

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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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): September 24, 2010

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Jurisdiction  
of Incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

4520 East-West Highway, Suite 300  
Bethesda, Maryland

20814

(Address of Principal Executive Offices)

(Zip Code)

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

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(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))
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**Item 8.01. Other Events.**

Sucampo Pharmaceuticals, Inc., today announced that its subsidiary, Sucampo Pharma, Ltd., or SPL, has submitted a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency for approval to market Amitiza<sup>®</sup> (lubiprostone) 24 mcg for the treatment of chronic idiopathic constipation, or CIC. The full text of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference. All readers are encouraged to read the entire text of the press release attached hereto.

Under the terms of the February 19, 2009 agreement between SPL and Abbott Japan Co. Ltd., or Abbott Japan, to develop and commercialize lubiprostone in Japan for the treatment of CIC, SPL will receive from Abbott Japan a development milestone payment of \$5.0 million within 15 days of the submission of the marketing application to market lubiprostone for CIC, which occurred on September 24, 2010.

The submission also triggers milestone payments of \$1.25 million from Sucampo Pharmaceuticals Inc. to Sucampo AG under their Amended and Restated Patent Access Agreement.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

The following exhibit relating to Item 8.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on October 7, 2010.

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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: October 7, 2010

/s/ JAN SMILEK

Name: Jan Smilek

Title: Chief Financial Officer

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## EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release issued by the registrant on October 7, 2010

**Sucampo Pharmaceuticals Submits Marketing Application to Japanese Regulatory Authorities for Amitiza (lubiprostone)**

BETHESDA, Md. & ABBOTT PARK, Ill.--(BUSINESS WIRE)--October 7, 2010--Sucampo Pharmaceuticals, Inc. (NASDAQ:SCMP) and Abbott (NYSE:ABT) today announced that Sucampo Pharma Ltd., a wholly owned subsidiary of Sucampo Pharmaceuticals, Inc., has submitted a marketing application to the Japanese Pharmaceuticals and Medical Devices Agency for approval to market Amitiza<sup>®</sup> (lubiprostone) 24 mcg for the treatment of chronic idiopathic constipation (CIC).

The submission includes the results of a phase 3 efficacy trial. The efficacy trial, which enrolled 124 patients, met its primary endpoint with statistical significance ( $p < 0.001$ ) and demonstrated a safety profile consistent with previously reported lubiprostone clinical data. The submission will be amended in early 2011 with the complete results of the phase 3 long-term, open-label, multi-center, confirmatory, safety trial in 209 Japanese CIC patients. Top-line interim results from this trial were disclosed in August 2010 and top-line final results from this safety trial continue to be expected during the fourth quarter of 2010.

"We are pleased to have submitted the Japanese regulatory application for Amitiza, a first in class therapeutic. We will work diligently to achieve licensure in order to bring this potentially important new therapeutic tool to Japanese patients," said Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo's Chairman and Chief Executive Officer.

"Amitiza represents a major breakthrough in improving the quality of life for CIC patients, and we are excited to be able to make the product available for Japanese patients suffering from this condition," said Gary M. Winer, President, Abbott Japan, which holds commercialization rights to lubiprostone in Japan.

In February 2009, Sucampo entered into a license, commercialization and supply agreement for lubiprostone with Abbott Japan Co. Ltd. under which Abbott received exclusive rights to commercialize lubiprostone in Japan for the treatment of CIC. Sucampo led the development program and is leading the regulatory activity of lubiprostone in Japan. This regulatory submission triggers a \$5,000,000.00 milestone payment from Abbott Japan to Sucampo Pharmaceuticals, Inc. The submission also triggers a \$1,250,000 milestone payment from Sucampo Pharmaceuticals Inc. to Sucampo AG.

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## **About lubiprostone**

Lubiprostone (trade named Amitiza<sup>®</sup>) is a local activator of type-2 chloride channels in cells lining the small intestine. Lubiprostone increases fluid secretion into the intestinal tract. This increased fluid level softens the stool, facilitating intestinal motility and bowel movements. Sucampo management believes the type 2 chloride channels also play an important role in the restoration of tight junction complexes and in the recovery of barrier function in the body.

Amitiza<sup>®</sup> 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 the last three months with symptom onset at least six months prior to diagnosis. 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., an international biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, which occur naturally in the human body by enzymic, 15-PGDH, transformation of certain fatty acids, 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 and a member of the Board of Directors. For more information about Sucampo Pharmaceuticals, please visit [www.sucampo.com](http://www.sucampo.com).

## **About Abbott**

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries. Abbott's news releases and other information are available on the company's Web site at [www.abbott.com](http://www.abbott.com).

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## About AMITIZA (lubiprostone) for Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation

AMITIZA (lubiprostone) is indicated for the treatment of Chronic Idiopathic Constipation (24 mcg twice daily) in adults and for Irritable Bowel Syndrome with Constipation (8 mcg twice daily) in women  $\geq 18$  years of age and older.

AMITIZA 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 to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.

The safety of AMITIZA in pregnancy has not been evaluated in humans. AMITIZA should be used during pregnancy only if the benefit justifies the potential risk to the fetus. Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.

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 healthcare provider.

AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment and inform their healthcare provider if the diarrhea becomes severe.

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 healthcare provider. Some patients have discontinued therapy because of dyspnea.

In clinical trials of AMITIZA (24 mcg twice daily vs. placebo: N=1113 vs. N=316) in patients with Chronic Idiopathic Constipation, 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 distention (6% vs. 2%), and flatulence (6% vs. 2%).

In clinical trials of AMITIZA (8 mcg twice daily vs. placebo: N=1011 vs. N=435) in patients with Irritable Bowel Syndrome with Constipation, the most common adverse reactions (incidence  $>4\%$ ) were nausea (8% vs. 4%), diarrhea (7% vs. 4%), and abdominal pain (5% vs. 5%).

Please see complete Prescribing Information at [www.amitiza.com](http://www.amitiza.com).

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## 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 the potential utility of Amitiza to treat particular indications. 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, 2009 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 data. Sucampo does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise, except as required by law.

### CONTACT:

Sucampo Pharmaceuticals, Inc.

Kate de Santis, 240-223-3834

or

Westwicke Partners (for Sucampo)

John Woolford, 410-213-0506

or

Abbott

Alysa Hackett, 847-938-8446