## **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): April 29, 2008

# **Sucampo Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

Delaware	001-33609	13-3929237
(State or Other Jurisdiction of Incorporation)	(Commission	(IRS Employer
	File Number)	Identification No.)
4520 East-West Highway, Suite 300		
Bethesda, Maryland		20814
(Address of Principal Executive Offices)		(Zip Code)
(Former Nam	e or Former Address, if Changed Since Las	t Report)
Check the appropriate box below if the Form 8-K filing i following provisions ( <i>see</i> General Instruction A.2. below):	ý 6	1 /
o Written communications pursuant to Rule 425 under th	e Securities Act (17 CFR 230.425)	
o Soliciting material pursuant to Rule 14a-12 under the E	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 April 29, 2008, Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceutical Company Limited and its wholly owned subsidiary, Takeda Pharmaceuticals North America, Inc. announced that the U.S. Food and Drug Administration has approved Sucampo Pharmaceuticals' supplemental New Drug Application (sNDA) for AMITZA (lubiprostone) 8 mcg capsules twice daily to treat irritable bowel syndrome with constipation in women 18 years of age or older. As a result of this sNDA approval, Sucampo Pharmaceuticals will receive a development milestone payment of \$50.0 million from Takeda in accordance with the Collaboration and License Agreement dated October 29, 2004 between Sucampo Pharmaceuticals and Takeda to jointly market AMITIZA in the United States and Canada. 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.

Under the restated license agreement between Sucampo Pharmaceuticals and Sucampo AG, a Swiss patent-holding company and an affiliate through common ownership, dated June 30, 2006, Sucampo Pharmaceuticals will pay Sucampo AG \$2.5 million, reflecting 5% of the \$50.0 development milestone obligation from Takeda.

The information in Item 7.01 of 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 April 29, 2008.

## 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.

Date: April 30, 2008

SUCAMPO PHARMACEUTICALS, INC.

/s/ MARIAM E. MORRIS Name: Mariam E. Morris Title: Chief Financial Officer Exhibit No.

99.1

Press release issued by the registrant on April 29, 2008.

Description

For Immediate Release



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## Sucampo Pharmaceuticals Obtains FDA Approval for AMITIZA® for the Treatment of Irritable Bowel Syndrome with Constipation in Adult Women

Sucampo Pharmaceuticals' Second Consecutive Successful FDA Approval for AMITIZA; 8 mcg Dose to Fill the Void in the Currently Available Therapies for IBS-C in Adult Women

**Bethesda** — **Maryland, Deerfield** – **Illinois, and Osaka** – **Japan, April 29, 2008** ---- Sucampo Pharmaceuticals, Inc., (NASDAQ: SCMP, Sucampo Pharmaceuticals) and Takeda Pharmaceutical Company Limited (TSE: 4502, Takeda) and its wholly owned subsidiary, Takeda Pharmaceuticals North America, Inc., today announced that the U.S. Food and Drug Administration (FDA) has approved Sucampo Pharmaceuticals' supplemental New Drug Application (sNDA) for AMITIZAO (lubiprostone) 8 mcg capsules twice daily to treat irritable bowel syndrome with constipation (IBS-C) in women 18 years of age or older. As a result of this sNDA approval, Sucampo Pharmaceuticals will receive a development milestone payment of \$50 million from Takeda in accordance with the Collaboration and License Agreement dated on October 29, 2004 between Sucampo Pharmaceuticals and Takeda to jointly market AMITIZA in the United States and Canada.

AMITIZA, developed by Sucampo Pharmaceuticals, is an established therapy for Chronic Idiopathic Constipation in adults. It received FDA approval in January 2006 and has been available for that indication in the United States since April 2006. The product is co-marketed in the United States by Sucampo Pharmaceuticals and Takeda through Takeda Pharmaceuticals North America, Inc.

"Sucampo Pharmaceuticals is very pleased to have the FDA approval for the IBS-C indication for AMITIZA within the 10-month PDUFA date," said Ryuji Ueno, M.D., Ph.D., Ph.D., founder, chairman and chief executive officer, Sucampo Pharmaceuticals. "Currently, AMITIZA is the only widely available prescription drug therapy to treat Chronic Idiopathic Constipation in adults. The approval of IBS-C as an



## EXHIBIT 99.1

additional indication for adult women validates our commitment to the continued development of AMITIZA for further indications and dedication to patients and physicians in bringing forth effective drugs to serve unmet medical needs. Sucampo Pharmaceuticals and Takeda will begin promotion for this indication at Digestive Disease Week 2008, the largest gathering of gastroenterologists, to raise awareness regarding IBS-C and the ability of AMITIZA to treat this condition."

"AMITIZA's approval for the IBS-C indication obtained by Sucampo Pharmaceuticals is important for Takeda since gastroenterology is one of the core therapeutic areas for our company," said Yasuchika Hasegawa, president of Takeda. "This additional indication for AMITIZA will help Takeda further enhance our position in the U.S. primary care and GI specialty markets."

