# 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): August 3, 2009

	Sucampo Pharmaceuticals, Inc.				
(Exact Name of Registrant as Specified in Charter)					
Delaware	001-33609	30-0520478			
(State or Other Jurisdiction	(Commission	(IRS Employer			
of Incorporation)	File Number)	Identification No.)			
4520 East-West Highway	y, Suite 300				
Bethesda, Maryl	Bethesda, Maryland 20814				
(Address of Principal Exec	(Address of Principal Executive Offices) (Zip Code)				
(Former	r Name or Former Address, if Changed Since Last	: Report)			
Check the appropriate box below if the Form 8-1	K filing is intended to simultaneously satisfy the fi	•			
following provisions: (see General Instruction A.2. be	low):				
☐ Written communications pursuant to Rule 425	under the Securities Act (17 CFR 230.425)				
☐ Soliciting material pursuant to Rule 14a-12 un	der the Exchange Act (17 CFR 240.14a-12)				
Pre-commencement communications pursuant	to Rule 14d-2(b) under the Exchange Act (17 CF	R 240.14d-2(b))			
☐ Pre-commencement communications pursuant	to Rule 13e-4(c) under the Exchange Act (17 CF)	R 240.13e-4(c))			

#### Item 2.02 Results of Operations and Financial Condition

On August 6, 2009, Sucampo Pharmaceuticals, Inc. announced its consolidated financial results for the quarter ended June 30, 2009. 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 3, 2009, John Wright resigned as a member of the registrant's Board of Directors.

#### **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 August 6, 2009.

### 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: August 6, 2009 By: /s/ JAN SMILEK

Name: Jan Smilek

Title: Chief Financial Officer

# EXHIBIT INDEX

Exhibit No. Description

99.1 Press release issued by the registrant on August 6, 2009

#### Sucampo Pharmaceuticals Reports Financial Results for the Second Quarter of 2009

BETHESDA, Md.--(BUSINESS WIRE)--August 6, 2009--Sucampo Pharmaceuticals, Inc. (NASDAQ:SCMP) today reported its consolidated financial results for the quarter and six months ended June 30, 2009.

## Financial Highlights of the Quarter:

- Product royalty revenue from sales of Amitiza® (lubiprostone) in the U.S. for the second quarter 2009 was \$8.9 million compared to \$10.9 million during the prior year period. The product royalty revenue for the second quarter of 2008 included about \$1.9 million from the initial stocking of Amitiza (8 mcg).
- Sucampo reported a net loss of (\$0.2) million, or \$0.01 per diluted share, in the second quarter of 2009 compared to net income of \$29.9 million, or \$0.71 per diluted share, in the prior year period. During the second quarter of 2008, Sucampo received and recognized as revenue a \$50.0 million milestone payment from its North American partner, Takeda Pharmaceuticals, upon FDA approval of a second indication for Amitiza, 8 mcg, for irritable bowel syndrome with constipation (IBS-C) in adult women.
- The income/(loss) before income taxes for each of Sucampo's reportable segments for the second quarter of 2009 was: a pre-tax income of \$2.2 million from Sucampo Pharma Americas; a pre-tax loss of (\$0.8) million from Sucampo Pharma Europe; and, a pre-tax loss of (\$0.8) million from Sucampo Pharma (Asia). These results compare with income/(loss) before income taxes at the operating companies for the second quarter of 2008 of \$47.6 million, (\$0.6) million and (\$2.6) million, respectively. These results continue to reflect the respective varying stages of the segments' developments.
- Sucampo's cash, cash equivalents and short and long-term investments increased to \$131.5 million as of June 30, 2009 from \$121.5 million at December 31, 2008. The increase is attributable to payments received under an agreement with Abbott Japan for lubiprostone in Japan, which were partially offset by the upfront payment of \$3.0 million for the rights to Rescula. Both of these transactions are detailed below. Sucampo had no debt as of June 30, 2009.

