

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 4, 2013

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, 3<sup>rd</sup> Floor  
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.**

During April 4-5, 2013, Sucampo Pharmaceuticals, Inc. (“Company”) will make corporate update presentations at one-on-one meetings with analysts and investors and at an investor conference in New York City, NY. On April 5, 2013, the Company will make a corporate update presentation via webcast at an investor conference in New York City, NY at the 20th Annual Future Leaders in the Biotech Industry Conference. All meetings will include modifications to eight slides from those slides filed on Form 8K dated January 7, 2013 and six new slides. The additional slides are being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 to this Form 8-K 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, as amended, 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

99.1 The modifications of the eight slides and the six new slides to the corporate update presentation slides dated April 5, 2013.

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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: April 4, 2013

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and Corporate Secretary

# Sucampo Snapshot: **Prostone** Pioneers

## **Sucampo Mission**

To develop and commercialize prostone-based medicines to meet the major unmet medical needs of patients on a global basis

## **Commercial-stage, global pharmaceutical company**

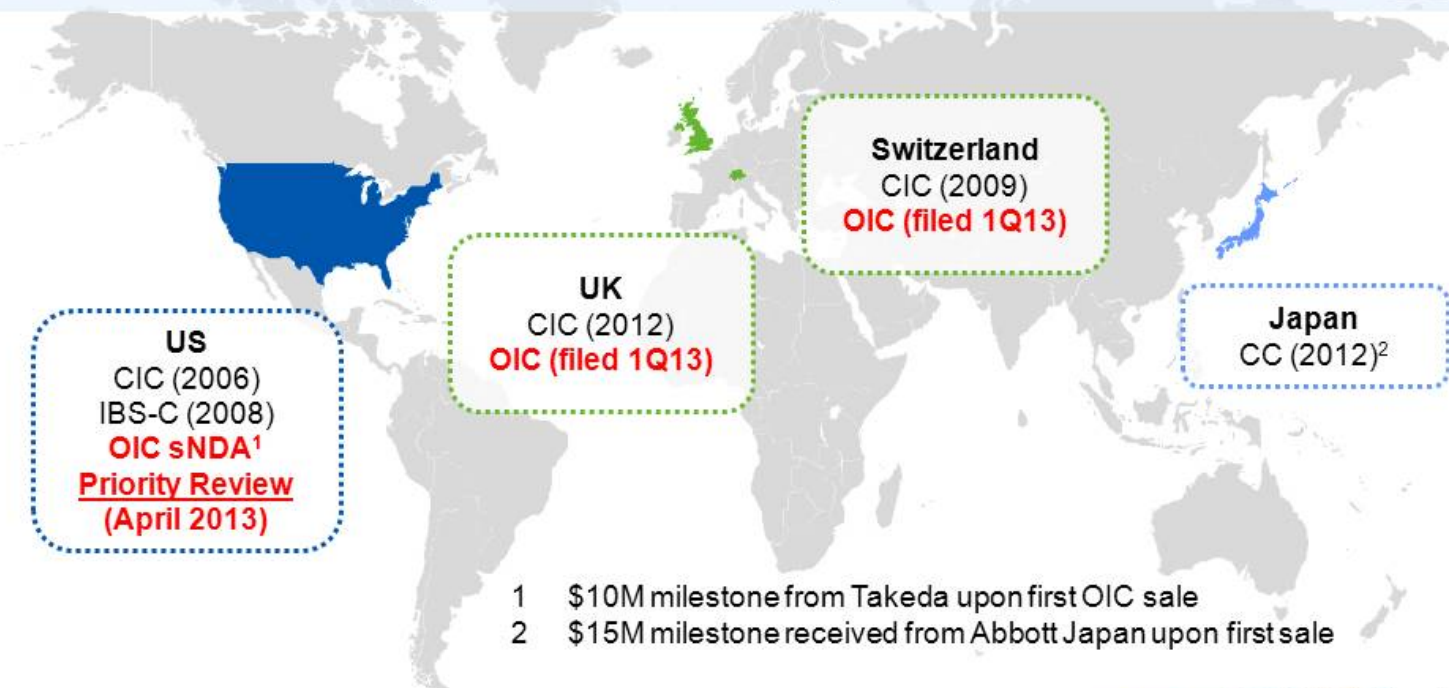
- 2 FDA-approved drugs based on our proprietary prostone technology
  - AMITIZA® (lubiprostone) in gastroenterology
  - RESCULA® (unoprostone isopropyl) in ophthalmics

## **Prostone pioneers**

- Therapeutic potential 1st identified by Sucampo's founders, Drs Ryuji Ueno and Sachiko Kuno

# Global AMITIZA Approvals and Regulatory Filings

AMITIZA has been used for >7 y with >7 million prescriptions by patients suffering from chronic idiopathic constipation and irritable bowel syndrome with constipation



