
**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): November 27, 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 November 27, 2020, Sorrento Therapeutics, Inc. (the “Company”) issued a press release announcing that SmartPharm Therapeutics, Inc., a wholly-owned subsidiary of the Company, was awarded a contract from the Defense Advanced Research Projects Agency (DARPA), co-funded by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), to develop a rapid countermeasure to COVID-19 using gene-encoded neutralizing antibodies. 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 November 27, 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: November 27, 2020

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



FOR IMMEDIATE RELEASE

November 27, 2020

DARPA AND JPEO AWARD CONTRACT TO SMARTPHARM, A SUBSIDIARY OF SORRENTO, FOR DEVELOPMENT OF RAPID COUNTERMEASURE AGAINST COVID-19 USING GENE-ENCODED NEUTRALIZING ANTIBODIES

- Initial funding of up to \$34 million for the project “Gene Mabs: A Scalable, Economic, Gene-Encoded Protective Antibody Platform Against Coronavirus” (HR0011-21-9-0015) to support the development of an STI-2020-encoded Gene MAbTM through Phase 2 clinical studies.
- STI-2020-encoded Gene MAb is in development for intramuscular injection against the SARS-CoV-2 virus and its variant strains to produce potent STI-2020 nAbs in the body.
- STI-2020-encoded Gene MAb products can potentially be stored at refrigerator temperatures, avoiding some of the cold chain management challenges associated with the deployment of COVID-19 vaccines currently in development.
- Sorrento has a cGMP facility in place to meet initial production demand and Sorrento expects that STI-2020-encoded Gene MAb can be produced in large quantity to meet potentially high demand.

SAN DIEGO, November 27, 2020 (GLOBE NEWSWIRE) – SmartPharm Therapeutics, Inc. (“SmartPharm”), a wholly-owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE, “Sorrento”), and developer of next-generation, non-viral gene therapy technologies, announced today that it has been awarded a contract from the Defense Advanced Research Projects Agency (DARPA) co-funded by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) to develop a rapid countermeasure to COVID-19. The contract would provide SmartPharm up to USD \$34 million for development through Phase 2 clinical studies of a gene-encoded antibody (“Gene MAb”) that could enable rapid protection from and/or treatment of SARS-CoV-2 infection and COVID-19. Sorrento will seek further funding in support of the COVID Gene MAb program toward EUA (emergency use authorization) approval and large-scale manufacturing pending successful clinical studies.

For this Gene MAb approach, the SmartPharm/Sorrento team will produce plasmid DNA encoding the SARS-CoV-2 neutralizing antibody STI-2020 (COVI-AMGTM). The FDA is currently reviewing IND filings for STI-2020 as an IV-delivered neutralizing antibody and STI-2099 as an intranasal-delivered neutralizing antibody for the treatment of COVID-19. The expected higher potency of the STI-2020 antibody makes it an ideal candidate for Gene MAb delivery against COVID-19.

The DARPA/JPEO contract supports the accelerated development of a Gene MAb’s neutralizing antibody that can be delivered by a simple intramuscular injection, enabling the recipient to produce the protective antibody, potentially within days of the injection. Such an approach would permit the rapid translation of fully characterized potent neutralizing antibodies into clinical use, which Sorrento believes will be important for responding to potential mutations of SARS-CoV-2 that may emerge. It would also enable broader deployment of the Gene MAb approach as a prophylactic solution, as it can be conveniently administered into the muscle like an annual flu vaccine. If successful, it could provide an alternative method of protecting populations where vaccines do not work as well, such as the elderly or immunocompromised.

Dr. Henry Ji, CEO of Sorrento, commented, “We are excited that DARPA and JPEO have recognized our Gene MAb platform as a potential rapid countermeasure for COVID-19 and the potential value for other applications to combat future viral diseases of pandemic potential. We acquired SmartPharm with the vision of combining the power of our antibody and biologic therapies for cancer and infectious diseases with next-generation gene-encoded technologies. We look forward to working with our Department of Defense partners to potentially add a novel approach to the arsenal of solutions for combating this devastating disease.”

DARPA, founded in 1958, is an agency of the U.S. Department of Defense. Through collaborations with academic, industry, and government partners, DARPA makes investments across multiple sectors to drive breakthrough technologies for U.S. national security. Through the collaboration with JPEO-CBRND, this work is supported by the Office of the Assistant Secretary of Defense for Health Affairs with funding from the Defense Health Agency.

About SmartPharm Therapeutics

SmartPharm Therapeutics, Inc., a wholly owned subsidiary of Sorrento Therapeutics, Inc. (Nasdaq: SRNE), is a development stage biopharmaceutical company focused on developing next-generation, non-viral gene therapies for the treatment of serious or rare diseases with the vision of creating “biologics from within.” SmartPharm is currently developing a novel pipeline of non-viral, gene-encoded proteins for the treatment of conditions that require biologic therapy such as enzyme replacement and tissue restoration. SmartPharm commenced operations in 2018 and is headquartered in Cambridge, MA, USA. For more information, please visit www.smartpharmtx.com.

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 1B 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 aggregate amount of funding available pursuant to the DARPA contract; the development of a Gene MAb against SARS-CoV-2 infection and COVID-19; the expectation of the commencement of any clinical trials for a Gene MAb, including phase 2 clinical studies; the potential for a Gene MAb to provide rapid protection and/or treatment of SARS-CoV-2 infection and COVID-19; the potential potency and potential neutralizing profile of STI-2020 and its impact on COVID-19; the potential potency and potential neutralizing profile of STI-2099 and its impact on COVID-19; the expected administration of STI-2020 and STI-2099; the potential for STI-2020 to be an ideal candidate for gene-mediated delivery; the potential administration method of a Gene MAb neutralizing antibody; the potential ability of a recipient of a Gene MAb neutralizing antibody to produce protective antibodies; the expected timing for a recipient of a Gene MAb neutralizing antibody to begin producing protective antibodies; the ability of a Gene MAb platform to translate recognized neutralizing antibodies into clinical use; the potential for a Gene MAb neutralizing antibody approach to COVID-19 to be used as a prophylactic solution; the potential for a Gene MAb neutralizing antibody to provide an alternative method of protection against SARS-CoV-2 and COVID-19; the potential for a Gene MAb platform to be used with future viral diseases; the potential for Gene MAb products to be stored at room temperature and/or in refrigeration to avoid cold chain management concerns; the potential for Sorrento's cGMP facility to meet initial production demand; the potential for Sorrento to mass produce sufficient quantities of STI-2020-encoded Gene MAb to meet demand; the ability of Sorrento to combine its antibody and biologic therapies with SmartPharm's gene-encoded technologies; 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 technologies and prospects with newly acquired technologies, including the acquisition of SmartPharm and the utilization of SmartPharm's Gene-Encoded Therapeutics (GET) platforms for the treatment and prevention of coronavirus infections and other pathogens and cancer cells; risks related to seeking regulatory approvals and conducting clinical trials; the clinical and commercial success of the treatment and prevention of coronavirus infections using gene-encoded antibodies; the viability and success of using gene-encoded antibodies for treatments 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 prior study and trial results may not be replicated in future studies and trials; 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 related to seeking regulatory approvals and conducting clinical 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 candidate 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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Media and Investor Relations

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