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): September 28, 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 September 28, 2020, Sorrento Therapeutics, Inc. issued a press release announcing that it released preclinical data reporting on COVI-GUARD™ (STI-1499) and COVI-AMG™ (STI-2020; **A**ffinity **M**atured COVI-**G**uard) neutralizing antibodies (nAbs) against SARS-CoV-2 as well as a D614G virus variant infection in a preprint publication. 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 September 28, 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: September 29, 2020

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

SORRENTO RELEASES PRECLINICAL DATA FOR STI-1499 (COVI-GUARD™) AND STI-2020 (COVI-AMG™), POTENT NEUTRALIZING ANTIBODIES AGAINST SARS-COV-2

- In preclinical studies, both STI-1499 and STI-2020 demonstrated potent neutralizing activity against SARS-CoV-2 virus isolates, including the emerging Spike D614G variant virus.
- Both STI-1499 and STI-2020 demonstrated protective activities against SARS-CoV-2 infection in Syrian golden hamsters.
- At day 5, STI-2020 at 500 µg reduced virus load in hamster lungs to undetectable levels in 100% of animals tested, whereas STI-1499 at 2,000 µg reduced virus load below the detection limit in 60% of animals tested and showed a 10-fold reduction in the remaining 40% of animals.

SAN DIEGO, Sept. 28, 2020 (GLOBE NEWSWIRE) - Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") released preclinical data reporting on COVI-GUARD™ (STI-1499) and COVI-AMG™ (STI-2020; **A**ffinity **M**atured COVI-**G**uard) neutralizing antibodies (nAbs) against SARS-CoV-2 as well as a D614G virus variant infection in a preprint publication, which can be found at {https://biorxiv.org/cgi/content/short/2020.09.27.316174v1}. Both STI-1499 and STI-2020 demonstrated potent neutralizing activities against SARS-CoV-2 virus infection in preclinical models. STI-1499 nAb has been cleared by the FDA for a Phase 1 clinical trial in hospitalized COVID-19 patients. STI-2020 is an affinity-matured version of the COVI-GUARD nAb and has demonstrated a greater than 50-fold increase in potency in *in vitro* experiments.

In preclinical cell-based assay, both STI-1499 and STI-2020 have shown 100% *in vitro* neutralization of SARS-CoV-2 at concentrations of 6 µg/ml and 78 ng/ml, respectively. The neutralization activity at these concentrations protected against both SARS-CoV-2 and the highly contagious Spike D614G isolate.

Dr. Slobodan Paessler's laboratory at the University of Texas Medical Branch at Galveston (UTMB) has generated promising preclinical animal data for STI-1499 and STI-2020 nAbs in a Syrian golden hamster model infected with SARS-CoV-2. A few highlights of the data from the most recent STI-2020 study:

- Hamsters infected with SARS-CoV-2 and then treated with a single dose of 500 µg STI-2020 started gaining weight within 48 hours of STI-2020 administration, as compared to control animals that steadily lost weight for 5 days before recovery.
- At day 5, STI-2020-treated (500 µg) hamsters had gained 5% weight, versus a weight loss of about 10% for the control animals (15% difference).
- At day 5, all STI-2020-treated (500 µg) hamsters (5 out of 5 analyzed animals) had undetectable virus load in lungs as compared to the lungs of animals in the control group, where more than 1,000 infectious viral particles per gram of tissue were readily detected.

Based on interspecies allometric scaling methods, the 500 µg single dose of STI-2020 administered to the hamsters in the preclinical studies would be equivalent to a human dose of less than 100 mg of antibody (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4804402/). In contrast to other currently-used dosing regimens requiring grams of antibody per patient for treating COVID-19, this antibody could be highly potent at a very low dose. COVI-AMG could therefore potentially be administered as a simple and rapid injection to treat COVID-19 patients.

“We believe that the results for STI-1499 and STI-2020 are truly remarkable. Based on the preclinical testing we have conducted to date, STI-2020 is our most promising SARS-CoV-2 antibody so far. The potency of both nAbs and their ability to mitigate SARS-CoV-2 infection from the lungs in a Syrian golden hamster model is very impressive, strongly supporting further development of these antibodies,” stated Dr. Henry Ji, Chairman and CEO of Sorrento. “STI-1499 has been cleared by the FDA for a Phase 1 clinical trial in hospitalized COVID-19 patients. STI-2020 has the potential to be utilized for both early and late therapeutic interventions, as well as for prophylaxis, with the potential of having a low efficacious dose, which could enable efficient manufacturing and ultimately result in higher affordability for patients.”

Sorrento has received FDA clearance for its Phase 1 clinical trial for STI-1499 in hospitalized COVID-19 patients and intends to submit an IND for STI-2020 as soon as possible.

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®", “Seprehvec™”). Sorrento is also developing potential antiviral therapies and vaccines against coronaviruses, including COVIDTRAP™, ACE-MAB™, COVI-MAB™, COVI-GUARD™, COVI-SHIELD™ and T-VIVA-19™; and diagnostic test solutions, including COVI-TRACK™, COVI-STIX™, COVI-TRACE™ and COVI-AMG™.

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 ZTlido® (lidocaine topical system) 1.8% for the treatment of post-herpetic neuralgia. RTX has completed a phase 1B trial for intractable pain associated with cancer and a phase 1B trial in osteoarthritis patients. 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 blocking capabilities of STI-1499 and STI-2020 and the impact on SARS-CoV-2; the preclinical testing of STI-1499 and STI-2020; the safety and efficacy of STI-1499 and STI-2020; the expectation of the commencement of any pivotal trials for STI-1499 and STI-2020; the predictive value of the animal model used in preclinical studies; the human equivalent dose of STI-1499 and STI-2020 that may be required; the expected method of administration of STI-2020 and the expected dosage amount and rate thereof; the potential applications for STI-1499 and STI-2020; the potential of having a low efficacious dose; the potentially faster or efficient manufacturing speed, availability and potential lower cost for STI-2020; the strategic prioritization of an IND submission for STI-2020; 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 preclinical studies and seeking IND regulatory approval for STI-2020; conducting and receiving results of clinical trials for STI-1499 and STI-2020; the clinical and commercial success of STI-1499 and STI-2020 against preventing and treating SARS-CoV-2 virus infections; the viability and success of STI-1499 and 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, study and trial 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.

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