Sorrento Therapeutics, Inc.

4955 Directors Place
San Diego, CA 92121

Form 8-K

Date of Report (Date of earliest event reported): August 29, 2017
Item 7.01. Regulation FD Disclosure.

On August 29, 2017, Sorrento Therapeutics, Inc. (the “Company”) issued a press release announcing that Scilex Pharmaceuticals Inc., a majority-owned subsidiary of the Company, resubmitted the new drug application and responded to all of the U.S. Food and Drug Administration’s comments related to the initial new drug application submission for its lead product candidate, ZTlido™ (lidocaine patch 1.8%). 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.

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: August 29, 2017

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

Name: Henry Ji, Ph.D.
Title: Chairman of the Board, President and Chief Executive Officer
SORRENTO THERAPEUTICS, INC. SUBMITS NDA FOR ZTLIDO™ NEXT GENERATION LIDOCAINE PATCH

SAN DIEGO, August 29, 2017 /PRNewswire/ -- SAN DIEGO, Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced today that SCILEX Pharmaceuticals Inc. ("SCILEX"), a majority-owned subsidiary of Sorrento, resubmitted the NDA and responded to all of FDA comments related to the initial NDA submission for its lead product candidate, ZTlido™ (lidocaine patch 1.8%).

ZTlido is a next-generation non-opioid, lidocaine patch currently in development for the relief of pain associated with post-herpetic neuralgia ("PHN"), a severe neuropathic pain condition.

ZTlido anhydrous patch is based on a novel and proprietary technology that delivers bioequivalent levels of lidocaine to Lidoderm® (lidocaine patch 5%), which has been confirmed in two separate clinical studies. Scilex has also confirmed bioequivalence between ZTlido and Versatis® (lidocaine medicated plaster 5%), which is the European brand name for the comparator product. A clinical adhesion study demonstrated that greater than 90% of the subjects had greater than 90% adhesion over the 12-hour administration period using an FDA recommended 5-point scale. In a separate clinical study, ZTlido demonstrated strong adhesive properties even during moderate exercise with no meaningful impact on pharmacokinetics.

The novel technology allows ZTlido to achieve the ability to deliver a bioequivalent therapeutic dose of lidocaine for the treatment of PHN pain, but does so with a drug load of 36 mg/patch versus 700 mg/patch for Lidoderm and Versatis. This biopharmaceutic efficiency leads to an approximate 30-fold reduction in residual drug in ZTlido after use compared to Lidoderm and Versatis, which can significantly reduce safety risks to children and pets, and presents less drug waste entering the environment when discarded after use.

"We are excited about the opportunity to bring to the market a product that will adhere during the full prescribed treatment period as well as be able to be worn during exercise" said Anthony Mack, President of SCILEX Pharmaceuticals. “As a company, our desire is to help patients by developing better products to treat pain."

“The state-of-the-art manufacturing technology used for ZTlido production enables high drug delivery efficiency with strong adhesive properties. The thought behind this lidocaine patch product exemplifies Sorrento’s commitment to bringing life-enhancing therapies to patients in need.” said Dr. Henry Ji, Chairman and CEO of Sorrento.
If the NDA is accepted by the FDA, the review clock could be six-months. If approved, ZTlido could be ready for commercial launch in the US in 2018.

The Company intends to submit a marketing authorization application for ZTlido in Europe in the fourth quarter of this year. Total 2016 sales of currently approved prescription lidocaine patches in the US and Europe were approximately $750 million and we expect ZTlido to be a significant player in the market.

A teleconference call to answer questions about this important announcement will be set-up in the upcoming weeks. Details will be separately communicated for time and call-in number.

**About SCILEX Pharmaceuticals Inc.**

SCILEX, a majority-owned subsidiary of Sorrento Therapeutics located in San Diego, California, leverages on its core, proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage critical conditions and maximize the quality of life of patients and healthcare providers. We are uncompromising in our focus to become the global pharmaceutical leader committed to social, environmental, economic, and ethical responsibility. Leveraging on our global partnerships, we deliver the next generation of trailblazing products that are responsible by design. The Company's lead product under development, ZTlido™ (lidocaine patch 1.8%), is a branded lidocaine patch formulation for the treatment of relieving the pain of post-herpetic neuralgia, also referred to as after-shingles pain. For more information visit www.scilexpharma.com.

**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 (“Sephrevir®”).

Sorrento's commitment to life-enhancing therapies for cancer patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin (“RTX”) and ZTlido. Resiniferatoxin is completing a phase IB trial in terminal cancer patients. ZTlido is in regulatory review following NDA re-submission.

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. and its subsidiaries under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the clinical data for ZTlido, the safety profile and other benefits of ZTlido, the filing of an MAA for ZTlido, the potential approval, including timing, of the NDA for ZTlido, the timing of commercial launch for ZTlido, ZTlido’s ability to be a player in the market, Scilex’s prospects, Sorrento’s strategy and other forward-looking statements. 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: that ZTlido may not meet all endpoints of the clinical study, that the data may not support an MAA filing 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, 2015, as amended. 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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ZTlido™ and G-MAB™ are trademarks owned by Scilex Pharmaceuticals, Inc. and Sorrento, respectively.

Seprehvir®, is a registered trademark of Virttu Biologics Limited, a wholly-owned subsidiary of TNK Therapeutics, Inc. and part of the group of companies owned by Sorrento Therapeutics, Inc.

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