

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): March 13, 2013

Sucampo Pharmaceuticals, Inc.

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(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

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(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

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(Address of Principal Executive Offices)

(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 2.02 Results of Operations and Financial Condition**

On March 13, 2013, Sucampo Pharmaceuticals, Inc. (“the Company”) announced its consolidated financial results for the fourth quarter and year ended December 31, 2012. 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 and the transcript of the webcast 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 March 13, 2013, the Company hosted a conference call with investors to discuss the Company's financial and operating results for the fourth quarter and fiscal year 2012 ended December 31, 2012. The conference call including slides was made available to the public via conference call and webcast. The slides from the presentation are being furnished as Exhibit 99.2 and the transcript is being furnished as Exhibit 99.3 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibits 99.2 and 99.3 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 Items 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on March 13, 2013.

99.2 The corporate update presentation slides dated March 13, 2013.

99.3 Transcript of March 13, 2013 investor conference call dated March 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: March 15, 2013

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 2012 Financial and Operating Results*****Fourth Quarter Net Income Reported of \$13.5 million; Full-Year Net Income Reported of \$4.8 million;******Fourth Quarter Total Revenues Increased 145% to \$34.9 million; Full-Year Revenues Increased 49% to \$81.5 million;******Company to Host Conference Call Today at 5:00 pm Eastern***

BETHESDA, Md.--(BUSINESS WIRE)--March 13, 2013--Sucampo Pharmaceuticals, Inc. ("Sucampo") (NASDAQ: SCMP), a global pharmaceutical company, today reported its consolidated financial results for the quarter and full year ending December 31, 2012.

For the fourth quarter of 2012, total revenue grew approximately 145%, to \$34.9 million from \$14.2 million for the same period in 2011. Net sales of AMITIZA<sup>®</sup> (lubiprostone), as reported to us by our partner increased 31% to \$74.6 million for the fourth quarter of 2012, compared to \$56.8 million in the same period of 2011. During the fourth quarter of 2012, Sucampo reported product sales revenue and cost of goods sold primarily representing sales of AMITIZA to Abbott Japan Co., Ltd. (Abbott) in Japan. Sucampo reported \$5.0 million of product sales revenue and \$3.0 million of cost of goods sold compared to nil in 2011, respectively. Sucampo also received a \$15.0 million milestone payment from Abbott associated with the initial sale of AMITIZA in Japan.

"This was a tremendous year of achievement for Sucampo," said Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman, Chief Executive Officer, and Chief Scientific Officer of Sucampo. "With the approval of the sNDA for RESCULA<sup>®</sup>, we now have two FDA approved products marketed in the United States. As the first-ever prescription medicine approved in Japan for chronic constipation, we launched AMITIZA in Japan and received a \$15 million milestone payment related to the first commercial sale of AMITIZA. We look forward to upcoming catalysts for 2013, including the continued rollout of RESCULA in the U.S., the PDUFA date for opioid-induced constipation for AMITIZA in the U.S., the launch of AMITIZA in the U.K. and Switzerland, and the continued development of our pipeline."

Sucampo reported a net income of \$13.5 million, or \$0.32 per diluted share, for the fourth quarter of 2012 compared to a net income of \$2.7 million, or \$0.06 per diluted share, for the fourth quarter of 2011. Sucampo reported a net income of \$4.8 million, or \$0.12 per diluted share for the full year 2012, compared to a net loss of \$17.3 million, or \$0.41 per diluted share, for the full year 2011. The primary driver of the net profit was the \$15.0 million milestone payment from Abbott for Japan AMITIZA sales.

For the fourth quarter of 2012, income from operations was \$13.0 million, an increase of \$9.4 million, compared to \$3.6 million in income from operations for the fourth quarter of 2011. For the full year 2012, income from operations was \$8.3 million, compared to a loss from operations of \$17.7 million for the full year 2011.

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## Quarter Operational Highlights –

- As previously reported, on December 11, 2012, Sucampo announced the receipt of a \$15.0 million milestone payment from Abbott, pursuant to the existing license, commercialization, and supply agreement between Sucampo and Abbott. The milestone payment was triggered by the approval and first sale of AMITIZA at a dosage strength of 24 micrograms in Japanese adults. AMITIZA is available through Abbott in Japan as a prescription medication for chronic constipation not caused by organic diseases, and was available in Japan to primary care and specialist physicians beginning in November 2012.
- On December 12, 2012, Sucampo announced that it received approval of a supplemental new drug application (sNDA) for RESCULA<sup>®</sup> (unoprostone isopropyl ophthalmic solution) 0.15% for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension from the U.S. Food and Drug Administration (FDA).
- On November 30, 2012, Sucampo announced the receipt of a supplement approval from the U.S. FDA that removed pregnancy “warnings and precautions” and clarified information regarding the use of AMITIZA by pregnant and/or nursing women. In addition, the FDA expanded the labeling text of the Mechanism of Action section in the prescribing information for AMITIZA.
- On November 30, 2012, Sucampo announced that the FDA extended the Prescription Drug User Fee Act (PDUFA) goal date for the Agency’s priority review of the sNDA for an additional indication for lubiprostone for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain. The revised goal date is late April of this year.

## Key Value Drivers –

### 2012 Value Drivers Achieved:

#### AMITIZA

##### U.S.

- Sucampo filed an sNDA with the FDA for the treatment of OIC in patients with chronic, non-cancer pain, and received priority review.

##### Japan

- AMITIZA received regulatory approval in Japan for the treatment of CC (excluding constipation caused by organic disease).
  - Sucampo received the pricing reimbursement from the Japanese regulatory authorities and our partner, Abbott, conducted a comprehensive launch of AMITIZA in Japan to primary care and specialist physicians.
  - Following the November launch of the product, Sucampo received a \$15.0 million milestone payment, referenced above, and recorded product sales revenue of \$5.0 million for sales of AMITIZA to Abbott.
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## Europe

- In Switzerland, Sucampo concluded pricing negotiations with the regulatory authorities for an appropriate reimbursement price for the treatment of chronic idiopathic constipation (CIC) and made the product available to specialists.
- AMITIZA was approved by the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) for the treatment of CIC and Sucampo began the process to obtain National Institute for Health and Clinical Excellence (NICE) endorsement.

## RESCULA

- Sucampo received approval of an sNDA for RESCULA for the lowering of IOP in patients with open-angle glaucoma or ocular hypertension and prepared to launch in first quarter 2013.

## Other

- Sucampo received the binding decision from the International Court of Arbitration, International Chamber of Commerce, which has concluded our dispute with Takeda.

## 2013 Value Drivers:

Sucampo is pursuing the following value drivers in 2013:

### AMITIZA

#### U.S.

- Sucampo is pursuing approval of an OIC indication for AMITIZA, and the PDUFA goal date is late April 2013. Upon the first sale of AMITIZA for OIC, we will receive a \$10.0 million milestone payment from Takeda.
- Sucampo expects to have First Patient First Visit in our AMITIZA phase 3 trial for pediatric functional constipation by the third quarter of 2013.

#### Japan

- Growth of AMITIZA sales is a priority.

#### Europe

- In the U.K. and Switzerland in the first quarter of 2013, Sucampo submitted for regulatory approval of AMITIZA for the treatment of OIC.
  - In the U.K., Sucampo plans to seek endorsement from NICE for both OIC and CIC and will make AMITIZA available with reimbursement by some local budget holders.
  - Sucampo will soon begin active marketing of AMITIZA for CIC in Switzerland.
  - Sucampo will use the MHRA approval to seek expansion of AMITIZA's CIC indication to other European markets via the mutual recognition procedure.
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## **RESCULA**

- Following the RESCULA sNDA approval, Sucampo launched the drug in the U.S. RESCULA is now available in all major pharmacies.

## **Other**

### **Oral Mucositis**

- Sucampo expects to complete its oral mucositis phase 1a trial for cobiprostone in the second quarter of 2013.
- Sucampo plans to initiate a phase 1b/2a trial in the fourth quarter of 2013.

### **Spinal Stenosis**

- Sucampo plans to complete its phase 2a trial for SPI-017 in the fourth quarter of 2013.

As previously announced, in February R-Tech Ueno, Sucampo's development partner, signed an agreement for unoprostone isopropyl with the Japan Science and Technology Agency in which the Japanese government shall provide the majority of funding for phase 3 clinical development costs for unoprostone isopropyl for retinitis pigmentosa (RP). Sucampo is co-developing unoprostone isopropyl with R-Tech Ueno and may file for FDA approval of the product for RP in the future assuming the successful trials.

## **Financial Results for the Quarter and Full Year 2012**

For the fourth quarter of 2012, Sucampo reported total revenue of \$34.9 million compared to \$14.2 million for the same period in 2011, a growth of approximately 145%. The key components of revenue for the fourth quarter included R&D revenue of \$15.1 million, product royalty revenue of \$14.2 million and product sales revenue of \$5.0 million which compare to \$2.7 million, \$10.8 million and nil, respectively, in the same period of 2011.

For the full year 2012, Sucampo reported total revenue of \$81.5 million, compared to \$54.8 million for the full year 2011, a growth of approximately 49%. The key components of total revenue for the full year 2012 were product royalty revenue of \$50.7 million, R&D revenue of \$21.5 million and product sales revenue of \$5.0 million compared to \$41.5 million, \$9.2 million and nil, respectively, for the full year 2011. The increase in R&D revenue was primarily due to the receipt of the \$15.0 million milestone payment from Abbott upon the first commercial sale of AMITIZA at a dosage strength of 24 micrograms in Japanese adults.

U.S. net sales of AMITIZA, as reported to us by our partner, Takeda, increased 31% to \$74.6 million for the fourth quarter of 2012, compared to \$56.8 million in the same period of 2011. U.S. net sales of AMITIZA, as reported to us by our partner, Takeda, increased 20% to \$271.9 million for the full year of 2012, compared to \$226.4 million in the same period of 2011. For both periods the increase in AMITIZA U.S. net sales was primarily due to both volume and price increases, as reported to us by our partner.

## **Operating Expenses**

R&D expenses were \$7.1 million for the fourth quarter of 2012, compared to \$7.7 million for the same period of 2011. For the full year 2012, R&D expenses were \$21.3 million, compared to \$33.5 million for the full year 2011. For both periods, the decrease was primarily due to higher expenses in 2011 associated with the completion of the phase 3 OIC trial for AMITIZA.

G&A expenses were \$7.6 million for the fourth quarter of 2012, compared to \$12.0 million for the fourth quarter of 2011. G&A expenses were \$30.2 million for the full year 2012, compared to \$41.3 million for the full year 2011. For both periods, 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, partially offset by increases in corporate marketing and branding and staff to support business growth.

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Selling and marketing expenses were \$4.2 million for the fourth quarter of 2012, compared to \$2.1 million for the fourth quarter of 2011. Selling and marketing expenses for the full year 2012 were \$18.7 million, compared to \$8.8 million for the full year 2011. The increase in selling and marketing expenses relates primarily to some non-recurring pre-commercialization planning activities for AMITIZA, and commercialization and launch costs for RESCULA.

