

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): February 19, 2009**

**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, Suite 300  
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.**

### ***Agreement with Abbott Japan***

On February 19, 2009, Sucampo Pharma, Ltd., or SPL, a wholly owned Japanese subsidiary of the Registrant, entered into a License, Commercialization and Supply Agreement with Abbott Japan Co. Ltd., or Abbott Japan, relating to the commercialization of lubiprostone (trade name Amitiza®) in Japan.

Under the terms of the agreement, Abbott Japan has exclusive rights to commercialize lubiprostone in Japan for the treatment of chronic idiopathic constipation, or CIC. Abbott Japan is responsible for all commercialization expenses and efforts. SPL retains the right to co-promote lubiprostone in Japan with its own sales force and at its own expense.

SPL will receive an upfront payment of \$10 million within 15 days of execution of the agreement. In addition, SPL has the potential to receive additional significant milestone payments subject to achieving specified development, regulatory and sales milestones.

SPL is responsible for, and will bear all costs relating to, the development and regulatory activity for lubiprostone for the treatment of CIC in Japan, including conducting and paying for all clinical trials required to obtain and maintain regulatory approval.

Following marketing authorization and pricing approval, Abbott Japan will purchase finished product from SPL for distribution in Japan.

SPL is responsible for manufacturing the product to be sold by Abbott Japan or having the product manufactured on its behalf.

Abbott Japan has a right of first refusal to negotiate with SPL to develop and commercialize any additional indications for lubiprostone in Japan.

The agreement has a term extending until the later of 18 years after its effectiveness or 15 years after the first commercial sale under the agreement, subject to further extension if a regulatory authority grants market exclusivity for a longer period.

In connection with entering into the agreement, SPL and Abbott Japan or their respective affiliates have separately agreed to negotiate in good faith a license, commercialization and supply agreement for lubiprostone in markets outside Japan, the U.S., Canada and Western Europe and to use commercially reasonable efforts to enter into such an agreement.

The Registrant intends to file a copy of the License, Commercialization and Supply Agreement with Abbott Japan as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2008.

### ***Addendum to Patent Access Agreement***

On February 18, 2009, the Registrant's operating subsidiaries, including SPL, entered into an Addendum to the Amended and Restated Patent Access Agreement originally entered into between the Registrant and Sucampo AG, on June 30, 2006. Sucampo AG is the Swiss patent-holding company that owns the prostone-related patents being developed and commercialized by the Registrant.

Under the Addendum, the patent and know-how royalties SPL is obligated to pay to Sucampo AG are reduced with respect to sales of lubiprostone in Asia, Australia and New Zealand as follows:

- the patent royalty on net sales, due until the expiration of the last patent covering lubiprostone that existed at the time of the Registrant's initial public offering, is reduced from 4.5% to 2.2%;
  - the patent royalty on net sales, due thereafter until all other patents covering lubiprostone have expired in the relevant country, is reduced from 2.25% to 1.1%; and
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- the know-how royalty on net sales, due until the fifteenth anniversary of the first commercial sale of lubiprostone, is reduced from 2.0% to 1.0%

A copy of the Addendum to the Amended and Restated Patent Access Agreement is filed as Exhibit 10.1 to this Current Report on Form 8-K, and the summary description of that agreement set forth above is qualified in its entirety by reference to the complete agreement as filed.

Dr. Ryuji Ueno and Dr. Sachiko Kuno, the founders of the Registrant, together own, directly or indirectly all of the stock of Sucampo AG. Drs. Ueno and Kuno also are controlling stockholders of the Registrant and are married to each other. Dr. Ueno is the Registrant's chief executive officer and chairman of the board and Dr. Kuno is a director and an advisor of international business development.

**Item 7.01. Regulation FD Disclosure.**

On February 19, 2009, the Registrant issued a press release announcing the agreement with Abbott Japan, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

10.1 Addendum to Amended and Restated Patent Access Agreement: Reduction of Royalties with respect to SPL Territory dated February 18, 2009 between the Registrant, its operating subsidiaries and Sucampo AG.