# Operational Update:

- On April 23, 2009, Sucampo Pharma Americas entered into agreements with R-Tech Ueno Ltd. (RTU), of Tokyo, Japan, a related party, to acquire development and commercialization rights to Rescula® (unoprostone isopropyl) as well as to have them supply Rescula for sale in the United States and Canada. Sucampo made an upfront payment of \$3.0 million to RTU and may pay up to \$5.5 million in additional payments based on the achievement of specified development and sales milestones.
- On May 19, 2009, Sucampo Pharma (Japan) announced the initiation of enrollment and completed the randomization of the first patient into pivotal phase 3 efficacy and safety trials of lubiprostone for chronic idiopathic constipation (CIC) in Japanese patients. Under the terms of the license, commercialization and supply agreement with Abbott, signed in February 2009, Sucampo received a development milestone payment of \$7.5 million during the second quarter of 2009. This milestone payment and the \$10.0 million upfront payment received in February 2009 are being recognized as revenue using a percentage-of-completion method over the estimated development period.
- On July 1, 2009, Sucampo Pharma Americas reported top-line results from its phase 2 clinical trial of orally administered cobiprostone for the prevention of gastric ulcers and other gastrointestinal injuries in patients treated with non-steroidal anti-inflammatory drugs (NSAID). Cobiprostone patients experienced an overall statistically significant reduction in the number of gastric erosions through the treatment period of twelve weeks compared to placebo patients. In addition, the high-dose cobiprostone group experienced a 50.0% reduction in the overall incidence of gastric ulcers when compared to placebo. Sucampo intends to contact potential partners to explore commercial alternatives for cobiprostone.
- On July 21, 2009, Sucampo Pharma Americas reported top-line results from two identically-designed phase 3 clinical trials of lubiprostone (24 mcg, twice daily) for the management of opioid-induced bowel dysfunction (OBD) in subjects with chronic, non-cancer pain. In one trial, the primary endpoint of a statistically significant change from baseline in the frequency of spontaneous bowel movements (SBMs) was met when lubiprostone was compared to placebo. The other trial did not achieve statistical significance for the same primary endpoint. In both trials, a post-hoc sub-analysis showed that subjects on methadone treatment regimens who were randomized to receive lubiprostone showed a lower SBM response when compared to lubiprostone subjects treated with other opioid medications. The fully-enrolled, long-term, follow-on, open-label safety study of lubiprostone in OBD subjects continues, and data from this study is expected to be reported in late 2009. Data from all three trials are anticipated to be submitted to the FDA in 2010.

"Despite the disappointing sales of Amitiza by Takeda in the U.S., the second quarter results of all our operating segments were substantially in line with our expectations," said Ryuji Ueno, M.D., Ph.D., Ph.D., Co-Founder, Chairman and Chief Executive Officer. "We were able to reach another milestone with Abbott in Japan and we progressed in our R&D activities in the U.S. and Japan. Additionally, the acquisition of Rescula and cobiprostone's positive results may open up new opportunities for Sucampo to address unmet medical needs and possible allegiances in the future."

#### Financial Results for the Quarter and Year-to-Date

<u>Total revenues</u> for the second quarter of 2009 were \$17.7 million, compared to \$67.7 million for the second quarter of 2008, which included a \$50.0 million milestone payment recognized as revenue upon the FDA approval of Amitiza (8 mcg) for the treatment of IBS-C in adult women. Total revenues for the first six months of 2009 were \$33.2 million compared to \$81.3 million for the first six months of 2008. The key elements of the changes in total revenues are:

- Research and development (R&D) revenue for the second quarter 2009 was \$7.4 million. This consisted of \$3.8 million recognized primarily with respect to the phase 3 trials in OBD patients in the U.S. funded by Takeda, and of \$3.6 million of revenue recognized from the payments received under the agreement with Abbott. R&D revenue for the second quarter of 2008 was \$55.4 million and included the \$50.0 million milestone payment from Takeda as well as \$5.4 million in revenue recognized with respect to the development programs of Amitiza in the U.S. that are supported by Takeda. R&D revenue for the first six months of 2009 was \$12.9 million compared to \$61.5 million for the first six months of 2008.
- Product royalty revenue for the second quarter of 2009 was \$8.9 million compared to \$10.9 million during the second quarter of 2008. The prior year period included \$1.9 million in revenue recognition related to the initial stocking of Amitiza (8 mcg) and \$0.7 million in revenue from shipments delayed by Takeda at the end of the first quarter of 2008. Product royalty revenue during the six months ended June 30, 2009 was \$17.9 million, an increase of \$0.9 million, or 5.2%, compared to \$17.0 million in the prior year period.

