



---

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 17, 2007**

**Sucampo Pharmaceuticals, Inc.**

---

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

13-3929237

(State or Other Juris-  
diction 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

---

(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 7.01 Regulation FD Disclosure**

On September 17, 2007, Sucampo Pharmaceuticals, Inc. announced that the supplemental New Drug Application for lubiprostone (8 mcg, oral gel capsules, twice daily) for the treatment of irritable bowel syndrome with constipation has been accepted for review by the U.S. Food and Drug Administration. 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 17, 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 17, 2007

By: /s/ Mariam E. Morris

Name: Mariam E. Morris

Title: Chief Accounting Officer

---

EXHIBIT INDEX

Exhibit No.   Description

---

99.1      Press release issued by the registrant on September 17, 2007



**For Immediate Release**

**Contact:**

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

**FDA Accepts Sucampo's sNDA for Lubiprostone (8 mcg) for the Treatment of Irritable Bowel Syndrome with Constipation (IBS-C)**

*Lower Strength of Approved Constipation Drug Offers Potential Treatment Option to Americans Suffering from IBS-C*

**BETHESDA, MD**, September 17, 2007 — Sucampo Pharmaceuticals, Inc., (NASDAQ: SCMP) today announced that the supplemental New Drug Application (sNDA) for lubiprostone (8 mcg, oral gel capsules, twice daily) for the treatment of irritable bowel syndrome with constipation (IBS-C) has been accepted for review by the U.S. Food and Drug Administration (FDA). Sucampo Pharmaceuticals currently anticipates a decision from the FDA in the second quarter of 2008.

Lubiprostone, a chloride channel activator with a novel mechanism of action, was developed by Sucampo Pharmaceuticals. The 24-mcg formulation of the drug (AMITIZA®) is approved for the treatment of Chronic Idiopathic Constipation in adults and is marketed for this indication in the United States by Sucampo Pharmaceuticals and Takeda Pharmaceuticals North America, Inc.

“The FDA’s decision to accept our sNDA submission for review is an important step in filling an unmet medical need for patients with the debilitating disease of IBS-C,” said Ryuji Ueno, M.D., Ph.D., founder, chairman and chief executive officer of Sucampo Pharmaceuticals. “IBS-C has a significant impact on millions of Americans and, if approved, lubiprostone may offer a valuable new treatment option for people living with this condition.”

Approximately 58 million Americans have irritable bowel syndrome (IBS), with IBS-C accounting for approximately one-third of these cases. IBS-C symptoms include abdominal pain and discomfort associated with defecation or a change in bowel habits with features of disordered defecation.

**About lubiprostone (8 mcg) and its supplemental New Drug Application**

The sNDA, filed with the FDA on June 29, 2007, was based on a clinical study program that included two Phase 3, multi-center, double-blinded, randomized, placebo-controlled trials involving 1,171 adults, followed by one long-term, open-label safety and efficacy extension trial involving 522 adults diagnosed with IBS-C. In the two Phase 3 trials, patients received lubiprostone 8 mcg twice daily or placebo twice daily over a 12-week period. Patients receiving lubiprostone were nearly twice as likely to achieve overall relief that was statistically significant compared to those receiving placebo (17.9% vs. 10.1%; P=0.001). Individually, each study

---

showed lubiprostone's efficacy over placebo for overall relief (P=0.009 and P=0.031). In the combined studies, secondary endpoints included abdominal discomfort/pain, stool consistency, straining, constipation severity and quality of life; these endpoints showed statistically significant improvement in patients receiving lubiprostone vs. placebo. The long-term extension trial demonstrated that the efficacy of lubiprostone continued through the open-label period, with increasing overall improvement to the end of the 52-week program.

In the two Phase 3 pivotal trials, lubiprostone and placebo groups showed a similar incidence of serious adverse events (1% in both the lubiprostone and placebo groups) and related adverse events (22% in lubiprostone vs. 21% in the placebo group). The most common treatment-related adverse events (>5% of patients) were nausea (8% vs. 4%, respectively), diarrhea (6% vs. 4%, respectively) and abdominal pain (4% vs. 5%, respectively).

#### **About Irritable Bowel Syndrome with Constipation (IBS-C)**

IBS is a chronic functional bowel disorder in which abdominal discomfort or pain is associated with defecation or a change in bowel habit and with features of disordered defecation. IBS is further sub-classified into IBS with constipation, IBS with diarrhea and mixed IBS, depending upon stool consistency. Patients with IBS-C have hard or lumpy stools, but unlike patients with chronic constipation the frequency of bowel movements is not part of the diagnostic criteria.

It is the temporal relationship of pain, bowel habit and stool characteristics that is the most prominent feature of IBS-C. The hypersensitivity of the gastrointestinal system of individuals with IBS-C makes them more prone to experience the effects of even mild symptoms associated with defecation or a change in bowel habit. In contrast to chronic constipation, the treatment of IBS-C is directed toward the improvement of the dominant symptoms (abdominal discomfort/pain and stool consistency) rather than increasing the frequency of bowel movements.

#### **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](http://www.amitiza.com).

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

#### **About 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 chief executive officer 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 through an alliance between Sucampo Pharmaceuticals and Takeda Pharmaceutical Company Limited (Osaka, Japan). 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. 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, review 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 the 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.*

###