

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 5, 2015

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Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

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Delaware

(State or Other Jurisdiction  
of Incorporation)

001-33609

(Commission  
File Number)

30-0520478

(IRS Employer  
Identification No.)

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

(Address of Principal Executive Offices)

20814

(Zip Code)

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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 August 5, 2015, Sucampo Pharmaceuticals, Inc. (“the Company”) announced its consolidated financial results for the quarter ended June 30, 2015. 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 Item 2.02 and Exhibit 99.1 to this Form 8-K 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 August 5, 2015, the Company will host a conference call with investors to discuss the Company’s financial and operating results for the quarter ended June 30, 2015. The conference call including slides will be made available to the public via conference call and webcast. The slides from the presentation are being furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.2 to this Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

## **Item 9.01 Financial Statements and Exhibits**

### (d) Exhibits

The following exhibits relating to Item 2.02 and Item 7.01 shall be deemed to be furnished, and not filed:

99.1 Press Release issued by the Company on August 5, 2015.

99.2 The corporate update presentation slides dated August 5, 2015.

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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: August 5, 2015

By: /s/ Andrew P. Smith  
Name: Andrew P. Smith  
Title: Chief Financial Officer

## Sucampo Reports Second Quarter 2015 Financial Results and Corporate Update

*Year-over-Year Earnings Growth of 495% and EPS Growth of 425%*

*Year-over-Year Revenue Growth of 45%*

*Company Increases 2015 Earnings Guidance*

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

BETHESDA, Md., Aug. 5, 2015 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ:SCMP) today reported consolidated financial results for the second quarter ended June 30, 2015.

Sucampo reported year-over-year growth of 45% to \$34.9 million in total revenue, 16% to \$16.1 million in product royalty revenue and 92% to \$14.5 million in product sales revenue. Sucampo reported net income of \$9.6 million and fully-diluted earnings per share (EPS) of \$0.21 during the second quarter of 2015, compared to net income of \$1.6 million and fully-diluted EPS of \$0.04 in the same period in 2014.

"In the second quarter, we delivered outstanding earnings growth, driven mainly by AMITIZA's continued growth in the U.S. and Japan," said Peter Greenleaf, Chief Executive Officer of Sucampo. "Based on our solid performance in the first half of this year and our expectations for the rest of 2015, we are raising our full year guidance. Our financial strength will fuel the continued transformation of our business, enabling expansion of the AMITIZA franchise via sustained revenue growth, new markets, and lifecycle management programs; development of cobiprostone in two therapeutic areas of significant unmet need; and execution of business development transactions to diversify our business and pipeline."

### Second Quarter 2015 Operational Review

#### AMITIZA

##### United States

- AMITIZA total prescriptions were 362,976, an increase of 10%, compared to the second quarter of 2014. Net sales of AMITIZA, reported by Takeda Pharmaceuticals U.S.A., Inc. for royalty calculation purposes, increased 15% to \$88.2 million for the second quarter of 2015, compared to \$77.0 million in the same period of 2014.

##### Global Markets

- In Japan, Sucampo's revenue from sales of AMITIZA to Mylan N.V. increased 101% to \$14.5 million for the second quarter of 2015, compared to \$7.2 million in the same period of 2014.
- Following a recommendation for marketing authorization for AMITIZA for the treatment of chronic idiopathic constipation (CIC) in early 2015, Ireland, Luxembourg, the Netherlands, Belgium, Austria, Germany and Italy have issued marketing authorizations. Sucampo anticipates receiving approval by Spain in the second half of 2015.
- In May 2015, Sucampo entered into an exclusive license, development, commercialization and supply agreement with Harbin Gloria Pharmaceuticals Co., Ltd. (Gloria), for AMITIZA in the People's Republic of China. Through this agreement, Sucampo granted Gloria the rights to develop and commercialize AMITIZA in China, subject to regulatory approval of the product by the China Food and Drug Administration (CFDA). Gloria will be responsible for all development activities and costs in China. In addition, Gloria will be responsible for all commercialization and regulatory activities in China. As a result of this agreement, Sucampo recognized a \$1.0 million payment from Gloria, which was the first tranche of the \$1.5 million upfront payment. In June 2015, the CFDA accepted an IND application for a pivotal study of AMITIZA in patients with CIC. The acceptance triggered a \$0.5 million payment from Gloria; this was the second tranche of the \$1.5 million upfront payment.

