

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): February 26, 2014

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Juris-  
diction 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 2.02 Results of Operations and Financial Condition**

On February 26, 2014, Sucampo Pharmaceuticals, Inc. (“the Company”) announced its consolidated financial results for the four quarter and year ended December 31, 2013. 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 slides from the presentation will be referenced below are incorporated by reference.

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, as amended, (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 (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

## **Item 7.01 Regulation FD Disclosure**

On February 26, 2014, the Company will host a conference call with investors to discuss the Company's financial and operating results for the fourth quarter and year ended December 31, 2013. The conference call including slides will be made available to the public via conference call and webcast. The slides from the presentation are being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.2 to this Form 8-K shall not be deemed “filed” for purposes of Section 18 of 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 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 2.02 shall be deemed to be furnished, and not filed:

- 99.1 Press Release issued by the Company on February 26, 2014.
  - 99.2 The corporate update presentation slides dated February 26, 2014.
-

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: February 26, 2014

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and Corporate Secretary

## Sucampo Pharmaceuticals, Inc. Reports Fourth Quarter and Full Year 2013 Financial and Operating Results

*Full Year Net Income Excluding Special Items of \$9.4 Million, Up 94% over 2012 and Exceeds Guidance*

*Company to Host Conference Call Today at 5:00 pm Eastern*

BETHESDA, Md., Feb. 26, 2014 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (Nasdaq:SCMP), a global biopharmaceutical company, today reported consolidated financial results for the fourth quarter and full year ending December 31, 2013, with earnings that exceeded Sucampo's previously-issued guidance.

### Financial Highlights for the Fourth Quarter of 2013

- Net Income excluding Special Items was \$2.4 million compared to \$13.5 million in the same period in 2012. GAAP net income was \$2.2 million compared to \$13.5 million in the same period in 2012. The decrease was due to the receipt of a \$15.0 million milestone in the fourth quarter of 2012 that did not occur in 2013.
- Total revenues were \$24.5 million, compared to \$34.9 million in the same period in 2012. The decrease in revenue compared to the prior year was driven by the receipt of a \$15.0 million milestone payment in the fourth quarter of 2012 associated with the launch of AMITIZA<sup>®</sup> (lubiprostone) in Japan. Excluding the impact of the milestone payment, revenue increased \$4.6 million in the fourth quarter of 2013 versus the prior year.
- United States (U.S.) net sales of AMITIZA, as reported to us by our partner, Takeda Pharmaceuticals U.S.A., Inc. (Takeda), for royalty calculation purposes, increased 4.6% to \$78.0 million in the fourth quarter of 2013, compared to \$74.6 million in the same period of 2012.
- Diluted earnings per share excluding Special Items were \$0.06 compared to \$0.32 in the same period in 2012. GAAP diluted earnings per share (EPS) were \$0.05 compared to \$0.32 in the same period in 2012.

### Financial Highlights for the Full Year of 2013

- Net Income excluding Special Items was up 94% to \$9.4 million compared to \$4.8 million in the same period in 2012. GAAP net income was \$6.4 million compared to \$4.8 million in the same period in 2012.
- Total revenues were \$89.6 million compared to \$81.5 million in the same period in 2012, a growth rate of 9.9%.
- U.S. net sales of AMITIZA, as reported to us by our partner, Takeda, for royalty calculation purposes, increased 3.8% to \$282.1 million for 2013, compared to \$271.9 million for 2012.
- Diluted earnings per share excluding Special Items were \$0.22 compared to \$0.12 in the same period in 2012. GAAP diluted EPS were \$0.15 compared to \$0.12 in the same period in 2012.

(In thousands, except per share data)	Three Months	
	Ended December 31, 2013	Year Ended December 31, 2013
Total revenues	\$ 24,490	\$ 89,594
GAAP Diluted EPS	0.05	0.15
Non-GAAP Diluted EPS that exclude RESCULA inventory/samples non-cash write-off and restructuring costs <sup>1</sup>	0.06	0.22
GAAP net income <sup>2</sup>	2,153	6,419
Non-GAAP net income that excludes RESCULA inventory/samples non-cash write-off and restructuring costs <sup>1, 2</sup>	2,420	9,402

<sup>1</sup> Sucampo is providing certain 2013 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of Sucampo's performance. This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP.

<sup>2</sup> Net income is attributable to Sucampo Pharmaceuticals, Inc. on a consolidated basis.

"2013 was a year of significant growth for Sucampo," said Ryuji Ueno, M.D., Ph.D., Ph.D., the company's co-founder, who as previously reported is stepping down as Chairman and member of the Board of Directors (Board) and Chief Executive Officer (CEO) on March 3, 2014 and as Chief Scientific Officer (CSO) on March 31, 2014. "AMITIZA received approval as the first and only oral prescription treatment option for opioid induced constipation (OIC) in adult patients with chronic, non-cancer pain, bringing an important new treatment to patients who suffer from this debilitating side effect of chronic opioid use. Sales for AMITIZA continued to increase in Japan, and with the launch of AMITIZA for chronic idiopathic constipation (CIC) in Switzerland, Sucampo is now recognizing revenue on three continents. We also made important progress in making RESCULA<sup>®</sup> (unoprostone isopropyl) commercially available in the U.S., and we made important advances in our clinical development programs. As I prepare to transition out of my roles as CEO, member and Chairman of the Board and CSO with Sucampo, I am confident that under the leadership of the new CEO, we are well-positioned to accelerate our legacy of growth."

### Fourth Quarter 2013 and Recent Highlights

#### AMITIZA in the U.S.

- AMITIZA total prescriptions increased 5% in 2013 and 6% in the fourth quarter. Total prescriptions of AMITIZA in 2013 were 1.3 million, the highest total in one year ever recorded for AMITIZA. Fourth quarter total prescriptions of AMITIZA were 341,000,

making the fourth quarter in 2013 the highest ever.

- Among pain specialists, the monthly average total prescriptions for AMITIZA increased 31% since OIC approval in April and through the month of December, as compared to the eight months prior to approval.
- AMITIZA maintained a preferred managed care position, with 90% of insured lives covered nationally.

### **AMITIZA in Global Markets**

- Sucampo revenue from sales of AMITIZA in Japan was \$5.1 million in the fourth quarter of 2013, an increase of \$0.1 million versus Q4 2012 which was the initial inventory stocking quarter for the product launch. For 2013, Sucampo revenue from sales of AMITIZA in Japan was \$15.8 million, an increase of 215% versus 2012, in which AMITIZA was launched in late November.
- Sucampo made AMITIZA available in the United Kingdom (U.K.) in the latter half of the fourth quarter of 2013.
- In Switzerland, Sucampo showed sequential quarterly sales growth for AMITIZA for CIC. Additionally, in February, Sucampo announced that the Bundesamt für Gesundheit (BAG) in Switzerland revised several limitations with which AMITIZA was first approved for reimbursement and inclusion in its specialty list, allowing all Swiss physicians to prescribe AMITIZA, not just Swiss gastroenterologists, and increasing the maximum treatment duration of AMITIZA from 12 to 52 weeks before a review is needed by a health insurance health care practitioner.
- Sucampo continued partnership discussions for strategic alliances for AMITIZA for global markets outside of the U.S. and Japan, including China, Russia, Europe, Latin America and emerging markets.