Settlement of Legal Dispute in 2011 – In 2011 Sucampo reported income of \$11.1 million from the settlement of a legal dispute related to a dispute with Covance, a CRO that performed clinical trials for the OBD or OIC indication. The amount represents receipt of \$10.0 million in cash and cancellation of outstanding payables of \$1.1 million and was reported as a reduction to operating expenses. There were no corresponding amounts in 2012.

### **Income from Operations**

For the fourth quarter of 2012, income from operations was a profit of \$13.0 million, an increase of \$9.4 million, compared to a profit of \$3.6 million for the same period in 2011. For the full year of 2012, income from operations was a profit of \$8.3 million, compared to a loss of \$17.7 million for the full year 2011.

### **Non-Operating Income (Expense)**

Non-operating income was \$0.4 million for the fourth quarter of 2012, compared to expenses of \$0.5 million for the fourth quarter of 2011. The fourth quarter of 2012 included a foreign exchange gain of \$0.9 million, compared to a gain of \$14,000 for the same period 2011. Non-operating expenses for the full year 2012 were \$0.6 million, compared to \$4.2 million for the full year 2011. Non-operating expenses for the full year 2012 included a foreign exchange gain of \$1.6 million, compared to foreign exchange loss of \$2.0 million for the same period 2011.

### **Net Income**

Net income for the fourth quarter of 2012 was \$13.5 million, compared to net income of \$2.7 million for the same period of 2011. For the full year 2012, net income was \$4.8 million, compared to a net loss of \$17.3 million for the full year 2011.

### **Comprehensive Income (Loss)**

Comprehensive income for the full year of 2012 was \$3.1 million, compared to comprehensive loss of \$16.0 million for the same period in 2011. Comprehensive loss for the full year 2012 includes a \$1.7 million foreign currency translation loss compared to a foreign currency translation gain of \$1.3 million for the same period in 2011.

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

At December 31, 2012, cash, cash equivalents, restricted cash and investments were \$91.4 million, compared to \$93.4 million at December 31, 2011. At December 31, 2012, notes payable were \$52.9 million, compared to \$59.6 million at December 31, 2011, including current notes payable of \$19.1 million at December 31, 2012, and \$20.4 million at December 31, 2011.

### **Stock Repurchase Plan**

In September 2011, the Board of Directors authorized the repurchase of our class A common stock under the previously approved repurchase plan, up to an aggregate of \$2.0 million. On November 2, 2012, the Board authorized the increase of the program amount up to an aggregate of \$5.0 million. During the fourth quarter of 2012, we repurchased 146,908 shares at a cost of \$721,487.

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## **Board Members**

In February 2013, the Board of Directors appointed Barbara A. Munder and Maureen E. O'Connell to the Board of Directors.

## **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 800-688-0836 (domestic) or 617-614-4072 (international), and provide the participant passcode 62809438, 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 95378400.

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 unoprostone isopropyl (RESCULA®)**

In 2009, 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 (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.

## **About lubiprostone (AMITIZA®)**

AMITIZA (lubiprostone) is a prostone, a locally acting chloride channel activator, indicated for the treatment of CIC (24 mcg twice daily) in adults and for IBS-C (8 mcg twice daily) in women 18 years of age and older in the United States. 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 chronic idiopathic constipation. In the U.K., lubiprostone 24 mcg twice daily is indicated for the treatment of chronic idiopathic constipation and associated symptoms in adults.

## **About Sucampo Pharmaceuticals, Inc.**

Sucampo Pharmaceuticals, Inc. is a global pharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostones. The therapeutic potential of prostones was first discovered by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo's Chairman, Chief Executive Officer, Chief Scientific Officer, and co-founder. Prostones, naturally occurring fatty acid metabolites that have emerged as promising compounds with unique physiological activities, can be targeted for the treatment of unmet or underserved medical needs. For more information, please visit [www.sucampo.com](http://www.sucampo.com).

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

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

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**Sucampo Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations and Comprehensive Income (unaudited)**  
*(in thousands, except per share data)*

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2011</b>	<b>2012</b>	<b>2011</b>
<b>Revenues:</b>				
Research and development revenue	\$ 15,127	\$ 2,658	\$ 21,545	\$ 9,249
Product royalty revenue	14,175	10,793	50,696	41,517
Co-promotion revenue	323	610	3,576	3,378
Contract and collaboration revenue	200	154	633	617
Product sales revenue	5,037	-	5,037	-
Total revenues	<u>34,862</u>	<u>14,215</u>	<u>81,487</u>	<u>54,761</u>
Cost of goods sold	<u>3,030</u>	<u>-</u>	<u>3,030</u>	<u>-</u>
Gross profit	<u>31,832</u>	<u>14,215</u>	<u>78,457</u>	<u>54,761</u>
<b>Operating expenses:</b>				
Research and development	7,090	7,659	21,292	33,497
Settlement of legal dispute	-	(11,100)	-	(11,100)
General and administrative	7,559	11,953	30,157	41,270
Selling and marketing	4,217	2,094	18,691	8,783
Total operating expenses	<u>18,866</u>	<u>10,606</u>	<u>70,140</u>	<u>72,450</u>
Income (loss) from operations	12,966	3,609	8,317	(17,689)
<b>Non-operating income (expense):</b>				
Interest income	61	89	179	249
Interest expense	(566)	(611)	(2,346)	(2,455)
Other income (expense), net	875	14	1,602	(2,019)
Total non-operating income (expense), net	<u>370</u>	<u>(508)</u>	<u>(565)</u>	<u>(4,225)</u>
Income (loss) before income taxes	13,336	3,101	7,752	(21,914)
Income tax benefit (provision)	196	(402)	(2,916)	4,608
Net income (loss)	<u>\$ 13,532</u>	<u>\$ 2,699</u>	<u>\$ 4,836</u>	<u>\$ (17,306)</u>
<b>Net income (loss) per share:</b>				
Basic net income (loss) per share	<u>\$ 0.33</u>	<u>\$ 0.06</u>	<u>\$ 0.12</u>	<u>\$ (0.41)</u>
Diluted net income (loss) per share	<u>\$ 0.32</u>	<u>\$ 0.06</u>	<u>\$ 0.12</u>	<u>\$ (0.41)</u>
Weighted average common shares outstanding - basic	<u>41,553</u>	<u>41,766</u>	<u>41,660</u>	<u>41,839</u>
Weighted average common shares outstanding - diluted	<u>41,991</u>	<u>41,832</u>	<u>41,785</u>	<u>41,839</u>
<b>Comprehensive income (loss):</b>				
Net income (loss)	\$ 13,532	\$ 2,699	\$ 4,836	\$ (17,306)
<b>Other comprehensive income gain (loss):</b>				
Unrealized loss on investments, net of tax effect	13	(110)	36	(2)
Foreign currency translation	43	121	(1,724)	1,282
Comprehensive income (loss)	<u>\$ 13,588</u>	<u>\$ 2,710</u>	<u>\$ 3,148</u>	<u>\$ (16,026)</u>

**Sucampo Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets (unaudited)**  
*(in thousands, except share data)*

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 52,022	\$ 50,662
Investments, current	6,035	24,452
Product royalties receivable	14,175	10,795
Unbilled accounts receivable	732	2,036
Accounts receivable, net	1,360	4,616
Prepaid and income taxes receivable	-	2,845
Deferred tax assets, current	874	163
Deferred charge, current	673	3,057
Restricted cash, current	15,113	15,113
Prepaid expenses and other current assets	1,930	1,177
Total current assets	<u>92,914</u>	<u>114,916</u>
Investments, non-current	14,408	998
Property and equipment, net	1,540	1,669
Intangibles assets, net	7,415	8,364
Deferred tax assets, non-current	1,654	2,089
Deferred charge, non-current	5,213	26,751
Restricted cash, non-current	3,832	2,129
Other assets	820	653
Total assets	<u>\$127,796</u>	<u>\$157,569</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
Current liabilities:		
Accounts payable	\$ 5,496	\$ 6,978
Accrued expenses	10,595	13,648
Deferred revenue, current	3,700	3,888
Deferred tax liability, current	-	2,167
Income tax payable	148	-
Notes payable, current	19,129	20,400
Other current liabilities	1,003	-
Total current liabilities	<u>40,071</u>	<u>47,081</u>
Notes payable, non-current	33,722	39,227
Deferred revenue, non-current	7,093	7,045
Deferred tax liability, non-current	2,627	23,019
Other liabilities	1,253	2,603
Total liabilities	<u>84,766</u>	<u>118,975</u>
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at December 31, 2012 and 2011; no shares issued and outstanding at December 31, 2012 and 2011	-	-
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at December 31, 2012 and 2011; 41,964,905 and 15,690,780 shares issued and outstanding at December 31, 2012 and 2011, respectively	420	157
Class B common stock, \$0.01 par value; 0 and 75,000,000 shares authorized at December 31, 2012 and 2011; 0 and 26,191,050 shares issued and outstanding at December 31, 2012 and 2011, respectively	-	262
Additional paid-in capital	62,521	59,957
Accumulated other comprehensive income	16,166	17,854
Treasury stock, at cost; 457,030 and 186,987 shares	(1,977)	(700)
Accumulated deficit	(34,100)	(38,936)
Total stockholders' equity	<u>43,030</u>	<u>38,594</u>
Total liabilities and stockholders' equity	<u>\$127,796</u>	<u>\$157,569</u>

Sucampo Pharmaceuticals, Inc.  
Key Segment Information (unaudited)

(In thousands)

Three Months Ended December 31, 2012

	Americas	Europe	Asia	Consolidated
Research and development revenue	\$ 311	\$ (74)	\$ 14,890	\$ 15,127
Product royalty revenue	14,175	-	-	14,175
Co-promotion revenue	323	-	-	323
Contract and collaboration revenue	141	46	13	200
Product sales revenue	-	14	5,023	5,037
Total revenues	14,950	(14)	19,926	34,862
Cost of goods sold	98	9	2,923	3,030
Gross profit	14,852	(23)	17,003	31,832
Research and development expenses	1,559	4,166	1,365	7,090
Depreciation and amortization	118	255	10	383
Other operating expenses	8,935	417	2,041	11,393
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 expense, net	10	(269)	1,134	875
Income (loss) before income taxes	\$ 4,306	\$ (5,653)	\$ 14,683	\$ 13,336
Capital expenditures	\$ 108	\$ 25	\$ -	\$ 133

Three Months Ended December 31, 2011

Research and development revenue	\$ 2,478	\$ -	\$ 180	\$ 2,658
Product royalty revenue	10,793	-	-	10,793
Co-promotion revenue	610	-	-	610
Contract and collaboration revenue	141	-	13	154
Total revenues	14,022	-	193	14,215
Research and development expenses	4,593	2,002	1,064	7,659
Settlement for legal dispute	(11,100)	-	-	(11,100)
Depreciation and amortization	(133)	405	10	282
Other operating expenses	13,094	285	386	13,765
Income (loss) from operations	7,568	(2,692)	(1,267)	3,609
Interest income	85	3	1	89
Interest expense	-	(569)	(42)	(611)
Other non-operating expense, net	(21)	(105)	140	14
Income (loss) before income taxes	\$ 7,632	\$ (3,363)	\$ (1,168)	\$ 3,101
Capital expenditures	\$ 52	\$ 3	\$ -	\$ 55