##### Research and Development

- In May 2015, the United States Food and Drug Administration (FDA) granted Fast Track Designation for cobiprostone for the prevention of oral mucositis. The FDA also accepted the company's Investigational New Drug (IND) application to initiate a Phase 2a clinical trial in patients suffering from head and neck cancer for the prevention of severe oral mucositis. The clinical trial is expected to begin shortly.

### Second Quarter 2015 Financial Review

- Net income was \$9.6 million for the second quarter of 2015 compared to net income of \$1.6 million, in the same period in 2014, an increase of 495%. Fully-diluted EPS for the second quarter of 2015 was \$0.21 compared to fully-diluted EPS of \$0.04 in the same period in 2014, an increase of 425%. Non-GAAP earnings before interest, tax, depreciation, amortization and stock option expense was \$16.6 million for the second quarter of 2015 compared to \$4.7 million in the same period in 2014, an increase of 251%.
- Total revenues were \$34.9 million for the second quarter of 2015 compared to \$24.1 million in the same period in 2014, an increase of 45%. The increase was primarily due to the growth of AMITIZA sales in Japan and higher product royalty revenue on AMITIZA net sales in the U.S.
- Costs of goods sold were \$7.3 million for the second quarter of 2015 compared to \$3.8 million for the same period in 2014, an increase of 92%. The increase was primarily due to increased AMITIZA sales in Japan.

- Research and development expenses were \$7.1 million for the second quarter of 2015 compared to \$4.3 million for the same period of 2014, an increase of 68%. The increase was primarily due to increased activity on our development programs of cobiprostone for PPI-refractory non-erosive reflux disease/gastro-esophageal reflux disease and AMITIZA for pediatric functional constipation, part of which is reimbursed by Takeda.
- General and administrative expenses were \$8.3 million for the second quarter of 2015 compared to \$8.2 million for the same period of 2014.
- Selling and marketing expenses were \$0.6 million for the second quarter of 2015 compared to \$4.0 million for the same period of 2014, a decrease of 85%. The decrease was primarily due to the reduction in direct commercial operations in the fourth quarter of 2014 in the U.S. and Europe.
- Effective tax rate for the second quarter of 2015 was 29%, compared to 53% in the same period of 2014. The effective rate for the quarter is based on a projection of the full year rate. The reduction in tax rate is due to the timing of the allowable deduction of intangible impairment expense, together with the effect on the treatment of non-U.S. income following the reduction in holdings of Sucampo's founding stockholders below 50% of Sucampo's outstanding shares.

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

At June 30, 2015, cash, cash equivalents, restricted cash and investments were \$127.7 million, compared to \$110.0 million at December 31, 2014. At June 30, 2015 and December 31, 2014, notes payable were \$21.7 million and \$25.8 million, including current notes payable of \$8.4 million and \$8.2 million, respectively.

For the quarter ended June 30, 2015, cash flow from operating activities was \$15.1 million, compared to \$4.1 million for the same period in 2014.

#### **Guidance**

Sucampo today increased its earnings guidance for 2015. Sucampo now expects full year 2015 GAAP net income to be in the range of \$30.0 million to \$35.0 million, or \$0.65 to \$0.75 per diluted share.

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

Sucampo will host a conference call and webcast today at 8:30 am EDT. To participate on the live call, please dial 877-415-3180 (domestic) or 857-244-7323 (international) and use passcode 18259780, 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), passcode 42482402. Investors interested in accessing the live audio webcast of the teleconference may do so at <http://www.sucampo.com/investors/events-presentations/> and should log on before the teleconference begins in order to download any software required. The archive of the teleconference will remain available for 30 days.