### **Research & Development**

- In December, Sucampo announced the initiation of a global pivotal phase 3 clinical program of lubiprostone in pediatric functional constipation, with the anticipation of the first patient to roll over into a long-term safety extension study within the first half of 2014. Sucampo plans to initiate another well-controlled study in younger children with pediatric functional constipation following successful completion of the adult study of the liquid formulation, which is expected within the first half of 2014.
- Also in December, Sucampo announced the results of its double-blind, placebo-controlled phase 2a proof of concept study evaluating an intravenous (IV) formulation of our proprietary ion channel activator in patients with lumbar spinal stenosis (LSS), a degenerative disease of the lumbar spine. A responder analysis of data from the trial revealed that patients receiving the ion channel activator experienced a statistically significant improvement in pain, as determined by improvements in the Visual Analog Scale (VAS) pain score, versus placebo (94.4% versus 62.5%; p=0.035). Sucampo plans to conduct an additional phase 2a study in the second half of 2014 to evaluate the clinical effectiveness of the IV ion channel activator. Sucampo also plans to initiate a phase 1b study in the first quarter of 2014 for its oral ion channel activator for LSS.
- In October, Sucampo announced that its development partner, R-Tech Ueno Ltd., completed patient enrollment of a phase 3 clinical trial for unoprostone isopropyl for retinitis pigmentosa in Japan. A substantial portion of the development costs for the program are being funded by the Japan Science and Technology Agency. Sucampo has rights to the clinical data for potential filing in Europe and the U.S., where unoprostone isopropyl has orphan drug designation, and Sucampo will decide on future development assuming the Japanese trial is successful.
- Sucampo initiated a phase 1b trial for cobiprostone for the treatment of oral mucositis, a debilitating side effect of chemotherapy and radiation therapy in cancer patients, in the fourth quarter of 2013.

### **Corporate**

- Sucampo recently announced that Peter Greenleaf will join Sucampo as CEO and a member of the Board on March 3. Dr. Ueno will step down as CEO and member and Chairman of the Board on March 3, and as CSO on March 31. Dan Getman, Ph.D., will become Chairman of the Board on March 3.
- Dr. Ueno, as the Co-founder, Chairman Emeritus and Scientific Advisor, will provide consulting services to Sucampo on the development of its pipeline and other strategic activities.

#### **2013 Value Drivers:**

**Sucampo achieved eleven (denoted with a +) of its thirteen value drivers for 2013; unchecked items are still in progress:**

#### **AMITIZA**

##### **U.S.**

- + Achieved approval of the OIC indication for AMITIZA in the U.S.
- + Received a \$10.0 million milestone payment from Takeda upon the approval and first commercial sale of AMITIZA for OIC in the U.S.

##### **Global**

- Engaging in discussions for strategic alliances for AMITIZA for new indications and new territories outside of the U.S., including Latin America, China, Russia, Europe and emerging markets

##### **Japan**

- + Strong sales growth of AMITIZA

## Europe

- + Began active marketing of AMITIZA for CIC in Switzerland
- + Completed in the first half of 2013 the submission for regulatory approval of AMITIZA in the U.K. and Switzerland for the treatment of OIC. Sucampo anticipates approval from each respective regulatory authority in the first half of 2014
- + Submission of filings via the mutual recognition procedure (MRP) for AMITIZA in other European markets following the U.K. OIC approval
- + Filed for National Institute for Health and Care Excellence endorsement for CIC and OIC and launched AMITIZA in the U.K.

## RESCULA

- + Launched RESCULA in February in the U.S.

## Pipeline

### Lubiprostone

- + Achieved First Patient First Visit in our AMITIZA phase 3 trial for pediatric functional constipation in the second half of 2013

### Oral Mucositis

- + Completed our oral mucositis phase 1a trial for cobiprostone in the second quarter of 2013
- + Initiated a phase 1b trial for cobiprostone on October 31

### Spinal Stenosis

- + Completed our spinal stenosis phase 2a, double-blind, placebo-controlled trial for our IV ion channel activator for LSS

## Financial Results for the Quarter

For the fourth quarter of 2013, Sucampo reported total revenue of \$24.5 million compared to \$34.9 million for the same period in 2012, a decrease of approximately 29.8% or \$10.4 million. The decrease in revenue compared to the prior year was primarily driven by the receipt of a \$15.0 million milestone payment in the fourth quarter of 2012 associated with the launch of AMITIZA in Japan. Excluding the impact of the milestone payment, revenue increased \$4.6 million in the fourth quarter of 2013 versus the prior year. The key components of revenue for the fourth quarter included R&D revenue of \$4.1 million, product royalty revenue of \$14.8 million, product sales revenue of \$5.4 million and co-promotion revenue of nil which compare to \$15.1 million, \$14.2 million and \$5.0 million and \$0.3 million, respectively, in the same period of 2012.

For the full year 2013, Sucampo reported total revenue of \$89.6 million, compared to \$81.5 million for the full year 2012, a growth of approximately 9.9%. The key components of total revenue for the full year 2013 were product royalty revenue of \$52.1 million, R&D revenue of \$20.4 million, product sales revenue of \$16.4 million and co-promotion revenue of \$0.1 million which compare to \$50.7 million, \$21.5 million, \$5.0 million and \$3.6 million, respectively, for the full year 2012.

U.S. net sales of AMITIZA, as reported to us by our partner, Takeda, for royalty calculation purposes, increased 4.6% to \$78.0 million for the fourth quarter of 2013 and 3.8% to \$282.1 million for the full year 2013, compared to \$74.6 million and \$271.9 million respectively in the same periods of 2012.

## Cost of Goods Sold

Cost of goods sold relates to purchase and distribution costs of Sucampo's products sold by Sucampo, including changes in inventory provisions for excess and obsolete inventory. Cost of goods sold were \$2.9 million for the fourth quarter of 2013, compared to \$3.0 million for the fourth quarter of 2012, a decrease of \$0.1 million. Cost of goods sold were \$12.4 million for the full year 2013, compared to \$3.0 million for the prior year period, an increase of \$9.4 million. The increase in cost of goods sold relates to drug product sales of AMITIZA in Japan and Europe and RESCULA in the U.S. During the full year of 2013, Sucampo recorded a non-cash write-off of its RESCULA inventory of \$3.0 million to reflect excess quantities of dated product. The excess inventory was largely a result of the necessity to pre-order product in advance of FDA approval due to a planned change in manufacturing facility and lower than anticipated sales within the useful life of the dated product.

