

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

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FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 9, 2012

Sucampo Pharmaceuticals, Inc.

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(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Jurisdiction  
of Incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

4520 East-West Highway, 3<sup>rd</sup> Floor  
Bethesda, Maryland

20814

(Address of Principal Executive Offices)

(Zip Code)

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

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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 May 9, 2012, Sucampo Pharmaceuticals, Inc. announced its consolidated financial results for the quarter ended March 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 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 (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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the registrant on May 9, 2012.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SUCAMPO PHARMACEUTICALS, INC.

Date: May 9, 2012

By:           /s/ CARY J. CLAIBORNE          

Name: Cary J. Claiborne

Title: Chief Financial Officer

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## EXHIBIT INDEX

Exhibit No.

Description

99.1

Press release issued by the registrant on May 9, 2012

**Sucampo Pharmaceuticals, Inc. Reports First Quarter 2012 Financial and Operating Results***Conference Call Today at 5:00 pm Eastern*

BETHESDA, Md.--(BUSINESS WIRE)--May 9, 2012--Sucampo Pharmaceuticals, Inc. ("Sucampo" or the "Company"), (NASDAQ: SCMP), a global pharmaceutical company, today reported its consolidated financial results for the first quarter ended March 31, 2012.

Sucampo reported a net loss of \$1.9 million, or \$0.05 per diluted share, for the first quarter of 2012 compared to a net loss of \$6.9 million, or \$0.17 per diluted share, for the first quarter of 2011.

"Sucampo continues to build on the successes from 2011 with the positive results in the third phase 3 trial of lubiprostone for the treatment of opioid-induced bowel dysfunction (OBD) or opioid-induced constipation (OIC) in patients with chronic non-cancer pain and we are on track for the sNDA filing. We are making progress regarding the RESCULA label and anticipate a final label in the third quarter. As we look forward to the binding decision in our arbitration dispute with Takeda, we continue to progress our strategic plan while managing our costs and cash and continue to urge our partner to maximize the net sales revenue of AMITIZA," said Ryuji Ueno, M.D., Ph.D., Ph.D., Chair and Chief Executive Officer.

**Operational Highlights**

- As previously reported, the third phase 3 clinical trial of lubiprostone for the treatment of OBD in patients with chronic non-cancer pain, excluding those taking methadone, met the primary endpoint of the overall spontaneous bowel movement (SBM) response rate. We expect to submit to the FDA a sNDA at mid-year and plan to seek priority review. We also plan to use these data to file submissions this year with the European Union (EU) and Swiss regulatory authorities to seek marketing approvals for this indication.
  - With regards to the RESCULA label, we have received a complete response letter from the FDA which recommended improvements to the label. These improvements include removal of second line therapy language to enable first line use, removal of the prostaglandin description, and inclusion of BK potassium channel and CIC-2 chloride channel activator to the mechanism of action section. However we will continue to seek further revisions to the label to more accurately reflect current scientific understanding through the FDA's administrative appeal process. We anticipate agreement on the final RESCULA label during the third quarter of this year.
  - We have had final labeling meetings with the Japanese Pharmaceuticals and Medical Devices Agency and anticipate receiving approval of the NDA for AMITIZA for CIC in the second quarter of 2012. If successful, this NDA approval will be followed by a reimbursement negotiation with the Japanese regulatory authorities.
  - In the United Kingdom, we have responded to the questions from the Medicines and Healthcare products Regulatory Agency on our marketing authorization application (MAA) for lubiprostone for the treatment of CIC, submitted under the national procedure. We anticipate receiving a decision in the third quarter. If this application is successful we will file an application under the mutual recognition procedure to seek approval in a number of other European Union states.
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- In the United States, we continued to plan for the binding decision from the International Court of Arbitration, International Chamber of Commerce (ICC) in our dispute with Takeda. The ICC has notified us that the date on which it renders its decision has been extended from April 30, 2012 to May 31, 2012 though the decision may not be issued on that date.

## 2012 Key Value Drivers

Sucampo management confirmed that it is pursuing the following key drivers of shareholder value:

AMITIZA-related value drivers include:

1. In the US, receiving the binding decision from the ICC in our dispute with Takeda and the filing of a sNDA for the treatment of OBD or OIC in non-cancer, non-methadone patients, with the FDA at mid-year 2012, and requesting priority review. In the EU and Switzerland, the filing of MAAs for that indication.
2. In Japan, receiving regulatory approval decision in the second quarter of 2012, the pricing decision in the third quarter, to be followed by a launch in the fourth quarter of 2012.
3. In the EU, receiving approval of the MAA in the UK for the treatment of CIC in the third quarter 2012, to be followed by a mutual recognition procedure application to the EU. Approval of this MAA will trigger filing of MAAs in the UK, the rest of the EU and Switzerland for the OBD indication.
4. In Switzerland, concluding pricing negotiations with the authorities for an appropriate reimbursement price.

