small volume IV-push formulation, made possible by the high potency of this unique antibody, we expect trials to enroll very quickly. This combination potentially makes STI-2020 an ideal candidate for the early treatment of SARS-CoV-2 infection in an outpatient setting," stated Mike Royal, MD, Chief Medical Officer of Sorrento.

More information about the Phase 1 clinical trials can be found at www.clinicaltrials.gov (NCT#: NCT04584697).

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers. 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"), clinical stage immuno-cellular therapies ("CAR-T", "DAR-T™"), antibody-drug conjugates ("ADCs"), and clinical stage oncolytic virus ("Seprehvir®"). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVI-GUARD™, COVI-AMG™, COVI-SHIELD™, Gene-MAb™, COVI-MSC™ and COVI-DROPS™; and diagnostic test solutions, including COVI-TRACK™, COVI-STIX™ and COVI-TRACE™.

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

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sorrento Therapeutics, Inc., under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the potency and potential neutralizing profile of STI-2020 and the impact on SARS-CoV-2; the preclinical and clinical testing of STI-2020; the safety, pharmacokinetics and efficacy of STI-2020; the expected speed and timing for enrolling patients in the phase 1 trials; the expectation of the commencement of any pivotal trials for STI-2020; the expected timing of any EUA submission; the potential receipt of an EUA for STI-2020 and expected timing for any receipt thereof; the expected availability of doses of STI-2020 and the timing thereof; the predictive value of the animal model used in preclinical studies; the potential potency of STI-2020; the binding affinity of STI-2020 against antibody drug-resistant SARS-CoV-2 variants; the expected effective dose of STI-2020 in humans; the potentially faster manufacturing speed, availability and/or potential lower cost for STI-2020; the potential for rapid scaling up of manufacturing operations for STI-2020; the potential for STI-2020 to be used as an early treatment of SARS-CoV-2 infection in an outpatient setting; and Sorrento's potential position in the antiviral industry. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: risks related to Sorrento's and its subsidiaries', affiliates' and partners' technologies and prospects and collaborations with partners, including, but not limited to risks related to conducting and receiving results of clinical trials for STI-2020; the clinical and commercial success of STI-2020 against preventing and treating SARS-CoV-2 virus infections; the viability and success of STI-2020 in anti-viral therapeutic areas, including coronaviruses; clinical development risks, including risks in the progress, timing, cost, and results of clinical trials and product development programs; risk of difficulties or delays in obtaining regulatory approvals; risks that clinical study results may not meet any or all endpoints of a clinical study and that any data generated from such studies may not support a regulatory submission or approval; risks that prior test results may not be replicated in future studies and trials; risks of manufacturing and supplying drug product; risks related to leveraging the expertise of its employees, subsidiaries, affiliates and partners to assist the company in the execution of its COVID-19 therapeutic product candidates strategies; risks related to the global impact of COVID-19; and other risks that are described in Sorrento's most recent periodic reports filed with the Securities and Exchange Commission, including Sorrento's Annual Report on Form 10-K for the year ended December 31, 2019, and subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, 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 we undertake no obligation to update any forward-looking statement in this press release except as required by law.

Contact
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