## Operating Expenses

R&D expenses, comprised of expenses for clinical development of the lubiprostone pediatric indication and liquid formulation, phase 1 trial expenses for oral mucositis, and clinical development expenses for Sucampo's lumbar spinal stenosis program, were \$7.0 million for the fourth quarter of 2013, compared to \$7.1 million for the same period of 2012. For the full year 2013, R&D expenses were \$21.5 million, compared to \$21.3 million for the prior year period. The increase in expenses was primarily due to the higher costs associated with clinical development of Sucampo's phase 2a trial for lumbar spinal stenosis and of the lubiprostone pediatric indication and liquid formulation, partially offset by lower costs associated with Sucampo's terminated collaboration with Numab AG.

G&A expenses were \$6.8 million for the fourth quarter of 2013, compared to \$7.6 million for the same period of 2012, a decrease of \$0.8 million or 10.3%. G&A expenses were \$25.4 million for the full year 2013, compared to \$30.2 million for the prior year period, a decrease of \$4.7 million or 15.7%. For the full year period, the decrease in G&A expense was primarily due to lower legal, consulting and other professional expenses as a result of the conclusion of certain legal matters in 2012, as well as expense reductions from 2013 productivity initiatives.

S&M expenses were \$5.1 million for the fourth quarter of 2013, compared to \$4.2 million for the fourth quarter of 2012. Selling and marketing expenses were \$21.1 million for the full year 2013 compared to \$18.7 million for the prior year period. For the full year period,

the increase in selling and marketing expenses relates primarily to launch and restructuring costs for RESCULA and a \$1.5 million non-cash write-off recorded for excess RESCULA samples, partially offset by non-recurring pre-commercialization planning activities for AMITIZA and RESCULA that occurred in 2012 that did not occur in 2013.

## Net Income

Net income for the fourth quarter was \$2.2 million, compared to net income of \$13.5 million for 2012. For the quarter, the decrease was due to the receipt of a \$15 million milestone in the fourth quarter of 2012 that did not occur in 2013. For the full year 2013, net income was \$6.4 million, compared to net income of \$4.8 million for 2012.

## Earnings Excluding Special Items

Net income excluding special items for the fourth quarter of 2013 was \$2.4 million, or \$0.06 per diluted share, compared to net income of \$13.5 million, or \$0.32 per diluted share, in the fourth quarter of 2012. Net income excluding special items for the full year 2013 was \$9.4 million, or \$0.22 per diluted share, compared to net income of \$4.8 million, or \$0.12 per diluted share, for 2012.

Non-GAAP (generally accepted accounting principles) EPS for the fourth quarter and full year 2013 of \$0.06 and \$0.22, respectively, exclude RESCULA inventory, sample non-cash write-off costs, and restructuring costs.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the tables that follow.

(In thousands, except per share data)	Three Months	Year Ended
	Ended December 31, 2013	December 31, 2013
<b>EPS</b>		
GAAP Diluted EPS	\$ 0.05	\$ 0.15
Difference <sup>3</sup>	0.01	0.07
Non-GAAP Diluted EPS that exclude RESCULA inventory/samples non-cash write-off and restructuring costs <sup>1</sup>	0.06	0.22
<b>Net income</b>		
GAAP net income <sup>2</sup>	\$ 2,153	\$ 6,419
Difference	267	2,983
Non-GAAP net income that excludes RESCULA inventory/samples non-cash write-off and restructuring cost <sup>1, 2</sup>	2,420	9,402
<b>Decrease in net income due to excluded items:</b>		
Net decrease in income before income taxes	\$ 445	\$ 4,972
Estimated income tax benefit	(178)	(1,989)
Decrease in net income	267	2,983

<sup>3</sup>Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the period.

## Cash, Cash Equivalents, Restricted Cash and Marketable Securities

At December 31, 2013, cash, cash equivalents, restricted cash and investments were \$95.9 million, compared to \$91.4 million at December 31, 2012. At December 31, 2013, notes payable were \$52.7 million, compared to \$52.9 million at December 31, 2012, including current notes payable of \$26.9 million at December 31, 2013, and \$19.1 million at December 31, 2012.

## Stock Repurchase Plan

During the full year 2013, Sucampo repurchased 67,762 shares at a cost of \$0.3 million. During the fourth quarter, Sucampo made no share repurchases under this program. Since inception, Sucampo has repurchased approximately \$2.3 million of its common stock.

## Cantor Sales Agreement

As previously disclosed, on January 11, 2013, Sucampo entered into a sales agreement with Cantor Fitzgerald & Co. (Cantor Sales Agreement), which enables Sucampo to offer and sell shares of the Sucampo's class A common stock with aggregate class A common stock sales of up to \$20.0 million, from time to time through Cantor Fitzgerald & Co. as our sales agent. Sales of class A common stock under the Cantor Sales Agreement are made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. Cantor Fitzgerald & Co. is entitled to receive a commission rate of 3.0% of gross sales in connection with the sale of Sucampo's class A common stock sold on Sucampo's behalf. From November 22, 2013 through December 31, 2013, Sucampo had sold through the Cantor Sales Agreement an aggregate of 749,383 shares of Sucampo's class A common stock, and received gross proceeds of approximately \$5.3 million, before deducting issuance expenses.

## Future Guidance

Sucampo today affirmed its earnings guidance for 2014. Sucampo expects to be profitable in 2014 and expects to issue more specific guidance soon.

## Company to Host Conference Call Today

In conjunction with this fourth quarter financial and operating results press release, Sucampo will host a conference call today at 5:00 pm Eastern. To participate on the live call, please dial 877-280-4955 (domestic) or 857-244-7312 (international), and provide the participant passcode 98843095, five to ten minutes ahead of the start of the call. A replay of the call will be available within a few hours after the call ends. Investors may listen to the replay by dialing 888-286-8010 (domestic) or 617-801-6888 (international), with the passcode 42236766.

Investors interested in accessing the live audio webcast of the teleconference may do so at <http://investor.sucampo.com> and should log on before the teleconference begins in order to download any software required. The archive of the teleconference will remain available for 30 days.

### About lubiprostone (AMITIZA®)

AMITIZA (lubiprostone) is a prostone, a locally acting chloride channel activator, indicated for the treatment of CIC in adults and OIC in adults with chronic, non-cancer pain (24 mcg twice daily) and for IBS-C (8 mcg twice daily) in women 18 years of age and older in the U.S. In Japan, lubiprostone (24 mcg twice daily) is indicated for the treatment of chronic constipation (excluding constipation caused by organic diseases). In Switzerland, lubiprostone (24 mcg twice daily) is indicated for the treatment of CIC. In the U.K., lubiprostone (24 mcg twice daily) is indicated for the treatment of CIC and associated symptoms in adults.