Year Ended December 31, 2012


Research and development revenue	\$ 6,189	\$ -	\$ 15,356	\$ 21,545
Product royalty revenue	50,696	-	-	50,696
Co-promotion revenue	3,576	-	-	3,576
Contract and collaboration revenue	565	16	52	633
Product sales revenue	-	14	5,023	5,037
Total revenues	61,026	30	20,431	81,487
Cost of goods sold	98	9	2,923	3,030
Gross profit	60,928	21	17,508	78,457
Research and development expenses	7,809	9,571	3,912	21,292
Depreciation and amortization	484	964	40	1,488
Other operating expenses	41,410	2,993	2,957	47,360
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	77	(187)	1,712	1,602
Income (loss) before income taxes	\$ 11,463	\$ (15,861)	\$ 12,150	\$ 7,752
Capital expenditures	\$ 401	\$ 3,470	\$ -	\$ 3,871

Year Ended December 31, 2011

Research and development revenue	\$ 8,033	\$ -	\$ 1,216	\$ 9,249
Product royalty revenue	41,517	-	-	41,517
Co-promotion revenue	3,378	-	-	3,378
Contract and collaboration revenue	565	-	52	617
Total revenues	53,493	-	1,268	54,761
Research and development expenses	24,058	4,354	5,085	33,497
Settlement for legal dispute	(11,100)	-	-	(11,100)
Depreciation and amortization	791	474	43	1,308
Other operating expenses	46,326	1,092	1,327	48,745
Income (loss) from operations	(6,582)	(5,920)	(5,187)	(17,689)
Interest income	240	6	3	249
Interest expense	-	(2,288)	(167)	(2,455)
Other non-operating expense, net	(42)	(1,884)	(93)	(2,019)
Income (loss) before income taxes	\$ (6,384)	\$ (10,086)	\$ (5,444)	\$ (21,914)
Capital expenditures	\$ 145	\$ 6,006	\$ 133	\$ 6,284

CONTACT:

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[staylor@sucampo.com](mailto:staylor@sucampo.com)



# Fourth Quarter and Full Year 2012 Results





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## **Introductions and Forward-Looking Statements**

### **Silvia Taylor**

*Senior Vice President, Investor  
Relations, Public Relations and  
Corporate Communications*



# Agenda

<b>Introductions and Forward-Looking Statements</b>	Silvia Taylor
<b>Highlights of the Quarter and Year</b>	Ryuji Ueno, MD, PhD, PhD
<b>Commercial Update</b>	Stanley G. Miele Andrew Smith
<b>Pipeline and R&amp;D Update</b>	Peter Lichtlen, MD, PhD
<b>Financial Performance</b>	Cary J. Claiborne
<b>Closing Remarks</b>	Ryuji Ueno, MD, PhD, PhD



# 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 US 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.



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## **Q4 and FY 2012 Highlights**

**Ryuji Ueno, MD, PhD, PhD**

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



# Highlights

## RESCULA

- sNDA approved
- Launched with our own sales force; initial feedback positive

## AMITIZA

- Abbott Japan launched in Japan for CC; \$15M milestone payment received
- Strong US sales growth – Q4 up 31.3% in U.S. to \$74.6 million
- US label update approved
- OIC indication PDUFA date April 2013
- Reached agreement on Swiss reimbursement price
- UK approval for CIC

## Pipeline

- P1 trial of SPI-8811, cobiprostone, for oral mucositis on track
- Initiated P2 trial of SPI-017 and P1 program for SPI-3608 for severely symptomatic lumbar spinal stenosis
- R-Tech Ueno, Ltd. (RTU) received funding from the Japan Science and Technology Agency for P3 program in retinitis pigmentosa using unoprostone isopropyl



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## Commercial Update



**Stanley G. Miele**  
*President, Sucampo  
Pharma Americas and  
SVP, Sales and  
Marketing*



**Andrew Smith**  
*Vice President of  
Operations and Finance*

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# RESCULA US

- sNDA approved December 2012
  - Patients with open-angle glaucoma or ocular hypertension
  - In the US: 2 million US glaucoma patients<sup>1</sup>, additional 3-6 million with ocular hypertension<sup>2</sup>
  - Unique mechanism of action (BK channel activator) and well-tolerated safety profile
- Launched with our own sales force
  - Expect 11% share of voice
- Positive feedback and significant progress
  - More than 5,000 face-to-face calls
  - Over 50,000 samples shipped
  - 47 face-to-face meetings with plans and PBMs



See References 1-2

# AMITIZA US

- January 2013 second highest month of TRx ever (+9.7%)
- Q4 TRx and NRx growth: 6% YoY
- Q4 net sales increase: up 31.3% to \$74.6 million
- Over 7 million prescriptions over 7 years
  - Growth trajectory expected to continue
- sNDA for OIC
  - PDUFA date April 2013
  - Unmet need: 2-2.5 million moderate to severe non-cancer, chronic pain patients, most dissatisfied with current treatment options<sup>3-6</sup>
  - \$10 million milestone payment upon first sale for OIC



# AMITIZA Japan and Europe

## Japan

- Abbott Japan launch late November
- \$15 million milestone payment received in Q4
- First-ever prescription medicine approved for chronic constipation
- Q4 product sales at \$5 million

## Europe/UK

- On track to commence active marketing (CIC) in Switzerland
- UK approval (CIC)
  - On track to launch ourselves
  - Initiated NICE endorsement process
- Filing for approval for CIC in other EU markets this year using MRP
- OIC indication recently filed in both Switzerland and UK
  - Initiated NICE endorsement process



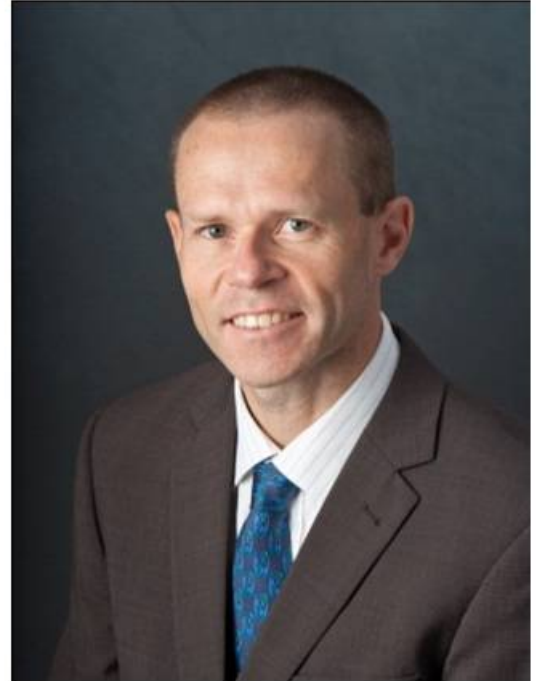
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## **Pipeline and R&D Update**

**Peter Lichtlen, MD, PhD**

*Senior Medical Officer and Vice  
President, European Operations*





- Development of new liquid dosage form
  - Some patients cannot swallow gel caps
    - Pediatric
    - Geriatric
  - 100% of development costs to be reimbursed by Takeda
- Initiate P3 pediatric trials in Q3 2013
  - Pediatric functional constipation indication
  - Takeda to fund significant amount of developmental costs

# SPI-8811 (cobiprostone) for Oral Mucositis

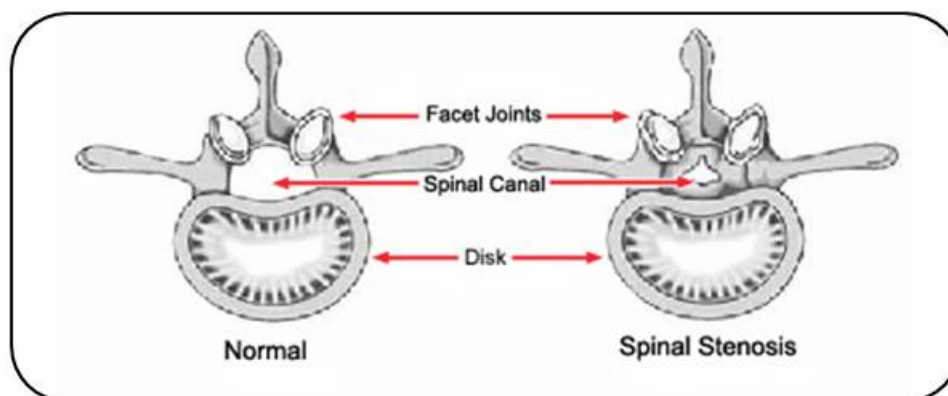
- Oral mucositis is a severely painful inflammation of the oral cavity
- 100% incidence rate in certain cancers
- Unmet medical need
- P1 trial in healthy volunteers initiated
  - New oral spray formulation
  - Expect to complete P1 in Q2 2013



See Reference 7; photos from Silverman. Diagnosis and management of oral mucositis. J Support Oncol 2007; 5 (2 Suppl 1):13-21.

# SPI-017 and SPI-3608 for Lumbar Spinal Stenosis

- LSS caused by degenerative change in lumbar spine; very common disease observed in growing aged population
- Unmet medical need
- SPI-017 (IV) P2 trial and SPI-3608 (oral) P1 trial ongoing; expect to conclude in Q4



Source: Photos from American Academy of Orthopaedic Surgeons website: [www.orthoinfo.aaos.org](http://www.orthoinfo.aaos.org)

# Unoprostone Isopropyl for Retinitis Pigmentosa

- Japan Science and Technology Agency to provide RTU with the majority of funding for P3 clinical developmental costs
- Co-developing with RTU
- Retinitis pigmentosa (RP) begins with degeneration of rods, followed by progressive and irreversible death of cones leading to blindness
- Currently no drugs or treatments approved for RP
- Sucampo received orphan drug designation for unoprostone isopropyl in US



Source: Photos from Foundation Fighting Blindness website: [www.blindness.org](http://www.blindness.org)



