## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

#### 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): November 9, 2016

#### Sucampo Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

**Delaware** 

(State or other jurisdiction of incorporation)

001-33609

(Commission File Number)

<u>30-0520478</u>

(IRS Employer Identification No.)

805 King Farm Blvd, Suite 550 Rockville, Maryland 20850

(Address of principal executive offices, including zip code)

(301) 961-3400

(Registrant's telephone number, including area code)

N/A

(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:

- [] 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))

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

On November 9, 2016, Sucampo Pharmaceuticals, Inc. ("the Company") announced its consolidated financial results for the third quarter ended September 30, 2016. 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"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

#### Item 7.01 Regulation FD Disclosure.

On November 9, 2016, the Company will host a conference call with investors to discuss the Company's financial and operating results for the third quarter ended September 30, 2016. 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 November 9, 2016.
- 99.2 The corporate update presentation slides dated November 9, 2016.

#### 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: November 9, 2016 By: /s/ Andrew P. Smith

Name: Andrew P. Smith Title: Chief Financial Officer

#### **Sucampo Reports Third Quarter 2016 Financial Results**

Results Driven by 73% Growth in Revenue

GAAP EPS Growth of 12%; Adjusted EPS Growth of 58%

Company Raises 2016 Guidance and Provides Preliminary 2017 Guidance

Announces Settlement with Dr. Reddy's Laboratories for AMITIZA

Reports Phase Three Results for AMITIZA in Pediatric Population

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

ROCKVILLE, Md., Nov. 09, 2016 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ:SCMP), a global biopharmaceutical company, today reported consolidated financial results for the third quarter ended September 30, 2016. The company also highlighted important corporate updates.

<b>Summary of Results</b>	Q3-16	% Increase / (Decrease) over Q3-15
Revenue	\$57.9M	73%
Net Income GAAP	\$8.1M	12%
EPS GAAP – diluted	\$ 0.19	19%
EBITDA	\$35.6M	197%
Adjusted Net Income	\$12.4M	58%
Adjusted EPS – diluted	\$ 0.28	68%
Adjusted EBITDA	\$28.8M	97%

#### **Key Updates**

- Recently completed a settlement and license agreement with Dr. Reddy's Laboratories, Ltd. and certain of its affiliates (Dr. Reddy's) that resolves patent litigation in the United States related to Sucampo's AMITIZA (lubiprostone) 8 mcg and 24 mcg soft gelatin capsules. The agreement provides for an entry date more than six years from today's date and profit sharing on product sales by Dr. Reddy's.
- A phase 3 trial of AMITIZA in pediatric functional constipation in children six to seventeen years of age did not achieve its primary
  endpoint of overall spontaneous bowel movement (SBM) response. However, the trial did show a trend in favor of lubiprostone for
  the primary endpoint, and achieved statistical significance in some secondary endpoints, notably overall SBM frequency, straining,
  and stool consistency. Clinical development of AMITIZA with a sprinkle formulation and phase three trials in adults and children
  six months to less than six years of age using the sprinkle formulation will continue as planned.
- Increased adjusted 2016 guidance as follows: revenue guidance to \$220-225 million, adjusted net income guidance to \$50-55 million, adjusted EPS guidance to \$1.20-1.25, and adjusted EBITDA guidance to \$110-115 million.

"We are very excited that we have achieved another significant quarter of strong financial results, driven by solid global performance of our flagship brand, AMITIZA. Additionally, we continued to make significant progress on many important areas of our business, including the resolution of our patent litigation with Dr. Reddy's Laboratories that affords us greater certainty on the significant future value of the AMITIZA franchise, "said Peter Greenleaf, Chairman and Chief Executive Officer of Sucampo. "Looking forward to the remainder of 2016 and throughout 2017, we will be focused on the execution of our base business, next steps in our phase three program for AMITIZA in pediatric functional constipation and development of a sprinkle formulation, and completion of strategic transactions to further boost growth and diversify our company."

For the three months ended September 30, 2016, Sucampo reported year-over-year total revenue growth of 73% to \$57.9 million. Product sales revenue increased to \$31.6 million, representing 186% year-over-year growth, and product royalty revenue grew 7% year-over-year to \$20.8 million. Revenue for the quarter included an additional \$13.3 million because of the R-Tech Ueno acquisition. Excluding this additional revenue from the acquisition, base revenue grew by 33%.

Sucampo reported a GAAP net income of \$8.1 million, or \$0.19 per diluted share during the third quarter of 2016 compared to GAAP net income of \$7.2 million, or \$0.16 per diluted share, during the third quarter of 2015, an increase of 12% and 19% respectively. On an adjusted basis, Sucampo reported net income of \$12.4 million, or \$0.28 per diluted share, during the third quarter of 2016, compared to net income of \$7.8 million, or \$0.17 per diluted shares, during the third quarter of 2015, an increase year-over-year of 58% and 68% respectively.

#### Third Quarter 2016 Operational Review

#### **AMITIZA**

**Corporate** 

• Sucampo Pharmaceuticals, Inc., together with certain of its affiliates and Takeda Pharmaceutical Company Limited (Takeda) and certain of its affiliates, have entered into a settlement and license agreement with Dr. Reddy's and certain of its affiliates that resolves patent litigation in the United States related to AMITIZA 8 mcg and 24 mcg soft gelatin capsules.