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

99.1 Press release issued by the Registrant on February 19, 2009

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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: February 19, 2009

By: /s/ Jan Smilek

Name: Jan Smilek

Title: Chief Financial Officer

**ADDENDUM  
TO  
AMENDED AND RESTATED PATENT ACCESS AGREEMENT:  
REDUCTION OF ROYALTIES WITH RESPECT TO SPL TERRITORY**

**THIS ADDENDUM** (“Addendum 1”) is made as February 18, 2009, among (1) Sucampo AG, a corporation organized and existing under the laws of Switzerland and having its principal office at Graben 5, CH-6300 Zug, Switzerland (“SAG”), (2) Sucampo Pharmaceuticals, Inc., a corporation organized and existing under the laws of the state of Delaware, U.S.A. and having its principal office at 4520 East West Highway, 3rd Floor, Bethesda, MD 20814, U.S.A. (and as of December 29, 2008, d/b/a Sucampo Pharma Americas, Inc.) (“SPI”), (3) Sucampo Pharma, Ltd., a corporation organized and existing under the laws of Japan and having its principal office at 2-2-16 Sonezakishinchi, Kita-Ku, Osaka, Japan 530-0002 (“SPL”), and (4) Sucampo Pharma Europe, Ltd., a corporation organized and existing under the laws of the United Kingdom and having its principal office at John Eccles House, Robert Robinson Avenue, Oxford Science Park, Oxford, OX4 4GP U.K. (“SPE”) (each referred to herein as a “party” and collectively as the “parties”).

**WHEREAS**, the undersigned are parties to that certain Amended and Restated Patent Access Agreement of June 30, 2006 (the “Agreement”), which governs among other things, the amount of the patent and know-how royalties payable to SAG by the other parties as consideration for licenses granted by SAG;

**WHEREAS**, regarding Lubiprostone Products, it has become evident that due to current lower approved prices and higher distribution costs than expected as of the date of the Agreement, it would not be profitable to distribute Lubiprostone Products in certain countries of the SPL Territory at the patent and know-how royalties initially set forth in the Agreement; and

**WHEREAS**, Section 12.3 of the Agreement states that the Agreement cannot be modified in any manner, except by an instrument in writing signed on behalf of each of the parties;

**NOW, THEREFORE**, the parties hereto agree that:

**Addendum 1, Article 1:**

Section 3.2 and 3.3 of the Agreement shall be modified as follows:

Section 3.2 Patent Royalty. In consideration of the licenses granted in Section 2.1, each Operating Company shall pay to SAG, on a country-by-country basis, the following royalties on Net Sales of Licensed Products in such Operating Company’s respective Territory:

- (a) With respect to Net Sales of Licensed Products for which the manufacture, use or sale of such Licensed Products is covered by an Unexpired patent that is included in the Original Patents:
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- i. During the period from the first commercial sale of such Licensed Product until such time as all of the Pre-IPO Patents (as defined below) that would be infringed by the sale of such Licensed Product have Expired in the country of sale, four and one-half percent (4.5%); (provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory and by SPL its Affiliates and sublicensees in the SPL Territory, such rate shall be two and two-tenths percent (2.2%)); and
- ii. If applicable, thereafter until such time as all of the remaining Licensed Patents that would be infringed by the sale of such Licensed Product have Expired in the country of sale, two and one-quarter percent (2.25%) (provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory and by SPL its Affiliates and sublicensees in the SPL Territory, such rate shall be one and one-tenth percent (1.1%)).

For purposes of this Section 3.2, a "Pre-IPO Patent" means a Licensed Patent which was owned by or licensed (with right of sublicense) to SAG on or before the Effective Time, and all reissues, continuations, continuations-in-part, extensions, reexaminations, and foreign counterparts thereof. Upon expiration of the royalty obligation set forth in this Section 3.2, such Operating Company's license under Section 2.1 shall continue on a fully-paid and royalty-free basis.

#### Section 3.3 SAG Know-How Royalty.

(a) In consideration of the licenses granted in Section 3.3(a), each Operating Company shall pay to SAG, on a country-by-country basis, a royalty of two percent (2%) of Net Sales of Licensed Products in such Operating Company's respective Territory (provided that, with respect to Net Sales of Lubiprostone Product by SPI, its Affiliates and sublicensees in the SPI Territory and by SPL its Affiliates and sublicensees in the SPL Territory, such rate shall be one percent (1%)).

(b) The royalty obligation set forth in (a) shall continue, on a country-by-country basis, until the fifteenth anniversary of the first commercial sale of the Licensed Products. Upon expiration of such royalty obligation, such Operating Company's license under Section 2.2 shall continue on a fully-paid and royalty-free basis.

#### Addendum 1, Article 2:

All other sections of the Agreement remain unchanged.

(signature page to follow)

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IN WITNESS WHEREOF, each of the parties has caused this Addendum 1 to the Patent Access and Data Sharing Agreement to be executed in the manner appropriate to each, effective as of the date first above written.

SUCAMPO AG

BY: /s/ Eric Buis  
Dr. Eric Buis  
Director

SUCAMPO PHARMACEUTICALS, INC.