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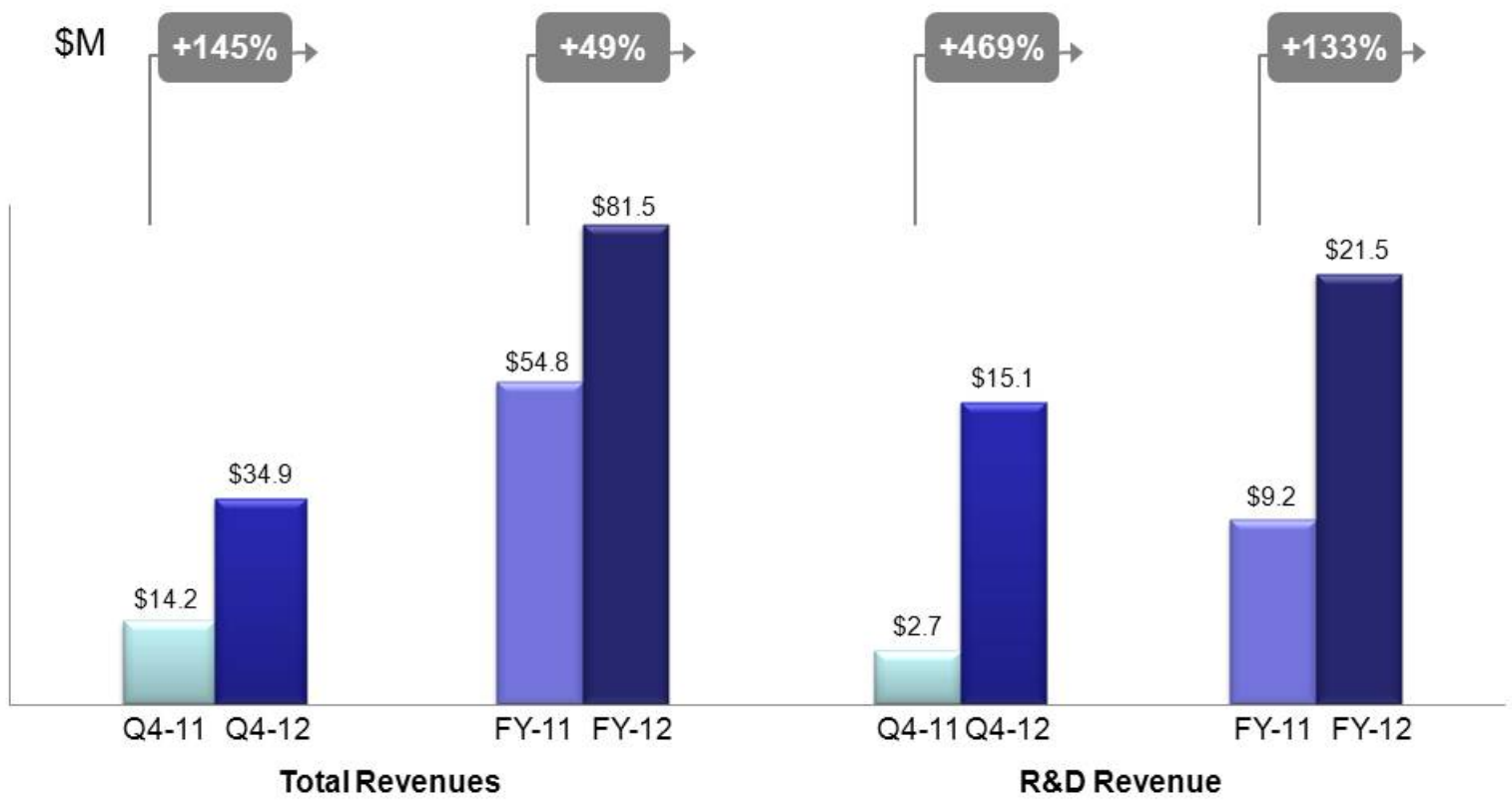
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## **Financial Performance**

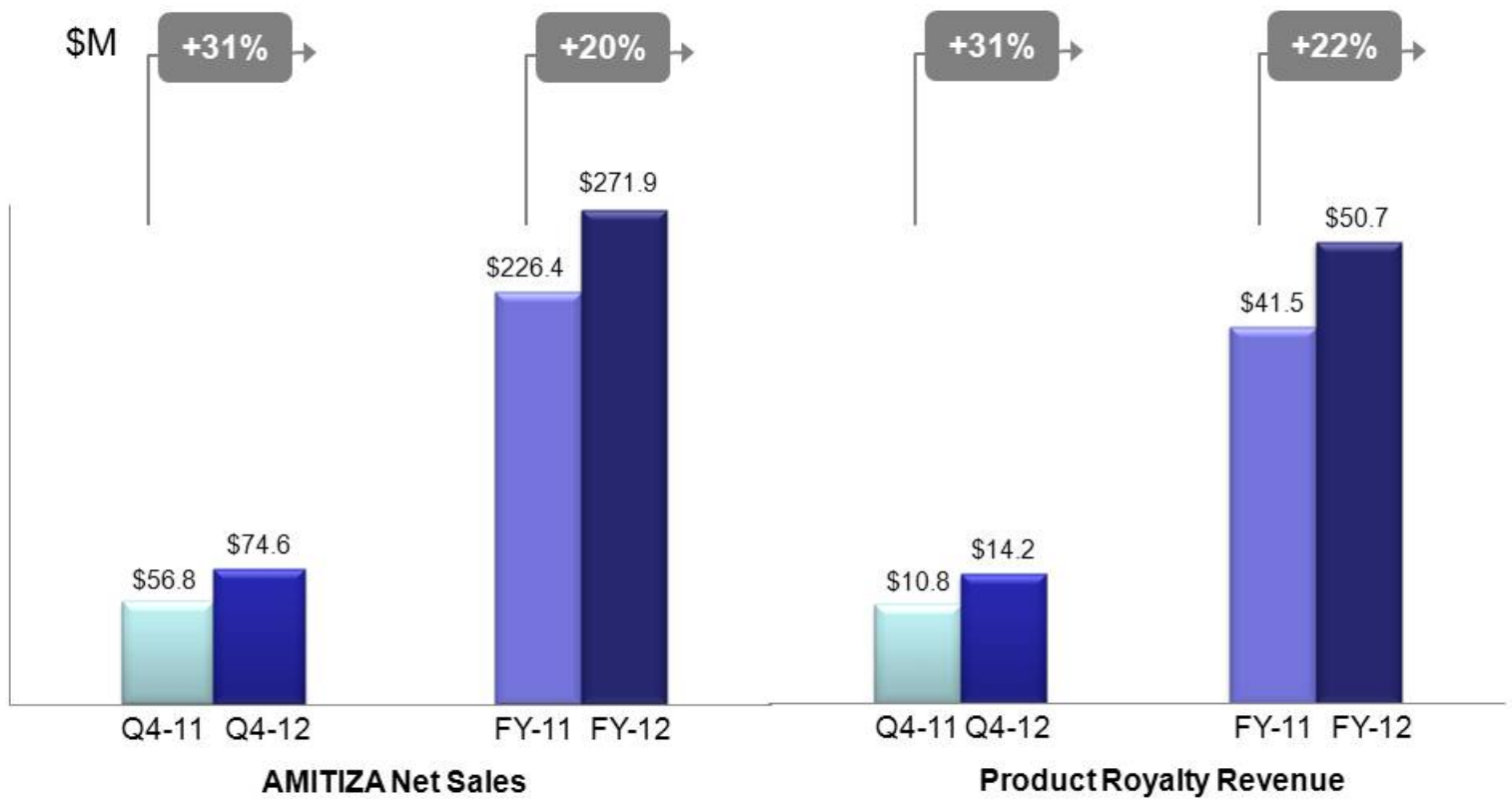
**Cary J. Claiborne**  
*Chief Financial Officer*



# Q4 and FY 2012 Financial Highlights



# Q4 and FY 2012 Financial Highlights



# Q4 2012 & FY 2012 Financial Highlights

\$M except EPS	Q4 2011	Q4 2012	FY 2011	FY 2012
Operating Income	\$3.6	\$13.0	(\$17.7)	\$8.3
Net Income	\$2.7	\$13.5	(\$17.3)	\$4.8
EPS	\$0.06	\$0.32	(\$0.41)	\$0.12
R&D	\$7.7	\$7.1	\$33.5	\$21.3
G&A	\$12.0	\$7.6	\$41.3	\$30.2
Selling & Marketing	\$2.1	\$4.2	\$8.8	\$18.7



## Q4 and FY 2012 Financial Highlights

- Cash position \$91.4 million as of December 31, 2012
- \$15 million milestone payment received from Abbott Japan
- Repurchased 146,908 shares during quarter
  - Recently raised authorized amount to \$5 million
  - One class of common stock
- Operating cash flow of \$17.2 million for Q4 and \$12 million for FY 2012



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## Closing Remarks

**Ryuji Ueno, MD, PhD, PhD**

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



# 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 Q3 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



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**Q** & **A**

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# References

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2. Kass MA et al. Arch Ophthalmol. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. 2002 Jun;120(6):701-13; discussion 829-30.
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5. Physician Interviews
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## PRESENTATION

### Operator

Good afternoon and welcome to Sucampo's fourth-quarter and full-year 2012 financial results and operating highlights conference call. For opening remarks and introductions, I would like to turn the call over to Silvia Taylor, Sucampo's Senior Vice President of Investor Relations, Public Relations and Corporate Communications. Please proceed.

### Silvia Taylor - Sucampo Pharmaceuticals Inc - SVP, IR

Thank you, operator, and good afternoon, everyone. Thank you for joining us today. The earnings release and its attachments announcing Sucampo's fourth-quarter and full-year 2012 financial and operational highlights is being distributed this afternoon. For those of you who have not yet seen it, you will find it posted in For Investor section of our website at [www.sucampo.com](http://www.sucampo.com) shortly. We also plan to file our 10-K shortly and once filed, a link to that document will also be posted on our website. Now, please turn to slide 3 of our presentation deck. Our agenda today is as follows. Dr. Ryuji Ueno, the Chairman of the Board, Chief Executive Officer and Chief Scientific Officer will provide an overview of the quarter and highlights for the year. Stanley Miele, Senior Vice President of Sales and Marketing and President of Sucampo Pharma America will review development in the US for AMITIZA and RESCULA. Andrew Smith, Vice President of Operations and Finance will review AMITIZA development in Japan and Europe. Dr. Peter Lichtlen, Senior Medical Officer and Vice President of European Operations will review our pipeline activity, followed by Cary Claiborne, Sucampo's Chief Financial Officer, who will review the financials. Finally, Dr. Ueno will provide closing comments just ahead of the Q&A portion of the call. Additional members of Sucampo's team are present and available to answer your questions then. Before we begin, on slide 4, please note that various remarks management makes on this conference call and the information contained in today's earnings release are as of March 13, 2012. The Company assumes no obligation to update forward-looking statements contained in this conference call earnings release or the attachments as a result of new information or future events or developments. This conference call, earnings release, and the attachments contain forward-looking information about the Company's future operating and financial performance, business plans and prospects, inline products and product candidates and share repurchase plans to that involve substantial risks and uncertainties. Please refer to the forward-looking statement and the 10-K found on our website for additional risk factors affecting our forward-looking statements.

Now, I will turn the call over to Dr. Ueno. Dr. Ueno, please go ahead.

