Sorrento Therapeutics, Inc.

Form 8-K

Report Date: September 12, 2017

Address: 4955 Directors Place
San Diego, CA 92121

Telephone Number: (858) 203-4100

Emerging Growth Company: No

No new or revised financial accounting standards.

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.

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Item 7.01.  Regulation FD Disclosure.

On September 12, 2017, Sorrento Therapeutics, Inc. (the “Company”) issued a press release announcing that Scilex Pharmaceuticals Inc., a majority-owned subsidiary of the Company, has received from the U.S. Food and Drug Administration (the “FDA”) acknowledgement of receipt of its recently resubmitted new drug application submission (the “NDA”) for its lead product candidate, ZTlido™ (lidocaine patch 1.8%), which has been considered a complete, class 2 response to the prior action letter. In the press release, the Company also announced that the Prescription Drug User Fee Act goal date for completion of the FDA’s review of the NDA has been set for February 28, 2018, which is the standard six-month review period for a class 2 response. 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: September 12, 2017

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

Name: Henry Ji, Ph.D.
Title: Chairman of the Board, President and Chief Executive Officer
FDA ACKNOWLEDGES RECEIPT OF SORRENTO THERAPEUTICS INC, NDA FOR ZTLIDO™. PDUFA DATE SET FOR FEBRUARY 28, 2018.

SAN DIEGO, September 12, 2017 /PRNewswire/ -- SAN DIEGO, - Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced today that SCILEX Pharmaceuticals Inc. ("SCILEX"), a majority-owned subsidiary of Sorrento, has received from the U.S. Food and Drug Administration ("FDA") acknowledgement of receipt of its recently resubmitted New Drug Application ("NDA") for ZTlido™ (lidocaine patch 1.8%) which has been considered a complete, class 2 response to the prior action letter.

The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA’s review of the SCILEX NDA is set for February 28, 2018, which is the standard six-month review period for a class 2 response.

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 timing of the review of the NDA for ZTlido, 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 the review of the NDA may not proceed in a timely manner 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, 2016, 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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Media and Investor Relations

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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.

All other trademarks are the property of their respective owners.

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