See Reference 1

# Opioid-Induced Constipation: Increase Potential Population for AMITIZA and Strengthen Efficacy Positioning

- More than 230 M prescriptions for opioid use in the U.S. annually
- Moderate–severe OIC affects ~2.0M–2.5M patients
  - Currently no approved oral product for OIC
  - Most common reason for discontinuation of opioid therapy
  - OIC patients are viewed as “difficult to treat” and are dissatisfied
  - PCPs welcome 1 medicine indicated for multiple causes of constipation
- AMITIZA does not act on opiate receptors or inhibit analgesic activity of opioid therapy
- Mu-opioid–receptor agonist compounds under development may have cardiac safety concerns

**FDA priority review action date: late April 2013**

# Summary and Outlook for AMITIZA

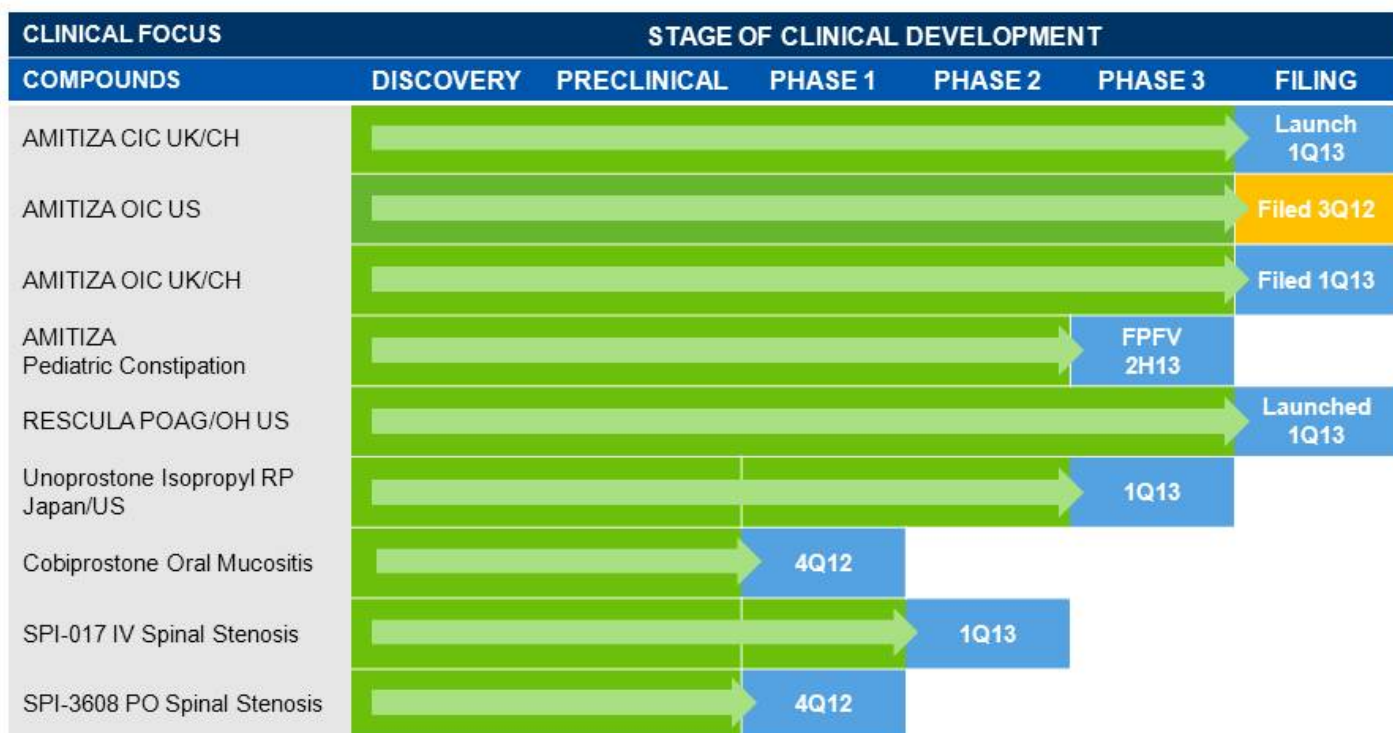
- Continue growth in US: over 7M prescriptions used over 7+ years, with favorable benefit-risk profile
- Near-term goals
  - Leverage new US product label, which removed pregnancy warnings and precautions (including removal of requirement for negative pregnancy test prior to therapy initiation), clarified information regarding use in pregnant and/or nursing women, and expanded labeling text of the Mechanism of Action
  - Seek approvals for OIC indication in US, UK and Switzerland
  - Expand global approvals and launches for AMITIZA worldwide
  - Develop and seek approval for AMITIZA in pediatric constipation
    - Currently unmet medical need; no approved prescription medications
  - Develop liquid formulation of AMITIZA for pediatric and long-term care markets

