

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) **August 18, 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 August 18, 2014, Sucampo Pharmaceuticals, Inc. (the "Company") subsidiary, Sucampo AG, entered into an exclusive global manufacturing and supply agreement (the "EMSA") with R-Tech Ueno, Ltd. (the "R-Tech") for ten years with an automatic renewal of ten more years unless the parties terminate the EMSA. R-Tech shall provide to the Company and its subsidiaries clinical and commercial supply of lubiprostone, in certain circumstances, as API, intermediate or finished product globally at supply prices that are reduced from the current supply prices. The current manufacturing and supply agreements for lubiprostone are superseded by the EMSA; except that the EMSA will not apply to the clinical and commercial supply of lubiprostone to the United States and Canada until the Supply and Purchase Agreement among Takeda Pharmaceutical Company, Ltd., R-Tech and us has expired and to Japan until the expiration of the manufacturing and supply agreement for Japan or certain material circumstances occur. We also have the right to qualify a back-up supplier for lubiprostone in expanded situations, e.g. authorized generic, additional formulations, inability to supply in certain circumstances, and others. There are no commercial or development milestones in the EMSA and all other terms contained in the superseded manufacturing and supply agreements are generally contained in the EMSA. The EMSA is effective as of January 1, 2014, notwithstanding the date the Company signed the Agreement.

The foregoing description of the EMSA 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.

### **Item 1.02. Termination of a Material Definitive Agreement.**

The information set forth under "Item 1.01. Entry into a Material Definitive Agreement" of this report relating to the superseding of the certain current manufacturing and supply agreements is hereby incorporated by reference in this Item 1.02.

### **Item 8.01. Other Events.**

On August 21, 2014, the Company issued a press release pursuant to which it announced that it had entered into the EMSA. A copy of the press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

### **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 August 21, 2014

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## 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: August 21, 2014

By: /s/ THOMAS J. KNAPP

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Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and Corporate Secretary

## Sucampo Announces New Exclusive Global Manufacturing and Supply Agreement for Lubiprostone

### New Agreement Lowers Cost of Goods for AMITIZA(R) in Certain Global Markets

BETHESDA, Md., Aug. 21, 2014 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (Nasdaq:SCMP), a global biopharmaceutical company, today announced that its subsidiary, Sucampo AG, has signed an exclusive global manufacturing and supply agreement (EMSA) with its manufacturing and development partner, R-Tech Ueno, Ltd. (R-Tech), for clinical and commercial supplies of AMITIZA<sup>®</sup> (lubiprostone) in most global markets.

Under the new EMSA, Sucampo receives a new, lower price for certain components of or finished product of lubiprostone globally, except for the United States and Canada until the collaboration and license agreement with Takeda Pharmaceutical Company, Ltd. expires in December 31, 2020, and except for Japan until the manufacturing and supply agreement for Japan expires or certain material circumstances occur. Additionally, under the EMSA Sucampo has the right to qualify a back-up supplier for lubiprostone in expanded circumstances, such as an authorized generic, additional formulations, and/or inability to supply product in certain circumstances, among others. The new EMSA supersedes the current manufacturing and supply agreements with R-Tech except in those situations noted above and is effective as of January 1, 2014.

"Continuing the growth of AMITIZA is the top imperative I outlined earlier this month in my strategic plan for Sucampo. The new EMSA announced today will be critical to growing AMITIZA and facilitating our global expansion plans around the world by providing us with greater operational flexibility, lowered overall cost of goods manufactured, and greater margin control," stated Peter Greenleaf, Chief Executive Officer of Sucampo. "As we progress our plans to partner AMITIZA globally, including Europe and emerging markets outside of the U.S. and Japan, having greater control over our cost structure will enable us to access markets with tighter reimbursement restrictions. Ultimately, this will make AMITIZA more widely accessible to patients around the world who may benefit from its more than eight years of experience and eight million prescriptions dispensed globally."

#### About AMITIZA (lubiprostone)

AMITIZA (lubiprostone) is a prostone, a locally acting chloride channel activator, indicated in the United States for the treatment of chronic idiopathic constipation (CIC) in adults and opioid-induced constipation (OIC) in adults with chronic, non-cancer pain (24 mcg twice daily). The effectiveness in patients with OIC taking diphenylheptane opioids (e.g., methadone) has not been established. AMITIZA is also indicated in the U.S. for irritable bowel syndrome with constipation (IBS-C) (8 mcg twice daily) in women 18 years of age and older in the U.S.

#### Important Safety Information

- AMITIZA (lubiprostone) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating healthcare provider (HCP) to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.
- Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their HCP.
- AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. Patients should be instructed to discontinue AMITIZA and inform their HCP if severe diarrhea occurs.
- Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their HCP. Some patients have discontinued therapy because of dyspnea.
- In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=1113 vs N=316, respectively) in patients with CIC, the most common adverse reactions (incidence > 4%) were nausea (29% vs 3%), diarrhea (12% vs < 1%), headache (11% vs 5%), abdominal pain (8% vs 3%), abdominal distension (6% vs 2%), and flatulence (6% vs 2%).
- In clinical trials of AMITIZA (24 mcg twice daily vs. placebo; N=860 vs. N=632) in patients with OIC, the most common adverse reactions (incidence > 4%) were nausea (11% vs 5%) and diarrhea (8% vs 2%).
- In clinical trials of AMITIZA (8 mcg twice daily vs. placebo; N=1011 vs. N=435, respectively) in patients with IBS-C the most common adverse reactions (incidence > 4%) were nausea (8% vs 4%), diarrhea (7% vs 4%), and abdominal pain (5% vs 5%).
- Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of AMITIZA.
- The safety of AMITIZA in pregnancy has not been evaluated in humans. Based on animal data, AMITIZA may cause fetal harm. AMITIZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution

should be exercised when AMITIZA is administered to a nursing woman. Advise nursing women to monitor infants for diarrhea.

- Reduce the dosage in CIC and OIC patients with moderate and severe hepatic impairment. Reduce the dosage in IBS-C patients with severe hepatic impairment.

Please see the Full Prescribing Information here. For further information on AMITIZA, please visit [www.sucampo.com/products](http://www.sucampo.com/products).

### **About Sucampo Pharmaceuticals, Inc.**

Sucampo Pharmaceuticals, Inc. is focused on the development and commercialization of medicines to meet the major unmet medical needs of patients on a global basis. Sucampo has two marketed products – AMITIZA<sup>®</sup> and RESCULA<sup>®</sup> – 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 U.K. For more information, please visit [www.sucampo.com](http://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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