"Through this approval, we are pleased to be able to offer a medication that can provide overall symptom relief for the millions of adult women in the U.S. with IBS-C," said Art Rice, general manager, Gastroenterology, of Takeda Pharmaceuticals North America, Inc. "We are prepared to rapidly roll out our extensive efforts together with Sucampo Pharmaceuticals to educate both physicians and adult women with IBS-C to help them understand the condition and how it may be treated with AMITIZA."

The sNDA was based on a clinical study program that included two Phase III, multi-center, double-blinded, randomized, placebo-controlled trials involving 1,154 adults, followed by one long-term, open-labeled extension trial involving 476 adults diagnosed with IBS-C. In the two Phase III studies, patients received AMITIZA 8 mcg or placebo taken twice daily over a 12-week period. In both trials, patients receiving AMITIZA 8 mcg twice daily were nearly twice as likely to achieve an overall response that was statistically significant compared to those receiving placebo. The safety profile of AMITIZA was established during the double-blinded period, and further confirmed by an open-labeled extension period with a total treatment period of up to 52 weeks.

In the pivotal three-month trials, AMITIZA and placebo groups showed a similar incidence of serious adverse events (one percent in both the AMITIZA and placebo groups) and related adverse events (22 percent in AMITIZA vs. 21 percent in the placebo group). The most common treatment-related adverse events (>4 percent of patients) were nausea (8 percent in the AMITIZA group vs. 4 percent in the placebo group), diarrhea (7 percent vs. 4 percent, respectively) and abdominal pain (5 percent vs. 5 percent, respectively).

Sucampo Pharmaceuticals is currently conducting additional trials with AMITIZA, including a clinical study for treatment of constipation in pediatric patients; a clinical study of AMITIZA in patients with hepatic impairment, and a full clinical development for the treatment of opioid-induced bowel dysfunction, with two pivotal Phase III efficacy and safety studies and one long-term safety study ongoing.

# Important Safety Information about AMITIZA® (lubiprostone) for Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation

AMITIZA® (lubiprostone) is indicated for the treatment of Chronic Idiopathic Constipation in adults and Irritable Bowel Syndrome with Constipation (IBS-C) in women <sup>3</sup> 18 years old.

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 physician 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. Patients who experience severe nausea should inform their physician.

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 physician if the diarrhea becomes severe.

Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within 3 hours, but may recur with repeat dosing.

In clinical trials of patients with Chronic Idiopathic Constipation, the most common adverse reactions (incidence > 4%) for Chronic Idiopathic Constipation were nausea (29%), diarrhea (12%), headache (11%), abdominal pain (8%), abdominal distention (6%), and flatulence (6%).

In clinical trials of patients with IBS-C, the most common adverse reactions (incidence > 4%) were nausea (8%), diarrhea (7%) and abdominal pain (5%).

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

AMITIZAÒ is a registered trademark of Sucampo Pharmaceuticals, Inc.

### About Irritable Bowel Syndrome with Constipation

Irritable Bowel Syndrome with Constipation (IBS-C) is a disorder characterized by symptoms including abdominal pain or discomfort, bloating, and changes of bowel habits such as constipation and/or diarrhea. There are three main types of IBS: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), and IBS mixed with both constipation and diarrhea (IBS-M). Approximately 58 million Americans have IBS, with IBS-C accounting for approximately one-third of these cases. In IBS-C, symptoms are present for at least three months with symptom onset at least six months prior to diagnosis. Although people with IBS-C report many of the symptoms associated with constipation, the presence of abdominal pain or discomfort is what mainly differentiates IBS-C from chronic constipation. Additionally, the hypersensitivity of the gastrointestinal system of individuals with IBS-C makes them prone to experience the effects of even mild symptoms of constipation. IBS is more prevalent in women than men.

### Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc., a specialty biopharmaceutical company based in Bethesda, MD, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, 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

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Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding chief executive officer and advisor, international business development.

Sucampo Pharmaceuticals is marketing AMITIZA (lubiprostone) in the U.S. for chronic idiopathic constipation in adults and is developing the drug for additional gastrointestinal disorders with large potential markets. In addition, Sucampo Pharmaceuticals has a robust pipeline of compounds with the potential to target underserved diseases affecting millions of patients worldwide. Sucampo Pharmaceuticals has two wholly owned subsidiaries: Sucampo Pharma Europe, Ltd. headquartered in Oxford, UK with a branch office in Basel, Switzerland, and Sucampo Pharma, Ltd. located in Tokyo and Osaka, Japan. To learn more about Sucampo Pharmaceuticals and its products, visit <u>www.sucampo.com</u>.

#### **Takeda Pharmaceutical Company Limited**

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to striving toward better health for individuals and progress in medicine by developing superior pharmaceutical products. Additional information about Takeda is available through its corporate website, http://www.takeda.com.

#### Takeda Pharmaceuticals North America, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals North America, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited. In the United States, TPNA 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. To learn more about the company and its products, visit <u>www.tpna.com</u>.

#### **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' Annual Report on Form 10-K filed with the Securities and Exchange Commission for the year ended December 31, 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.