

August 3, 2016



# Sucampo Reports Second Quarter 2016 Financial Results

***Results Driven by 49% Growth in Revenue***

***Adjusted EPS Growth of 10%***

***Company Reiterates 2016 Guidance***

***Company to Host Conference Call Today at 8:30 a.m. ET***

ROCKVILLE, Md., Aug. 03, 2016 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ:SCMP), a global biopharmaceutical company, today reported consolidated financial results for the second quarter ended June 30, 2016.

<b>Summary of Results</b>	<b>Q2-16</b>	<b>% Increase / (Decrease) over Q2-15</b>
Revenue	\$52.0M	49 %
Net Loss GAAP	(\$0.8M)	(109 %)
EPS GAAP – diluted	(\$ 0.02 )	(109 %)
EBITDA	\$20.5M	75 %
Adjusted Net Income	\$10.0M	2 %
Adjusted EPS – diluted	\$ 0.23	10 %
Adjusted EBITDA	\$24.9M	68 %

“Our strong second quarter results demonstrate the continued growth of AMITIZA and the sustained significant benefit derived from our acquisition of R-Tech Ueno,” said Peter Greenleaf, Chairman and Chief Executive Officer of Sucampo. “As we look to the second half of the year, we will continue our focus on AMITIZA growth and focus our pipeline efforts on our life cycle management programs for lubiprostone, our partnership with Cancer Prevention Pharmaceuticals regarding its Phase 3 familial adenomatous polyposis program, and continuing to evolve our company through business development.”

For the three months ended June 30, 2016, Sucampo reported year-over-year total revenue growth of 49% to \$52.0 million. Product sales revenue increased to \$28.4 million, representing 96% year-over-year growth, and product royalty revenue grew 16% year-over-year to \$18.7 million. Revenue for the quarter included an additional \$13.8 million as a result of the R-Tech Ueno acquisition. Excluding this additional revenue from the acquisition, base revenue grew by 9%.

Sucampo reported a GAAP net loss of \$0.8 million, or (\$0.02) per diluted share during the second quarter of 2016 compared to net income of \$9.6 million, or \$0.21 per diluted share, during the second quarter of 2015, a decrease of 109% and 109% respectively. On

an adjusted basis, Sucampo reported net income of \$10.0 million, or \$0.23 per diluted share, during the second quarter of 2016, compared to net income of \$9.8 million, or \$0.21 per diluted shares, during the second quarter of 2015, an increase year-over-year of 2% and 10% respectively.

## **Second Quarter 2016 Operational Review**

### **AMITIZA**

#### *United States*

- AMITIZA total prescriptions were 366,524 in the second quarter of 2016, as reported by IMS, an increase of 1% compared to the second quarter of 2015. For the first six months of 2016, AMITIZA total prescriptions were 726,695, an increase of 3% compared to the first six months of 2015. Net sales of AMITIZA, reported by Takeda Pharmaceuticals U.S.A., Inc. (Takeda) for royalty calculation purposes, increased 15% to \$101.7 million for the second quarter of 2016, compared to \$88.2 million in the same period of 2015. Royalty revenue was \$18.7 million compared to \$16.1 million, an increase of 16%. Also included in second quarter revenue are Takeda AMITIZA sales from R-Tech Ueno of \$12.4 million.

#### *Global Markets*

- In Japan, Sucampo's revenue from sales of AMITIZA to Mylan N.V. was \$14.6 million for the second quarter of 2016, compared to \$14.5 million in the same period of 2015.

#### *Corporate*

- In July, Paul Edick was appointed to Sucampo's Board of Directors.

## **Research and Development**

- An ongoing phase 3 trial of AMITIZA in pediatric functional constipation in children six to seventeen years of age completed enrollment during April. Top-line data from this trial and a new drug application (NDA) filing are expected in the second half of this year, with the potential for approval in the second half of 2017.
- Sucampo discontinued the development of cobiprostone after top-line data from a Phase 2a study of cobiprostone in patients with proton pump inhibitor (PPI)-refractory non-erosive reflux disease (NERD) or symptomatic gastroesophageal reflux disease (sGERD) did not meet its primary endpoints and also based on the results of a futility analysis of a Phase 2a study in the prevention of oral mucositis in patients undergoing radio chemotherapy for head and neck cancer. There were no safety concerns identified and cobiprostone demonstrated a well-tolerated safety profile consistent with earlier Phase 1 studies.