### About unoprostone isopropyl (RESCULA®)

In 2009 and 2011, Sucampo acquired development and commercialization rights to unoprostone isopropyl throughout the world except in Japan, Korea, Taiwan and the People's Republic of China. Unoprostone isopropyl 0.12% (trade named RESCULA) first received marketing authorization in 1994 in Japan and was subsequently approved in over 40 countries, including approval in 2000 by the FDA. RESCULA (unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension in the U.S.

### About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is focused on the discovery, development and commercialization of drugs based on ion channel activators known as prostones. Discovered by the company's scientific founder, prostones are naturally occurring fatty acid metabolites with unique physiological activities. Sucampo has two marketed products – AMITIZA and RESCULA – and a pipeline of prostone-based product candidates in clinical development. A global company, Sucampo is headquartered in Bethesda, Maryland, and has operations in the U.K., Switzerland and Japan. For more information, please visit [www.sucampo.com](http://www.sucampo.com).

The Sucampo logo and the tagline, The Science of Innovation, are registered trademarks of Sucampo AG.

AMITIZA is a registered trademark of Sucampo AG. RESCULA is a registered trademark of R-Tech Ueno, Ltd, and has been licensed to Sucampo AG.

Follow us on Twitter (@Sucampo\_Pharma). Follow us on LinkedIn (Sucampo Pharmaceuticals).

Twitter LinkedIn

### Sucampo Forward-Looking Statement

This press release 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; 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 well as its filings on Form 10-Q and 8-K, which Sucampo incorporates by reference.

#### Sucampo Pharmaceuticals, Inc.

#### Consolidated Statements of Operations and Comprehensive Income (unaudited)

(in thousands, except per share data)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
Revenues:				
Research and development revenue	\$ 4,066	\$ 15,127	\$ 20,354	\$ 21,545
Product royalty revenue	14,829	14,175	52,100	50,696
Product sales revenue	5,431	5,037	16,425	5,037
Co-promotion revenue	--	323	61	3,576



Contract and collaboration revenue	164	200	654	633
Total revenues	<u>24,490</u>	<u>34,862</u>	<u>89,594</u>	<u>81,487</u>
Cost and expenses:				
Cost of goods sold	2,945	3,030	12,402	3,030
Research and development	6,996	7,090	21,524	21,292
General and administrative	6,778	7,559	25,413	30,157
Selling and marketing	<u>5,092</u>	<u>4,217</u>	<u>21,059</u>	<u>18,691</u>
Total costs and expenses	<u>21,811</u>	<u>21,896</u>	<u>80,398</u>	<u>73,170</u>
Income from operations	2,679	12,966	9,196	8,317
Non-operating income (expense):				
Interest income	61	61	124	179
Interest expense	(445)	(566)	(1,894)	(2,346)
Other income (expense), net	<u>1,145</u>	<u>875</u>	<u>2,921</u>	<u>1,602</u>
Total non-operating income (expense), net	<u>761</u>	<u>370</u>	<u>1,151</u>	<u>(565)</u>
Income before income taxes	3,440	13,336	10,347	7,752
Income tax benefit (provision)	<u>(1,287)</u>	<u>196</u>	<u>(3,928)</u>	<u>(2,916)</u>
Net income	<u>\$ 2,153</u>	<u>\$ 13,532</u>	<u>\$ 6,419</u>	<u>\$ 4,836</u>
Net income per share:				
Basic net income per share	<u>\$ 0.05</u>	<u>\$ 0.33</u>	<u>\$ 0.15</u>	<u>\$ 0.12</u>
Diluted net income per share	<u>\$ 0.05</u>	<u>\$ 0.32</u>	<u>\$ 0.15</u>	<u>\$ 0.12</u>
Weighted average common shares outstanding - basic	<u>41,929</u>	<u>41,553</u>	<u>41,716</u>	<u>41,660</u>
Weighted average common shares outstanding - diluted	<u>42,986</u>	<u>41,991</u>	<u>42,544</u>	<u>41,785</u>
Comprehensive income (loss):				
Net income	\$ 2,153	\$ 13,532	\$ 6,419	\$ 4,836
Other comprehensive income gain (loss):				
Unrealized loss on investments, net of tax effect	18	13	2	36
Foreign currency translation	<u>(180)</u>	<u>43</u>	<u>(567)</u>	<u>(1,724)</u>
Comprehensive income	<u>\$ 1,991</u>	<u>\$ 13,588</u>	<u>\$ 5,854</u>	<u>\$ 3,148</u>

**Sucampo Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets (unaudited)**

(in thousands, except share data)

	<u>December 31,</u>	
	<u>2013</u>	<u>2012</u>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 44,102	\$ 52,022
Investments, current	16,003	6,035
Product royalties receivable	14,829	14,175
Unbilled accounts receivable	1	732
Accounts receivable, net	5,407	1,360
Prepaid and income taxes receivable	9	--
Deferred tax assets, current	2,028	874
Deferred charge, current	673	673
Restricted cash, current	26,115	15,113
Inventory	209	--
Prepaid expenses and other current assets	<u>3,977</u>	<u>1,930</u>
Total current assets	113,353	92,914
Investments, non-current	7,219	14,408
Property and equipment, net	1,156	1,540
Intangible assets, net	6,438	7,415
Deferred tax assets, non-current	1,212	1,654
Deferred charge, non-current	4,540	5,213
Restricted cash, non-current	2,471	3,832
Other assets	584	820

Total assets

\$ 136,973 \$ 127,796**LIABILITIES AND STOCKHOLDERS' EQUITY:**

## Current liabilities:

Accounts payable	\$ 7,614	\$ 5,496
Accrued expenses	5,682	10,595
Deferred revenue, current	1,365	3,700
Income tax payable	701	148
Notes payable, current	26,892	19,129
Other current liabilities	358	1,003
Total current liabilities	<u>42,612</u>	<u>40,071</u>

Notes payable, non-current	25,828	33,722
Deferred revenue, non-current	6,169	7,093
Deferred tax liability, non-current	2,066	2,627
Other liabilities	2,150	1,253
Total liabilities	<u>78,825</u>	<u>84,766</u>

## Stockholders' equity:

Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2013 and 2012; no shares issued and outstanding at December 31, 2013 and 2012	--	--
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2013 and 2012; 43,315,749 and 41,964,905 shares issued and outstanding at December 31, 2013 and 2012, respectively	432	420
Additional paid-in capital	72,109	62,521
Accumulated other comprehensive income	15,601	16,166
Treasury stock, at cost; 524,792 and 457,030 shares	(2,313)	(1,977)
Accumulated deficit	<u>(27,681)</u>	<u>(34,100)</u>
Total stockholders' equity	<u>58,148</u>	<u>43,030</u>
Total liabilities and stockholders' equity	<u>\$ 136,973</u>	<u>\$ 127,796</u>