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

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 chronic idiopathic constipation. 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 *in 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 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 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 one marketed product – AMITIZA – and a pipeline of product candidates in clinical development. A global company, Sucampo is headquartered in Bethesda, 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.

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

Twitter LinkedIn

## Sucampo Forward-Looking Statements

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 include statements regarding Sucampo's expectations for financial performance for the full year 2015, as well as product development, market potential, its strategy of pursuing business development transactions, 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; the ability of Sucampo to continue to develop the market for AMITIZA; the ability of Sucampo to develop, commercialize or license existing pipeline products or compounds or license or acquire non-prostone products or drug candidates; 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; the effects of competitive products on Sucampo's products; and the exposure to litigation and/or regulatory actions.

The forward-looking statements included in this press release represent Sucampo's views as of the date of this press release. No forward-looking statement can be guaranteed and actual results may differ materially from those anticipated. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo's business, particularly those mentioned in the risk factors and cautionary statements in Sucampo's most recent Form 10-K as filed with the Securities and Exchange Commission on March 9, 2015 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. Accordingly, these forward-looking statements should not be relied upon as representing Sucampo's views as of any date subsequent to the date of this press release.

## Non-GAAP Financial Measures

This press release contains non-GAAP earnings, which is GAAP net income (loss) before interest, tax, depreciation, amortization and stock option expense. 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. 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.

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.

### Sucampo Pharmaceuticals, Inc.

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

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenues:				
Research and development revenue	\$ 2,409	\$ 1,700	\$ 4,754	\$ 3,484
Product royalty revenue	16,136	13,888	31,881	27,389
Product sales revenue	14,511	7,543	25,656	13,855
Co-promotion revenue	--	723	--	1,085
Contract and collaboration revenue	1,828	215	2,073	417
Total revenues	<u>34,884</u>	<u>24,069</u>	<u>64,364</u>	<u>46,230</u>
Costs and expenses:				
Costs of goods sold	7,260	3,796	13,370	7,189
Research and development	7,124	4,252	13,917	9,387
General and administrative	8,328	8,197	14,611	15,454
Selling and marketing	592	4,013	1,232	7,660
Total costs and expenses	<u>23,304</u>	<u>20,258</u>	<u>43,130</u>	<u>39,690</u>
Income from operations	11,580	3,811	21,234	6,540
Non-operating income (expense):				
Interest income	53	23	93	80
Interest expense	(265)	(392)	(541)	(792)
Other expense, net	2,063	(53)	1,860	(376)
Total non-operating expense, net	<u>1,851</u>	<u>(422)</u>	<u>1,412</u>	<u>(1,088)</u>

Income before income taxes	13,431	3,389	22,646	5,452
Income tax provision	<u>(3,855)</u>	<u>(1,779)</u>	<u>(6,662)</u>	<u>(3,086)</u>
Net income	<u>\$ 9,576</u>	<u>\$ 1,610</u>	<u>\$ 15,984</u>	<u>\$ 2,366</u>
Net income per share:				
Basic	\$ 0.21	\$ 0.04	\$ 0.36	\$ 0.05
Diluted	\$ 0.21	\$ 0.04	\$ 0.35	\$ 0.05
Weighted average common shares outstanding:				
Basic	44,627	43,640	44,497	43,521
Diluted	46,199	43,640	46,046	43,609

**Reconciliation of Income from Operations to Earnings before Interest, Tax, Depreciation, Amortization and Stock-based Compensation (unaudited)**

Income from operations	\$ 11,580	\$ 3,811	\$ 21,234	\$ 6,540
Other income / (expense), net	<u>2,063</u>	<u>(53)</u>	<u>1,860</u>	<u>(376)</u>
Earnings before interest and tax (EBIT)	13,643	3,758	23,094	6,164
Depreciation and amortization	132	360	215	721
Stock-based compensation	<u>2,820</u>	<u>604</u>	<u>3,889</u>	<u>832</u>
Earnings before interest, tax, depreciation & amortization and stock-based compensation	<u>\$ 16,595</u>	<u>\$ 4,722</u>	<u>\$ 27,198</u>	<u>\$ 7,717</u>

