

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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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): December 17, 2013

Sucampo Pharmaceuticals, Inc.

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(Exact Name of Registrant as Specified in Charter)

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Delaware  
(State or Other Juris-  
diction of Incorporation)

001-33609  
(Commission  
File Number)

30-0520478  
(IRS Employer  
Identification No.)

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4520 East-West Highway, 3<sup>rd</sup> Floor  
Bethesda, Maryland  
(Address of Principal Executive Offices)

20814  
(Zip Code)

Registrant's telephone number, including area code: (301) 961-3400

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(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))
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**Item 7.01. Regulation FD Disclosure.**

On December 17, 2013, Sucampo Pharmaceuticals, Inc. (“Company”) will make a corporate update presentation at one-on-one meetings with analysts and investors in Boston, MA at the Guggenheim Boston Healthcare Day – Life Sciences. All meetings will include the slides filed on Form 8K dated November 13, 2013 including modifications to nine slides. The modified 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 nine slides to the corporate update presentation slides dated November 13, 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: December 17, 2013

By: /s/ Thomas J. Knapp  
Name: Thomas J. Knapp  
Title: EVP, Chief Legal Officer and Corporate Secretary



### Continued AMITIZA YOY Growth

- Takeda reported Q3 net sales at \$72.5M\*; 3.5% YoY increase in net sales to \$204M through September
- Growth trend continued as October reached highest TRx on record for AMITIZA – up 4% in October YoY to 117K<sup>1</sup>

### OIC Opportunity

- 40-80% of non-cancer patients on chronic opioids will suffer from OIC<sup>2</sup>; moderate to severely constipated market estimated at 2-2.5M<sup>3</sup>
- 26.5% increase\*\* in TRx for targets in pain management, rheumatology, surgery and anesthesiology specialists<sup>4</sup>
- Sucampo to exercise co-promote option in OIC targets with contract sales organization; Takeda to reimburse Sucampo based on details to healthcare prescribers

### Base Business Remains Strong

- Preferred managed care position, Medicare Part D plan share continues to grow
- Significantly lower copay vs. competition

See Reference 1-4; \*AMITIZA net sales reported by Takeda for royalty calculation purposes \*\*26.5% growth in new targets for the first full quarter post the launch of the OIC indication

# Sucampo Prostone Pipeline Key Highlights

## AMITIZA Clinical Development & Life Cycle Management

### New liquid dosage form

- Initiated liquid formulation pivotal trial in CIC in adults October 2013; alternative treatment for patients who prefer not to take capsules
  - Takeda funding 100% of development costs
  - NDA filing planned after trial ends 1H 2014

### Pediatric Constipation

- Pediatric Functional Constipation P3 program began Q4 2013
- Very common GI complaint in children; WW prevalence ranges from 4-37%<sup>9</sup>
- Only 50-70% of children demonstrate long-term improvement with current treatments<sup>10</sup>
- Previous open-label study results published October in JPGN\* online
- Takeda funding 70% of development costs



Abdominal radiograph of constipated child showing stool throughout the colon

## Unoprostone Isopropyl for Retinitis Pigmentosa

### Retinitis Pigmentosa (RP)

- Degenerative retinal disease with no approved prescription medicines available<sup>4</sup>
- Ongoing P3 clinical trial in unoprostone isopropyl by development partner, R-Tech Ueno
  - Patient enrollment completed October 2013
  - Interim one-year results available early 2015
- Unoprostone isopropyl has received orphan drug designation for RP in the U.S. & E.U.
- Sucampo will work with regulatory authorities in the U.S. & E.U. to determine required incremental data for filing in each region



Normal Vision



Retinitis Pigmentosa

See References 4, 9-12  
\*Journal of Pediatric Gastroenterology and Nutrition

# Clinical Pipeline & Product Development Highlights

CLINICAL FOCUS	STAGE OF CLINICAL DEVELOPMENT				
	LEAD COMPOUNDS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Lubiprostone Liquid Formulation CIC					Began 3Q13
Unoprostone Isopropyl Retinitis Pigmentosa*					Began 1Q13
Lubiprostone Pediatric Functional Constipation					Began 4Q13
IV Ion Channel Activator Spinal Stenosis				Phase 2a Began 1Q13	
PO Ion Channel Activator Spinal Stenosis			Phase 1b 1Q14		
Cobiprostone Oral Mucositis			Phase 1b Began 4Q13		

■ SUCCESSFULLY COMPLETED ■ PROJECTED START ■ ONGOING

\*Co-developing with R-Tech Ueno, Ltd.

