

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): May 19, 2014

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Sucampo Pharmaceuticals, Inc.  
(Exact Name of Registrant as Specified in Charter)

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Delaware (State or Other Jurisdiction 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)
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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 May 19, 2014, Sucampo Pharmaceuticals, Inc. (“Company”) will make corporate update presentations at one-on-one meetings with analysts and investors in New York, NY. On May 20, 2014, the Company will make a corporate update presentation via webcast at an investor conference in New York, NY at the UBS Global Healthcare Conference. All meetings will include written communications comprised of slides. The 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 corporate update presentation slides dated May 19, 2014.

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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: May 19, 2014

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and  
Corporate Secretary

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# Sucampo Pharmaceuticals, Inc. Corporate Update

May 19, 2014

**Peter Greenleaf**

Chief Executive Officer

**Cary Claiborne**

Chief Financial Officer

**Silvia Taylor**

Senior Vice President, Investor Relations and Corporate Communications



1. **Introductions and Forward-Looking Statements**
2. **Leadership Update**
3. **Company Introduction & Value Proposition**
4. **Prostone Platform Technology Overview**
4. **Commercial Overview**
6. **Pipeline and Product Development Guidance**
7. **Key Upcoming Events**
8. **Conclusion**

# Forward-Looking Statements

This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; the ability of Sucampo to develop and commercialize existing and pipeline products; Sucampo's ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the U.S. and internationally and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities Exchange Commission (SEC) on March 12, 2014 and the Form 8-K as filed with the SEC on May 9, 2014.

# Sucampo Leadership Update

## **Peter Greenleaf, Chief Executive Officer**

- 20 years of biopharmaceutical experience in commercialization, strategic planning & drug development
- Former CEO and Director of Histogenics
- Former President of MedImmune, the worldwide biologics R&D arm of AstraZeneca
- Board Member: BIO and Tech Council of Maryland
- Chairman Maryland Venture Fund Authority

# Sucampo Value Proposition: Commercial-Stage, Global Biopharmaceutical Company

## Great People

- Entrepreneurial
- Passionate
- Lean and Nimble Organization

## Great Science

- Proprietary Prostone Technology
- 2 Approved Products
  - AMITIZA® (lubiprostone) in gastroenterology
  - RESCULA® (unoprostone isopropyl ophthalmic solution) 0.15% in ophthalmics
- Robust Pipeline

## Strong Fundamentals

- Significant source of funding
- Profitable
- Global Partnerships

Comprehensive Corporate Strategy Review: Q3 2014

# Sucampo's Proprietary Prostone Technology

**Has generated two globally approved products**

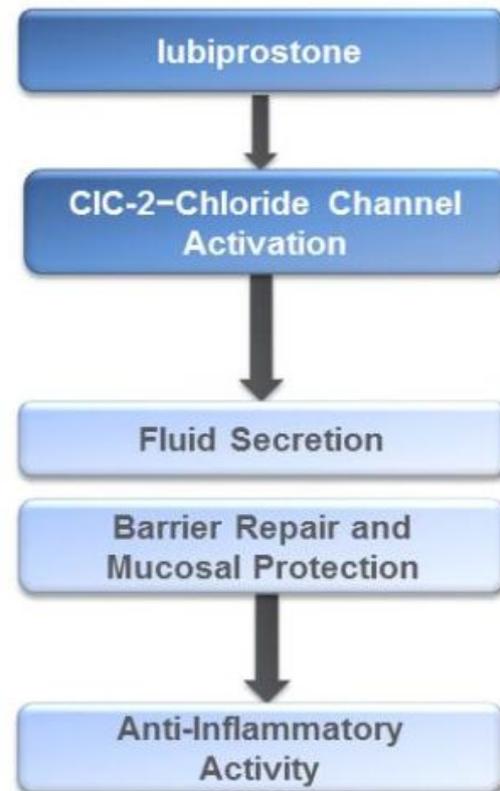
- AMITIZA<sup>®</sup>, RESCULA<sup>®</sup>

**What are prostones?**

- Functional fatty acids naturally occurring in the human body
- Ion-channel activators
- Physiological mediators of restoration of cellular homeostasis and tissue regeneration