**Dr. Ryuji Ueno - Sucampo Pharmaceuticals Inc - Chairman of the Board, CEO & Chief Scientific Officer** Thank you, Sylvia. Hello, everyone. Thank you for joining our conference call today. Please turn the slide. In the fourth quarter of 2012, we continued to fulfill our mission of bringing prostone-based medicines to patients around the world. 2012 was a year of tremendous achievement for Sucampo as we reached several important milestones for both our AMITIZA and RESCULA franchise. With AMITIZA approval and launches in Japan and the UK, this year we will be recognizing revenue on three continents. Our pipeline is also continuing to progress, and with two new prostones progressing into the clinic, we now have a total of five prostone-based compounds in clinical development. We're also eagerly anticipating the late April PDUFA date for AMITIZA for opioid-induced constipation (technical difficulty) of its kind. In the United States, in December, the FDA approved our sNDA for RESCULA unoprostone isopropyl for the lowering of interocular pressure in patients with open angle glaucoma for ocular hypertension. Open angle glaucoma is the most common form of glaucoma, and ocular hypertension affects millions more in the United States alone. RESCULA is the first BK channel activator approved for this indication. RESCULA's strength is its safety and tolerability profile. As you heard during our RESCULA update call last month, Sucampo has begun active commercialization of the product, and it is now available in pharmacies across the US. We are pleased to say that the early response to the RESCULA launch has been quite positive, and we expect to carry this momentum through the remainder of 2013. Additionally, early reports from the [ocular] market are that it is favorable to receiving a product that has a different and unique mechanism of action. Turning now to AMITIZA, as Stan Miele will expand upon later, we've experienced solid growth and expansion in the quarter and the year in the United States, even in the presence of the competitive launch at the end of 2012. I am also pleased to let you know that, in December, we received a \$15 million milestone payment from Abbott Japan, triggered by the first commercial sale of AMITIZA in Japan, the second largest pharmaceutical market in the world. AMITIZA is the first prescription medicine ever available in Japan for chronic constipation, and it was launched by Abbott Japan to primary care and specialist physicians on November 22, 2012. Fourth-quarter sales in Japan were double our initial expectations. We are particularly proud of the fact that this is the first time that Japan has ever approved a drug for chronic constipation and that patients now have a treatment option for this condition. In the United States, AMITIZA continues to demonstrate strong dollar sales growth as reported to us by our partner. AMITIZA year-over-year net sales during the fourth quarter grew by 31.3% to \$74.6 million. As we look at monthly data, we have continued to see solid growth with January 2013 being our second highest month of AMITIZA net sales ever. Also in the United States, we received supplemental approval of AMITIZA from the FDA that removed pregnancy warning and precautions from the label and clarified the information regarding the use of AMITIZA by pregnant and/or nursing women. We believe this will help physicians and women of child-bearing age who are suffering from OIC or CIC to better evaluate the risk benefit profile of AMITIZA and it will provide a competitive advantage for the product in the market. The supplemental approval also added details to the mechanism of the action section of the label which highlight AMITIZA's ability to reduce intestinal permeability via the restoration of tight junction protein complexes. We believe this is important to further clarify understanding of how AMITIZA may work for clinicians evaluating the treatment of patients with IBSC since the increase in permeability and distraction of tight junctions is thought to be one of the major causes of IBSC. The PDUFA date for the opioid-induced constipation indications remains late April 2013. We are pleased with how the review is proceeding, and we continue to maintain ongoing discussion with the FDA on our filing. Following the first sale for this indication, Sucampo will earn \$10 million-milestone payment from Takeda per the terms of our contract with them. In Switzerland, we reached an agreement with authorities for the reimbursement price for AMITIZA for CIC, and we have begun to build the sales organization in Switzerland. Another achievement for AMITIZA in the second half of 2012 was its approval in the United Kingdom for the treatment of CIC. Our priority now is to achieve National Institute for Clinical Excellence, in short, nice endorsements so that we can actively market AMITIZA in the United Kingdom, and we have already had our first meeting with NICE. We have begun commercialization efforts while we await NICE's endorsement.

In addition to the success we achieved with AMITIZA and RESCULA, we also continue to make progress in our budding pipeline of prostone-based candidates. As you may recall, we discussed our pipeline priorities at our September 12 analyst day, our phase I trial of an oral formulation of SPI-8811, or Cobiprostone, for the prevention and treatment of oral mucositis remains on track. We expect to complete the trial in the second quarter of 2013. As you will hear more during this call, development of oral mucositis is a common severe side effect of cancer treatment. This is an area of our met medical need because there are no prescription drugs available for prevention or treatment of oral mucositis. Progress with SPI-017 and SPI-3608 for the management of CVLE symptomatic lumbar spinal stenosis continues. Lumbar spinal stenosis is caused by a degenerative change in the lumbar spine and is a common disease among the aging population. We initiated our phase IIA trial for SPI-017, the IV formulation of the product, in the first quarter of 2013. We also initiated a phase I program for SPI-3608, the oral version of the product in the fourth quarter of 2012. We remain on track to report on the progress of both trials in the fourth quarter of 2013. We are very pleased that we now have two products in phase III clinical development. As we will discuss in that call, later this year we will begin a phase III program for a pediatric indication for AMITIZA. And after a successful phase II trial for unoprostone isopropyl in retinitis pigmentosa, unoprostone isopropyl will move into phase III clinical development and that a guidance of our development partner, R-Tech Ueno Limited. As we reported earlier this year, the Japanese government has adopted unoprostone isopropyl into a technology transfer program which will provide funding for R-Tech Ueno's phase III development cost in retinitis pigmentosa. Unoprostone isopropyl's mechanizable action, BK channel activation, has demonstrated strong evidence of the protective effect of unoprostone on the retina in both in vitro and in vivo non-clinical models. We are very encouraged by the successful phase II clinical data from Japan where a significant positive differences we are seeing on the evaluation of visual sensitivity when comparing unoprostone isopropyl versus placebo treatment of mid to late stage retinitis pigmentosa patients. Sucampo is, quote, developing unoprostone isopropyl with R-Tech Ueno, and we may proceed with the development program for retinitis pigmentosa in the future, assuming the phase III Japanese program is successful. I am also pleased with the appointment of our two newest board members, Barbara Munder and Maureen O'Connell. They are both highly qualified and bring a breath of experience in public companies to Sucampo board that we think will be very valuable as we move forward. I am very pleased with the progress we made in 2012. It was truly a transformational year for Sucampo, and I am confident that we will successfully execute against our plans for 2013 as we grow AMITIZA and RESCULA and advance our product pipeline portfolio. I will now turn the call over to Stan Miele who will give a commercial update regarding the launch of RESCULA in the United States and the continued commercialization of AMITIZA in the US. Stan?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America Thank you, Dr. Ueno. Good afternoon. It's a pleasure to speak with everyone. I am very excited to speak with you about two key areas. First, Sucampo's launch of RESCULA in the United States, where we are ahead of schedule on many fronts, and second, the update on AMITIZA as we evaluate an additional entrant into the market. Please turn to slide 8. Our sNDA for RESCULA for the lowering of intraocular pressure, or IOP, in patients with open angle glaucoma or ocular hypertension was approved in December, and we moved quickly to launch the product in the first quarter of this year. In February, we announced that RESCULA was available in pharmacies across the US. Dr. Ueno mentioned, open angle glaucoma is the most common form of glaucoma and currently affects in excess of 2 million people in the US. It is estimated that ocular hypertension also affects an additional 3 million to 6 million patients in the US. This results in approximately 30 million prescriptions per year in the United States. RESCULA provides an alternate route for intraocular pressure, or IOP reduction in the treatment of these conditions. Its mechanism of action affects the BK channels, which increases the outflow of aqueous humor through the trabecular meshwork. As a result, there have been over 6.4 million dispensed bottles of RESCULA on the global basis, primarily in the Japanese market. We expect to build upon the Japanese experience and accelerate patient utilization in the US. We are positioning RESCULA as an appropriate choice for eye specialists who are trying to balance efficacy with the management of side effects, particularly the 5% to 10% of patients who cannot tolerate a prostaglandin analogue due to ocular side effects. We are excited to have an 11% share of voice through our 40 Sucampo sales representatives. The first 12 months of launch, we expect to have approximately 60,000 face-to-face interactions in which we will reach prescribers representing 80% of the market. In fact, we've made over 5,000 calls since early February and have provided over 50,000 samples to eye specialists. As a reminder, this market is highly sample sensitive; it is typical for patients to receive a 30-day sample to assess both efficacy and safety before a prescription is written. The early feedback is positive, and many clinicians have begun using RESCULA samples with some prescribing the medicine which should be reflected in the IMS data over the next several months. Achieving managed care coverage of RESCULA is also a high priority. So far we have had 47 face-to-face meetings with the plans and pharmacy benefit managers that constitutes 80% of the covered lives. We are pleased that managed care is seeing the value of RESCULA, and many of the top plans are providing interim coverage of the product while they await making a final decision through their P&T committees. In summary, we are pleased by the favorable reception to RESCULA so far and will continue to work hard toward the goal of minimizing any potential obstacles for patients and physicians and ensuring a positive experience with RESCULA. I look forward to continuing to update on the RESCULA launch throughout the year. Now, turning to AMITIZA in the US, I would like to first give a brief review of the recent AMITIZA prescription trends and how we are pleased with what we are seeing thus far. Please refer to slide 9. If we look at reported IMS monthly prescription data, January 2013 was the second highest month of total prescriptions ever, up 9.7% from January 2012. In the fourth quarter of 2012, both TRX and NRX growth over the same period last year were up 6%. We believe that based on the revised AMITIZA label removing the negative pregnancy test, along with the updated mechanism of action highlighting the reduction in intestinal permeability, this will further differentiate AMITIZA and be a catalyst for continued growth, regardless of new competition. As we reported earlier today, AMITIZA net sales have increased during the quarter by 31.3% to \$74.6 million as reported to us by our partner, Takeda. This growth in net sales was primarily due to both volume and price increases. We expect this trajectory of strong growth to continue, given AMITIZA's well-tolerated safety profile and the desire by prescribers, particularly primary care physicians, to prescribed drugs that have a established track record of safety over several years. Since its launch almost seven years ago, AMITIZA has been prescribed more than 7 million times. Toward the end of 2012, we saw the addition of the new entrant into the marketplace, which will continue to bring a heightened level of awareness of the CIC and IBSC diseases and help bring new patients into the market. As this market continues to grow, we expect AMITIZA to capture an increasing number of patients and market share. As stated above, January 2013 was the second highest month of total prescriptions in AMITIZA's history. Based on some early data points, AMITIZA has grown the business in the face of a competitive launch. Our position is to, again, focus on our product strengths and also exploit some of the strong managed care gains over the past year along with our label revisions. Turning to our potential new indication for AMITIZA, our PDUFA date for the opioid-induced constipation indication remains late April. We are pleased with how the review is proceeding and we continue to maintain ongoing discussions with the FDA on our filing. We still strongly believe that the priority review demonstrates a significant unmet medical need for the condition of OIC and we believe AMITIZA, when approved, will be well-positioned by our partner to take advantage of this unmet medical need. In the US, there are over 200 million opioid prescriptions written annually, and our research shows that moderate to severe OIC affects conservatively between 2 million to 2.5 million non-cancer chronic pain patients in the US. OIC is an area of high unmet medical need, and patients are suffering with few, if any, viable treatment options. The scientific literature states that anywhere between 40% to 80% of chronic opioid users will experience constipation as a side effect, and that when it occurs, the constipation is likely to be moderate to severe. So severe, in fact, that some patients choose to live in pain and discontinue their opioid treatment, rather than suffer the constipation that ensues. In addition, we know that primary care physicians who prescribe the majority of these patients are also looking for a medicine indicated to treat their patients with OIC. We are working with Takeda to prepare for the launch of the new indication when it is approved. Also, upon the first sale of AMITIZA for this indication, we will receive a \$10 million milestone payment from our US alliance partner. I would like to now turn the call over to Andrew Smith, Vice President of Operations and Finance to provide comments on the AMITIZA commercialization efforts in Japan and Europe. Andrew?