## **Second Quarter 2016 Financial Review**

- On a GAAP basis, Sucampo reported a net loss of \$0.8 million and a diluted loss per share of \$.02 during the second quarter of 2016, compared to net income of \$9.6 million and diluted EPS of \$0.21 in the same period in 2015. Adjusted net income was \$10.0 million, or \$0.23 per diluted share, during the second quarter of 2016, compared to net income of \$9.8 million, or \$0.21 per diluted share, in the same period of 2015, an increase year-over-year of 2% and 10% respectively.
- EBITDA was \$20.5 million for the second quarter of 2016 compared to EBITDA of \$11.7 million for the same period in 2015. Adjusted EBITDA, defined as net income before interest, taxes, depreciation, amortization, stock-based compensation expense, restructuring and intangible impairment, was \$24.9 million for the second quarter of 2016 compared to \$14.8 million in the same period in 2015, an increase of 68%.
- Total revenues were \$52.0 million for the second quarter of 2016 compared to \$34.9 million in the same period in 2015, an increase of \$17.1 million or 49%. The increase was primarily due to the inclusion of R-Tech Ueno results and increase in royalty revenues from Takeda.
- Cost of goods sold were \$20.4 million for the second quarter of 2016 compared to \$7.3 million for the same period in 2015, an increase of \$13.1 million or 180%. The increase was primarily due to the amortization of the R-Tech Ueno inventory step-up and acquired intangible asset amortization. Excluding the step-up of inventory and intangible asset amortization of \$12.7 million, cost of goods sold was \$7.7 million. The amortization of inventory step-up costs continued through May 2016.
- Gross margin calculated as product sales revenue less cost of goods sold as a percentage of product sales revenue, was 28% for the second quarter of 2016, compared to 50% for the same period in 2015, a decrease of 22%. The decrease was primarily due to the amortization of the R-Tech Ueno inventory step-up and acquired intangible asset amortization. Excluding the step-up of inventory and intangible asset amortization, gross margin was 73%, an increase of 23%.
- Research and development expenses were \$11.3 million for the second quarter of 2016 compared to \$6.7 million for the same period of 2015, an increase of \$4.6 million or 68%. The increase was primarily due to increased spending on lubiprostone pediatric studies and costs associated with cobiprostone clinical development.
- General and administrative expenses were \$12.0 million for the second quarter of 2016 compared to \$8.7 million for the same period of 2015, an increase of \$3.3 million or 38%. The increase was primarily due to the inclusion of R-Tech Ueno in 2016 and restructuring costs related to the integration of R-Tech.
- Selling and marketing expenses were \$0.6 million for the second quarter of 2016 compared to \$0.6 million for the same period of 2015.
- The effective tax rate for the second quarter of 2016 was 5.8%, compared to 29% in

the same period of 2015. The decrease in the tax rate is primarily due to the treatment of non-U.S. income.

**Certain prior year non-GAAP amounts have been reclassified for consistency with the current period- adjusted presentation. These reclassifications had no effect on the reported results of operations. A reconciliation of adjusted Net Income to GAAP Net Income and adjusted EBITDA to income from operations, the most directly comparable GAAP financial measure, is included in the tables below.**

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

	Three months ended June 30,	
	2016	2015
<b>Adjusted Non-GAAP Income</b>		
<b>GAAP net income</b>	(832 )	9,576
Amortization Intangibles	6,329	-
Amortization Inventory Step Up	6,303	-
Restructuring Costs	1,504	-
Acquisition Related Expenses	1,105	278
Amortization of Financing Costs	889	-
Tax Effect of Adjustments	(5,347 )	(92 )
<b>Adjusted Net Income</b>	<b>9,951</b>	<b>9,762</b>

Adjusted Net Income Per Share:

Diluted	\$ 0.23	\$ 0.21
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	2016	2015
<b>EBITDA</b>		
GAAP Income from Operations	7,620	11,580
Depreciation	205	129
Amortization of Acquired Intangibles	6,329	-
Amortization Inventory Step Up	6,303	-
<b>EBITDA</b>	<b>20,458</b>	<b>11,709</b>

Non-GAAP Adjustments		
Share Based Compensation Expense	1,783	2,820
Restructuring Costs	1,504	-
Acquisition Related Expenses	1,105	278
<b>Adjusted EBITDA</b>	<b>24,850</b>	<b>14,807</b>