**Clinical safety profile well-tolerated, e.g. clinical safety record of AMITIZA and RESCULA**

**Clinical potential: broad, applicable to various therapeutic areas**





# AMITIZA U.S.



## Continued AMITIZA YOY Growth

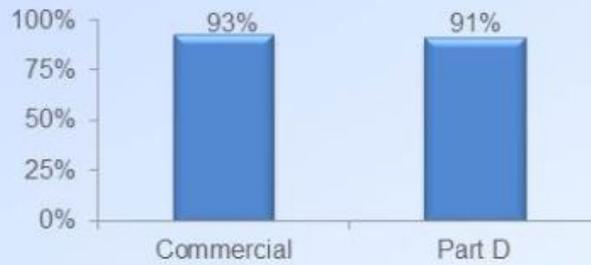
- Net sales growth of 16% for Q1 2014 compared to Q1 2013
- TRx growth of 3% for Q1<sup>1</sup>

## Market Growth Accelerating

- Class up 6% for Q1 2014 vs. Q1 2013

## Strong Partner Commercial Execution Driving Sales Growth

- Over 8M TRx's in  $\approx$  8 years<sup>2</sup>; heritage is driver of increased sales
- Managed care advantage and broad patient access vs. competition; increasing patient- focused efforts



AMITIZA is covered for 90% of lives nationally for all channels<sup>3</sup>

# Global AMITIZA Approvals and Regulatory Filings



# AMITIZA Global Snapshot

## Japan

- Continued success; sales continue to be above our and Abbott's expectations
- AMITIZA sales in Japan grew to \$6.1M in Q1 2014 (+177%)
- Abbott applying more than half of its detailing efforts in Japan to AMITIZA
- 2 week limitation removed in December 2013

## Europe

### Switzerland

- OIC decision ≈ 2H 2014
- Several reimbursement limitations revised

### U.K.

- CIC NICE\* submission; decision ≈ 2H 2014
- MHRA\*\* did not approve OIC; evaluating path forward

### E.U.

- Initiating MRP\*\*\*; anticipate approvals Q1 2015

## Rest of World

- Continued partnership discussions with global and regional companies for AMITIZA for new indications and new territories (Europe, Latin America, China, Russia and other emerging markets)



\*National Institute for Health and Care Excellence \*\*Medicines and Healthcare Products Regulatory Agency; \*\*\* Mutual Recognition Procedure



**SUCAMPO**

The Science of Innovation

## AMITIZA has a robust U.S. patent estate

- 13 patents in Orange Book; latest patents expire in 2027

## Paragraph IV certification notice letter to Sucampo: January 2, 2013 regarding ANDA submitted to FDA by Anchen Pharmaceuticals

- Notice letter alleges claims in AMITIZA's composition, method of use, and/or formulation patents are invalid, unenforceable, and/or will not be infringed by Anchen's manufacture, use or sale of the product described in its ANDA
  - Sucampo, joined by Takeda and R-Tech Ueno, filed a patent infringement lawsuit on 7 patents which comprise 126 claims against Anchen and Par Pharmaceuticals on February 8, 2013
  - 30-month stay through July 2015
  - Markman hearing occurred March 31, 2014; judge ruled in favor of Sucampo
    - Trial in December 2014

## Well-positioned to defend AMITIZA IP

- Only one claim out of 126 claims covered in lawsuit needs to be successful



# RESCULA U.S. Overview



- **RESCULA Commercial Strategy**

- Implemented new commercial strategy for RESCULA
  - Reducing investment in product
  - Focus on current RESCULA prescribers
- Contract sales representatives are spending 20% of time calling on current RESCULA prescribers

- **Belief in value of continued development of unoprostone isopropyl**

# At-A-Glance: Sucampo Pipeline

CLINICAL FOCUS LEAD COMPOUNDS	STAGE OF CLINICAL DEVELOPMENT			
	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Lubiprostone Pediatric Functional Constipation				Began Q4 13
Lubiprostone Alternate Formulation CIC				Began Q3 13
Unoprostone Isopropyl Retinitis Pigmentosa*				Began Q1 13
Cobiprostone Oral Mucositis		P1b Q1 14	P2a 2H 14	
IV Ion Channel Activator Lumbar Spinal Stenosis			P2 Q4 13	P2a 2H 14
PO Ion Channel Activator Lumbar Spinal Stenosis		P1b Began Q1 14		