**Sucampo Pharmaceuticals, Inc.****Key Segment Information (unaudited)**

(In thousands)	Americas	Europe	Asia	Consolidated
<b>Three Months Ended December 31, 2013</b>				
Research and development revenue	\$ 4,066	\$ --	\$ --	\$ 4,066
Product royalty revenue	14,829	--	--	14,829
Product sales revenue	279	25	5,127	5,431
Co-promotion revenue	--	--	--	--
Contract and collaboration revenue	142	12	10	164
Total revenues	19,316	37	5,137	24,490
Cost of goods sold	123	3	2,819	2,945
Research and development expenses	4,644	1,138	1,214	6,996
Depreciation and amortization	193	168	10	371
Other operating expenses	8,543	2,526	430	11,499
Income (loss) from operations	5,813	(3,798)	664	2,679
Interest income	58	3	--	61
Interest expense	(1,427)	1,024	(42)	(445)
Other non-operating expense, net	(5)	3	1,147	1,145
Income (loss) before income taxes	<u>\$ 4,439</u>	<u>\$ (2,768)</u>	<u>\$ 1,769</u>	<u>\$ 3,440</u>
Capital expenditures	<u>\$ --</u>	<u>\$ (5)</u>	<u>\$ 20</u>	<u>\$ 15</u>

(In thousands)	Americas	Europe	Asia	Consolidated
<b>Three Months Ended December 31, 2012</b>				
Research and development revenue	\$ 311	\$ (74)	\$ 14,890	\$ 15,127
Product royalty revenue	14,175	--	--	14,175
Product sales revenue	--	14	5,023	5,037
Co-promotion revenue	323	--	--	323
Contract and collaboration revenue	141	46	13	200
Total revenues	14,950	(14)	19,926	34,862

Cost of goods sold	98	9	2,923	3,030
Research and development expenses	1,559	4,166	1,365	7,090
Depreciation and amortization	118	255	10	383
Other operating expenses	<u>8,935</u>	<u>417</u>	<u>2,041</u>	<u>11,393</u>
Income (loss) from operations	4,240	(4,861)	13,587	12,966
Interest income	56	4	1	61
Interest expense	--	(527)	(39)	(566)
Other non-operating income (expense), net	<u>10</u>	<u>(269)</u>	<u>1,134</u>	<u>875</u>
Income (loss) before income taxes	<u>\$ 4,306</u>	<u>\$ (5,653)</u>	<u>\$ 14,683</u>	<u>\$ 13,336</u>
Capital expenditures	<u>\$ 108</u>	<u>\$ 25</u>	<u>\$ --</u>	<u>\$ 133</u>

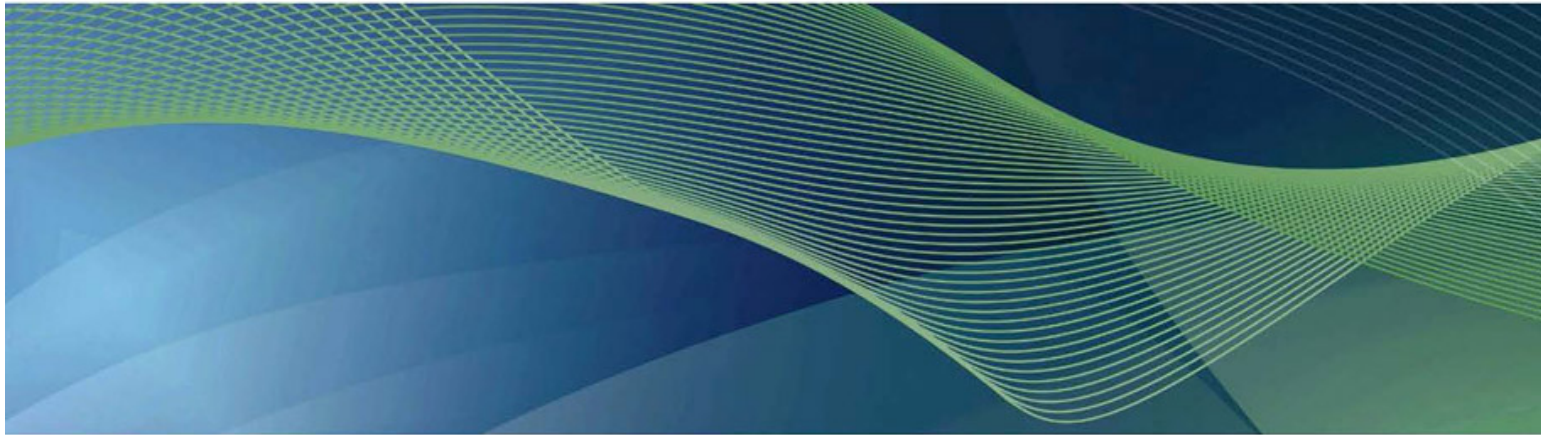
**Year Ended December 31, 2013**

Research and development revenue	\$ 20,354	\$ --	\$ --	\$ 20,354
Product royalty revenue	52,100	--	--	52,100
Product sales revenue	556	62	15,807	16,425
Co-promotion revenue	61	--	--	61
Contract and collaboration revenue	<u>566</u>	<u>46</u>	<u>42</u>	<u>654</u>
Total revenues	73,637	108	15,849	89,594
Cost of goods sold	3,588	15	8,799	12,402
Research and development expenses	11,090	5,445	4,989	21,524
Depreciation and amortization	736	716	36	1,488
Other operating expenses	<u>35,911</u>	<u>5,900</u>	<u>3,173</u>	<u>44,984</u>
Income (loss) from operations	22,312	(11,968)	(1,148)	9,196
Interest income	112	11	1	124
Interest expense	(1,427)	(302)	(165)	(1,894)
Other non-operating expense, net	<u>(14)</u>	<u>(166)</u>	<u>3,101</u>	<u>2,921</u>
Income (loss) before income taxes	<u>\$ 20,983</u>	<u>\$ (12,425)</u>	<u>\$ 1,789</u>	<u>\$ 10,347</u>
Capital expenditures	<u>\$ 40</u>	<u>\$ 105</u>	<u>\$ 23</u>	<u>\$ 168</u>