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

At June 30, 2016, cash, cash equivalents, restricted cash and investments were \$154.9 million compared to \$163.5 million at December 31, 2015. This change is primarily due to the investment in CPP of \$5.0 million and the associated option payment of \$3.0 million made in January 2016. At June 30, 2016 and December 31, 2015, notes payable were \$224.1 million and \$252.4 million, respectively, including current portions of \$21.7 million and \$39.1 million, respectively. The change in the overall note payable balance is due to

debt repayments made during 2016. Sucampo's net debt position at June 30, 2016 is \$69.2 million, compared to \$88.9 million at December 31, 2015.

## Geographic Sales

Company revenues by product type and geographic location for the three months ended June 30, 2016 and 2015 were as follows

(In thousands)	Three months ended June 30, 2016			Three months ended June 30, 2015		
	USA	Japan	Total	USA	Japan	Total
AMITIZA Product sales	12,375	14,626	27,001	-	14,500	14,500
AMITIZA Royalty	18,735	-	18,735	16,136	-	16,136
Rescula Product Sales	2	1,385	1,387	-	11	11
Total	<u>31,112</u>	<u>16,011</u>	<u>47,123</u>	<u>16,136</u>	<u>14,511</u>	<u>30,647</u>

## Guidance

Sucampo today reiterated its earnings guidance for the full year ending December 31, 2016. Sucampo expects total revenue of \$195.0 million to \$205.0 million, adjusted net income of \$45.0 million to \$50.0 million, adjusted EPS of \$0.97 to \$1.07, and adjusted EBITDA of \$100.0 million to \$105.0 million. Adjusted net income guidance excludes amortization of acquired intangibles of approximately \$17.6 million and amortization of the remaining inventory step-up costs of approximately \$8.9 million.

## Non-GAAP Financial Measures

This press release contains non-GAAP earnings as listed in the first table above, which is GAAP net income before interest, tax, depreciation, amortization, stock option expense and intangible impairment. Sucampo believes that this non-GAAP measure of financial results provides useful information to management and investors relating to its results of operations. Sucampo's management uses this non-GAAP measure to compare Sucampo's performance to that of prior periods for trend analyses, and for budgeting and planning purposes, as management believes this provides a more comparable measure of our continuing business, as it adjusts for special items that are not reflective of the normal earnings of our business. Sucampo believes that the use of non-GAAP financial measures provides an additional tool for investors to use in evaluating ongoing operating results and trends and in comparing the Sucampo's financial measures with other companies in its industry, many of which present similar non-GAAP financial measures to investors, and that it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making.

Adjusted EBITDA provides us with an understanding of one aspect of earnings before the impact of investing and financing charges, income taxes and special items. Adjusted EBITDA may be useful to an investor in evaluating our operating performance and liquidity because this measure is widely used by investors to measure a company's operating

performance without regard to items excluded from the calculation of such measure, which can vary substantially from company to company. In addition, this is a financial measure that is used by rating agencies, lenders and other parties to evaluate credit worthiness. Finally, this measure is used by management for various purposes, including as a measure of performance of our operating entities and as a basis for strategic planning and forecasting.

Management of the company does not consider non-GAAP measures in isolation or as an alternative to financial measures determined in accordance with GAAP. The principal limitation of non-GAAP financial measures is that they exclude significant expenses that are required by GAAP to be recorded in the Sucampo's financial statements. In order to compensate for these limitations, management presents non-GAAP financial measures together with GAAP results. Non-GAAP measures should be considered in addition to results and guidance prepared in accordance with GAAP, but should not be considered a substitute for, or superior to, GAAP results. Reconciliation tables of the most comparable GAAP financial measure to the non-GAAP financial measure used in this press release are included with the financial tables at the end of this release. Sucampo urges investors to review the reconciliation and not to rely on any single financial measure to evaluate the Sucampo's business. In addition, other companies, including companies in our industry, may calculate similarly named non-GAAP measures differently than we do, which limits their usefulness in comparing our financial results with theirs.

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

Sucampo will host a conference call and webcast today, Wednesday, August 3rd at 8:30 am ET.