**Sucampo Pharmaceuticals, Inc.**

**Consolidated Balance Sheets (unaudited)**

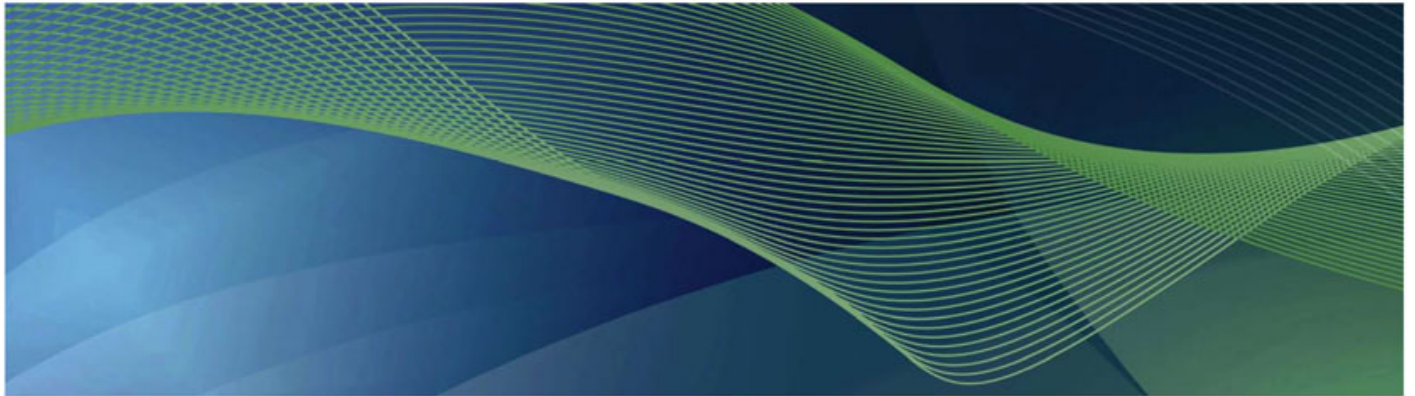
(in thousands, except share and per share data)

	June 30, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,343	\$ 71,622
Investments, current	37,153	22,393
Product royalties receivable	16,136	18,576
Accounts receivable, net	8,202	5,338
Deferred tax assets, current	259	476
Deferred charge, current	295	295
Restricted cash, current	213	213
Inventory	308	--
Prepaid expenses and other current assets	<u>2,804</u>	<u>3,411</u>
Total current assets	136,713	122,324
Investments, non-current	16,655	13,540
Property and equipment, net	526	763
Intangible assets, net	141	151
Deferred tax assets, non-current	2,065	571
Deferred charge, non-current	1,548	1,695
Restricted cash, non-current	2,356	2,224
Other assets	<u>253</u>	<u>306</u>
Total assets	<u>\$ 160,257</u>	<u>\$ 141,574</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,910	\$ 4,143
Accrued expenses	8,660	8,467
Deferred revenue, current	1,728	2,051
Collaboration obligation	5,774	6,000
Income tax payable	2,279	1,291
Notes payable, current	8,411	8,240
Other current liabilities	<u>2,079</u>	<u>3,618</u>
Total current liabilities	32,841	33,810
Notes payable, non-current	13,330	17,578
Deferred revenue, non-current	4,801	5,118
Deferred tax liability, non-current	436	820