RESCULA-related value drivers include:

1. In the US, obtaining further improvements in the label to reflect current scientific understanding in advance of the launch later this year.
2. Completing the analysis of data from the exploratory trial in dry AMD patients.
3. In the EU and Switzerland, file MAAs for the treatment of glaucoma.

## Financial Results for the Quarter

For the first quarter of 2012, Sucampo reported total revenue of \$14.4 million compared to \$12.2 million for the same period in 2011. Key components of revenue for the quarter included product royalty revenue of \$10.9 million and R&D revenue of \$2.6 million, compared to \$9.1 million and \$2.0 million, in the same period in 2011. The increase in R&D revenue was primarily due to revenue associated with the ongoing third phase 3 clinical trial of lubiprostone for OBD and re-monitoring costs for previous trials. Net sales of AMITIZA as reported to us by our partner, increased 19.8%, to \$60.7 million, for the first quarter of 2012, compared to \$50.7 million in the same period of 2011. The increase in AMITIZA net sales was primarily due to both volume and price increases compared to the first quarter of 2011, as reported to us by our partner.

## Operating Expenses

R&D expenses were \$3.3 million for the first quarter of 2012, compared to \$9.2 million for the first quarter of 2011. The decrease was primarily due to higher expenses in 2011 associated with initiating the additional phase 3 trial of lubiprostone for OBD patients.

G&A expenses were \$7.3 million for the first quarter of 2012, compared to \$9.7 million for the first quarter of 2011. The decrease in G&A expenses was primarily attributable to a decrease in legal, consulting and other professional expenses, which related to costs incurred in connection with legal matters.

Selling and marketing expenses were \$4.1 million for first quarter of 2012, compared to \$2.4 million for the first quarter of 2011. The increase in selling and marketing expenses relates primarily to some pre-commercialization planning activities for AMITIZA, in the event of a favorable arbitration decision.

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

Non-operating income was \$0.7 million for the first quarter of 2012, compared to non-operating expenses of \$0.7 million for the same period in 2011. The first quarter of 2012 includes a foreign exchange gain of \$1.3 million compared to a loss of \$0.1 million in the same period in 2011.

## **Net Income (Loss)**

Net loss for the first quarter of 2012 was \$1.9 million, compared to net loss of \$6.9 million for the same period in 2011.

## **Comprehensive Income (Loss)**

Comprehensive loss for the first quarter of 2012 was \$3.5 million, compared to comprehensive loss of \$6.5 million for the same period in 2011. Comprehensive loss for the first quarter of 2012 includes a \$1.6 million foreign currency translation loss compared to a gain of \$0.4 million for the same period in 2011.

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

At March 31, 2012, cash, cash equivalents, restricted cash and investments were \$92.5 million, compared to \$93.4 million at December 31, 2011. The slight decrease in cash reflects the improvement in operating results discussed above, as well as continued working capital management. At March 31, 2012, notes payable were \$59.5 million, compared to \$59.6 million at December 31, 2011. These include current notes payable of \$19.7 million at March 31, 2012, compared to \$20.4 million at December 31, 2011.

In September 2011, the Board of Directors approved a program to repurchase our Class A common stock under the previously approved repurchase plan, up to an aggregate of \$2.0 million. During the first quarter of 2012, we did not repurchase any shares.

## **Company to Host Conference Call Today**

In conjunction with this first 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 1-866-831-6267 (domestic) or 1-617-213-8857 (international), and provide the participant passcode 57549793, 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 1-888-286-8010 (domestic) or 1-617-801-6888 (international), with the passcode 74158841.

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**

Sucampo holds development and commercialization rights to unoprostone isopropyl throughout the world except in Japan, Korea, Taiwan and the Peoples 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 (lubiprostone) is a 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.

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

Sucampo Pharmaceuticals, Inc. is a global pharmaceutical company focused on the discovery, development and commercialization of proprietary drugs based on prostanes. The therapeutic potential of prostanes, which occur naturally in the human body as a result of enzymatic catalysis by 15-PGDH of eicosanoids and docosanoids, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo's Chairman and CEO. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding CEO and currently Executive Advisor, International Business Development, and a member of the Board of Directors. For more information, please visit [www.sucampo.com](http://www.sucampo.com).

