
**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 12, 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 1.01. Entry into a Material Definitive Agreement.

On October 12, 2020, Sorrento Therapeutics, Inc. (the “Company”) entered into a license agreement (the “License Agreement”) with Personalized Stem Cells, Inc. (“PSC”). Pursuant to the License Agreement, among other things, PSC granted the Company an exclusive license and right under certain patents, certain know-how and other intellectual property to fully utilize, exploit and commercialize certain products and services using allogeneic adipose-derived stem cells for or in respect of human health, including the diagnosis and treatment and/or cure of any human disease or disorder (excluding commercial sales for the diagnosis, treatment and/or cure of SARS-CoV-2 or other respiratory diseases in the People’s Republic of China) worldwide (excluding the People’s Republic of China for products directed at COVID-19 or other respiratory diseases). PSC also agreed to transfer certain cell lines composed of stromal vascular cells, master cell banks and finished final drug lots (the “Product Materials”) to the Company. The Company agreed to grant PSC rights to use data derived by the Company from a certain Phase 1 COVID-19 study for PSC’s own programs that are not competitive with the businesses or activities of the Company, and for PSC to sublicense such data to third parties for research, development and regulatory purposes.

As consideration for the license under the License Agreement, the Company has agreed to pay PSC an upfront license fee of \$3.5 million in cash.

The Company also agreed to pay PSC (i) a milestone payment upon the issuance of a regulatory approval, and (ii) certain milestone payments upon PSC’s manufacture and delivery of the Product Materials to the Company.

The Company will also pay royalties in the low-single digit percentages of annual net sales of licensed products and services by the Company and a share of any sublicense revenue received by the Company from sublicensees.

The foregoing summary of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement. A copy of the License Agreement will be filed with the Securities and Exchange Commission (the “SEC”) as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2020 (the “Form 10-K”) or via an amendment to this Current Report on Form 8-K. Certain terms of the License Agreement have been omitted from this Current Report on Form 8-K and will be omitted from the version of the License Agreement to be filed as an exhibit to the Form 10-K or via an amendment to this Current Report on Form 8-K pursuant to Item 601(b)(10) of Regulation S-K because such terms are both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

The representations, warranties and covenants contained in the License Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to the License Agreement, and may be subject to limitations agreed upon by the contracting parties. Accordingly, the License Agreement is incorporated herein by reference only to provide investors with information regarding the terms of the License Agreement, and not to provide investors with any other factual information regarding the Company or its business, and should be read in conjunction with the disclosures in the Company’s periodic reports and other filings with the SEC.

Item 8.01. Other Events.

On October 12, 2020, the Company issued a press release announcing its entry into the License Agreement. 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) Exhibits.

[99.1](#) [Press Release, dated October 12, 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: October 13, 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

October 12, 2020

SORRENTO ADDS MESENCHYMAL STEM CELL PROGRAM (MSC) THAT HAS BEEN CLEARED FOR A PHASE 1 TRIAL BY THE FDA TO THE PIPELINE OF COVID-19 FOCUSED RESCUE THERAPIES

SAN DIEGO, October 12th, 2020 /GlobeNewswire/ -- Sorrento Therapeutics, Inc. (Nasdaq: SRNE, "Sorrento") announced today that it has entered into an exclusive license agreement with Personalized Stem Cells, Inc. (PSC) to acquire global rights to its adipose derived mesenchymal stem cells (MSCs) for patients suffering from acute respiratory distress syndrome (ARDS) associated with COVID-19, which have been cleared for a Phase 1 clinical trial by the FDA.

The study is a single arm, non-randomized Phase 1 study of the safety and preliminary efficacy of an adipose-derived allogeneic MSC product candidate. The outcome data will be compared to contemporaneous non-enrolled patients at the same clinical site(s) as the enrolled patients. The primary objective is to evaluate the safety of intravenous infusion of allogeneic adipose stem cells in patients with COVID-19 and in respiratory distress. The secondary objective is to evaluate a set of safety and efficacy outcome variables to give guidance regarding the risk/benefit ratio in patients with COVID-19 respiratory distress.

