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): January 22, 2019

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))

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 7.01. Regulation FD Disclosure.

On January 22, 2019, Sorrento Therapeutics, Inc. (the "Company") issued a press release announcing interim results for the Company's Phase 1b study of its non-opioid, afferent nerve ablating drug candidate (resiniferatoxin or RTX) for the treatment of pain from osteoarthritis in the knee (intra-articular route of administration). A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01 and Exhibit 99.1 furnished as part of Item 9.01 of this Current Report on Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release dated January 22, 2019.

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: January 22, 2019

By: /s/ Henry Ji, PhD.
Name: Henry Ji, Ph.D.
Title: President and Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

January 22, 2019

SORRENTO THERAPEUTICS ANNOUNCES INTERIM RESULTS IN OSTEOARTHRITIS KNEE PAIN PHASE 1B TRIAL OF RESINIFERATOXIN WITH POSITIVE THERAPEUTIC SIGNAL AND ABSENCE OF DOSE LIMITING TOXICITIES. PIVOTAL TRIALS TARGETED TO START LATER 2019.

SAN DIEGO, January 22nd, 2019 /GlobeNewswire/ -- SAN DIEGO – Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced that the phase 1b study of its non-opioid, afferent nerve ablating drug candidate (resiniferatoxin or "RTX") for the treatment of pain from osteoarthritis in the knee (intra-articular route of administration) interim data analysis of over 30 patients had positive activity, prompting Sorrento to start planning pivotal studies to start in 2019.

- **Rapid onset of pain relief (day following injection) and sustained clinical benefits (84 days) at the lowest dose tested.**
- **Pain at walking (10 points Womac scale) reduced by 4.7 points versus control at day 84.**
- **No dose limiting toxicities, nor adverse events of interest noted for any dose group**.

The "Phase 1b double-blind study to assess the safety and preliminary efficacy of intra-articular administration of resiniferatoxin versus placebo for the treatment of pain due to moderate to severe osteoarthritis of the knee" was expected to recruit about 40 patients in 5 dose level cohorts or until a maximum tolerated dose (MTD) was reached. In each cohort six patients received intra-articular RTX and two received a saline control (placebo arm).

No dose limiting toxicities have been observed to date at any dose group (see table 1) and a majority of the patients treated with the active drug are reporting positive clinical benefits in pain reduction.

The lowest dose cohort treated with a single injection into the knee joint (with 5 mcg RTX) was unblinded after twelve weeks of observation as authorized per protocol. The RTX treated patients had a mean pain score 4.7 points lower than controls (on the 10 point WOMAC pain scale) at Day 84 (see figure 1). Onset of pain reduction was as early as the day following drug administration and sustained over time. Patients in higher dose groups are also displaying rapid and sustainable improvements (data still blinded). As specified in the current protocol, patients will be monitored for 12 months after injection. A clinically effective dose will be determined by the end of the current study.

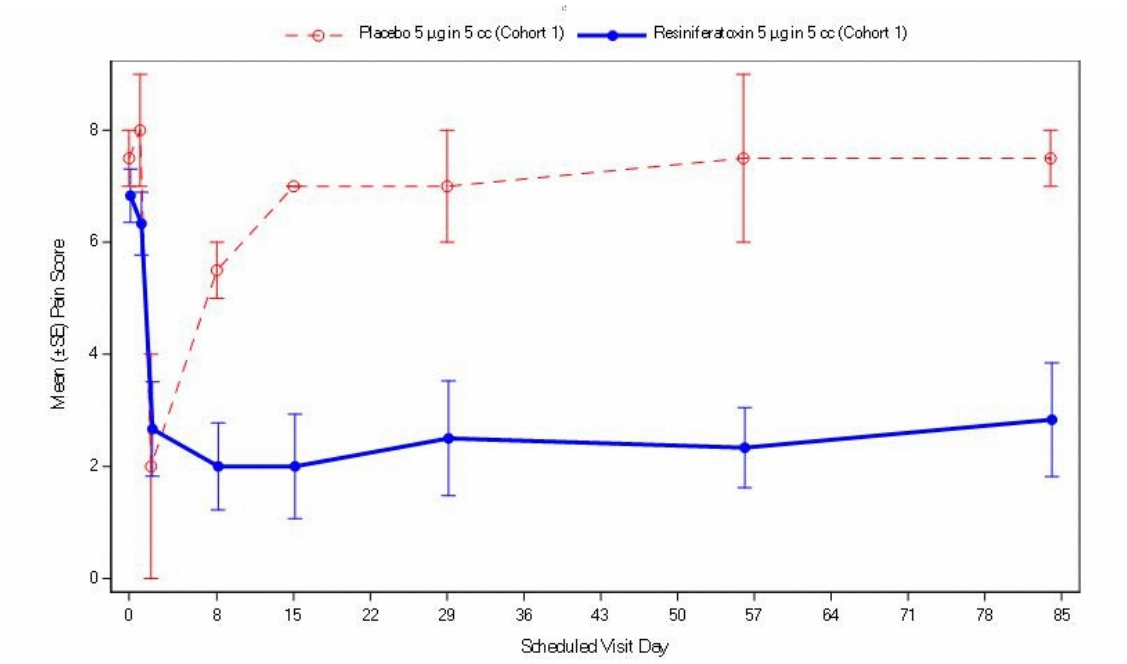
"Given these initial results and the feedback from our investigators, we have started the process of planning our pivotal studies so they can be initiated later this year (2019)" stated Dr. Henry Ji, Chairman and CEO for Sorrento. "We believe this drug has the potential to rival the best selling non-opiod pain drugs on the market, and make Sorrento an industry leader in non-opioid pain management. We look forward to discussing our phase 1b data with the FDA and plan the final phase of our RTX knee osteoarthritis pain development "program".

