



---

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 20, 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:

- 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 20, 2007, Sucampo announced that it has enrolled the first patient in a multi-center Phase 2 trial evaluating one of its clinical compounds, cobiprostone, for the prevention of ulcers and other gastrointestinal injuries in arthritis patients treated with nonsteroidal anti-inflammatory drugs. 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 20, 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 20, 2007

By: /s/ Mariam E. Morris

Name: Mariam E. Morris

Title: Chief Accounting Officer

---

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by the registrant on September 20, 2007



**For Immediate Release**

**Contact:**

Scott Solomon  
Vice President  
Sharon Merrill Associates, Inc.  
617-542-5300  
[ssolomon@investorrelations.com](mailto:ssolomon@investorrelations.com)

**Sucampo Pharmaceuticals Initiates Phase 2, Dose-Finding Trial of  
Cobiprostone for the Prevention of NSAID-Induced Ulcers in Arthritis Patients**

*Novel Chloride Channel Activator to be Evaluated  
in 120 Patients at up to 15 U.S. Sites*

**BETHESDA, MD**, September 20, 2007 — Sucampo Pharmaceuticals, Inc., (Nasdaq: SCMP), an emerging pharmaceutical company developing prostone-based therapies for age-related and other diseases, today announced that it has enrolled the first patient in a multi-center Phase 2, dose-finding trial evaluating one of its clinical compounds, cobiprostone (SPI-8811), for the prevention of ulcers and other gastrointestinal injuries in arthritis patients treated with nonsteroidal anti-inflammatory drugs (NSAIDs).

“While NSAIDs are among the most commonly used medications in the world, accounting for more than 70 million prescriptions in the U.S. alone, unfortunately these drugs also are responsible for significant gastrointestinal complications,” said Byron Cryer, M.D., of University of Texas Southwestern Medical Center. “We need to develop therapies which can effectively prevent NSAID-induced gastrointestinal ulcers.”

The double-blinded, randomized, placebo-controlled trial will assess cobiprostone’s safety and efficacy in preventing NSAID-induced gastric and duodenal ulcers, erosions and dyspeptic symptoms in patients with arthritis. The trial plans to enroll approximately 120 patients with osteoarthritis and/or rheumatoid arthritis at up to 15 sites in the United States.

The primary efficacy endpoint for the trial is the overall incidence of gastric ulcers during study treatment. The study will also evaluate secondary endpoints including overall incidence of duodenal ulcers; the change in the number of ulcers and/or erosions (gastric and duodenal) by patient; time-to-onset analysis of ulcer and/or erosion development; and the severity of overall gastrointestinal injury by using a standardized grading scale.

---

Cobiprostone is a functional fatty acid and a member of a class of compounds called prostones. It is a locally acting chloride-channel activator that works on ion channels located in the liver and the gastrointestinal tract. Cobiprostone has been evaluated in two Phase 1 trials in healthy volunteers, and in three Phase 2 proof-of-concept trials.

“Based on our pre-clinical experience with cobiprostone, which has shown the ability to inhibit gastric ulcer formation induced by an NSAID, and its favorable safety profile to date, we believe this compound has the potential to become the standard of care to prevent GI complications associated with NSAID use if it is approved,” said Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals’ founder, chairman and chief executive officer.

#### **About NSAID-Induced Gastric Ulcers**

NSAIDs are among the most commonly used drugs worldwide. Although the analgesic, anti-pyretic and anti-inflammatory properties of NSAIDs are very effective for the treatment of pain and inflammation, long-term use can cause gastrointestinal injury ranging from upset stomach to ulcer formation and gastrointestinal bleeding. While the COX-2 (cyclooxygenase-2) inhibitors subclass of NSAIDs appears to offer a reduced incidence of gastrointestinal injury, there are concerns regarding the potential risk of increased cardiovascular complications. Currently, misoprostol is the only the U.S. Food and Drug Administration (FDA) approved drug for reducing the risk of NSAID-induced gastric ulcers; however, the drug is frequently associated with diarrhea and abdominal pain. Proton pump inhibitors are extensively prescribed to treat existing gastric ulcers but have not been approved specifically to prevent ulcer development. Furthermore, there is cause for concern with calcium absorption interference by these agents in elderly patients and linkages to osteoporosis. H2-receptor antagonists have also been prescribed for preventing NSAID-induced gastric injury, but with limited success.

#### **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® (lubiprostone), received marketing approval from the FDA in January 2006 for the treatment of Chronic Idiopathic Constipation in adults. 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 outcome of Sucampo Pharmaceuticals’ Phase 2 trial of cobiprostone for the prevention of NSAID-induced ulcers in arthritis patients; Sucampo Pharmaceuticals’ ability to secure additional funding to conduct future clinical development of cobiprostone; Sucampo Pharmaceuticals’ dependence on its co-marketing alliance with Takeda Pharmaceutical Company Ltd. and Takeda Pharmaceuticals North America; 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 Sucampo Pharmaceuticals’ filings with the Securities and Exchange Commission (SEC), including the quarterly report on Form 10-Q for the period ended June 30, 2007, the final prospectus relating to Sucampo Pharmaceuticals’ initial public offering 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.*

###