<u>Total operating expenses</u> during the second quarter of 2009 were \$16.7 million compared to \$23.8 million during the second quarter of 2008. Total operating expenses during the six months ended June 30, 2009 were \$34.7 million compared to \$43.2 million during the prior year period. The key components of the changes in operating expense are:

- R&D expenses during the second quarter of 2009 were \$9.6 million, a decrease of 25.6%, from \$12.9 million during the prior year quarter. The decrease was mainly due to the completion of U.S. clinical trials of Amitiza and cobiprostone, offset by increased expenses from ongoing phase 3 clinical trials of Amitiza and phase 1 trials of SPI-017 in Japanese patients. R&D expenses during the first six months of 2009 were \$19.6 million, a decrease of 18.9%, from \$24.1 million during the prior year period, which included approximately \$2.5 million of filing and data purchase costs associated with our European marketing authorization applications for Amitiza.
- General and administrative (G&A) expenses during the second quarter of 2009 were \$2.9 million, a decrease of \$0.7 million, or 17.9%, from \$3.6 million during the prior year quarter, primarily due to a decrease in salaries, benefits and related costs resulting from cost containment initiatives implemented at the beginning of 2009, which were offset by expenses incurred in preparation of a performance audit under its contract with Takeda. G&A expenses during the first six months of 2009 were \$6.4 million, a decrease of \$0.3 million, or 5.2%, compared to \$6.7 million during the prior year period.
- Selling and marketing (S&M) expenses during the second quarter of 2009 were \$2.2 million, a decrease of \$0.7 million, or 23.8%, as compared to \$2.9 million during the prior year period, primarily resulting from streamlined operations in both sales and marketing. S&M expenses during the first six months of 2009 were \$4.7 million, a decrease of \$1.0 million, or 17.8%, as compared to \$5.7 million during the prior year period, resulting from the actions previously noted.

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- Milestone royalty expenses were \$0.4 million, representing 5% of the \$7.5 million milestone payment received from Abbott during the second quarter of 2009, compared with \$2.5 million for the prior year period, which represented 5% of the \$50.0 million milestone received upon the approval of Amitiza (8 mcg) for IBS-C, previously noted.
- Product royalty expenses during the second quarter of 2009 were \$1.6 million as compared to \$2.0 million for the prior year period in proportion to the product royalty revenue.

<u>Income tax</u> - Sucampo recorded an income tax provision of \$0.9 million for the second quarter of 2009 as compared to \$14.6 million for the second quarter of 2008. Sucampo recorded an income tax provision of \$1.3 million for the first six months of 2009 as compared to \$8.9 million for the first six months of 2008. The income tax provision relates to the profitable results of Sucampo's U.S. operations. The international subsidiaries continue to report net operating losses, for which the related deferred tax assets have a full valuation allowance.

The financial results for the second quarter of 2009 of Sucampo's reportable segments, continue to reflect their respective varying stages of development:

- Sucampo Pharma Americas recorded income before taxes of \$2.2 million for the second quarter of 2009. This compares to income before taxes of \$47.6 million in the second quarter of 2008, reflecting the \$50.0 million milestone payment from Takeda.
- Sucampo Pharma Europe reported a loss before taxes of \$0.8 million for the second quarter of 2009 compared to a loss before taxes of \$0.6 million in the second quarter of 2008, reflecting the expenses incurred for the regulatory approval and pre-commercialization activities for Amitiza in Europe.
- Sucampo Pharma (Asia) reported a loss before taxes of \$0.8 million in the second quarter of 2009 as compared to a loss before taxes of \$2.6 million during the second quarter of 2008. The results reflect a significant increase in R&D activities primarily associated with phase 3 trials of Amitiza in Japan. Sucampo Pharma (Asia) recorded approximately \$3.8 million in R&D revenue during the second quarter of 2009 under its agreement with Abbott in Japan and as of June 30, 2009, approximately \$13.2 million is recorded as deferred revenue out of \$17.5 million in payments received from Abbott.