More information on the Phase 1 trial can be found at:

<https://clinicaltrials.gov/ct2/show/NCT04486001?term=coronastem&draw=2&rank=1>

Sorrento will be assuming responsibility for executing the Phase 1 trial, which is targeted to enroll about 20 hospitalized COVID-19 patients in California. Pending the results of the Phase 1 trial, Sorrento expects to expand into Phase 2 trials in multiple relevant geographies as may be determined in consultation with applicable regulatory authorities.

Stem cells have been demonstrated to support resolution of symptoms in multiple disease settings and have the potential to reduce the long-term effects associated with pulmonary tissue damage for these patients. More information on the potential use and benefits of MSCs for patients with COVID-19 can be found in the recently published review at:

<https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-020-02380-2>

Stem cells represent a treatment modality with high potential to help in the fight against COVID-19 as a stand-alone therapy or in synergy with other product candidates in Sorrento's pipeline, including small molecules (abivertinib or salicyn-30) and neutralizing antibodies (STI-1499 or STI 2020).

Until a time where early treatments are more readily available, it is important to provide patients severely afflicted with COVID-19 multimodal solutions that can help increase survival, reduce the time spent in the hospital and reduce long-term sequelae. The long-term lingering effects of COVID-19 on the body can persist for months after patients leave the hospital, especially for patients that received ventilator support. Shortness of breath, difficulty doing simple tasks and pulmonary fibrosis are among the common complaints of long-term effects of the disease on COVID-19 patients leaving the ICU.

Dr Robert Harman, CEO of PSC stated, "We are delighted to be working with a company such as Sorrento, that has the vision and expertise to take our program through the next steps in the clinical development process. Sorrento saw the translational value of our decades of work in animal health and has acknowledged the extensive manufacturing and regulatory work we have done in bringing human cell lines to a Phase 1 FDA clearance. We are looking forward to collaborating on this initiative and beyond".

Dr Henry Ji, Chairman and CEO of Sorrento stated, "Stem cells were a missing piece in our comprehensive portfolio of potential solutions against COVID-19. We now cover multiple stages of the continuum of care from prevention to potential therapeutic solutions for the most advanced stages of the disease. With PSC's Phase 1 product candidate, we hope to move quickly through the next clinical trials, and, if successful, be able to provide a supportive therapy that may save the lives of the most advanced patients and may also ensure patients who have to undergo intensive care can benefit from a therapy with the potential to minimize the long-term effects of the disease due to the lung damage created by the virus early in the infection".

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to treat cancers and COVID-19. 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™, COVI-AMG™ and T-VIVA-19™; 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 IB trial for intractable pain associated with cancer and a phase IB 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 safety and efficacy of an adipose-derived allogeneic MSC product in patients with COVID-19 and in respiratory distress; the clinical testing of an adipose-derived allogeneic MSC product; the expected enrollment of the Phase 1 trial; the potential commencement of any future clinical trials for an adipose-derived allogeneic MSC product; the ability of an adipose-derived allogeneic MSC product to work as a stand-alone therapy or in synergy with our other product candidates; the ability of an adipose-derived allogeneic MSC product to support healing and reduce the long-term effects associated with pulmonary tissue damage for COVID-19 patients; our ability to provide a supportive therapy for COVID-19 patients using an adipose-derived allogeneic MSC product; the ability of an adipose-derived allogeneic MSC product to potentially save lives of COVID-19 patients and to potentially minimize the long-term effects of COVID-19; our ability to cover all stages of the continuum of care for COVID-19; and our 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 seeking regulatory approval for any adipose-derived allogeneic MSC product; 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 Sorrento 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

Contact: Alexis Nahama, DVM (SVP Corporate Development)

Telephone: 1.858.203.4120

Email: mediarelations@sorrentotherapeutics.com

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