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 8, 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 8, 2020, Sorrento Therapeutics, Inc. issued a press release announcing that it received a Clinical Laboratory Improvement Amendments (CLIA) license from the State of California for clinical sample testing. 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 8, 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 8, 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 8th, 2020

SORRENTO RECEIVES LICENSURE FROM THE STATE OF CALIFORNIA FOR CLINICAL TESTING LABORATORY (CLIA) ALLOWING FOR CLINICAL SAMPLE TESTING

- Sorrento receives Clinical Laboratory Improvement Amendments (CLIA) license from the State of California for clinical sample testing
- Sorrento intends to initially offer three diagnostic tests for SARS-CoV-2 infection:
  - RT-PCR Emergency Use Authorization (EUA)-approved test using nasal pharyngeal swab
  - Laboratory developed test (COVI-STIX™) using shallow nasal swab
  - Laboratory developed test (COVI-TRACE™) using shallow nasal swab

SAN DIEGO, December 8th, 2020 /GlobeNewswire/ -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced today that it has received CLIA Licensure from the State of California that permits testing of clinical samples. The Company intends to initially focus on testing for SARS-CoV-2 infection but expects to expand to include immuno-oncology tests to support its clinical trials.

Sorrento expects to establish field sites for the collection of samples and initially intends to offer three independent tests for SARS-CoV-2 infection:

- A standard RT-PCR EUA-approved test with immediate processing and results are generally reported within three hours of sample testing.
- A laboratory developed rapid lateral flow antigen test (COVI-STIX) for nasal swab specimens that has, to date, demonstrated comparable sensitivity and specificity to the RT-PCR EUA-approved test. The COVI-STIX test is expected to provide a qualitative result within 20 minutes.
- A laboratory developed High-Performance Loop-mediated isothermal amplification (HP-LAMP) test for detection of viral RNA (COVI-TRACE) in shallow nasal swab specimens. The COVI-TRACE test is expected to provide a qualitative result within 30 minutes.

Sorrento intends to provide test reports for its COVI-STIX and COVI-TRACE tests to patients within an hour of test completion. In parallel, Sorrento continues to generate the data required for EUA applications for the COVI-STIX and COVI-TRACE tests and anticipates submitting the applications shortly.

"The addition of a CLIA-licensed laboratory will allow Sorrento to commence generating revenues from clinical sample testing," stated Dr. Henry Ji, Chairman and CEO of Sorrento. "The ability to analyze clinical samples from our ongoing and future clinical trials in-house rather than out-sourcing to other CLIA facilities may also result in accelerated turn-around time, increased flexibility and potentially, significant direct savings."

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™ 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 expectation that Sorrento will initially offer three diagnostic tests for SARS-CoV-2 infection, including the RT-PCR EUA approved test, COVI-STIX and COVI-TRACE; the potential use and availability for distribution of the RT-PCR EUA approved test, COVI-STIX and COVI-TRACE; the expected timing for generating and reporting test results; expanding the clinical testing laboratory to include immuno-oncology tests to support Sorrento's clinical trials; establishing field sites for the collection of testing samples; the anticipated timing for completing EUA submissions for COVI-STIX and COVI-TRACE; the potential receipt of any EUA for COVI-STIX or COVI-TRACE; the potential for Sorrento to generate revenue from clinical sample testing from a CLIA laboratory; the potential for Sorrento's CLIA laboratory to accelerate turn-around time for testing of clinical samples from Sorrento's clinical trials, to increase flexibility or to result in any direct savings; and Sorrento's potential position in the diagnostic testing 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 establishing a CLIA laboratory; Sorrento's and its subsidiaries', affiliates' and partners' technologies and prospects and collaborations with partners, including, but not limited to risks related to conducting pre-clinical studies and seeking EUA regulatory approvals for COVI-TRACE and COVI-STIX, including the timing for such regulatory approvals; conducting and receiving results of clinical trials; 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
Alexis Nahama, DVM (SVP Corporate Development)
Email: mediarelations@sorrentotherapeutics.com

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