Sucampo's consolidated cash, cash equivalents and investments totaled \$131.5 million at June 30, 2009 as compared with \$121.5 million at December 31, 2008. Sucampo Pharmaceuticals Inc. had no debt as of June 30, 2009.

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

Sucampo management will host a conference call today, August 6, 2009 at 5:00 pm Eastern Time to discuss these results. To participate on the live call, please dial 800-435-1261 (domestic) or +1-617-614-4076 (international), and provide the participant passcode 30938195, 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 80476642.

A live and archived audio webcast of the call will be available via the "For Investors" page of the Sucampo Pharmaceuticals website, <a href="https://www.sucampo.com">www.sucampo.com</a>. Please dial in or log on through Sucampo Pharmaceuticals' website approximately 10 minutes prior to the scheduled start time.

## **About Sucampo Pharmaceuticals**

Sucampo Pharmaceuticals, Inc., an international biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, which are bio-lipids that occur naturally in the human body, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer and currently Director and Advisor, International Business Development.

Sucampo is marketing Amitiza (lubiprostone) 24 mcg in the U.S. for Chronic Idiopathic Constipation in adults and Amitiza 8 mcg in the U.S. to treat Irritable Bowel Syndrome with Constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In April 2009, Sucampo acquired U.S. and Canadian rights to Rescula, an FDA-approved treatment for open-angle glaucoma and ocular hypertension. Sucampo plans to re-launch the drug in 2010, and to develop it for additional ophthalmic indications. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases, including age-related diseases, affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. conducts its operations through three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., based in Japan; and Sucampo Pharma Americas, Inc., based in Maryland, US. To learn more about Sucampo and its products, visit <a href="https://www.sucampo.com">www.sucampo.com</a>.

Amitiza is registered trademark of Sucampo Pharmaceuticals, Inc. and Rescula is a registered trademark used under license.

Amitiza is co-marketed in the U.S. by Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals North America, Inc.

#### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals, Inc. and its subsidiaries are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "should," "would," "could," "will," "may" or other similar expressions. Forward-looking statements include statements about potential trial results, the potential utility of Amitiza and Rescula to treat particular indications and expected data availability, trial commencement and regulatory dates. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals' filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended December 31, 2008 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals' views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

# (Financial Schedules Follow)

# Sucampo Pharmaceuticals, Inc. Consolidated Statements of Operations (unaudited) (in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,				
		2009	2008	2009		2008	
Revenues:							
Research and development revenue	\$	7,395	\$ 55,436	\$	12,921	\$	61,546
Product royalty revenue		8,914	10,901		17,860		16,981
Co-promotion revenue		1,244	1,236		2,140		2,458
Contract and collaboration revenue		152	141		298		283
Total revenues		17,705	 67,714		33,219		81,268
Operating expenses:							
Research and development		9,621	12,931		19,586		24,147
General and administrative		2,924	3,561		6,379		6,728
Selling and marketing		2,188	2,870		4,700		5,718
Milestone royalties - related parties		375	2,500		875		3,531
Product royalties - related parties		1,583	1,951		3,173		3,032
Total operating expenses		16,691	23,813		34,713		43,156
Income (loss) from operations		1,014	43,901		(1,494)		38,112
Non-operating income (expense):							
Interest income		219	565		531		1,207
Other income (expense), net		(608)	(13)		214		(1)
Total non-operating income (expense), net		(389)	 552		745		1,206
Income (loss) before income taxes		625	44,453		(749)		39,318
Income tax provision		(863)	(14,577)		(1,264)		(8,937)
Net income (loss)	\$	(238)	\$ 29,876	\$	(2,013)	\$	30,381
Net income (loss) per share:							
Basic net income (loss) per share	\$	(0.01)	\$ 0.72	\$	(0.05)	\$	0.73
Diluted net income (loss) per share	\$	(0.01)	\$ 0.71	\$	(0.05)	\$	0.72
Weighted average common shares outstanding - basic		41,844	41,757		41,844	·	41,745
Weighted average common shares outstanding - diluted		41,844	42,038		41,844		42,026