# RESCULA US Launch Overview

- sNDA approved December 2012
  - RESCULA may be used as a first-line agent or concomitantly with other topical ophthalmic drug products to lower intraocular pressure
  - RESCULA is a BK (Big Potassium) channel activator, which is different from other intraocular pressure (IOP) lowering agents.
  - RESCULA is believed to reduce elevated IOP by increasing the outflow of aqueous humor through the trabecular meshwork
- RESCULA launch in US Q1 2013
  - 40 specialty reps; expect 11% share of voice
  - Positive feedback and significant progress
    - More than 7,000 face-to-face calls
    - Over 60,000 samples shipped
    - 48 face-to-face meetings with plans and PBMs



# Sucampo's Clinical Pipeline



■ Successfully completed    
 ■ Approval pending    
 ■ Projected start or submission

# Key Facts

Trading Symbol	SCMP (NASDAQ)
Corporate Headquarters	Bethesda, MD
Stock Price (03-29-2013), 52-Week Range	\$6.54, \$8.50 to \$3.78
Shares Outstanding (12-31-2012)	41.9 M (1 class of common stock)
Daily Volume (90-day average)	120,397
Market Capitalization (03-29-2013)	\$274.5 M
Debt (12-31-12)	\$52.9 M
Cash & Equivalents (12-31-12)	\$91.4 M
Enterprise Value (03-29-2013)	\$235.9 M
YTD Total Revenue (12-31-2012)	\$81.5 M
Full-time Employees (03-29-2013)	124
Fiscal Year Ends	December 31
Accounting Firm	PricewaterhouseCoopers, LLP

# 2013 Key Value Drivers

✓ Completed     In Process

AMITIZA	US	<input type="checkbox"/> Obtain approval of OIC sNDA: Q2 2013 <ul style="list-style-type: none"> <li>• \$10M milestone payment upon first OIC sale</li> </ul> <input type="checkbox"/> Achieve FPFV in Pediatric P3 trial by H2 2013
	Japan	<input type="checkbox"/> Grow sales in Japan in 2013
	EU	<input checked="" type="checkbox"/> Submit for regulatory approval of OIC in Switzerland and UK by Q1 2013 <input type="checkbox"/> Seek NICE endorsement for CIC and OIC and make AMITIZA available in UK <input type="checkbox"/> Begin active marketing in Switzerland for CIC <input type="checkbox"/> Use MHRA approval to seek expansion of CIC indication to other EU markets via MRP
RESCULA	US	<input checked="" type="checkbox"/> Launch: Q1 2013
Pipeline	Cobiprostone	<input type="checkbox"/> Complete oral mucositis P1A trial: Q2 2013 <input type="checkbox"/> Initiate P1B/2A trial in oral mucositis: Q4 2013
	SPI-017	<input type="checkbox"/> Complete spinal stenosis P2A trial: Q4 2013

# Terms of Sucampo's AMITIZA Agreements

- **Takeda Agreement**

- Takeda shall promote, market, and sell AMITIZA in US and Canada
- Sucampo's tiered royalty rate: 18%–26% of annual net sales
- Sucampo earned \$20M in upfront and \$130M in development milestone payments as of 9/30/12
- Sucampo received \$106M in reimbursement for R&D expenses from Takeda

- **Abbott Japan Agreement**

- Abbott Japan shall promote, market, and sell AMITIZA in Japan
- Sucampo will sell product to Abbott Japan at discount to Abbott Japan's approved reimbursement price
- Sucampo earned \$10M in upfront and \$12.5M in development milestone payments as of 9/30/12
- Sucampo earned \$15M milestone payment on 1st commercial sale in Japan by Abbott Japan in 4Q12

# Substantial Abdominal Pain Improvement in IBS-C Patients Reporting at Least Severe Abdominal Pain at Baseline\*

% Improvement	Placebo BID (n = 94)	Lubiprostone 8 µg BID (n = 183)	P Value†
≥10	53.9%	61.9%	<0.0001
≥20	40.1%	49.6%	<0.0001
≥30	24.2%	35.1%	<0.0001
≥40	14.5%	23.7%	<0.0001
≥50	9.4%	16.7%	<0.0001
≥60	4.7%	12.7%	<0.0001

\*LOCF analysis; †P value from CMH test.  
See Reference 25

# Issued Lubiprostone Patents

<u>US Patent No.</u>	<u>Expires</u>	<u>Type of patent</u>
5,284,858	2014	Composition of matter (drug substance)
6,414,016	2020	Therapeutic use (treating constipation)
6,583,174	2020	Composition of matter (drug product)
7,064,148	2022	Therapeutic use (treating constipation)
7,417,067	2020	Composition of matter (drug product)
7,795,312	2024	Therapeutic use (treating IBS)
8,026,393	2027	Composition of matter (drug product)
8,071,613	2020	Therapeutic use (treating constipation)
8,088,934	2021	Composition of matter (drug substance)
8,097,649	2020	Composition of matter (drug product)
8,097,653	2022	Therapeutic use (treating constipation)
8,114,890	2020	Composition of matter (drug product)
8,338,639	2027	Composition of matter (drug product)
8,389,542	2022	Composition of matter (drug product) and therapeutic use (treating constipation)