**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Thank you, Stan, and good afternoon, everyone. Welcome to the call. Please refer to slide 10. We're very pleased that AMITIZA was approved in Japan during the second quarter of 2012 for the treatment of chronic constipation and our partner, Abbott Japan, was successful in carrying out a comprehensive launch of AMITIZA beginning in late November, 2012. The first commercial sale of AMITIZA resulted in a \$15 million milestone payment to us from Abbott Japan in December. We are particularly proud of the fact that this is the first ever prescription medicine approved for chronic constipation in Japan. Abbott Japan deployed an extensive sales and marketing effort designed to introduce AMITIZA to the primary care and specialty physician audiences. Importantly, we have received guidance on pricing reimbursement for AMITIZA in Japan. This is important, because it will allow more patients to have access to the product. The launch continues to progress extremely well. Fourth-quarter product sales of \$5 million, exceeding Abbott Japan's initial projections. In addition, Abbott's detailing efforts for AMITIZA rank in the top 20 in GP segment of all pharmaceutical detailed products in Japan early into its sales efforts for the product. We are pleased that there is a now high level of product awareness and excitement among Japanese physicians about AMITIZA. So, we're pleased with these commercialization efforts and encouraging early results by our Japanese partner and look forward to strong sales of AMITIZA in Japan in the coming months. Turning now to AMITIZA in Europe, as mentioned in our last earnings call, we received the reimbursement price for AMITIZA in Switzerland on December 1, 2012, and we have begun to build the sales organization in Switzerland. As Dr. Ueno mentioned at the start of the call, we are making progress on our plans to launch AMITIZA in the UK. We have initiated the NICE endorsement process for both CIC and OIC indications, which we believe is one of the keys to gaining widespread adoption of AMITIZA in the UK and gain an established prescriber base. In addition, as we have previously disclosed, we are using the MHRA approval to seek expansion of AMITIZA's CIC indication to other European markets via the mutual recognition procedure. And finally, we have completed our filings for the OIC indication in Switzerland and the UK this quarter. With that, I would like to turn the call over to Peter Lichtlen to discuss our pipeline. Peter?

**Peter Lichtlen** - Sucampo Pharmaceuticals Inc - Senior Medical Officer & VP of European Operations

Thank you, Andrew. Good afternoon, everyone, it's a pleasure to speak with you. We have had a busy year in R&D this year, and we have a lot to talk about, so let's go to it. Please refer to slide 12. We continue to make progress on AMITIZA, including the development of a new liquid dosage form of the product. This liquid dosage form is significant because it can allow us to provide AMITIZA to new patient populations who can not swallow the current gel cap, namely pediatric and many geriatric patients. Our commercial team will be working with our partners to properly position this new dosage forum. Additionally, 100% of the development costs for the new liquid dosage form will be reimbursed by Takeda per the terms of our contract with them. We are pleased to let you know that we continue to make progress toward the pediatric functional constipation indications, and we plan to initiate a phase III program in the US, Canada, and Europe in the third quarter of this year. Importantly, Takeda will fund the majority of the development costs for the pediatric indication. Again, per our contract. Now please turn to slide 13. Our progress continues on SPI-8811, or Cobiprostone, for the prevention and treatment of oral mucositis. Development of oral mucositis, a severely painful inflammation of the oral cavity, is commonly associated with cancer treatments such as radiation and chemotherapy. Currently, no truly effective treatment option exists, making this an area of high unmet medical needs. Additionally, oral mucositis can have incident rates of approaching 100% in certain cancer types. The effect of oral mucositis can be devastating for cancer patients, leading to dehydration, insertion of feeding tubes and sometimes even discontinuation of cancer therapy in the more extreme cases. We have developed a new spray formulation of SPI-8811 for local use for this indication, and we are currently testing this compound in a phase IA clinical trial. This trial allows us to fulfill our corporate mission of using a nominative research and development and our proprietary prostone technology to meet the unmet medical needs of patients. We continue to expect to complete phase IA of this trial in the second quarter of 2013 and plan to initiate a phase IB/IIA clinical trial in the fourth quarter of this year. On slide 14, our progress on the phase II trial of SPI-017, an IV compound for the management of severely symptomatic lumbar spinal stenosis continues, and does our phase I trial of SPI-3608, an oral treatment modality for mild to moderate patients with the same disease. We plan to conclude these trials in the fourth quarter of this year. These trials are being conducted in Japan where the only currently approved medication of LSS is an oral PGE1 analog. We know that prostaglandins are associated with poor systemic safety and require careful and fractionated dosing. In the United States and Europe, no medications are approved for this specific indication. Again, this is clearly an area of unmet medical need. Finally, life cycle management unoprostone isopropyl is a priority for us. As Dr. Ueno briefly mentioned earlier, the Japan science and technology agency has agreed to provide the majority of the funding for R-Tech Ueno's phase III clinical development costs for unoprostone isopropyl for retinitis pigmentosa under the adaptable and seamless technology transfer program. Sucampo is co-developing unoprostone isopropyl with R-Tech Ueno. This program provides a participating institution with a total R&D funding of up to \$2 billion yen, approximately \$22 million US for up to seven years. If the development is successful, the participating institution repays the total amount of the provided funding by paying royalties based on product sales. If the development is not successful, the participating institution repays 10% of the provided funding with no interest payments due. As part of our agreement for unoprostone isopropyl with RTU, Sucampo will receive the data from this Japanese clinical development program which, if successful, will play a significant role in development efforts for retinitis pigmentosa for unoprostone isopropyl in the United States and Europe. Retinitis pigmentosa is a group of retinal degenerative diseases characterized by night blindness, the progressive loss of peripheral vision and, eventually, loss of central vision, leading to blindness. As retinitis pigmentosa progresses, daily life becomes increasingly more difficult. There are currently no drugs approved for the treatment of RP. Sucampo receives an orphan drug status from the FDA for the treatment of retinitis pigmentosa in 2010. We will seek orphan drug status in the EU as well this year. With that, I look forward to answering your questions at the end of this call and now turn it over to Cary Claiborne to provide our financial update. Cary?

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**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Thank you, Peter. Good afternoon, everyone. I would like to review the financial highlights for the quarter and the full year with you. I will start with slide 17. Total revenue for the fourth quarter of 2012 was \$34.9 million compared to \$14.2 million in the fourth quarter of 2011, a growth rate of 145%. Total revenue for the full-year 2012 was \$81.5 million compared to \$54.8 million in the prior year, a growth rate of 49%. I'll cover the drivers of the year-over-year increase in a few minutes. R&D revenue the fourth quarter of 2012 was \$15.1 million compared to \$2.7 million during last year's fourth quarter. For the full-year 2012, R&D revenue was \$21.5 million compared to \$9.2 million in the prior year. The increase in R&D revenue was primarily due to the receipt of the \$15 million-milestone payment from Abbott Japan, partially offset by lower activity associated with the completion of our phase III OIC trial for AMITIZA in the US. Now, please move to slide 18. Net sales of AMITIZA in the US, which are reported to Sucampo by our alliance partner Takeda, increased 31% to \$74.6 million in the fourth quarter of 2012, compared to \$56.8 million in last year's fourth quarter. Net sales of AMITIZA increased 20% to \$271.9 million for the full year of 2012, compared to \$226.4 million in the prior year. As reported to us by Takeda, for both periods, the increase in AMITIZA US net sales was primarily due to both volume and price increase. Product royalty revenue for the fourth quarter of 2012 was \$14.2 million, an increase of \$3.4 million, or 31% from \$10.8 million in last year's fourth quarter. Product royalty revenue for the full year 2012 was \$50.7 million, an increase of \$9.2 million, or 22% compared to \$41.5 million in the prior year. As Takeda reported, the increase was primarily due to higher price and volume of AMITIZA net sales in the US. As I've mentioned in some of our recent investor conferences, our revenues under the agreement with Abbott are not royalties but are actual sales of AMITIZA products to Abbott Japan under our license and commercialization agreement. You will see this reflected on our P&L as products sales revenue and cost of goods sold. Product sales revenue and costs of goods sold also include sales in AMITIZA in Europe, and, in future quarters, this will be where we report RESCULA sales. In 2012, we recognized \$5 million of product sales revenue and \$3 million of cost of goods sold compared to nil for both in 2011. The majority of the sales were related to our sales of AMITIZA to Abbott, Japan. Please move to slide 19 which features additional financial highlights. Let's take a look at income next. For the fourth quarter of 2012, income from operations was a profit of \$13 million, an increase of \$9.4 million compared to a profit from operations of \$3.6 million in the fourth quarter of 2011. For the full-year of 2012, income from operations was a profit of \$8.3 million compared to a loss from operations of \$17.7 million in the prior year. For the fourth quarter of 2012, Sucampo reported net income of \$13.5 million, or \$0.32 per share, an increase of \$10.8 million compared to a net income of \$2.7 million, or \$0.06 per share in last year's fourth quarter. The fourth quarter of 2012 included a foreign exchange gain of \$0.9 million compared to a gain of \$14,000 in last year's fourth quarter. For the full-year 2012, Sucampo reported a net income of \$4.8 million, or \$0.12 per share compared to a net loss of \$17.3 million, or \$0.41 per share in the prior year. Now, taking a look at operating expenses, R&D expenses were \$7.1 million in the fourth quarter of 2012 compared to \$7.7 million for the same period last year. For the full-year 2012, R&D expenses were \$21.3 million compared to \$33.5 million in the prior year. For both periods, the decrease was primarily due to higher expenses in 2011 associated with the completion of the phase III OIC trial for AMITIZA. G&A expenses were \$7.6 million in the fourth quarter of 2012 compared to \$12 million in last year's fourth quarter, a decrease of \$4.4 million, or 37%. G&A expenses were \$30.2 million for the full-year 2012 compared to \$41.3 million in the prior year, a decrease of \$11.1 million, or 27%. For both periods, the decrease in G&A expense is primarily due to lower legal, consulting and other professional expenses that were related to the conclusion of certain legal matters, partially offset by increases in corporate marketing and branding and staff organizations to support business growth. Selling and marketing expenses were \$4.2 million in the fourth quarter compared to \$2.1 million in last year's fourth quarter. For the full-year 2012, selling and marketing expenses were \$18.7 million compared to \$8.8 million in the prior years. For both periods, the increase in selling and marketing expenses relates primarily to some non-recurring precommercialization planning activities for AMITIZA and the commercialization and launch costs for RESCULA. And finally, as it relates to operating expense, in 2011, Sucampo reported income of \$11.1 million from the favorable settlement of a legal claim related to a dispute with Covance, a CRO that performed clinical trials for the OIC indication. The amount represented receipt of \$10 million in cash and cancellation of outstanding payables of \$1.1 million and was reported as a reduction to 2011 operating expenses. This was on a separate line on our income statement. There were no corresponding amounts in 2012. We think this is notable because when you exclude the one-time settlement, our year-over-year decrease in total operating expense is actually \$13.4 million. Let's move on to the balance sheet. Please refer to slide 20. As of December 31, 2012, cash, cash equivalents, restricted cash and investments were \$91.4 million compared to \$93.4 million at December 31, 2011. As was mentioned earlier on the call, upon Abbott Japan's first commercial sale of AMITIZA in Japan, Sucampo received the milestone payment of \$15 million. That was received in the fourth quarter of 2012. As we stated during our third quarter earnings call, on November 2, 2012, our board authorized an increase in the amount of our common stock repurchase program from the previously announced \$2 million, up to an aggregate of \$5 million. During the fourth quarter, we purchased 146,908 shares at a cost of \$721,487. For the full year of 2012, we purchased 270,043 shares at a cost of \$1.28 million. I'm also very pleased to report the Sucampo generated a positive operating cash flow of \$17.2 million in the fourth quarter and \$12 million for the full-year of 2012. The slight decrease in our cash position, as well as a positive cash flow for the year, reflects for the improvement in year-over-year operating results I just mentioned, as well as our continued focus on working capital management. Thank you for your attention. I look forward to your questions at the end of this call. Now, I will turn the call back to Dr. Ueno to summarize the value drivers achieved in 2012 and to discuss this year's value drivers. Dr. Ueno?

