

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 3, 2014**

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-33609

(Commission File Number)

30-0520478

(IRS Employer Identification No.)

**4520 East-West Highway, 3rd Floor
Bethesda, Maryland**

(Address of Principal Executive Offices)

20814

(Zip Code)

Registrant's telephone number, including area code: **(301) 961-3400**

(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 (see General Instruction A.2. below):

- 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))

Item 1.01. Entry into a Material Definitive Agreement.

On October 9, 2014, the Company and its affiliate, Sucampo AG (collectively, Sucampo), along with R-Tech Ueno, Ltd. (RTU), Takeda Pharmaceutical Company Limited and certain affiliates of Takeda (collectively, Takeda) executed a settlement and license agreement (Agreement) with Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par) that resolves patent litigation in the United States (U.S.) related to Sucampo's AMITIZA[®] (lubiprostone) 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule product. Under the terms of the Agreement, Sucampo and RTU will grant Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (licensed products) in the U.S. for the indications approved for AMITIZA[®] beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with Sucampo the gross profits of the licensed products sold during the term of the Agreement, which continues until each of the Sucampo patents has expired. In the event Par elects to launch an authorized generic, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additionally, Sucampo, RTU, Takeda, and Par have agreed to dismiss with prejudice the patent litigation filed in the U.S. District Court for the District of Delaware.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal period ending September 30, 2014.

On October 9, 2014, the Company issued a press release pursuant to which it announced that it had entered into the Agreement. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 8.01. Other Events.

On October 3, 2014 (the "Notice Date"), Sucampo received a Paragraph IV certification notice letter (the "Notice Letter") regarding an ANDA submitted to the FDA by Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") requesting approval to market, sell, and use a generic version of the 8 mcg and 24 mcg AMITIZA[®] soft gelatin capsule ("lubiprostone capsule") products.

In its Notice Letter, Dr. Reddy's alleges that U.S. Patent Nos. 6,414,016; 6,583,174; 7,064,148; 7,417,067; 8,026,393; 8,071,613; 8,088,934; 8,097,649; 8,114,890; 8,338,639; 8,748,481; 8,779,187; 7,795,312; 8,097,653; and 8,389,542 (collectively, the "Patents"), which cover compositions, formulations and methods of using AMITIZA[®], are invalid, unenforceable and/or will not be infringed by Dr. Reddy's manufacture, use or sale of the product described in its ANDA. The latest of the Patents expire in 2027.

The Company is currently reviewing the Notice Letter. By statute, if Sucampo initiates a patent infringement lawsuit against Dr. Reddy's within 45 days of the Notice Date, the FDA would automatically stay approval of Dr. Reddy's ANDA until the earlier of 30 months from the Notice Date or entry of a district court decision finding the Patents invalid or not infringed. The Company intends to vigorously enforce its intellectual property.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 1.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the Company on October 9, 2014

SIGNATURE

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.

Sucampo Pharmaceuticals, Inc.

Date: October 9, 2014

By: /s/ THOMAS J. KNAPP

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and Corporate Secretary

Sucampo Announces Settlement Agreement That Resolves Patent Litigation in U.S. Related to AMITIZA

Company Receives Additional Paragraph IV Notice

BETHESDA, Md., Oct. 9, 2014 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (Nasdaq:SCMP), a global biopharmaceutical company, today announced that Sucampo, R-Tech Ueno, Ltd. (RTU), Takeda Pharmaceutical Company Limited (Takeda) and certain affiliates of Takeda have entered into a settlement and license agreement with Anchen Pharmaceuticals, Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc., (collectively, Par) that resolves patent litigation in the United States (U.S.) related to Sucampo's AMITIZA[®] (lubiprostone) 8 mcg and 24 mcg soft gelatin capsules.

Under the terms of the settlement, Sucampo and RTU will grant Par a non-exclusive license to market Par's generic version of lubiprostone 8 mcg soft gelatin capsule and 24 mcg soft gelatin capsule (licensed products) in the U.S. for the indications approved for AMITIZA beginning January 1, 2021, or earlier under certain circumstances. Beginning on January 1, 2021, Par will split with Sucampo the gross profits of the licensed products sold during the term of the agreement, which continues until each of the Sucampo patents has expired. In the event Par elects to launch an authorized generic, Sucampo will supply Par under the terms of a manufacturing and supply agreement at a negotiated price. Additional details of the agreement remain confidential.

"This settlement agreement is an important step for Sucampo toward securing our foundation and continuing to grow sales of AMITIZA," said Peter Greenleaf, Chief Executive Officer of Sucampo. "We are on track with the strategic imperatives I communicated in August that include a sharp focus on our flagship product. This is not only beneficial to our company and shareholders, it is important to prescribing physicians and their patients who depend on AMITIZA for treatment."

Sucampo, RTU, Takeda and Par have agreed to dismiss with prejudice the patent litigation filed in the U.S. District Court for the District of Delaware.

Additionally, Sucampo said it has received a Paragraph IV certification notice letter (Notice Letter) regarding an Abbreviated New Drug Application (ANDA) submitted to the U.S. Food and Drug Administration (FDA) by Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), requesting approval to market, sell and use a generic version of the 8 mcg and 24 mcg AMITIZA[®] (lubiprostone) soft gelatin capsule products.

Sucampo is currently reviewing the Notice Letter. By statute, if Sucampo initiates a patent infringement lawsuit against Dr. Reddy's within 45 days of the Notice Date, the FDA would automatically stay approval of the Dr. Reddy's ANDA until the earlier of 30 months from the notice date or entry of a district court decision finding the patents invalid or not infringed. The product is currently protected by 15 issued patents that are listed in the FDA's Orange Book, with the latest expiring in 2027.

"We will continue to vigorously enforce AMITIZA's intellectual property rights," said Greenleaf. "Generic companies have made Paragraph IV certifications a routine part of business. Sucampo is well prepared to pursue all legal pathways in defense of AMITIZA."

About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is focused on the development and commercialization of medicines that meet unmet medical needs of patients worldwide. Sucampo has two marketed products – AMITIZA[®] and RESCULA[®] – and a pipeline of product candidates in clinical development. A global company, Sucampo is headquartered in Bethesda, Maryland, and has operations in Japan, Switzerland and the United Kingdom. For more information, please visit www.sucampo.com.

The Sucampo logo is the registered trademark and the tagline, The Science of Innovation, is a pending trademark of Sucampo AG. AMITIZA is a registered trademark of Sucampo AG. RESCULA is a registered trademark of R-Tech Ueno, Ltd, and has been licensed to Sucampo AG.

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Sucampo Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 8-K and 10-K, which Sucampo incorporates by reference.

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