Table 1: Safety Report as of January 2019

Cohort (escalation)	RTX Dose (mcg)	# Subjects	Current status	Blinding status	DMC assessment	Notable AE's
1	5 ug	6 + 2	Enrolled	Unblinded	No DLT's	None
2	12.5 ug	6 + 2	Enrolled	Blinded	No DLT's	None
3	12.5 ug (in 10ml)	6 + 2	Enrolled	Blinded	No DLT's	None
4	20 ug	1	Enrolled	Open	No DLT's	None
		5+2	Enrolling	Blinded	Pending	Pending

** DLT = dose limiting toxicity. AE = adverse event.*

Figure 1: Womac Question A1 Pain Score Averages (Treated versus Saline Control) – Cohort 1 (5 ug).



About Resiniferatoxin (RTX) and the PTVA-OA-001 Study

Joint pain affects over 30 million patients in major markets, half of which suffer from knee osteoarthritis pain[1].

A thousand times "hotter" than pure capsaicin (16 Billion Scoville units versus 16M), and with a high affinity for afferent pain nerves, resiniferatoxin binds to TRPV1 receptors and selectively ablates the nerve endings responsible for pain signals experienced by patients[2]. Delivered peripherally (into the joint space) the transient nerve ending ablation effect can have profound clinical benefits lasting for months to years (as shown in canine studies[3]).

PTVA-OA-001 is a multicenter, placebo-controlled phase 1b study (being expanded into a phase 2 study) to assess the safety and define the maximally tolerated dose of resiniferatoxin administered in the knee joint for the reduction of moderate to severe pain signal intensity associated with osteoarthritis. The study is a dose-escalation protocol in which cohorts of patients will receive increasing doses of resiniferatoxin until the maximum tolerated dose (MTD) is achieved. The primary objective of the study is to evaluate the safety of resiniferatoxin and identify the recommended phase 2 dose. The secondary objective is to assess the preliminary efficacy of resiniferatoxin measured by assessing changes in the intensity of pain using the WOMAC Index, a widely used proprietary validated pain questionnaire.

Resiniferatoxin is not approved by regulatory authorities. Safety and efficacy have not been established.

More information on this trial can be found at www.clinicaltrials.gov (NCT03542838).

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. 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"), intracellular targeting antibodies ("iTAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Seprehvir®").

Sorrento's commitment to life-enhancing therapies for patients is also demonstrated by its 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. Resiniferatoxin is completing a phase IB trial in terminal cancer patients and a phase 1B trial in osteoarthritis patients. ZTlido® was approved by the FDA on February 28, 2018.

---

[1] GlobalData Epicast (2017 report) states for year 2016: 17M cases of symptomatic hand OA (7 Major Markets, 7.6M in the USA) + 15.2M symptomatic Knee OA (4.4M in the US) + 3.34M symptomatic hip OA (1.7M in the US).

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC398431/

[3] Sorrento Therapeutics (Ark Animal Health) internal data (on file).

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 expectations for Sorrento's and its subsidiaries' technologies and product candidates, including, but, not limited to, resiniferatoxin (RTX). 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' technologies and prospects, including, but not limited to, RTX; risks related to seeking regulatory approvals and conducting and obtaining results of clinical trials, including, but not limited to, the PTVA-OA-001 study or trial and any prior RTX studies in animals; the clinical and commercial success of RTX; the viability and success of using RTX for treatments in certain therapeutic areas, including osteoarthritis (OA) 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, 2017, 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.

# # #

Media and Investor Relations

Contact: Alexis Nahama, SVP Corporate Development

Telephone: 1.858.203.4120

Email: mediarelations@sorrentotherapeutics.com

# # #