**Year Ended December 31, 2012**

Research and development revenue	\$ 6,189	\$ --	\$ 15,356	\$ 21,545
Product royalty revenue	50,696	--	--	50,696
Product sales revenue	--	14	5,023	5,037
Co-promotion revenue	3,576	--	--	3,576
Contract and collaboration revenue	<u>565</u>	<u>16</u>	<u>52</u>	<u>633</u>
Total revenues	61,026	30	20,431	81,487
Cost of goods sold	98	9	2,923	3,030
Research and development expenses	7,809	9,571	3,912	21,292
Depreciation and amortization	484	964	40	1,488
Other operating expenses	<u>41,410</u>	<u>2,993</u>	<u>2,957</u>	<u>47,360</u>
Income (loss) from operations	11,225	(13,507)	10,599	8,317
Interest income	161	16	2	179
Interest expense	--	(2,183)	(163)	(2,346)
Other non-operating expense, net	<u>77</u>	<u>(187)</u>	<u>1,712</u>	<u>1,602</u>
Income (loss) before income taxes	<u>\$ 11,463</u>	<u>\$ (15,861)</u>	<u>\$ 12,150</u>	<u>\$ 7,752</u>
Capital expenditures	<u>\$ 401</u>	<u>\$ 3,470</u>	<u>\$ --</u>	<u>\$ 3,871</u>

CONTACT: Sucampo Pharmaceuticals, Inc.  
Silvia Taylor  
Senior Vice President, Investor Relations and  
Corporate Communications  
1-240-223-3718  
staylor@sucampo.com



# Fourth Quarter and Full Year 2013 Results

February 26, 2014



# Introductions and Forward-Looking Statements



**Silvia Taylor**

*Senior Vice President, Investor Relations  
and Corporate Communications*

# Agenda

<b>Introductions and Forward-Looking Statements</b>	Silvia Taylor
<b>Highlights of the Quarter</b>	Ryuji Ueno, M.D., Ph.D., Ph.D.
<b>AMITIZA® (lubiprostone) &amp; RESCULA® (unoprostone isopropyl) Commercial Update</b>	Stanley G. Miele
<b>Pipeline and R&amp;D Update</b>	Taryn Losch-Beridon
<b>Financial Performance</b>	Cary J. Claiborne
<b>Closing Remarks</b>	Ryuji Ueno, M.D., Ph.D., Ph.D.

# 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; 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 8-K and 10-K, which Sucampo incorporates by reference.

# Q4 and FY 2013 Highlights



**Ryuji Ueno, M.D., Ph.D., Ph.D.**

*Chairman, Chief Executive Officer,  
Chief Scientific Officer, and Co-founder*



# 2013 Highlights

## 2013: Significant Growth

- Expansion of business: new indications, new markets
- Profitable
  - Increase in revenue
  - Efficient use of capital
- Progress in clinical development

### AMITIZA®

### RESCULA®

#### United States

- Approval for OIC in chronic, non-cancer pain
- YoY revenue growth

#### Japan

- Strong performance
- Exceeding Sucampo's and Abbott's expectations

#### Europe

- Launched for CIC in Switzerland
- Product available in the U.K.
- Positive early feedback

#### United States

- Launched in the U.S.

## **Ryuji Ueno, M.D., Ph.D., Ph.D. to step down as CEO, Chairman and Director on March 3, 2014**

- Will step down as CSO on March 31, 2014
- Will consult to Sucampo as Co-founder, Chairman Emeritus, and Scientific Advisor on transition, pipeline development and other strategic activities

## **Peter Greenleaf named new Sucampo CEO effective March 3, 2014**

- 20 years of biopharma experience in commercialization & drug development
- Current CEO and Director of Histogenix, former President of MedImmune, the worldwide biologics R&D arm of AstraZeneca

## **Dan Getman, Ph.D. becomes Chairman of the Board effective March 3, 2014**

- Extensive experience in leadership positions within pharmaceutical and life science organizations
- Personal research experience spans medicinal chemistry in the areas of arthritis, cancer and infectious diseases

# Financial Highlights 2013

## **Exceeded 2013 Earning Guidance of \$3-5M of Net Income**

- Net income excluding special items of \$9.4M for 2013, \$0.22 cents per share

## **2014 Guidance: Expect to be Profitable**

- Will provide more specific guidance at later time

# Commercial Update



## **Stanley G. Miele**

*President, Sucampo Pharma Americas, LLC  
and SVP, Sales and Marketing*



# AMITIZA U.S.



## Continued AMITIZA YOY Growth

- Q4: Strongest quarter ever for AMITIZA
  - Net sales growth of 5% for Q4
  - TRx growth of 6% for Q4
- Calendar year high of 1.3M TRx in 2013 AMITIZA
  - TRx up 5% YoY through December YTD<sup>1</sup>

## Market Growth Accelerating

- Class up almost 7% for 1H 2014 vs 1H 2013

## OIC Opportunity

- 40-80% of non-cancer patients on chronic opioids will suffer from OIC<sup>3</sup>; moderate to severely constipated market estimated at 2-2.5M<sup>4</sup>
- AMITIZA growth from high OIC targets outpaced the national average by more than two times

## Strong Commercial Execution Driving Sales Growth

- Managed care advantage vs. competition; increasing patient-focused efforts
- Heritage: 8M Rx's over ≈ 8 years; driver of increased sales

See Reference 1-4; \*AMITIZA net sales reported by Takeda for royalty calculation purposes



# RESCULA U.S. Overview



## RESCULA Commercial Strategy

- Implemented new commercial strategy for RESCULA
  - Focus on current RESCULA prescribers
- Contract sales representatives are spending 20% of time calling on current RESCULA prescribers
- Belief in value of continued development
  - Excited about the development of unoprostone isopropyl for additional diseases, such as retinitis pigmentosa

See References 5-6

# AMITIZA Global Snapshot

## Japan

- Continued success; sales continue to be above our and Abbott's expectations
- AMITIZA sales in Japan contributed \$16 million to topline in 2013
- Abbott applying more than half of its detailing efforts in Japan to AMITIZA
- 2 week limitation removed in December



## Europe

- OIC filings in the U.K. and Switzerland on-track for approval 1H 2014
- Increased patient access in Switzerland as BAG\* revised several key reimbursement limitations to AMITIZA on the specialty list
- NICE endorsement process in the U.K. ongoing



## Rest of World

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



See Reference 6; \*Bundesamt für Gesundheit

# Pipeline and R&D Update



**Taryn Losch-Beridon**

*Vice President, Clinical Development*



# Sucampo Prostone Pipeline Key Highlights

## Lubiprostone Clinical Development & Life Cycle Management

### Pediatric Functional Constipation

- Initiated global P3 clinical program for lubiprostone in children and adolescents aged 6 to 17 years with pediatric functional constipation
- Takeda is funding 70% of development costs
- Anticipate the first patient to roll over into a long-term, open-label safety extension study within 1H 2014

### Liquid Formulation

- In October, initiated pivotal study of a liquid formulation of lubiprostone in adults 18 years of age and older
- Takeda funding 100% of the costs
- Upon reviewing the results of the trial (anticipated to be available 1H 2014) we plan to file NDA
- Launch in 2015, pending approval



