
**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): October 29, 2020

SORRENTO THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

**Delaware
(State or Other Jurisdiction
of Incorporation)**

**001-36150
(Commission
File Number)**

**33-0344842
(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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 October 29, 2020, Sorrento Therapeutics, Inc. issued a press release announcing that its affinity-matured neutralizing antibody, COVI-AMGTM nAb (STI-2099), has demonstrated in preclinical studies a neutralizing effect against SARS-CoV-2 through intranasal administration. 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 October 29, 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.

Date: October 29, 2020

SORRENTO THERAPEUTICS, INC.

By: /s/ Henry Ji, Ph.D.

Name: Henry Ji, Ph.D.

Title: Chairman of the Board, President and
Chief Executive Officer



SORRENTO ANNOUNCES THAT INTRANASAL ADMINISTRATION OF COVI-AMG™ NEUTRALIZING ANTIBODY PREVENTED COVID-19 DISEASE PROGRESSION IN INFECTED HAMSTERS FOLLOWING SARS-COV-2 INFECTION

- In an IND-enabling study, intranasal COVI-AMG nAb (STI-2099) very early on decreased COVID-19 disease severity and shortened the duration of the disease in infected hamsters, and
- Sorrento is in preparation for IND filings for both intranasal COVI-AMG nAb (STI-2099) and intravenous COVI-AMG nAb (STI-2020) in November 2020.

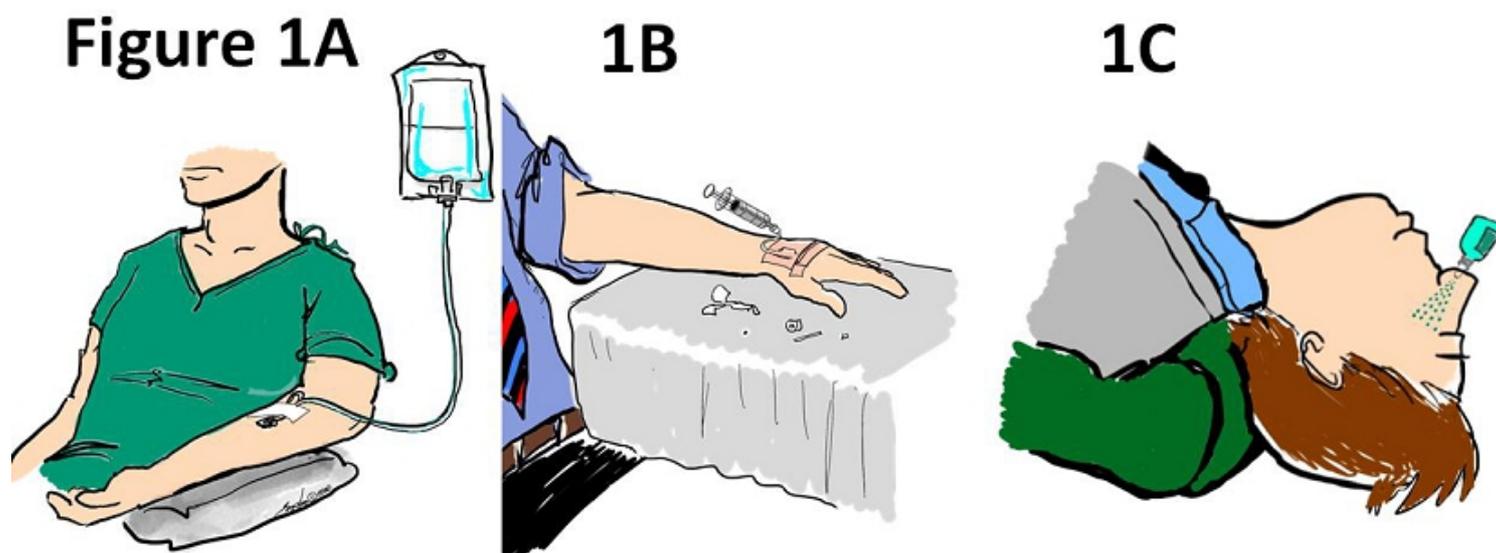
SAN DIEGO, October 29, 2020 (GLOBE NEWSWIRE) – Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”) previously released preclinical data about intravenous COVI-AMG™ (STI-2020; **A**ffinity **M**atured COVI-**G**UARD) neutralizing antibody (nAb) in a preprint publication, which can be found at <https://biorxiv.org/cgi/content/short/2020.09.27.316174v1>. Today, Sorrento announced the enhancement of the clinical potential of this antibody by releasing *in vivo* data of intranasal COVI-AMG nAb (STI-2099) in a new preprint publication, which can be found at <https://www.biorxiv.org/>.