BY: /s/ Gayle R. Dolecek  
Gayle R. Dolecek  
Sr. VP of R&D

SUCAMPO PHARMA EUROPE LIMITED

BY: /s/ Gayle R. Dolecek  
Gayle R. Dolecek  
Director

SUCAMPO AG

BY: /s/ Reto Steiger  
Reto Steiger  
Director

SUCAMPO PHARMA, LTD.

BY: /s/ Gayle R. Dolecek  
Gayle R. Dolecek  
Director



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### **Sucampo Licenses Lubiprostone in Japan to Abbott**

**Bethesda, Maryland, February 19, 2009** – Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) today announced that its subsidiary, Sucampo Pharma, Ltd., has entered into a license and commercialization agreement with Abbott Japan Co. Ltd. for Sucampo's lubiprostone (trade name Amitiza®) in Japan.

Lubiprostone is the only FDA-approved treatment for chronic idiopathic constipation (CIC) in adults and for the treatment of irritable bowel syndrome with constipation (IBS-C) in adult women. In September 2008, Sucampo reported results from a phase 2b dose-ranging study of lubiprostone for CIC in Japanese patients. Based on these results, Sucampo plans to initiate phase 3 clinical testing of lubiprostone for CIC in Japan in the second quarter of 2009.

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo, said, "We are very excited to enter into this agreement with Abbott because of their strong international presence and infrastructure. Entering the Japanese market represents a key element of Sucampo's overall growth strategy of bringing our proprietary products to the global-market place while also continuing to develop and commercialize other prostone-based portfolio product candidates."

#### **Terms of the Agreement**

Under the terms of the agreement, Abbott will receive exclusive rights to commercialize lubiprostone in Japan for the treatment of chronic idiopathic constipation (CIC) and will receive the right of first refusal to any additional indications for which lubiprostone is developed in Japan. Abbott will be responsible for all commercialization expenses and efforts.

Sucampo will receive an upfront payment of \$10 million and could receive additional milestone payments based on achieving specified development and commercialization goals. Sucampo will continue to lead the development of and regulatory activity for lubiprostone in Japan and will continue to be responsible for the costs of lubiprostone development. Following marketing authorization and pricing approval, Abbott will purchase finished product from Sucampo for distribution in Japan. Sucampo also will retain the right to co-promote lubiprostone in Japan.

In addition, Sucampo and Abbott have agreed to begin negotiating a license, commercialization and supply agreement with respect to other available territories.



## **About lubiprostone**

Lubiprostone is a selective activator of type-2 chloride channels through which negatively charged chloride ions flow out of the cells lining the small intestine and into the intestinal cavity. As these negatively charged chloride ions enter the intestine, positively charged sodium ions move through spaces between the cells into the intestine to balance the negative charge of the chloride ions. As these sodium ions move into the intestine, water is also allowed to pass into the intestine through these spaces between the cells. This movement of water into the small intestine promotes fluid content, which in turn softens the stool and facilitates its movement, or motility, through the intestine.

Amitiza is a registered trademark of Sucampo Pharmaceuticals, Inc.

## **About chronic idiopathic constipation**

Constipation is characterized by infrequent and difficult passage of stool and becomes chronic when a patient suffers specified symptoms for over 12 non-consecutive weeks within a 12-month period. Chronic constipation is idiopathic if it is not caused by other diseases or by use of medications. Symptoms of chronic idiopathic constipation include straining, hard stools, bloating and abdominal pain or discomfort. Factors contributing to the development of chronic idiopathic constipation include a diet low in soluble and insoluble fiber, inadequate exercise, bowel disorders and poor abdominal pressure and muscular weakness.

## **About Sucampo Pharmaceuticals**

Sucampo Pharmaceuticals, Inc., a biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostanes. The therapeutic potential of prostanes, which are bio-lipids that occur naturally in the human body, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer and currently Advisor, International Business Development.

Sucampo markets Amitiza® (lubiprostone) 24 mcg in the U.S. for chronic idiopathic constipation in adults and Amitiza 8 mcg in the U.S. to treat irritable bowel syndrome with constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. has three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., located in Japan; and, Sucampo Pharma Americas, Inc., located in Maryland. To learn more about Sucampo Pharmaceuticals and its products, visit [www.sucampo.com](http://www.sucampo.com).

## **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may" or other similar expressions. Forward-looking statements include statements about potential trial results, the potential utility of Amitiza to treat particular indications and expected trial initiation. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals' filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended

December 31, 2007 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals' views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

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