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

## **Sucampo Forward-Looking Statement**

*DISCLOSURE NOTICE: The information contained in this earnings release and the attachments is as of May 9, 2012. The Company assumes no obligation to update forward-looking statements contained in this earnings release or the attachments as a result of new information or future events or developments.*

*This earnings release and the attachments contain forward-looking information about the Company's future operating and financial performance, business plans and prospects, in-line products and product candidates, and share-repurchase plans that involves substantial risks and uncertainties. You can identify these statements by the fact that they use words such as "will," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," "forecast", "goal", "objective" and other words and terms of similar meaning or use future dates or are anticipated actions and events discussed under "Operational Highlights" or "2012 Key Value Drivers.". Among the factors that could cause actual results to differ materially are the following: the success of research and development activities, including, without limitation, the ability to meet anticipated clinical trial completion dates, regulatory submission and approval dates, and launch dates for product candidates; decisions by regulatory authorities regarding whether and when to approve our drug applications as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of our products; the speed with which regulatory authorizations, pricing approvals and product launches may be achieved; the success of external business-development activities; competitive developments, including the impact on our competitive position of new product entrants, in-line branded products, generic products, private label products and product candidates that treat diseases and conditions similar to those treated by our in-line drugs and drug candidates; the ability to meet generic and branded competition after the loss of patent protection for our products or competitor products; the ability to successfully market both new and existing products domestically and internationally; difficulties or delays in manufacturing; the impact of existing and future legislation and regulatory provisions on product exclusivity; trends toward managed care and healthcare cost containment; the impact of U.S. healthcare legislation enacted in 2010 – the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act - and of any modification, repeal or invalidation of any of the provisions thereof; U.S. legislation or regulatory action affecting, among other things, pharmaceutical product pricing, reimbursement or access, including under Medicaid, Medicare and other publicly funded or subsidized health programs, direct-to-consumer advertising and interactions with healthcare professionals, and the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on the cost differences and minimizes the therapeutic differences among pharmaceutical products and restricts access to innovative medicines; legislation or regulatory action in markets outside the U.S. affecting pharmaceutical product pricing, reimbursement or access, including, in particular, continued government-mandated price reductions for certain biopharmaceutical products in certain European, Asian and emerging market countries; claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates; significant breakdown, infiltration, or interruption of our information technology systems and infrastructure; legal defense costs, settlement costs, the risk of an adverse decision or settlement for ongoing legal proceedings or the initiation by or against us of future legal proceedings; the Company's ability to protect its patents and other intellectual property both domestically and internationally; interest rate and foreign currency exchange rate fluctuations; governmental laws and regulations affecting domestic and foreign operations, including, without limitation, tax obligations and changes affecting the tax treatment by the U.S. of income earned outside of the U.S. that may result from pending and possible future proposals; changes in U.S. generally accepted accounting principles; uncertainties related to general economic, political, business, industry, regulatory and market conditions including, without limitation, growth in costs and expenses; changes in our product, segment and geographic mix; and the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items, including (i) our ability to realize the projected benefits of our integration of Sucampo AG and consolidation of the intellectual property in Sucampo AG; and (ii) our ability to commercialize our in-line products. A further list and description of risks, uncertainties and other matters can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q, in each case including in the sections thereof captioned "Forward-Looking Information and Factors That May Affect Future Results" and "Item 1A. Risk Factors", and in its reports on Form 8-K.*

*This earnings release may include discussion of certain clinical studies relating to various in-line products and/or product candidates. These studies typically are part of a larger body of clinical data relating to such products or product candidates, and the discussion herein should be considered in the context of the larger body of data.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Revenues:		
Research and development revenue	\$ 2,585	\$ 1,964
Product royalty revenue	10,928	9,118
Co-promotion revenue	766	938
Contract and collaboration revenue	167	154
Total revenues	<u>14,446</u>	<u>12,174</u>
Operating expenses:		
Research and development	3,352	9,220
General and administrative	7,327	9,697
Selling and marketing	4,089	2,418
Total operating expenses	<u>14,768</u>	<u>21,335</u>
Loss from operations	(322)	(9,161)
Non-operating income (expense):		
Interest income	20	70
Interest expense	(592)	(611)
Other income (expense), net	1,274	(135)
Total non-operating income (expense), net	<u>702</u>	<u>(676)</u>
Income (loss) before income taxes	380	(9,837)
Income tax benefit (provision)	(2,308)	2,928
Net loss	<u>\$ (1,928)</u>	<u>\$ (6,909)</u>
Net loss per share:		
Basic net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.17)</u>
Diluted net loss per share	<u>\$ (0.05)</u>	<u>\$ (0.17)</u>
Weighted average common shares outstanding - basic	<u>41,702</u>	<u>41,851</u>
Weighted average common shares outstanding - diluted	<u>41,702</u>	<u>41,851</u>
Comprehensive loss:		
Net loss	\$ (1,928)	\$ (6,909)
Other comprehensive income (loss):		
Unrealized gain (loss) on investments, net of tax effect	(3)	11
Foreign currency translation	(1,592)	437
Comprehensive loss	<u>\$ (3,523)</u>	<u>\$ (6,461)</u>