Preclinical animal data generated at Dr. Slobodan Paessler’s laboratory at the University of Texas Medical Branch (UTMB) at Galveston in Syrian Golden hamsters infected with SARS-CoV-2 has demonstrated the following encouraging results:

- Hamsters were infected with 5×10^4 median tissue culture infectious dose (TCID₅₀) intranasally. Following infection, animals were rested for 12 hours. At that time, animals were administered a 500 ug dose of COVI-AMG nAb by either the intravenous (IV) or the intranasal (IN) route. Control animals were administered an isotype control antibody using the same IN and IV regimens.
- Intravenously-dosed animals recovered from the infection with noticeable differences in weight loss between the Control IgG and COVI-AMG-treatment groups reaching a maximum at Day-5 after infection. Remarkably, intranasally-treated animals showed evidence, as early as Day-2 into the experiment, of prevention of disease progression with limited weight loss in the very early stages of infection and reduced duration of disease symptoms as compared to COVI-AMG IV-treated animals.

“The simplicity of an intranasal administration of an extremely potent neutralizing antibody against COVID-19 would permit timely and massive access to much needed antiviral treatments. We at Sorrento are optimistic that if these findings in the COVID-19 hamster model of infection are replicated in patients with COVID-19 in planned clinical trials, we could be in a position to potentially open up society by preventing virus proliferation and spread, and potentially reduce or prevent hospitalizations or even hospital visits” stated Dr. Henry Ji, Chairman and CEO of Sorrento.

Based on interspecies allometric scaling methods, the 500 µg single dose of STI-2020 (IV) or STI-2099 (IN) administered to the hamsters in the preclinical studies would be equivalent to a human dose of approximately 45 mg of antibody (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4804402/>). Sorrento plans to investigate the intranasal formulation of STI-2099 in patients recently testing positive for COVID-19 as simple intranasal drops.



As illustrated above, current neutralization antibodies (or antibody cocktails) known to be in development or under FDA EUA approval review are administered in large amounts (often in grams) that require infusions over hours in a hospital setting (**Figure 1A**). Sorrento's intravenous COVI-AMG nAb (STI-2020) may require only an intravenous slow push due to the high potency demonstrated in animal models to date (**Figure 1B**). Furthermore, intranasal COVID-AMG (STI-2099) may be able to be administered as simple intranasal drops (**Figure 1C**), which would avoid the need for IV infusion or injection and a hospital visit for treatment.

Sorrento is in the final stages of cGMP manufacture of both forms of the antibodies and anticipates submitting IND filings for both intravenous STI-2020 and intranasal STI-2099 in November 2020. Sorrento intends to initiate studies in healthy volunteers to establish pharmacokinetics and safety, while also initiating studies in newly infected COVID-19 patients to demonstrate safety and reduction of virus load and COVID-19 symptoms.

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 COVI-AMG™; 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 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-2020 and STI-2099 and the impact on SARS-CoV-2; the preclinical testing of STI-2020 and STI-2099; the safety and efficacy of STI-2020 and STI-2099; the expectation of the commencement of any clinical trials for STI-2020 and STI-2099; the potential trial design for STI-2020 and STI-2099; the predictive value of the animal model used in preclinical studies; the human equivalent dose of STI-2020 or STI-2099 that may be required; the potential applications for STI-2020 and STI-2099; the potential of having a low efficacious dose; the potentially faster or efficient manufacturing speed, availability and potential lower cost for STI-2020 and STI-2099; the expected methods of administration of STI-2020 and STI-2099; the expected timing for submitting IND filings for STI-2020 and STI-2099; 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 and STI-2099; conducting and receiving results of clinical trials for STI-2020 and STI-2099; the clinical and commercial success of STI-2020 and STI-2099 against preventing and treating SARS-CoV-2 virus infections; the viability and success of STI-2020 and STI-2099 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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Contact

Alexis Nahama, DVM (SVP Corporate Development)
Email: mediarelations@sorrentotherapeutics.com

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