## Key Facts & Financial Highlights

Key Facts	
Trading Symbol	SCMP (NASDAQ)
Corporate Headquarters	Bethesda, MD
Stock Price (12-13-13), 52-Week Range	\$7.72, \$10.48 to \$4.55
Shares Outstanding (12-13-13)	43.3M (1 class of common stock)
Daily Volume (90-day average)	129,896
Market Capitalization (12-13-13)	\$334.3M
Enterprise Value (12-13-13)	\$301.3M
Financial Highlights as of 1 <sup>st</sup> 9 Months of 2013	
Cash & Equivalents	\$91.0M
Total Revenue	\$65.1M
Net Income, excluding special items	\$7.0M
EPS, excluding special items	\$0.16
AMITIZA U.S. Net Sales (as reported by Takeda for royalty calculation purposes):	\$204.1M

## 2013 Key Value Drivers

AMITIZA	U.S.	<ul style="list-style-type: none"> <li>✓ Obtain approval of OIC sNDA: 1Q 2013</li> <li>✓ \$10M milestone payment upon commercial launch of OIC</li> </ul>
	Global	<ul style="list-style-type: none"> <li><input type="checkbox"/> Pursue strategic alliances; new AMITIZA indications / territories</li> </ul>
	Japan	<ul style="list-style-type: none"> <li>✓ Grow sales in Japan in 2013</li> </ul>
	E.U.	<ul style="list-style-type: none"> <li>✓ Submit for regulatory approval of OIC in Switzerland and U.K. by 1Q 2013</li> <li>✓ Begin active marketing in Switzerland for CIC</li> <li><input type="checkbox"/> Use MHRA approval to seek expansion of CIC and OIC indication to other E.U. markets via MRP</li> <li><input type="checkbox"/> Seek NICE endorsement for CIC and OIC, and make AMITIZA available in U.K. for CIC</li> </ul>
RESCULA	U.S.	<ul style="list-style-type: none"> <li>✓ Launch: 1Q 2013</li> </ul>
Pipeline	Lubiprostone	<ul style="list-style-type: none"> <li>✓ Achieve FPFV in Pediatric P3 trial in 4Q 2013</li> </ul>
	Cobiprostone	<ul style="list-style-type: none"> <li>✓ Complete oral mucositis P1a trial: 2Q 2013</li> <li>✓ Initiate P1b trial in oral mucositis: 4Q 2013</li> </ul>
	IV Ion Channel Activator	<ul style="list-style-type: none"> <li><input type="checkbox"/> Complete spinal stenosis P2a trial: 4Q 2013</li> </ul>

✓ Completed    In Progress



## Key Upcoming Events

### Q4 2013

Top-line results of phase 2a trial of IV ion channel activator for Lumbar Spinal Stenosis

### Q4 2013 / 1H 2014

CEO Transition (EST)

### Q1 2014

AMITIZA OIC indication potential approval in Switzerland / U.K.

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Shares Outstanding (12-13-13)	43.3M (1 class of common stock)
Daily Volume (90-day average)	129,896
Market Capitalization (12-13-13)	\$334.3M
Enterprise Value (12-13-13)	\$301.3M

Financial Highlights as of 1 <sup>st</sup> 9 Months of 2013	
Debt	\$57.9M
Cash & Equivalents	\$91.0M
Total Operating Expense	\$49.1M
Total Revenue	\$61.5M
Net Income, excluding special items	\$7.0M
R&D Revenue	\$16.3M
Product Royalty Revenue	\$37.3M
R&D Expense	\$14.5M
EPS, excluding special items	\$0.16
AMITIZA U.S. Net Sales (as reported by Takeda for royalty calculation purposes):	\$204.1M

# Additional Issued Patents

## Lubiprostone Ex U.S.

Japanese Patent No.	Expires	Type of Patent
4,332,316	2023	Composition of matter (drug substance and drug product)
4,332,353	2025	Therapeutic use (treating OIC)
4,684,334	2023	Therapeutic use (treating constipation)
4,783,794	2028	Composition of matter (drug product)
4,786,866	2023	Therapeutic use (treating constipation)
4,852,229	2023	Therapeutic use (treating constipation)
4,889,219	2024	Therapeutic use (treating IBS)

European Patent No.	Expires	Type of Patent
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)
1,978,944	2027	Composition of matter (drug product)

## Unoprostone

U.S. Patent No.	Expires	Type of Patent
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)

\*Orange Book-listed patents concerning unoprostone isopropyl:

[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)

# References

1. IMS Smart View, NPA Report, client Factored Numbers, September 2012-October 2013
2. Camilleri M. Opioid-induced constipation: challenges and therapeutic opportunities. *Am J Gastroenterol*. 2011 May;106(5):835-42
3. Clearview Analysis 2008
4. Internal Research
5. AMITIZA Physician ATU W11 2013
6. Fingertip Formulary (NOV 2013)
7. IMS Smart View, RAPID Weekly, Client Factored Numbers
8. Sucampo data on file
9. Loening-Baucke V. Prevalence rates for constipation and faecal and urinary incontinence. *Arch Dis Child*. 2007 Jun;92(6):486-9
10. Biggs WS. *et al* Evaluation and treatment of constipation in infants and children. *Am Fam Physician* 2006 Feb;73(3):469-77
11. Radiograph from Borowitz - [Pediatric Constipation article](#) on Medscape website; accessed 09.19.13
12. Photos from Foundation Fighting Blindness website [What is Retinitis Pigmentosa?](#); accessed 09.19.13
13. The American Association of Neurological Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13
14. Diagram from American Academy of Orthopaedic Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13
15. Based on statistics from the American Cancer Society and the National Cancer Institute
16. Trotti A *et al*. Mucositis incidence, severity and associated outcomes in patients with head and neck cancer receiving radiotherapy with or without chemotherapy: a systematic literature review. *Radiother Oncol*. 2003 Mar;66(3):253-62
17. Photos from Silverman - Diagnosis and management of oral mucositis. *J Support Oncol* 2007; 5 (2 Suppl 1):13-21