	June 30, 2009		ember 31, 2008
ASSETS:			
Current assets:			
Cash and cash equivalents	\$ 41,737	\$	11,536
Investments, current	68,435		93,776
Product royalties receivable	8,913		9,725
Unbilled accounts receivable	3,623		4,373
Accounts receivable	889		878
Prepaid and income taxes receivable	1,069		133
Deferred tax assets, current	291		963
Prepaid expenses and other current assets	2,965		3,641
Total current assets	127,922		125,025
Investments, non-current	21,330		16,222
Property and equipment, net	2,330		2,275
Deferred tax assets, non-current	4,002		4,026
Other assets	4,354		3,246
Total assets	\$159,938	\$	150,794
LIABILITIES AND STOCKHOLDERS' EQUITY:			
Current liabilities:		_	
Accounts payable	\$ 2,029	\$	1,433
Accrued expenses	10,770		9,764
Deferred revenue - current	21,305		15,599
Total current liabilities	34,104		26,796
Deferred revenue, non-current	11,771		8,061
Other liabilities	2,024		2,147
Total liabilities	47,899		37,004
Commitments			
Stockholders' equity: Preferred stock, \$0.01 par value; 5,000,000 shares authorized at June 30, 2009 and December 31, 2008; no shares issued and outstanding at June 30, 2009 and December 31, 2008	_		_
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at June 30, 2009 and December 31, 2008; 15,653,375 and 15,651,849 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	156		156
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at June 30, 2009 and December 31, 2008; 26,191,050 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	262		262
Additional paid-in capital	98,440		98,243
Accumulated other comprehensive loss	419		354
Retained earnings	12,762	_	14,775
Total stockholders' equity	112,039		113,790
Total liabilities and stockholders' equity	\$159,938	\$	150,794

# Sucampo Pharmaceuticals, Inc. Key Segment Information (unaudited) (in thousands, net of intercompany eliminations)

	Americas		Europe	
Three Months Ended June 30, 2009				
Product royalty revenue	\$	8,914	\$	_
Research and development revenue	4	3,825	4	_
Other revenue		1,386		_
Total revenues	<u> </u>	14,125	\$	_
Total operating expenses	Ψ	11,933	Ÿ	482
Other non-operating income (expenses), net		256		(334)
Income (loss) before income tax	\$	2,238	\$	(816)
Six Months Ended June 30, 2009				
Product royalty revenue	\$	17,860	\$	_
Research and development revenue	Ψ	8,977	Ψ	_
Other revenue		2,423		_
Total revenues		29,260	\$	_
Total operating expenses	Ψ	26,298	Ψ	965
Other non-operating income (expenses), net		859		(370)
Income (loss) before income tax	\$	3,401	\$	(1,335)
Three Months Ended June 30, 2008				
Product royalty revenue	\$	10,901	\$	-
Research and development revenue		55,436		-
Other revenue		1,377		-
Total revenues	\$	67,714	\$	-
Total operating expenses		20,459		584
Other non-operating income (expenses), net		584		(31)
Income (loss) before income tax	\$	47,629	\$	(615)
Six Months Ended June 30, 2008				
Product royalty revenue	\$	16,981	\$	-
Research and development revenue	•	61,546	•	-
Other revenue		2,741		-
Total revenues	\$	81,268	\$	-
Total operating expenses		37,293		2,422
Other non-operating income (expenses), net		1,210		(8)
- · · · · · ·		44,768	\$	(2,430)

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# CONTACT:

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or

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