\*For Orange Book-listed patents concerning lubiprostone, see for example:

[http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=021908&Product\\_No=001&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021908&Product_No=001&table1=OB_Rx) or  
[http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=021908&Product\\_No=002&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021908&Product_No=002&table1=OB_Rx)

# Issued Lubiprostone Patents

## Japanese

<u>Patent No.</u>	<u>Expires *</u>	<u>Type of patent</u>
4,332,316	2020	Composition of matter (drug substance)
4,332,353	2022	Therapeutic use (treating OIC)
4,684,334	2021	Therapeutic use (treating constipation)
4,783,794	2027	Composition of matter (drug product)
4,786,866	2022	Therapeutic use (treating constipation)
4,852,229	2022	Therapeutic use (treating constipation)
4,889,219	2023	Therapeutic use (treating IBS)

\* The term of the plural eligible patents may be extended up to 5 years.

## European

<u>Patent No.</u>	<u>Expires *</u>	<u>Type of Patent</u>
1,220,849	2020	Composition of matter (drug product)
1,315,485	2021	Therapeutic use (treating constipation)
1,392,318	2022	Therapeutic use (treating OIC)
1,426,361	2020	Composition of matter (drug substance)
1,443,938	2022	Therapeutic use (treating constipation)

\* The term of one of the eligible patents may be extended up to 5 years.

# Issued Unoprostone Isopropyl Patents

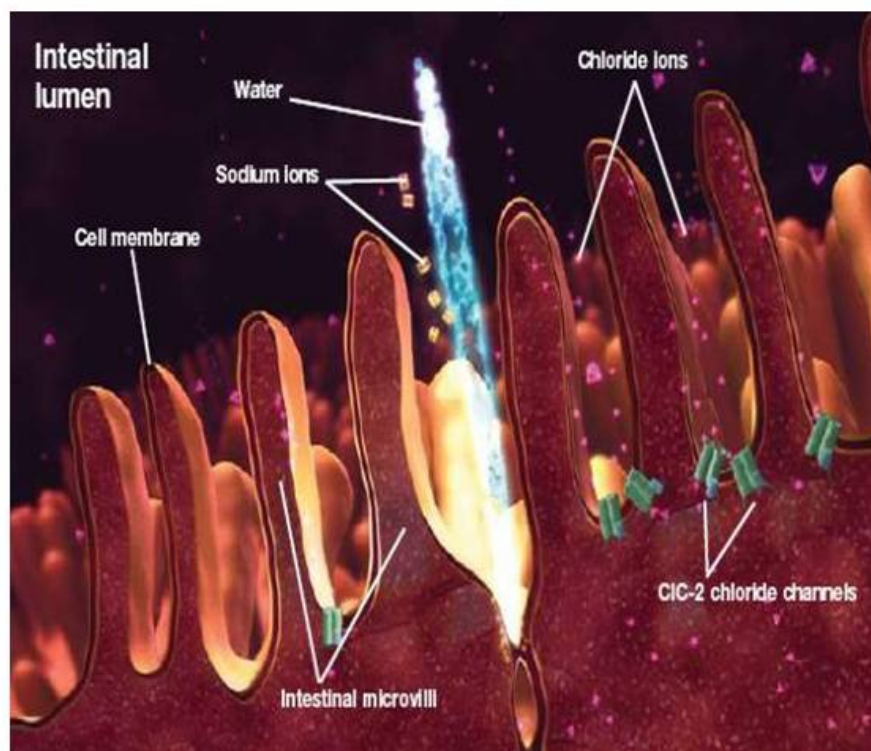
<u>US Patent No.</u>	<u>Expires</u>	<u>Type of patent</u>
6,770,675	2018	Composition of matter (drug product) and therapeutic use (treating ocular hypertension)
6,458,836	2021	Therapeutic use (treating ocular hypertension and glaucoma)

\*For Orange Book-listed patents concerning unoprostone isopropyl, see for example:

[http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl\\_No=021214&Product\\_No=001&table1=OB\\_Rx](http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021214&Product_No=001&table1=OB_Rx)



# AMITIZA Mechanism of Action: ClC-2 Ion-Channel Activation and Fluid Secretion



Highly selective activation  
of ClC-2 channels in  
intestinal lumen



Chloride efflux followed by  
passive efflux of sodium  
into small intestine



Enhanced intestinal fluid  
secretion without alteration  
of serum electrolyte levels

See Reference 1