# 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): September 13, 2007

### Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	001-33609	13-3929237	
(State or Other Juris-	(Commission	(IRS Employer	
diction of Incorporation)	File Number)	Identification No.)	
4520 East-West Highway, Suite 300		20814	
Bethesda, Maryland			
(Address of Principal Executive Offices)		(Zip Code)	

Registrant's telephone number, including area code: (301) 961-3000

(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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### **Item 7.01 Regulation FD Disclosure**

On September 13, 2007, Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals North America, Inc. announced that the first patient has been enrolled in a Phase III study of lubiprostone (24 mcg, oral gel capsules, twice daily) for treatment of Opioid-Induced Bowel Dysfunction. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this 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

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on September 13, 2007.

#### 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: September 13, 2007 By: <u>/s/ Kei S. Tolliver</u>

Name: Kei S. Tolliver Title: Secretary

#### EXHIBIT INDEX

Exhibit No. Description

99.1 Press release issued by the registrant on September 13, 2007





#### FOR IMMEDIATE RELEASE

Contact:

Scott Solomon Vice President Sharon Merrill Associates, Inc. 617-542-5300

David Buckalew Takeda Pharmaceuticals North America, Inc. 224-554-5486

#### Sucampo Pharmaceuticals, Inc. Begins Pivotal Phase III Studies of Oral Lubiprostone to Treat Opioid-Induced Bowel Dysfunction (OBD)

First Patient Enrolled in Pivotal Studies

**BETHESDA, MD**, September 13, 2007 — Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) and Takeda Pharmaceuticals North America, Inc. today announced that the first patient has been enrolled in a Phase III study of lubiprostone (24 mcg, oral gel capsules, twice daily) for the treatment of Opioid-Induced Bowel Dysfunction (OBD). The OBD Pivotal Assessment of Lubiprostone (OPAL) program consists of two 12-week double-blind studies, followed by a nine-month open-label safety extension study. The double-blind studies are expected to enroll approximately 840 patients at up to 190 sites in the United States and Canada and will evaluate the effects of lubiprostone as a treatment for constipation stemming from the use of narcotic medications, such as morphine and codeine, prescribed for chronic pain management.

Lubiprostone, a chloride channel activator developed by Sucampo Pharmaceuticals, is currently approved for the treatment of Chronic Idiopathic Constipation in adults as AMITIZA® (24 mcg, oral gel capsules, twice daily) and is under FDA review for Irritable Bowel Syndrome with constipation. AMITIZA is marketed in the United States by Sucampo Pharmaceuticals and Takeda Pharmaceuticals North America.

"Each year, millions of patients who suffer from chronic pain are treated with opiates," said Egilius L. H. Spierings, M.D., Ph.D, Associate Clinical Professor of Neurology at Brigham and Women's Hospital, Harvard Medical School. "Many of these patients frequently develop severe constipation from these powerful analgesics; however, there are currently no approved prescription products available to treat this condition. This study is designed to determine whether lubiprostone can help many Americans who have constipation as a result of taking opioid-based drugs for chronic pain."

According to the American Pain Foundation, more than 50 million Americans suffer from chronic pain. Opioid-based pain relievers are widely prescribed for these patients, and many of them also develop opioid-induced bowel dysfunction.

#### Lubiprostone OBD Study Page 2

Opioid drugs are known to increase absorption of electrolytes, including chloride, in the small intestine, contributing to the constipating effects of these analgesics. Lubiprostone, as a locally acting chloride channel activator, is being studied to evaluate if it may directly counteract this condition without interfering with the analgesic benefits of opioids in the gastrointestinal tract. Should lubiprostone be approved as a treatment of OBD, Sucampo Pharmaceuticals believes it may fill an important unmet need in the market. Sucampo Pharmaceuticals expects to file a supplemental new drug application for this indication in mid-2009 if the results of these studies are positive.

#### About Opioid-Induced Bowel Dysfunction (OBD)

Opioid-Induced Bowel Dysfunction comprises a variety of gastrointestinal conditions inclusive of severe constipation brought about by the use of narcotic medications such as morphine and codeine, which are commonly referred to as opioids. Physicians prescribe opioids for patients with advanced medical illnesses as well as those undergoing surgery. Despite their pain-relieving effectiveness, opioids are known to produce gastrointestinal effects that lead to opioid-induced constipation, including inhibition of large intestine motility, decreased gastric emptying and hard stools.

#### About AMITIZA® (lubiprostone) 24 mcg Twice Daily for Chronic Idiopathic Constipation

AMITIZA (24 mcg, oral gel capsules, twice daily) is indicated for the treatment of Chronic Idiopathic Constipation in adults. AMITIZA should not be used in patients with a known gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be evaluated 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. In guinea pigs, lubiprostone has been shown to have the potential to cause fetal loss. 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.

AMITIZA should not be administered to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment. If the diarrhea or nausea becomes severe, patients should consult their health professional.

In clinical trials for Chronic Idiopathic Constipation (24 mcg, oral gel capsules, twice daily), the most common adverse reaction was nausea (29%). Other adverse reactions (greater than or equal to 4% of patients) included diarrhea (12%), headache (11%), abdominal pain (8%), abdominal distension (6%) and flatulence (6%).

For full prescribing information, visit www.amitiza.com.

AMITIZA® is a registered trademark of Sucampo Pharmaceuticals, Inc.

#### Lubiprostone OBD Study Page 3

#### Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc., an emerging pharmaceutical company based in Bethesda, Md., focuses on the development and commercialization of drugs based on prostones, a class of compounds derived from functional fatty acids that occur naturally in the human body. The therapeutic potential of prostones 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 CEO and advisor, international business development. Sucampo Pharmaceuticals' first product, AMITIZA®, received marketing approval from the U.S. Food and Drug Administration in January 2006 for the treatment of Chronic Idiopathic Constipation in adults. AMITIZA is co-promoted in the United States and Canada through an alliance between Sucampo Pharmaceuticals and Takeda Pharmaceutical Company Limited (Osaka, Japan). Sucampo Pharmaceuticals' sales force targets the institutional marketplace, including academic medical centers and long-term care facilities, while Takeda focuses on office-based specialty and primary care physicians. To learn more about Sucampo Pharmaceuticals and its products, visit <a href="https://www.sucampo.com">www.sucampo.com</a>.

#### Takeda Pharmaceuticals North America, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals North America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. In the United States, Takeda currently markets products for diabetes, insomnia, wakefulness and gastroenterology. The company has a robust pipeline with compounds in development for diabetes, cardiovascular disease and other conditions. Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. To learn more about the company and its products, visit <a href="https://www.tpna.com">www.tpna.com</a>.

#### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals, Inc. 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: the results of clinical trials with respect to Sucampo Pharmaceuticals' products under development; the timing and success of submission, acceptance and approval of regulatory filings; Sucampo Pharmaceuticals' dependence on the commercial success of AMITIZA; Sucampo Pharmaceuticals' ability to obtain additional funding required to conduct its discovery, development and commercialization programs; Sucampo Pharmaceuticals' dependence on its co-marketing alliance with Takeda Pharmaceutical Company Limited; and Sucampo Pharmaceuticals' ability to obtain, maintain and enforce patent and other intellectual property protection for its discoveries. These and other risks are described in greater detail in the "Risk Factors" section of Sucampo Pharmaceuticals' quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 22, 2007. 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, it specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

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