Conference call and Webcast participation details are as follows:

Dial-in number: 888-636-8238 (domestic) or 484-747-6635 (international)

Passcode: 49003599

Webcast link: <http://www.sucampo.com/investors/events-presentations/>

Conference call replay:

Dates: Starting at 11:30 AM ET, August 3rd, 2016 a replay of the teleconference and webcast will be available

Dial-in number: 855-859-2056 (domestic) or 404-537-3406 (international)

Passcode: 49003599

Webcast link: <http://www.sucampo.com/investors/events-presentations/>; then click 'Archived Events'

### **About AMITIZA<sup>®</sup> (lubiprostone)**

AMITIZA (lubiprostone) is a chloride channel activator that acts locally in the small intestine. By increasing intestinal fluid secretion, lubiprostone increases motility in the intestine, thereby facilitating the passage of stool and alleviating symptoms associated with CIC. Lubiprostone, via activation of apical CIC-2 channels in intestinal epithelial cells, bypasses the antisecretory action of opiates that results from suppression of secretomotor neuron excitability. Activation of CIC-2 by lubiprostone has also been shown to stimulate recovery of mucosal barrier function and reduce intestinal permeability via the restoration

of tight junction protein complexes in ex vivo studies of ischemic porcine intestine.

AMITIZA (24 mcg twice daily) is indicated in the U.S. for the treatment of adults with CIC and opioid-induced constipation (OIC) with chronic, non-cancer pain. AMITIZA (8 mcg twice daily) is also approved in the U.S. for irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older. In Japan, AMITIZA (24 mcg twice daily) is indicated for the treatment of chronic constipation (excluding constipation caused by organic diseases). In Canada, AMITIZA (24 mcg twice daily) is indicated for the treatment of CIC in adults. In the U.K., AMITIZA (24 mcg twice daily) is indicated for the treatment of CIC and associated symptoms in adults, when response to diet and other non-pharmacological measures (e.g. educational measures, physical activity) are inappropriate. In Switzerland, AMITIZA (24 mcg twice daily) is indicated for the treatment of CIC in adults and for the treatment of OIC and associated signs and symptoms such as stool consistency, straining, constipation severity, abdominal discomfort, and abdominal bloating in adults with chronic, non-cancer pain. The efficacy of AMITIZA for the treatment of OIC in patients taking opioids of the diphenylheptane class, such as methadone, has not been established.

### **About RESCULA®**

Unoprostone isopropyl 0.12% (trade named RESCULA) first received marketing authorization in 1994 in Japan for the treatment of glaucoma and ocular hypertension. RESCULA is marketed in Japan by Santen Pharmaceutical Co., Ltd. (Santen). We acquired RESCULA as part of the acquisition of R-Tech Ueno in 2015.

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

Sucampo Pharmaceuticals, Inc. is focused on the development and commercialization of medicines that meet major unmet medical needs of patients worldwide. Sucampo has two marketed products – AMITIZA, its lead product, and RESCULA – and a pipeline of product candidates in clinical development. A global company, Sucampo is headquartered in Rockville, Maryland, and has operations in Japan, Switzerland and the U.K. For more information, please visit [www.sucampo.com](http://www.sucampo.com).

The Sucampo logo and the tagline, The Science of Innovation, are registered trademarks of Sucampo AG. AMITIZA is a registered trademark of Sucampo AG.

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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, 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 effects of competitive products on Sucampo's products; 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 press release should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 11, 2016, as amended, as well as its filings with the Securities and Exchange Commission on Forms 8-K and 10-Q since the filing of the Form 10-K, all of which Sucampo incorporates by reference.

**Sucampo Pharmaceuticals, Inc.**

**Consolidated Statements of Operations and Comprehensive Income (Loss) (unaudited)**

*(in thousands, except per share data)*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Revenues:				
Product royalty revenue	\$ 18,735	\$ 16,136	\$ 35,451	\$ 31,881
Product sales revenue	28,389	14,511	54,984	25,656
Research and development revenue	3,369	2,409	6,799	4,754
Contract and collaboration revenue	1,458	1,828	1,925	2,073
Total revenues	<u>51,951</u>	<u>34,884</u>	<u>99,159</u>	<u>64,364</u>
Costs and expenses:				
Costs of goods sold	20,354	7,260	43,692	13,370
Research and development	10,933	7,124	25,604	13,917
General and administrative	12,423	8,328	21,350	14,611
Selling and marketing	623	592	1,398	1,232
Total costs and expenses	<u>44,333</u>	<u>23,304</u>	<u>92,044</u>	<u>43,130</u>
Income (loss) from operations	7,618	11,580	7,115	21,234
Non-operating income (expense):				
Interest income	10	53	35	93