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

	<u>March 31,</u>	<u>December 31,</u>
	<u>2012</u>	<u>2011</u>
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 55,504	\$ 50,662
Investments, current	19,666	24,452
Product royalties receivable	10,928	10,795
Unbilled accounts receivable	497	2,036
Accounts receivable, net	1,097	4,616
Prepaid and income taxes receivable	1,582	2,845
Deferred tax assets, current	118	163
Deferred charge, current	3,057	3,057
Restricted cash, current	15,113	15,113
Prepaid expenses and other current assets	1,799	1,177
Total current assets	<u>109,361</u>	<u>114,916</u>
Investments, non-current	-	998
Property and equipment, net	1,561	1,669
Intangibles assets, net	8,146	8,364
Deferred tax assets, non-current	1,698	2,089
Deferred charge, non-current	25,986	26,751
Restricted cash, non-current	2,216	2,129
Other assets	1,148	653
Total assets	<u>\$150,116</u>	<u>\$ 157,569</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY:</b>		
Current liabilities:		
Accounts payable	\$ 5,638	\$ 6,978
Accrued expenses	7,167	13,648
Deferred revenue, current	6,558	3,888
Deferred tax liability, current	2,811	2,167
Notes payable, current	19,700	20,400
Total current liabilities	<u>41,874</u>	<u>47,081</u>
Notes payable, non-current	39,777	39,227
Deferred revenue, non-current	6,887	7,045
Deferred tax liability, non-current	23,012	23,019
Other liabilities	2,649	2,603
Total liabilities	<u>114,199</u>	<u>118,975</u>
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at March 31, 2012 and December 31, 2011; no shares issued and outstanding at March 31, 2012 and December 31, 2011	-	-
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at March 31, 2012 and December 31, 2011; 15,703,218 and 15,690,780 shares issued and outstanding at March 31, 2012 and December 31, 2011, respectively	157	157
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at March 31, 2012 and December 31, 2011; 26,191,050 shares issued and outstanding at March 31, 2012 and December 31, 2011	262	262
Additional paid-in capital	60,803	59,957
Accumulated other comprehensive income	16,259	17,854
Treasury stock, at cost; 186,987 shares	(700)	(700)
Accumulated deficit	<u>(40,864)</u>	<u>(38,936)</u>
Total stockholders' equity	<u>35,917</u>	<u>38,594</u>
Total liabilities and stockholders' equity	<u>\$150,116</u>	<u>\$ 157,569</u>

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

(In thousands of U.S. dollars)

**Three Months Ended March 31, 2012**

	Americas	Europe	Asia	Consolidated
Research and development revenue	\$ 2,479	\$ 3	\$ 103	\$ 2,585
Product royalty revenue	10,928	-	-	10,928
Co-promotion revenue	766	-	-	766
Contract and collaboration revenue	141	13	13	167
Total revenues	<u>14,314</u>	<u>16</u>	<u>116</u>	<u>14,446</u>
Research and development expenses	822	1,517	1,013	3,352
Depreciation and amortization	120	220	10	350
Other operating expenses	10,053	716	297	11,066
Loss from operations	<u>3,319</u>	<u>(2,437)</u>	<u>(1,204)</u>	<u>(322)</u>
Interest income	18	2	-	20
Interest expense	-	(550)	(42)	(592)
Other non-operating income (expense), net	75	190	1,009	1,274
Loss before income taxes	<u>\$ 3,412</u>	<u>\$ (2,795)</u>	<u>\$ (237)</u>	<u>\$ 380</u>
Capital expenditures	<u>\$ 40</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 40</u>

**Three Months Ended March 31, 2011**

Research and development revenue	\$ 1,448	\$ -	\$ 516	\$ 1,964
Product royalty revenue	9,118	-	-	9,118
Co-promotion revenue	938	-	-	938
Contract and collaboration revenue	141	-	13	154
Total revenues	<u>11,645</u>	<u>-</u>	<u>529</u>	<u>12,174</u>
Research and development expenses	7,326	527	1,367	9,220
Depreciation and amortization	227	5	17	249
Other operating expenses	11,275	304	287	11,866
Income (loss) from operations	<u>(7,183)</u>	<u>(836)</u>	<u>(1,142)</u>	<u>(9,161)</u>
Interest income	69	1	-	70
Interest expense	-	(570)	(41)	(611)
Other non-operating income (expense), net	(4)	(199)	68	(135)
Income (loss) before income taxes	<u>\$ (7,118)</u>	<u>\$ (1,604)</u>	<u>\$ (1,115)</u>	<u>\$ (9,837)</u>
Capital expenditures	<u>\$ 42</u>	<u>\$ 6,000</u>	<u>\$ 91</u>	<u>\$ 6,133</u>

**CONTACT:**

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