Abdominal radiograph of constipated child showing stool throughout the colon

## Unoprostone Isopropyl for Retinal Diseases

### Retinitis Pigmentosa (RP)

- Degenerative retinal disease with no approved prescription medicines available<sup>6</sup>
- Ongoing P3 clinical trial in unoprostone isopropyl by development partner, R-Tech Ueno
  - Patient enrollment completed October 2013 and interim 1yr results available early 2015
- 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



### Life-Cycle Management

- Exploring opportunities in other retinal diseases including AMD; will update further as research develops

See References 6-10

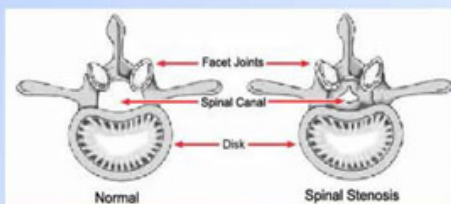
\*Journal of Pediatric Gastroenterology and Nutrition

# Sucampo Prostone Pipeline Key Highlights (cont.)

## Ion Channel Activators for Lumbar Spinal Stenosis

### Lumbar Spinal Stenosis (LSS)

- Degenerative change in lumbar spine; unmet medical need with limited treatment options globally<sup>6</sup>
- Prevalence: ~400,000 Americans, most >60 years of age<sup>11</sup>
- Top-line results of P2a, double-blind, placebo-controlled trial of IV ion channel activator showed statistically significant improvement in VAS\* pain



- Plan to initiate additional P2a study in 2H 2014 for IV ion channel activator
- P1a results for oral ion channel activator: generally well-tolerated

## Cobiprostone for Oral Mucositis

### Oral Mucositis

- P1b study of oral spray formulation of cobiprostone began October 31, 2013
- ~350,000 head and neck cancer patients in the U.S.<sup>13</sup>; oral mucositis affects 80-90%<sup>14</sup> of these patients
  - Total WW market estimated to be up to \$500M<sup>6</sup>
  - Also impacts patients treated for solid tumors, or receiving hematopoietic stem cell transplantation
- A few prescription treatments available, but currently no comprehensive treatments available<sup>6</sup>
- P1a results: oral spray formulation generally well-tolerated

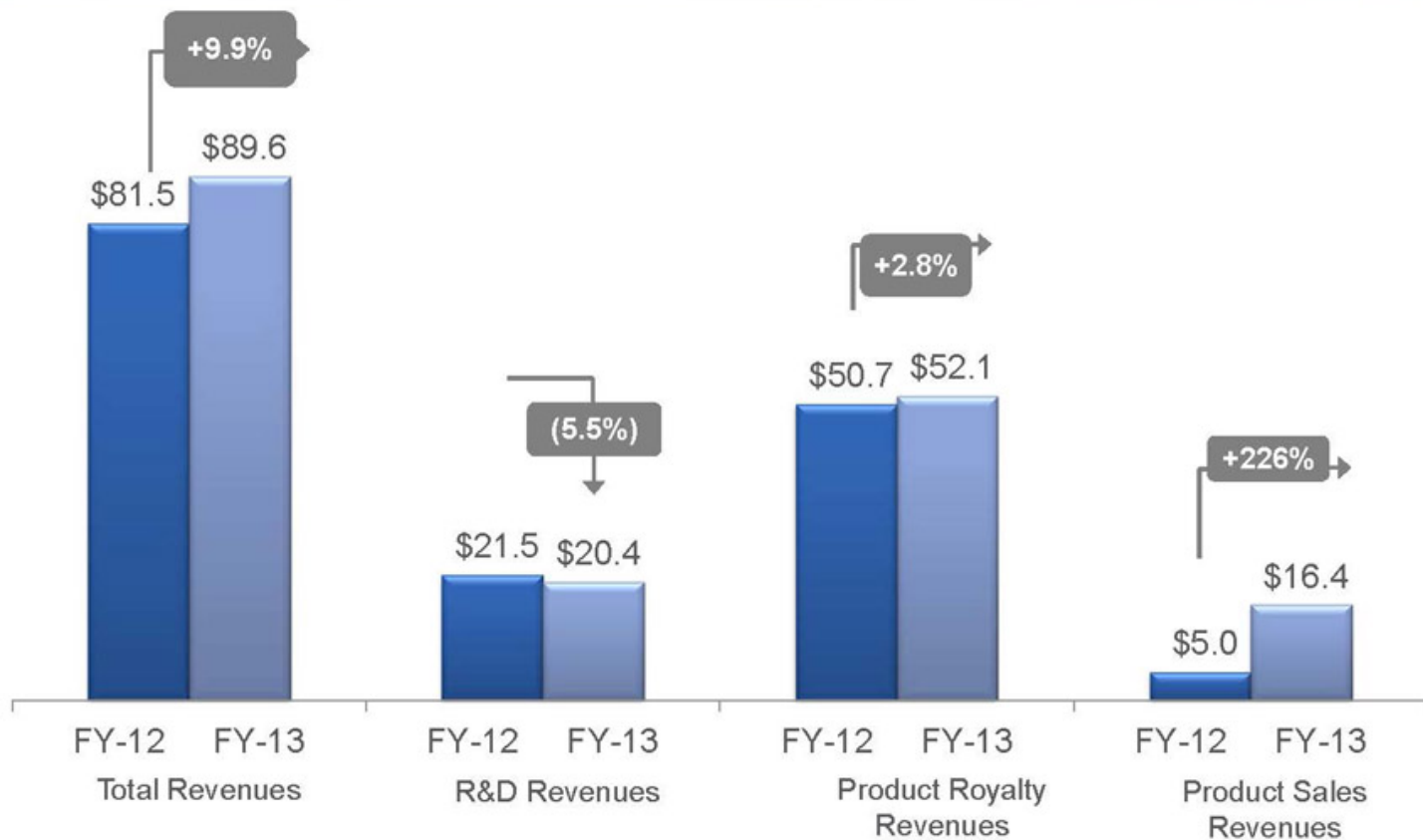


# Financial Performance



**Cary J. Claiborne**  
*Chief Financial Officer*

# FY 2013 Revenue Highlights (\$M)



\*Co-promotion, contract and collaboration revenue also are components of revenue.