Interest expense	(5,972 )	(265 )	(12,242 )	(541 )
Other income (expense), net	<u>(2,539 )</u>	<u>2,063</u>	<u>(2,886 )</u>	<u>1,860</u>
Total non-operating expense, net	<u>(8,501 )</u>	<u>1,851</u>	<u>(15,093 )</u>	<u>1,412</u>
Income (loss) before income taxes	(883 )	13,431	(7,978 )	22,646
Income tax benefit (provision)	<u>51</u>	<u>(3,855 )</u>	<u>3,089</u>	<u>(6,662 )</u>
Net income (loss)	<u>\$ (832 )</u>	<u>\$ 9,576</u>	<u>\$ (4,889 )</u>	<u>\$ 15,984</u>
Net income (loss) per share:				
Basic	\$ (0.02 )	\$ 0.21	\$ (0.11 )	\$ 0.36
Diluted	\$ (0.02 )	\$ 0.21	\$ (0.11 )	\$ 0.35
Weighted average common shares outstanding:				
Basic	42,759	44,627	42,649	44,497
Diluted	42,759	46,199	42,649	46,046
Comprehensive income (loss):				
Net income (loss)	\$ (832 )	\$ 9,576	\$ (4,889 )	\$ 15,984
Other comprehensive income (expense):				
Unrealized gain (loss) on pension benefit obligation	33	(12 )	25	(19 )
Unrealized gain (loss) on investments, net of tax effect	-	18	-	12
Foreign currency translation gain (loss)	<u>20,700</u>	<u>(337 )</u>	<u>36,255</u>	<u>(162 )</u>
Comprehensive income (loss)	<u>\$ 19,901</u>	<u>\$ 9,245</u>	<u>\$ 31,391</u>	<u>\$ 15,815</u>

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

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 127,981	\$ 108,284
Product royalties receivable	18,744	22,792
Accounts receivable, net	18,167	22,759
Restricted cash	26,916	55,218
Inventories	21,570	33,121
Prepaid expenses and other current assets	<u>24,324</u>	<u>9,186</u>
Total current assets	237,702	251,360
Property and equipment, net	6,340	6,393
Intangible assets	139,347	130,315

Goodwill	71,839	60,937
In-process research and development	7,228	6,171
Deferred charge, non-current	1,400	1,400
Convertible note receivable	5,118	-
Other assets	770	605
Total assets	<u>\$ 469,744</u>	<u>\$ 457,181</u>

## LIABILITIES AND STOCKHOLDERS' EQUITY

### Current liabilities:

Accounts payable	\$ 6,166	\$ 11,213
Accrued expenses	13,298	10,886
Collaboration obligation	3,797	5,623
Income tax payable	6,274	6,507
Notes payable, current	21,679	39,083
Other current liabilities	4,421	14,815
Total current liabilities	<u>55,635</u>	<u>88,127</u>

Notes payable, non-current	202,410	213,277
Deferred revenue, non-current	937	1,088
Deferred tax liability, net	68,570	52,497
Other liabilities	18,428	15,743
Total liabilities	<u>345,980</u>	<u>370,732</u>

Preferred stock, \$0.01 par value; 5,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued and outstanding at June 30, 2016 and December 31, 2015

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Class A common stock, \$0.01 par value; 270,000,000 shares authorized at June 30, 2016 and December 31, 2015; 45,820,058 and 45,509,150 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively

458 455

Class B common stock, \$0.01 par value; 75,000,000 shares authorized at June 30, 2016 and December 31, 2015; no shares issued and outstanding at June 30, 2016 and December 31, 2015

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Additional paid-in capital

105,133 99,212

Accumulated other comprehensive income

49,692 13,412

Treasury stock, at cost; 3,009,942 shares at June 30, 2016 and December 31, 2015

(46,269 ) (46,269 )

Retained earnings

14,750 19,639

Total stockholders' equity

123,764 86,449

Total liabilities and stockholders' equity

\$ 469,744 \$ 457,181

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Source: Sucampo Pharmaceuticals Inc