Sorrento Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware 001-36150 33-0344842
(State or other jurisdiction of (Commission IRS Employer
incorporation or organization) File Number) Identification No.)

6042 Cornerstone Ct. West, Suite B
San Diego, CA 92121
(Address of principal executive offices)

Registrant’s telephone number, including area code: (858) 210-3700

(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 communication 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))
Item 8.01 Other Events.

On March 31, 2014, Sorrento Therapeutics, Inc. (the “Company”) issued a press release announcing that the first patient has been dosed in the Company’s pivotal clinical trial designed to support approval of Cynviloq for the treatment of metastatic breast cancer and non-small cell lung cancer. The Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 8.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference in any registration statement filed under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

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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.

Dated: April 1, 2014

SORRENTO THERAPEUTICS, INC.

By:  /s/ Richard Vincent
     Name: Richard Vincent
     Title: Chief Financial Officer, EVP and Secretary
Sorrento Announces First Patient Dosed in Registration Trial to Evaluate Bioequivalence Between Cynviloq and Abraxane

San Diego, CA – March 31, 2014 – Sorrento Therapeutics, Inc. (NASDAQ: SRNE; Sorrento), a late-stage clinical oncology company developing new treatments for cancer and associated pain, today announced that the first patient has been dosed in the pivotal clinical trial designed to support approval of Cynviloq for the treatment of metastatic breast cancer and non-small cell lung cancer.

The registration trial referred to as TRIBECA™ (TRIal designed to evaluate BioEquivalence between Cynviloq™ and Abraxane®; clinicaltrials.gov identifier: NCT02064829) is an open-label, randomized, multi-center, single-dose, crossover registration study being conducted at clinical sites across the U.S., EU, and Singapore. A projected 100 patients with metastatic or locally recurrent breast cancer will be administered 260 mg/m² of Cynviloq or 260 mg/m² of Abraxane using a 30 minute infusion in a crossover design to compare the bioequivalence of both drugs. Based on the End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) in July 2013, this trial was designed to gain marketing approval for Cynviloq under the 505(b)(2) regulatory pathway in the U.S. Sorrento expects to file a New Drug Application with the FDA in the first half of 2015.

“The initiation of the TRIBECA trial represents a very important milestone in the development of Cynviloq as well as in the progression of our pipeline,” said Henry Ji, PhD, President and CEO of Sorrento.

“Cynviloq has already demonstrated bioequivalence in our animal studies, and we believe it has commercially-beneficial administration and storage properties compared to Abraxane,” said Vuong Trieu, Ph.D., CSO of Sorrento and co-inventor of Abraxane. “We are particularly pleased with the response shown by investigators who have exhibited strong interest in participating in this clinical trial.”

Lee Schwartzberg MD, Medical Director of the West Clinic said, “As a breast cancer investigator, I am excited about participating in the TRIBECA trial. Patients are always in need of new options to treat their cancer, and Cynviloq could be a very important addition to our treatment armamentarium.”

About Cynviloq™

Cynviloq (IG-001 or Genexol-PM®; a paclitaxel-loaded micellar diblock copolymer) is a next-generation branded paclitaxel formulation for the potential treatment of metastatic breast cancer, non-small cell lung cancer, pancreatic cancer, and other solid tumors. In July 2013, the FDA Division of Oncology Products 1 agreed that the 505(b)(2) BE approach is the appropriate regulatory pathway, using Abraxane® and Taxol® as the Reference Listed Drugs, to obtain approval. Sorrento initiated the single bioequivalence trial required for registration, on March 31, 2014.
Sorrento has exclusive distribution rights to Cynviloq™ in the U.S., the 27 countries of the European Union, Mexico, Canada, and Australia from Samyang Biopharmaceuticals, a South Korean corporation. Cynviloq is being marketed in Korea, Vietnam, Philippines, India, and Thailand under the names of Paxes-PM® and Genexol-PM.

About Sorrento Therapeutics, Inc.
Sorrento is an oncology company developing new treatments for cancer and associated pain. Sorrento’s most advanced asset Cynviloq™, the next-generation paclitaxel, will commence its registrational trial and be developed under the abbreviated 505(b)(2) regulatory pathway. Sorrento is also developing RTX, a non-opiate TRPV1 agonist currently in a Phase 1/2 study at the National Institutes of Health to treat terminal cancer patients suffering from intractable pain. The Company has made significant advances in developing human monoclonal antibodies, complemented by a comprehensive and fully integrated Antibody Drug Conjugate (ADC) platform that includes proprietary conjugation chemistries, linkers, and toxic payloads. Sorrento’s strategy is to enable a multi-pronged approach to combating cancer with small molecules, therapeutic antibodies, and ADCs.

More information is available at www.sorrentotherapeutics.com.

Forward-Looking Statements
This press release contains forward-looking statements 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 about commencing its Cynviloq™ registrational trial; and the advances made in developing human monoclonal antibodies, if any; and other matters that are described in Sorrento’s Annual Report on Form 10-K for the year ended December 31, 2012, 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. Genexol-PM® is a registered trademark of Samyang Corporation; Abraxane® is a registered trademark of Celgene, Inc; Taxol® is a registered trademark of Bristol-Myers Squibb, Inc.

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