**Dr. Ryuji Ueno** - Sucampo Pharmaceuticals Inc - Chairman of the Board, CEO & Chief Scientific Officer

Thank you, Cary. Please turn your attention to slide 22. I am proud of the fact that we met all of our key value drivers for 2012. We are excited as we look forward to a productive 2013. As we look to this year, we have set the following key value drivers for the year that we believe will increase shareholder value. These include, for AMITIZA, receiving approval of AMITIZA's sNDA for OIC in the second quarter of 2013. Upon the first sale of AMITIZA for OIC, Sucampo will receive \$10 million milestone payment. Achieving first patient, first visit, in our pediatric functional constipation phase III trial for AMITIZA by the third quarter of this year. Growth of AMITIZA sales in Japan. Permissions for regulatory approval of AMITIZA in the treatment in OIC in Switzerland and in the UK by the first quarter of 2013. I am pleased that we have just achieved this value driver today. Seeking nice endorsements for both CIC and OIC and making AMITIZA available in the UK with reimbursement by some local budget holders. Beginning active marketing in Switzerland for CIC. Use of MHRA approval to seek expansion of AMITIZA's CIC indication to other European markets via the mutual recognition procedure. For RESCULA, the successful rollout of RESCULA in the US. For the pipeline, completion of our oral mucositis phase IA trial for cobiprostone in the second quarter of 2013, and initiation of our phase IB/IIA trial in the fourth quarter of 2013. And finally, completion of our spinal stenosis phase IIA trial for SPI- 017 in the fourth quarter of 2013. As can you see, we have a busy year ahead of us. I thank you for your continued support as we move forward on these key priorities and work to increase shareholder value. We are now ready to start the Q&A portion of the call. Operator, please open up the lines for questions.

## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions)

Please stand by for your first question. Your first question comes from the line of Irina Rivkind with Cantor Fitzgerald. You may proceed.

**Irina Rivkind** - Cantor Fitzgerald - Analyst Hey, guys, thanks for the questions. Very nice quarter. I wanted to start by asking about the liquid AMITIZA dosage form. Can you walk us briefly through the plan for development of this form and its launch? Thanks.

**Taryn Joswick** - Sucampo Pharmaceuticals Inc - VP Clinical Development

So, I -- this is Taryn Joswick, I am the VP of clinical development, I will speak a little bit about the development plans, and then I'm going to pass it over to Stan for the discussion about the market. So, the liquid formulation, we have been working on it for some time now, and we're currently in the clinical study phase of evaluating the liquid formulation and preparing basically the data package that would constitute the data that we'll file with the FDA for the new formulation to be added to the labeling. And Stan, I will let you speak with --

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Right, as it relates to the commercialization side of this, we have certainly been focused on a liquid formulation for quite a while. I don't want to confuse things. We're still a bit of a ways off from actually bringing this to market, but we're focused on this from not only a pediatric perspective but also a geriatric or certain senior care populations as well. We have the ability to look at various concentrations at this point in time, though, are still focused on the existing CIC concentration, which is the 24 microgram. And -- but as we look at the pediatric side of things, we would -- we're evaluating other dosage concentrations for that. But on the senior care side, we would be focused on the 24 microgram as a liquid formulation.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Okay, for the \$5 million in AMITIZA sales to Abbott in Japan, does that reflect a load-in of inventory that's going to be worked down later, or is it more reflective of demand?

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

I think -- this is Cary, Irina. They are some loading of inventory as they were ramping up to launch in the fourth quarter.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Okay, have you disclosed AMITIZA pricing in Switzerland?

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Have we disclosed that?

**Taryn Joswick** - Sucampo Pharmaceuticals Inc - VP Clinical Development

Andrew, can you take that question, please.

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Sure. The AMITIZA pricing in Switzerland is publicly available. It's 2 francs 59, equivalent to about, \$275.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Is that per day or per dose?

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Per day.

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**Irina Rivkind** - Cantor Fitzgerald - Analyst

Okay. Thank you. And I guess I will jump back in the queue and let someone else go.

**Operator**

Your next question comes from the line of Tim Lynch with Stonepine Capital. You may proceed.

**Tim Lynch** - Stonepine Capital - Analyst

Hi, a lot of good stuff going on. The question about US AMITIZA sales, thanks for the color on Q4 in January. How is February in terms of IMS data in the face of competitive pressures?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

We can look at some of the weekly data, and we tend to look at weekly data, I don't want to say with skepticism, because you have to look at consecutive weeks to see if you have a pattern developing. We were down 0.1% versus the prior week when we looked at the first week of February and then in subsequent weeks, we were up over 8%. In general, we're still holding firm where we -- with what our expectations are for February. I think it's -- when we look at also new to brand prescriptions, there is an interesting phenomenon as we begin to analyze that where Linzess has started to decline as we look at those naive patients who are, in fact, entering the market. And we're actually gaining a larger share for some of these now to the brand patients entering into the market. So, I look at the first two months of December and January when Linzess was on the market initially launching. We were up over 6%, roughly 6.3% year-over-year. February weeklies, we're certainly keeping a close eye on that. At this point in time, even with new prescriptions, we feel confident that we're going to be able to maintain and grow our share respectively.

**Tim Lynch** - Stonepine Capital - Analyst

That's great. Do you think that is attributed to maybe a lack of historical marketing for AMITIZA now with the category getting more attention and perhaps Takeda putting more prominence to it, that that is the dynamic going on? What do you attribute that to, the strength and prescription trends?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

We have noticing over, certainly the last year, a revised effort post arbitration, but a lot of the consistency relative to the marketing effort focusing on the safety, focusing on the mechanism, Takeda buying into some of the targeting that we had been challenging them on all along. But I think of late, it's clearly -- I think we welcome the noise to the market. And the issue will be who wins the battle of the new naive patients coming to the market? Both of us want the market, both us and certainly Ironwood, to increase, and we want the -- those patients that are naive. And what we're pleased to see, again, if we take a look at the last -- since January, there has been a consistent decline in the newer patients going over to Linzess versus those that are actually coming over to AMITIZA. I think it's a focused market effort by Takeda and the safety message that is finally resonating with a lot of the primary care physicians as well in addition to a strong managed care position that Takeda has within the last 12 months done a very concentrated effort to put ourselves in a position of strength with respect to both commercial lives and managed care lives.

**Tim Lynch** - Stonepine Capital - Analyst

Great, and one last question, then I'll hop back in the queue. With the loading for Abbott -- sales to Abbott in Japan, and can you give us color and end user demand, you said exceeded expectations, doubled your expectations, more than Abbott's expectations. What percent of that \$5 million can we view as perhaps initial stocking?

**Taryn Joswick** - Sucampo Pharmaceuticals Inc - VP Clinical Development

Okay, Andrew, do you want to take that question about Japan sales?

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Sure.

**Taryn Joswick** - Sucampo Pharmaceuticals Inc - VP Clinical Development

Thank you.

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

The initial stocking -- the sales in Q4, the bulk of that was initial stocking. Remember, the launch was really November 22. It's quite early stages to see that. We are encouraged with the early signs of performance and growth, as we said, but I think probably you will see that in our next call.

**Tim Lynch** - Stonepine Capital - Analyst

Great. Thank you.

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**Operator**

Your next question comes from the line of Christian Glenline (sp) with Edison Investment Research. You may proceed.

**Christian Glennie** - Edison Investment Research - Analyst

Hi, good afternoon, just to followup on the Japan situation. Is that margin that you have got there, that 40%. Is that -- would that be -- is that a reasonable perspective, was that going to iron out over awhile?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

That's rough order what you would expect to see.

**Christian Glennie** - Edison Investment Research - Analyst

Okay. Thank you. And then on Europe for AMITIZA, can you talk a bit about the sort of the investments you're making there in the UK and Switzerland, in terms of preparing to get that fully commercial and/or considering local distribution partners and that sort of thing.

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Okay, it's quite early stages, as we've said, in those markets in the UK and Switzerland. We're directly marketing the product ourselves. Because it's the early stages, particularly in the UK where we're going through the NICE endorsement process and looking to have some demand with local budget holders were put in place the appropriate level of coverage to cover that growth. But it hasn't been significant to date.

**Christian Glennie** - Edison Investment Research - Analyst

Okay. Thank you, and then one final one on AMITIZA, US with the potential OIC approval. Aside from obviously the milestones, it was a bit about implications in terms of Takeda's commercialization of that opportunity there. Obviously the addition of that's enabled and how you see that.

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

This is Stan. I think we -- I hope we adequately covered that in the script, but I will say that based on the early discussions and the ongoing discussions with Takeda and the priority review, Takeda is committed to treating this as almost a relaunch opportunity, so we, as in both Takeda and Sucampo, see this as a great opportunity and are prepared to properly execute a relaunch with this additional indication when approved. e Call

**Christian Glennie** - Edison Investment Research - Analyst

Okay. Thank you.

**Operator**

You have a follow-up question from the line of Irina Rivkind with Cantor Fitzgerald. You may proceed.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Actually two follow-up questions. Stan, I'm very interested to learn about your methodology in figuring out how -- about the new patients to AMITIZA versus new patients to Linzess. Can you elaborate on that a little bit more?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Yes. This is actually something that you can actually get from when you start looking at the IMS data, and we can have a separate followup phone call.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Yes.