Other liabilities	<u>2,125</u>	<u>1,936</u>
Total liabilities	<u>53,533</u>	<u>59,262</u>
Stockholders' equity:		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding at June 30, 2015 and December 31, 2014	--	--
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at June 30, 2015 and December 31, 2014; 45,179,884 and 44,602,988 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	451	446
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued and outstanding at June 30, 2015 and December 31, 2014	--	--
Additional paid-in capital	92,238	83,646
Accumulated other comprehensive income	14,096	14,265
Treasury stock, at cost; 524,792 shares at June 30, 2015 and December 31, 2014	(2,313)	(2,313)
Retained earnings (accumulated deficit)	<u>2,252</u>	<u>(13,732)</u>
Total stockholders' equity	<u>106,724</u>	<u>82,312</u>
Total liabilities and stockholders' equity	<u>\$ 160,257</u>	<u>\$ 141,574</u>

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





# Q2 2015 Corporate Update and Financial Results

August 5, 2015



# Introductions and Forward-Looking Statements



**Silvia Taylor**

*Senior Vice President, Investor Relations  
and Corporate Communications*

# Agenda

<b>Introductions and Forward-Looking Statements</b>	Silvia Taylor
<b>Corporate Update</b>	Peter Greenleaf
<b>Pipeline Update</b>	Peter Kiener, D. Phil
<b>Financial Performance</b>	Andrew Smith
<b>Closing Remarks</b>	Peter Greenleaf

# Forward-Looking Statements

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# Q2 2015 Corporate Update



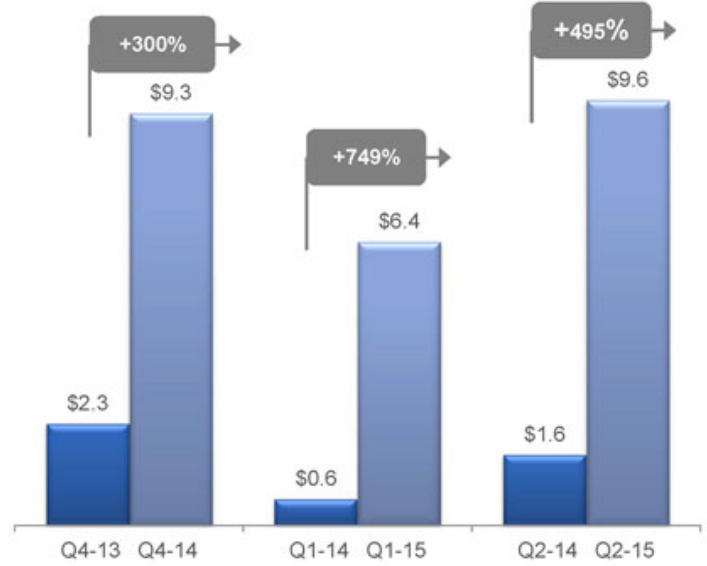
**Peter Greenleaf**  
*Chief Executive Officer*

# Outstanding Revenue and Earnings Growth

Revenue Growth



Earnings Growth



## Raising 2015 Guidance

- \$30 - \$35M for net income
- \$0.65 - \$0.75 per diluted share

In millions of USD

## Continued Financial Performance

### Significant gains drove strong financial performance

- Overall revenue grew 45%
- Product royalty revenue grew 16%
- Product sales revenue grew 92%

### Net income and EPS

- Net income: \$9.6M, increased 495%
- EPS: \$0.21, increased 425%

## U.S. AMITIZA Performance

### Takeda AMITIZA net sales\*

- Increased 15% to \$88.2M

### Sucampo AMITIZA revenue

- Royalty revenue grew 16%

### AMITIZA prescriptions

- 363,000 TRX's, increased 10%
- New Rx grew 13%
- Highest quarter of prescriptions since launch

### Constipation category grew 7%

\*Reported by Takeda, for royalty calculation purposes



## Japan AMITIZA Performance

### Sucampo revenue

- Sales grew 101% to \$14.5M

### Mylan committed to brand growth

- Significant detailing levels
- Brand “launch”

# AMITIZA Globally

## Asia

- Entered into exclusive agreement with Harbin Gloria Pharmaceuticals for AMITIZA in China
- June: Acceptance of IND for AMITIZA in CIC by the CFDA
- Recognized \$1.5M upfront payment