■ COMPLETED ■ PROJECTED START ■ ONGOING

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

## Pediatric Functional Constipation (PFC)

- Prevalence:  $\approx$  4 - 37% of children worldwide have functional constipation<sup>4</sup>
- Initiated global pivotal P3 clinical program for lubiprostone for children and adolescents aged 6 - 17 years with PFC
  - First patients enrolled into follow-on, open-label safety extension study in April 2014
  - Takeda is funding 70% of development costs



Abdominal radiograph of constipated child showing stool throughout the colon

## Liquid Formulation

- Based on FDA input and trial results, looking at alternative formulation
  - Takeda funding 100% of the costs, including additional formulation work

## Retinitis Pigmentosa (RP)

- Prevalence:  $\approx 1$  in 4,000 individuals WW suffer from RP
- Degenerative retinal disease with no approved prescription medicines available<sup>6</sup>
- Ongoing P3 clinical trial by development partner, R-Tech Ueno
  - Interim 1 yr results available early 2015
- Unoprostone isopropyl has orphan drug designation for RP in U.S. & E.U.
  - Sucampo will work with regulatory authorities in U.S. & E.U. to determine required incremental data for filing in each region



See Reference 6, 7 (Photo)

# Key Facts, Financial Highlights & Guidance

Key Facts	
Trading Symbol	SCMP (NASDAQ)
Corporate Headquarters	Bethesda, MD
Stock Price (05-14-14), 52-Week Range	\$6.80; \$11.00 to \$5.40
Shares Outstanding (05-14-14)	44.5M (1 class of common stock)
Daily Volume (90-day average)	237,252
Market Capitalization (05-14-14)	\$302.3M
Enterprise Value (05-14-14)	\$249.5M
Financial Highlights for Q1 2014	
Cash & Equivalents	\$106.0M
Total Revenue	\$22.2M
Net Income	\$0.7M
EPS	\$0.02
AMITIZA U.S. Net Sales (as reported by Takeda for royalty calculation purposes):	\$75.0M
Financial Guidance	
2014 Guidance – Net Income	\$3M - \$5M, or \$0.06 - \$0.11 (EPS)

# Upcoming Events

## 2H 2014

### Commercial

AMITIZA OIC indication potential approval in Switzerland

AMITIZA NICE endorsement potential in the U.K.

### Clinical

Beginning phase 2a trial of cobiprostone in oral mucositis

Conclusion in Q3 2014 of phase 1b trial of orally administered ion-channel activator for lumbar spinal stenosis

### Financial

Q2 2014 Earnings call August 2014

### Corporate

Corporate Strategy Update Q3 2014

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- 2 Approved Products
  - AMITIZA® (lubiprostone) in gastroenterology
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## Strong Fundamentals

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Comprehensive Corporate Strategy Review: Q3 2014

# Appendix

# Key Facts & Financial Highlights

Key Facts	
Trading Symbol	SCMP (NASDAQ)
Corporate Headquarters	Bethesda, MD
Stock Price (05-14-14), 52-Week Range	\$6.80, \$11.00 to \$5.40
Shares Outstanding (05-14-14)	44.5M (1 class of common stock)
Daily Volume (90-day average)	237,252
Market Capitalization (05-14-14)	\$302.3M
Enterprise Value (05-14-14)	\$249.5M

Financial Highlights for Q1 2014	
Debt	\$52.2M
Cash & Equivalents	\$106.0M
Total Operating Expense	\$16.0M
Total Revenue	\$22.2M
Net Income	\$0.7M
R&D Revenue	\$1.8M
Product Royalty Revenue	\$13.5M
R&D Expense	\$5.1M
EPS	\$0.02
AMITIZA U.S. Net Sales (as reported by Takeda for royalty calculation purposes):	\$75.0M