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Because you also go back historically as well, looking at the last 12 months. But there is a formula and a methodology that's used where you can look at the -- the only drawback is, for example, if a patient was on, let's say they were on AMITIZA and then they dropped AMITIZA and then three months later, they decided to go back on another product, they would actually still show up as a naive product. Or a naive patient, rather, but we can set up a call. I would be glad to.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Okay.

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**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America  
Go through that with you in a conversation.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Okay. And then the second one is about the OIC market. You mentioned that there is 2.5 million moderate to severe patients and I wanted to see if in your model assessment, are those patients already taking prescription medications? Or do you view these as being on OTC products that are going to enter the existing constipation market once there is an approved indication? Thanks.

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Right. So, this is through both our qual and quantitative research, and the majority of those patients are still taking over-the-counter products or Miralax, if required. So, we feel very confident that, even though there are some patients at this point in time taking AMITIZA for OIC, it's off-label, it's not formally indicated. And there is a small percentage of our current utilization that is for OIC; however, the majority of those moderate to severe patients are not -- they're still taking over the counter products and then PRN laxatives on an as-needed basis. We're -- what we're trying to do is focus on the moderate to severe because we believe strongly that those are the ones that would gravitate towards an RX product versus those that just have an occasional bout of constipation, and that is why we've been a bit more conservative than others as it relates to market size. But we still feel confident that the 2 million to 2.5 million are the ones that in research clearly indicate they are looking for something and they would welcome an RX product.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Do you have any estimates around how many days they would use this product? Is it similar to your other AMITIZA days used, or no?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

At this point in time, it's still similar to that of what we're looking at on the CIC side. And again, it's probably -- it's in the range from a modeling standpoint, we're still using that 156 days, that is what we're using internally.

**Irina Rivkind** - Cantor Fitzgerald - Analyst

Thanks very much.

**Operator**

You have a follow up question coming from the line of Tim Lynch with Stonepine Capital. You may proceed.

**Tim Lynch** - Stonepine Capital - Analyst

Thanks. On RESCULA, I know I used to know this. The sales force was shifted from focusing on institutional AMITIZA accounts to ophthalmology, if I understand correctly. And you used to receive some form of reimbursement from Takeda prior to that shift, and now they are all paid for in houses. Is that correct?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Yes, Tim. That's correct.

**Tim Lynch** - Stonepine Capital - Analyst

Okay. Okay. And with RESCULA, when do you expect we will see some visibility on usage? I know this is a relaunch and expectations are often low for a relaunch product. I know the label's new, but what kind of color do you think we'll get from you and when? Because it sounds like this will be grouped into your product sales line on your income statement, so we may not have it broken out. But in terms of script data, something to give us a sense of traction in the marketplace.

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Right, we're starting clearly with the early metrics of sampling, contacts, details, et cetera, but you will begin to see script trends within the IMS data. For all intents and purposes, we're not expecting things to start even showing up until we get into the March timeframe. But I have been fairly straightforward saying that due to the 30 days of sampling, bringing patients back, we're not looking at this as an early trajectory. When you see an acceleration, it's more in the latter part of this year once you get a lot of the samples utilized and the appropriate patients are identified, but you should be able to looking at script trends as early as the coming weeks. But I would say that if we really want to get a solid gauge of where we expect RESCULA to go from a trajectory standpoint, it's the second half of this year where we have the greater expectations of what we want to see with the lift from a NRX and TRX perspective.

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**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Tim, this is Cary, and even though you're right, on the P&L there won't be a separate line item, we will talk to the RESCULA sales versus the AMITIZA sales on our calls and in our investor meetings that we -- where we have conferences.

**Tim Lynch** - Stonepine Capital - Analyst

Great, and then last question, do you consider that sales force, now that it's a more expensive piece of infrastructure, something that you may leverage regarding business development and licensing products, things like that? Is this a strategic infrastructure or cost that you plan to look externally to potentially leverage?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Well, we're certainly always open and continuing to evaluate business development opportunities. And I could not agree with you more that from a cost effective standpoint, you always want to have more than one product in the bag. And I think at this point in time, we're focused on RESCULA, but with the assumptions that we will be successful, then it certainly can parlay into some other opportunities as well. And we are doing this in as judicious manner as possible, And -- but we will -- we are certainly entertaining and looking at other potential opportunities from a BD perspective.

**Tim Lynch** - Stonepine Capital - Analyst

Great. Thank you.

**Operator**

Your next question comes from the line of Marco Rodriguez with Stonegate Securities. You may proceed.

**Dan Trang** - Stonegate Securities - Analyst

Hi, everyone. This is Dan Trang actually sitting in for Marco Rodriguez. Stan, can you provide some color in regards to the sales force and how the launch of RESCULA, I believe it's the same sales force from AMITIZA. Am I correct there?

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America

Yes, sir. It's the same team they we had before. They -- our sales team, the average yearly experience is about 9.5 years. They're very -- they're experienced, one-third of our reps had prior ophthalmic experience, and they spent a significant amount of time profiling the targeted physicians even prior to launch. So, that is why we believe at time of launch we have been extremely successful, having access to the offices, having access to the key physicians, both ophthalmologists and optometrists, and we're also supported by the medical and scientific affairs team who did about three months worth of prelaunch activity. So, we're very pleased with the access that our team's been able to garner thus far.

**Dan Trang** - Stonegate Securities - Analyst

Okay.

**Operator**

(Operator Instructions) You have a follow-up question coming from the line of Christian Gelnine (sp) with Edison Investment Research. You may proceed.

**Christian Glennie** - Edison Investment Research - Analyst

Hi, thanks, a couple on the financials. I know you don't give duty specific guidance and such, but obviously looking at some of the key operating R&D and selling and marketing, in terms of Q4 numbers, how we should be thinking about that for 2013, any guidance you can provide.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

I will give you directionally. Selling and marketing, as you know, we're launching -- we've launched RESCULA, so we expect selling and marketing expenses to increase in 2013 as we're launching RESCULA. R&D, as you heard, we're going into a phase III trial for pediatric indication for AMITIZA, so you would expect R&D to increase as well. But keep in mind that a significant portion of that trial will be reimbursed by our partner, Takeda, in the US. And the G&A, G&A, we don't anticipate significant change year-over-year in G&A. We're continuing to focus on being productivity within our staff functions, and we built that up in 2012 to support the business growth.

**Operator**

You have a follow-up question coming from the line of [Jason Aria] with [Jolt Equities]. You may proceed.

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**Jason Aria** - Jolt Equities - Analyst

Hey, first of all, very nice quarter. Two questions, one for Stan, one for Cary. To pick up on Mr. Lynch's question about adding additional products to the bag, I assume, Stan, that you will probably wait to see how RESCULA launch plays out, and if it's successful, you will add products to the bag, but probably not prematurely.

**Stanley Miele** - Sucampo Pharmaceuticals Inc - SVP, Sales & Marketing & President of Sucampo Pharma America  
That is correct.

**Jason Aria** - Jolt Equities - Analyst

Great, I think that is very prudent. And Cary, you had just talked about G&A being steady from the 2012 levels where there was obviously a lot of legal expense in the first half of that, at least. Would that not -- would it not be lower because that, thankfully, comes off of the books?

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Well, yes, I think you saw we announced a little while ago about a generic lawsuit.

**Jason Aria** - Jolt Equities - Analyst

Yes.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

So, there will be legal expenses associated with that. There are definitely decreases, but there are some other things like that that are -- would be offsetting part of it.

**Jason Aria** - Jolt Equities - Analyst

So, probably a bit of staff that you have added and that lawsuit you think it would balance out.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

I think -- yes, without being specific, I think that is the way to think about it.

**Jason Aria** - Jolt Equities - Analyst

Great, and I am sorry, this has probably been asked in the Abbott Japan questions, but I am confused about your revenue recognition. You recognize revenue as you sell product to Abbott? So, in other words, it's not based on their stocking, their selling into the channel or sell through. Is that correct? Or is it --

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

That is correct.

**Jason Aria** - Jolt Equities - Analyst

Okay.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

That's correct.

**Jason Aria** - Jolt Equities - Analyst

So, really, it's completely -- could be completely non-correlated with either their selling into the channel or the sell-through.  
Call

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Well, I guess the way to think about it is that it is ahead of them selling into the market.

**Jason Aria** - Jolt Equities - Analyst

Yes.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

And then they will sell in the market and then replenish with additional orders to place to us and then we sell to them. The other thing that is important to note when you think about it that way, is you don't want to necessarily take that \$5 million in the fourth quarter and just annualize it when you think about 2013 because they may order sporadically and not necessarily order the same amount every month from us.

**Jason Aria** - Jolt Equities - Analyst

Sure.

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**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

But you will -- the trends should correlate if they're increasing selling more -- increasingly selling more in the market, then their orders to us would increase.

**Jason Aria** - Jolt Equities - Analyst

Sure. And so do you think -- when you think about that \$5 million, do you think that that is essentially what they put into the channel in initially? Or do you think there is some sell-through expectation there? How do you view what they doing? Maybe they have given you some guidance.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Andrew, do you want to comment on that? I know they -- we're very pleased with the robustness of their launch. They have a lot of reps out in the field in the early data we received on their detailing, they were doing a lot of detailing. But because of confidentiality, we can't really discuss their sales.

**Jason Aria** - Jolt Equities - Analyst

Understand.

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

And I don't think -- I would just reiterate the point earlier, that the launch was on November 22, and we had -- that the sales we're recognizing in the fourth quarter. It's a very early stage.

**Jason Aria** - Jolt Equities - Analyst

Well, again, congratulations on a nice quarter, nice to see AMITIZA holding up so well, and thanks.

**Andrew Smith** - Sucampo Pharmaceuticals Inc - VP, Operations & Finance

Thanks.

**Cary Claiborne** - Sucampo Pharmaceuticals Inc - CFO

Thank you.

**Operator**

(Operator Instructions) You have a follow-up question coming from the line of Tim Lynch with Stonepine Capital. You may proceed.

**Tim Lynch** - Stonepine Capital - Analyst

One last question, guys. I know you said late April is the PDUFA for OIC for AMITIZA, can you tell us the PDUFA date so we can be sure to be paying attention and be prepared for the potential results?

**Taryn Joswick** - Sucampo Pharmaceuticals Inc - VP Clinical Development

Yes, hi. This is Taryn again. Yes, we have not disclosed the exact PDUFA date and certainly, we are very pleased with how the review is progressing, I can tell you that much. And certainly, we expect to receive FDA's final decisions on or before that date in late April.

**Tim Lynch** - Stonepine Capital - Analyst

All right. Thank you.

**Operator**

There are no further questions in the queue at this time. I would now like to turn the call over to Silvia Taylor for closing remarks. You may proceed.

**Silvia Taylor** - Sucampo Pharmaceuticals Inc - SVP, IR

Thank you, everyone, for joining us this evening. We look forward to speaking with you again soon. If you have any followup questions, please do not hesitate to contact me. Thanks, and good night.

**Operator**

Thank you for your participation on today's conference. This concludes the presentation. You may now disconnect. Have a great day.