## Europe

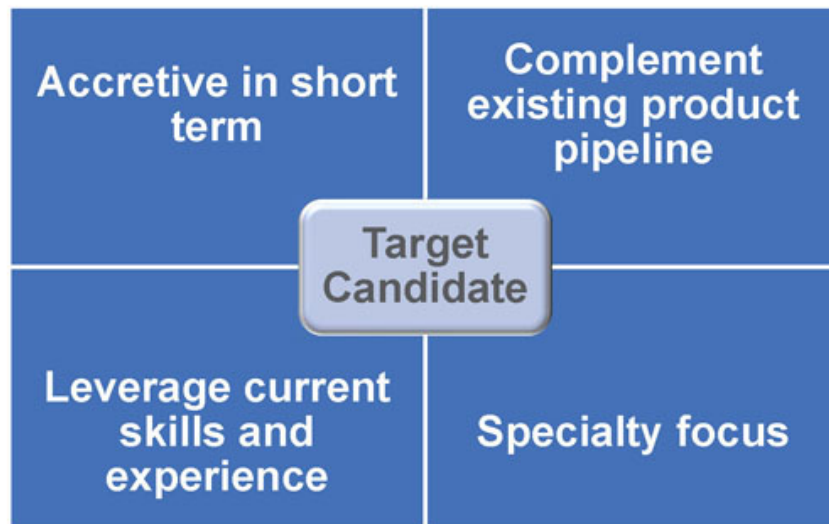
- Austria, Germany and Italy issued NMA
- Ireland, Luxembourg, the Netherlands and Belgium have already issued NMA
- Spain expected to issue in 2H15

## ROW

- Takeda actively working on dossier development for markets in Latin America, Middle East and Asia
- Expect NDA decision in Canada by 2H15
- Regulatory approval in Israel in 1H16

# Evaluation of External Assets

## Assessment of external programs ongoing



# Pipeline Update



**Peter Kiener, D. Phil**  
*Chief Scientific Officer*

## Pediatric Functional Constipation (PFC) 6-17 Years

Enrollment continues at development sites across the U.S., Europe in single pivotal clinical trial

Data expected in 1H16

Expect to file NDA in 2H16

## AMITIZA Alternate Formulation & PFC 6 Mos–6 Yrs

### Expect to initiate P3 study in adult CIC patients in 2H15

- Data expected in 1H16
- Expect to file NDA in 2H16

### Single pivotal trial in children (6 months–6 years) to commence once alternate formulation is available

- Expect to initiate in 1H16
- Expected follow on open-label study to commence in 2H16

## Cobiprostone for PPI-Refractory NERD/GERD

### Phase 2 study underway

- 140-person randomized, double-blind, placebo-controlled, multicenter study
- 14 week study comprising a total of 8 weeks of treatment