# Sucampo Prostone Pipeline Key Highlights

## Cobiprostone for Oral Mucositis

### Oral Mucositis

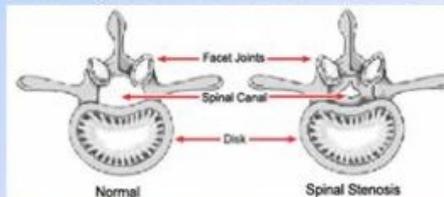
- Prevalence: ≈350,000 head and neck cancer patients in the U.S.<sup>11</sup>; oral mucositis affects 80-90%<sup>12</sup> of these patients
- Formation of ulcers that result from radiation therapy and chemotherapy in cancer patients
  - Total WW market estimated to be up to \$500M<sup>4</sup>
  - Also impacts patients treated for solid tumors, or receiving hematopoietic stem cell transplantation
- Completed a P1b trial of cobiprostone evaluating its safety and pharmacokinetics
  - Well-tolerated and low systemic exposure
- Expect to begin a P2a trial of cobiprostone in 2H 2014



## Ion Channel Activators for Lumbar Spinal Stenosis

### Lumbar Spinal Stenosis (LSS)

- Prevalence: ≈400,000 Americans, most >60 years of age<sup>8</sup>
- Degenerative change in lumbar spine; unmet medical need with limited treatment options globally<sup>4</sup>
- Top-line results of P2a, double-blind, placebo-controlled trial of IV ion channel activator showed statistically significant improvement in VAS\* pain



- Initiated P1b evaluating safety and PK of orally administered ion channel activator; conclude Q3 2014
- Currently assessing our next steps for both oral and IV ion channel activators; will update conclusions in Q3 2014

See References 8;9;11;12, References 10; 13 (Photo)

# Terms of Sucampo's AMITIZA Agreements

## **Takeda Agreement**

- Takeda shall promote, market, and sell AMITIZA in U.S. and Canada
- Sucampo's tiered royalty rate: 18%–26% of annual net sales
- Sucampo earned \$20M in upfront and \$140M in development milestone payments as of 3/31/14
- Sucampo received \$117M in reimbursement for R&D expenses from Takeda as of 3/31/14

## **Abbott Japan Agreement**

- Abbott Japan shall promote, market, and sell AMITIZA for CIC in Japan
- Sucampo will sell product to Abbott Japan at discount to Abbott Japan's approved reimbursement price
- Sucampo earned \$10M in upfront and \$27.5M in development milestone payments as of 3/31/14

# Issued Lubiprostone U.S. Patents

U.S. Patent No.	Expires	Type of Patent
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)
6,982,283*	2022	Therapeutic use (treating OIC)
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)

\*Orange Book-listed patents concerning lubiprostone:

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

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

# 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)
4,851,467 & 5,421,332	2027	Manufacturing
4,648,340	2028	Manufacturing

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)

\* Extended till 2024 in Switzerland. SPC was filed in UK, under examination.

## Unoprostone

U.S. Patent No.	Expires	Type of Patent
5,773,471	2016	Therapeutic use (treating retinitis pigmentosa)
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)
8,609,729	2031	Therapeutic use (treating AMD)

\*Orange Book-listed patents concerning unoprostone isopropyl:

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

# References

1. IMS SmartView, NPA Report, client Factored Numbers
2. Internal Research
3. Fingertip Formulary (NOV 2013)
4. Camilleri M. Opioid-induced constipation: challenges and therapeutic opportunities. *Am J Gastroenterol*. 2011 May;106(5):835-42
5. Radiograph from Borowitz - [Pediatric Constipation article](#) on Medscape website; accessed 09.19.13
6. Sucampo data on file
7. Photos from Foundation Fighting Blindness website [What is Retinitis Pigmentosa?](#); accessed 09.19.13
8. Based on statistics from the American Cancer Society and the National Cancer Institute
9. 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
10. Photos from Silverman - Diagnosis and management of oral mucositis. *J Support Oncol* 2007; 5 (2 Suppl 1):13-21
11. Clearview Analysis 2008
12. The American Association of Neurological Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13
13. Diagram from American Academy of Orthopaedic Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13