# AMITIZA U.S. Net Sales\* (\$M)



\*As reported by Takeda for royalty calculation purposes

# Condensed Consolidated Statements of Operations (Unaudited)

(\$M, except EPS)	FY 2013	FY 2012	% Change
Revenue	\$89.6	\$81.5	9.9%
Expenses:			
Cost of goods sold	\$12.4	\$3.0	309.3%
R&D expense	\$21.5	\$21.3	1.1%
G&A expense	\$25.4	\$30.2	(15.7%)
S&M expense	\$21.1	\$18.7	12.7%
Income from operations	\$9.2	\$8.3	10.6%
Non-operating income/(expense), net	\$1.2	(\$0.6)	F
Tax provision	(\$3.9)	(\$2.9)	34.7%
GAAP net income	\$6.4	\$4.8	32.7%
Net income – excl. special items	\$9.4	\$4.8	94.8%

**COGS:** Drug product sales of AMITIZA in Japan/Switzerland as well as RESCULA in the U.S. Sucampo recorded a non-cash write-off of RESCULA inventory of \$3.0M to reflect excess quantities of dated product

**R&D Expense:** Higher costs associated with clinical development of our phase 2a trial for LSS and of the lubiprostone pediatric indication and liquid formulation programs, partially offset by lower costs associated with our terminated collaboration with Numab AG

**G&A Expense:** Lower legal, consulting and other professional expenses as a result of the conclusion of certain legal matters in 2012, as well as expense reductions from 2013 productivity initiatives

**S&M Expense:** Launch and Restructuring costs for RESCULA and a \$1.5M non-cash write-off recorded for excess RESCULA samples, partially offset by non-recurring pre-commercialization planning activities for both AMITIZA and RESCULA that occurred in 2012 but not in 2013

# Earnings Excluding Special Items

(In thousands, except per share data)	Three Months Ended December 31, 2013	Year Ended December 31, 2013
<b>EPS</b>		
GAAP Diluted EPS	\$ 0.05	\$ 0.15
Difference <sup>3</sup>	0.01	0.07
Non-GAAP Diluted EPS that exclude RESCULA inventory/samples non-cash write-off <sup>1</sup>	0.06	0.22
<b>Net income</b>		
GAAP net income <sup>2</sup>	\$ 2,153	\$ 6,419
Difference	267	2,983
Non-GAAP net income that excludes RESCULA inventory/samples non-cash write-off <sup>1,2</sup>	2,420	9,402
<b>Decrease in net income due to excluded items:</b>		
Net decrease in income tax before taxes	\$ 445	\$ 4,972
Estimated income tax benefit	(178)	(1,989)
Decrease in net income	267	2,983

<sup>1</sup>Sucampo is providing certain 2013 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of Sucampo's performance. This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP. <sup>2</sup>Net income is attributable to Sucampo Pharmaceuticals, Inc. on a consolidated basis. <sup>3</sup>Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the period.

## **Solid Financial Performance in 2013**

- Grew total Net Revenue by 10% in 2013
- Generated non-GAAP Net Income of \$9.4M, up 94% over 2012
- Exceeded high end of November non-GAAP Net Income guidance of \$5M by 88%
- Ended the year with \$96M in Cash, Cash equivalents and Investments

## **Positioned Well for the Future**

- Expanded commercial products globally
- Advanced our clinical development programs

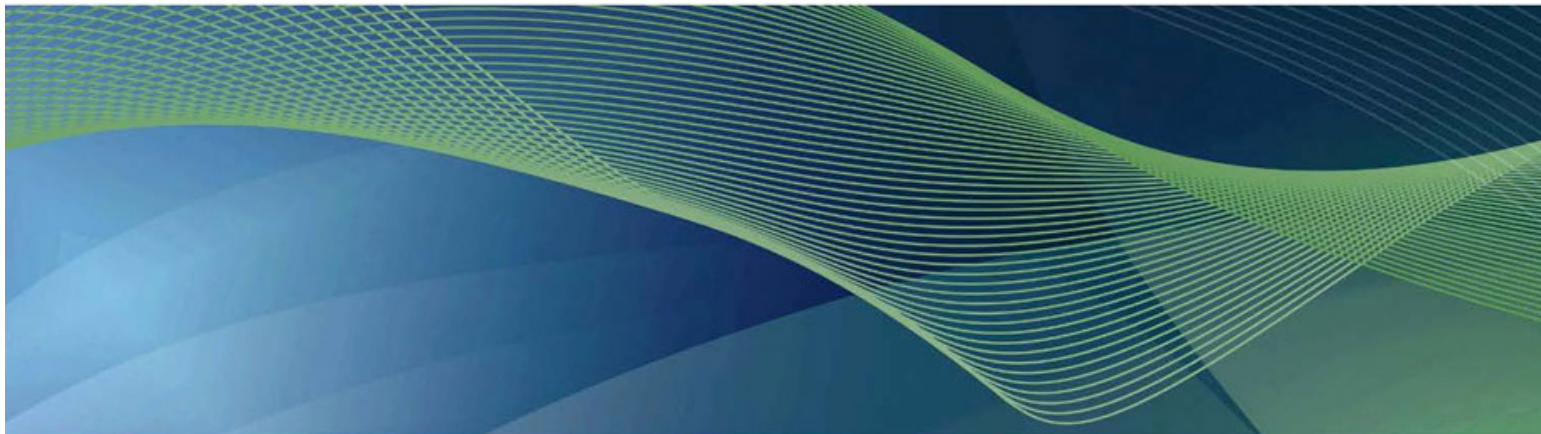


# Conclusion



**Ryuji Ueno, M.D., Ph.D., Ph.D.**

*Chairman, Chief Executive Officer,  
Chief Scientific Officer, and Co-founder*



# Q & A



# References

1. IMS Smart View, NPA Report, client Factored Numbers
2. IMS, NPA weekly data, DART
3. Camilleri M. Opioid-induced constipation: challenges and therapeutic opportunities. *Am J Gastroenterol*. 2011 May;106(5):835-42
4. Clearview Analysis 2008
5. IMS Smart View, RAPID Weekly, Client Factored Numbers
6. Internal Research
7. Loening-Baucke V. Prevalence rates for constipation and faecal and urinary incontinence. *Arch Dis Child*. 2007 Jun;92(6):486-9
8. Biggs WS. *et al* Evaluation and treatment of constipation in infants and children. *Am Fam Physician* 2006 Feb;73(3):469-77
9. Radiograph from Borowitz - [Pediatric Constipation article](#) on Medscape website; accessed 09.19.13
10. Photos from Foundation Fighting Blindness website [What is Retinitis Pigmentosa?](#); accessed 09.19.13
11. The American Association of Neurological Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13
12. Diagram from American Academy of Orthopaedic Surgeons website [Lumbar Spinal Stenosis](#); accessed 09.19.13
13. Based on statistics from the American Cancer Society and the National Cancer Institute
14. 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
15. Photos from Silverman - Diagnosis and management of oral mucositis. *J Support Oncol* 2007; 5 (2 Suppl 1):13-21

# 2013 Key Value Driver Summary

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>☐ Ongoing: 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>☐ Ongoing: Use MHRA approval to seek expansion of CIC and OIC indication to other E.U. markets via MRP</li> <li>✓ Filed for NICE endorsement for CIC and OIC, and made 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>✓ Complete spinal stenosis P2a trial: 4Q 2013</li> </ul>

✓ Completed ☐ In Progress

# 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				P2 PoC 4Q13	
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.