**Expect to announce top-line data in 1H16**

## Cobiprostone for Oral Mucositis

U.S. FDA Fast Track Designation granted in May

FDA accepted IND application for P2a clinical trial

Expect dosing of patients soon

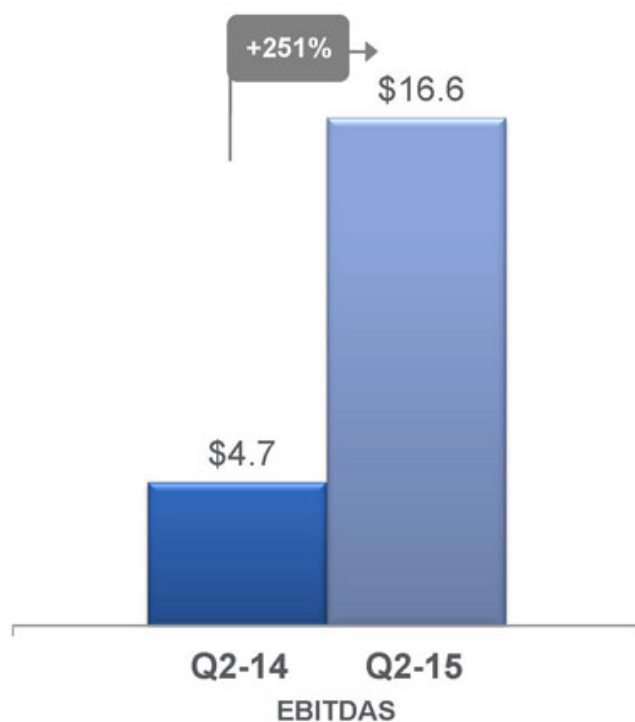


# Q2 Performance Update



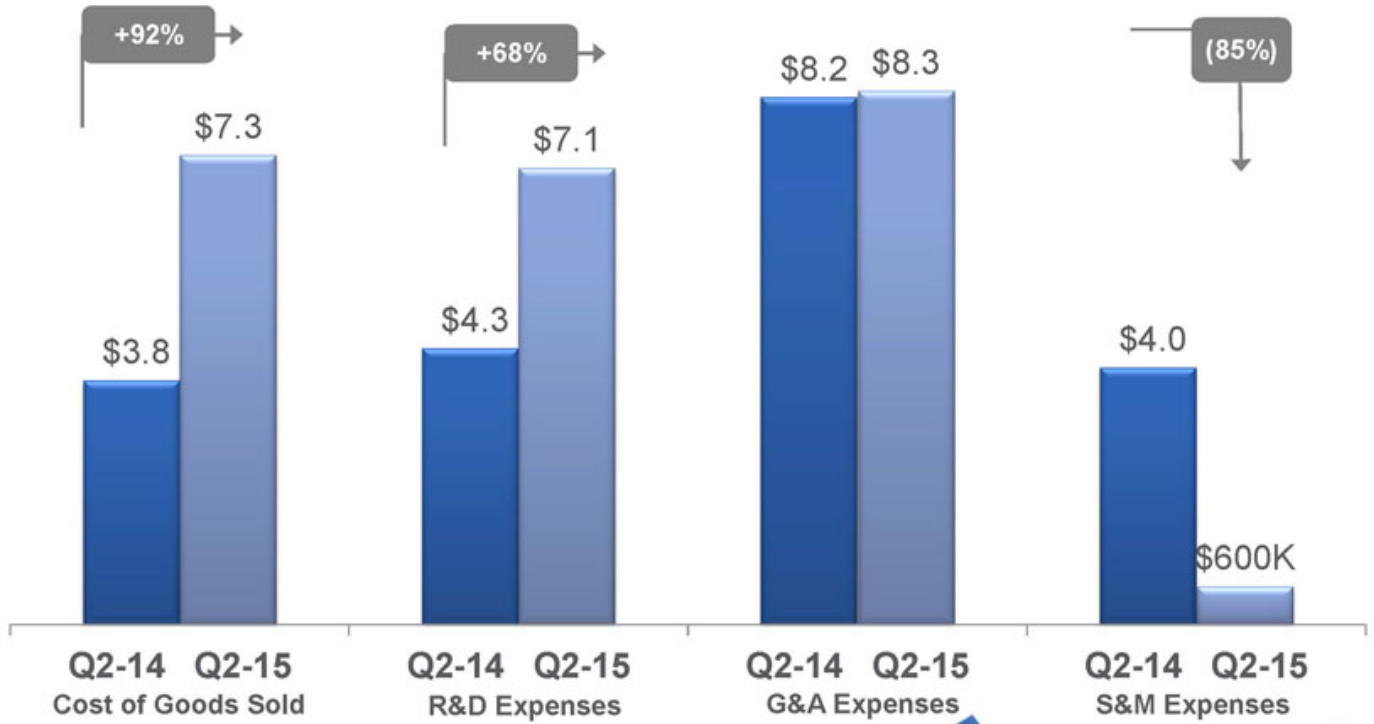
**Andrew Smith**  
*Chief Financial Officer*

## Significant Non-GAAP Earnings Growth



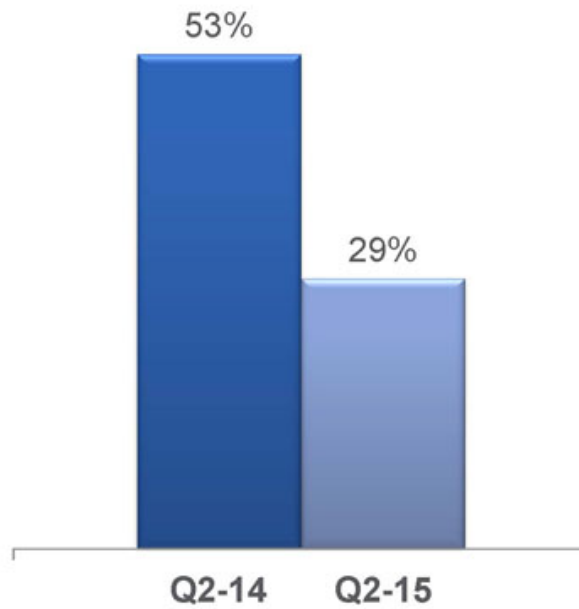
In millions of USD

# Expense Highlights



In millions of USD

## Improvements in Effective Tax Rate



## Strong Balance Sheet

Item	As of 06/30/15	Change	As of 06/30/14
Cash, Cash Equivalents, Restricted Cash and Investments	\$127.7M	\$24.1M	\$103.6M
Notes Payable	(\$21.7M)	\$27.8M	(\$49.5M)
Cash, Cash Equivalents, Restricted Cash and Investments, net of Debt	\$106.0M	\$51.9M	\$54.1M

Item	Six Months Ending 06/30/15	Increase	Six Months Ending 06/30/14
Cash Flow from Operations	\$15.1M	\$11.0M	\$4.1M

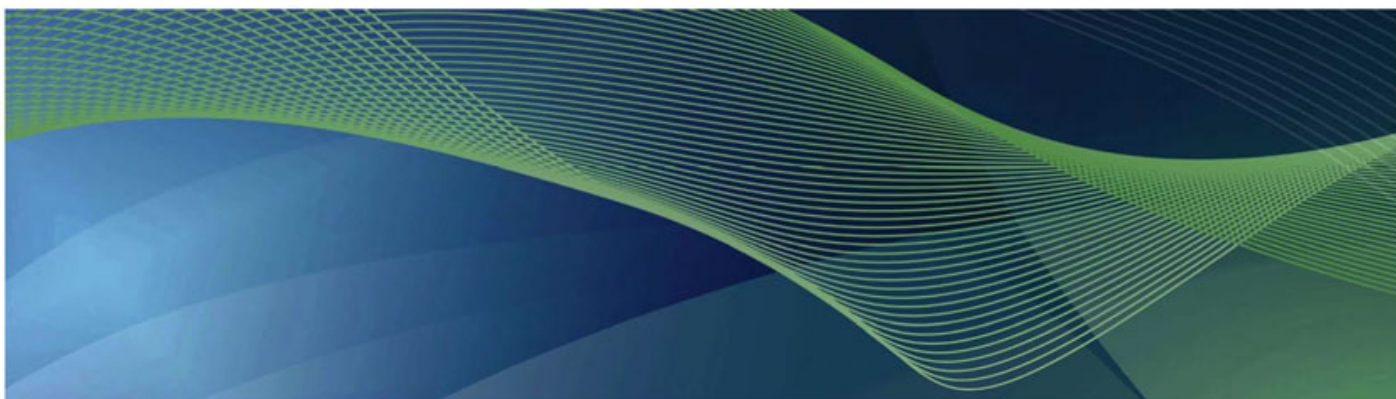
# Conclusion



**Peter Greenleaf**  
*Chief Executive Officer*

## Continuing to Make Progress on 2015 Expectations

- ✓ Outstanding financial performance
- ✓ Advancing our pipeline
- ✓ Evaluating opportunities for long-term growth



# Q & A