Under the terms of the settlement and license agreement, Sucampo is granting Dr. Reddy's a non-exclusive license to market a generic version of lubiprostone in the United States beginning more than six years from today's date, or earlier under certain circumstances. Dr. Reddy's would pay to Sucampo a share of net profits of generic lubiprostone products sold during the term of the agreement, which decreases over time and ends when all of the related patents have expired. Dr. Reddy's may elect to purchase generic lubiprostone products from Sucampo under the terms of a manufacturing and supply agreement at a negotiated price.

Sucampo, Takeda and Dr. Reddy's have agreed to dismiss with prejudice the patent litigation filed in the U.S. District Court for the Southern District of New Jersey.

#### **United States**

• AMITIZA total prescriptions were 374,194 in the third quarter of 2016, as reported by IMS, a decrease of 1.4% compared to the third quarter of 2015. For the first nine months of 2016, AMITIZA total prescriptions were 1,103,778, an increase of 2% compared to the first nine months of 2015. Net sales of AMITIZA, reported by Takeda Pharmaceuticals U.S.A., Inc. (Takeda) for royalty calculation purposes, increased 7% to \$108.8 million for the third quarter of 2016, compared to \$101.7 million in the same period of 2015. Royalty revenue was \$20.8 million compared to \$19.3 million, an increase of 7%. Also included in third quarter revenue are Takeda AMITIZA sales from R-Tech Ueno of \$10.9 million.

#### Global Markets

• In Japan, Sucampo's revenue from sales of AMITIZA to Mylan N.V. was \$17.4 million for the third quarter of 2016, compared to \$10.3 million in the same period of 2015, an increase of 69%. Unit volume as reported by Mylan grew more than 40% through the first nine months of 2016 compared to the first nine months of 2015, to 89.3 million units versus 62 million units in 2015.

#### **Research and Development**

- A phase 3 trial of AMITIZA in pediatric functional constipation in children six to seventeen years of age did not achieve its primary endpoint of overall spontaneous bowel movement (SBM) response. However, the trial did show a trend in favor of lubiprostone for the primary endpoint, and achieved statistical significance in some secondary endpoints, notably overall SBM frequency, straining, and stool consistency. In this study, tolerability of lubiprostone was consistent with the safety profile in adults. Sucampo will first review these results with the U.S. Food and Drug Administration and then will announce next steps at the completion of this review. Sucampo intends to initiate enrollment in its clinical development program of the sprinkle formulation of AMITZA in adults by the end of 2016 as planned. After completion of this sprinkle formulation program in adults, a further consultation with the FDA so as to better determine the doses and endpoints that should be studied in the younger pediatric population will follow, aiming at initiation of a phase three program in children 6 months to six years of age using the sprinkle formulation in mid 2017.
- Following a detailed review of the program, Sucampo has made the decision to discontinue development of RTU-1096, a compound in its vascular adhesion protein (VAP-1) inhibitor program.

#### Third Quarter 2016 Financial Review

- On a GAAP basis, Sucampo reported net income of \$8.1 million and a diluted EPS of \$0.19 during the third quarter of 2016, compared to net income of \$7.2 million and diluted EPS of \$0.16 in the same period in 2015. Adjusted net income was \$12.4 million, or \$0.28 per diluted share, during the third quarter of 2016, compared to net income of \$7.8 million, or \$0.17 per diluted share.
- EBITDA was \$35.6 million for the third quarter of 2016 compared to EBITDA of \$11.9 million for the same period in 2015, an increase of 196%. Adjusted EBITDA, defined as net income before interest, taxes, depreciation, amortization, stock-based compensation expense, restructuring and intangible impairment, was \$28.8 million for the third quarter of 2016 compared to \$14.6 million in the same period in 2015, an increase of 97%.
- Total revenues were \$57.9 million for the third quarter of 2016 compared to \$33.4 million in the same period in 2015, an increase of \$24.4 million or 73%. The increase was primarily due to the inclusion of R-Tech Ueno results and increased royalty related revenues from Takeda.
- Cost of goods sold were \$15.6 million for the third quarter of 2016 compared to \$5.3 million for the same period in 2015, an increase of \$10.3 million or 195%. The increase was primarily due to the inclusion of R-Tech Ueno results, acquired intangible asset amortization and increased product sales. Excluding intangible asset amortization of \$6.7 million, cost of goods sold was \$8.9 million.
- Gross margin, calculated as product sales revenue less cost of goods sold as a percentage of product sales revenue, was 50.6% for the third quarter of 2016, compared to 52.0% for the same period in 2015, a decrease of 3%. The decrease was primarily due to intangible asset amortization. Excluding the intangible asset amortization, gross margin was 71.8%, an increase of 38%. This increase is due to the inclusion of R-Tech Ueno results and the realization of the economics resulting from the acquisition.
- Research and development expenses were \$10.0 million for the third quarter of 2016 compared to \$8.4 million for the same period of 2015, an increase of \$1.6 million or 19%. The increase was primarily due to increased spending on lubiprostone pediatric studies,

as well as the inclusion of R-Tech Ueno.

- In connection with the discountinuation of the VAP-1 Inhibitor development program, the Company has impaired the related in process research and development assets and recognized a one time non-cash write-down of \$7.3 million in the third quarter of 2016, compared to \$0.0 for the prior year period. The Company has adjusted for this one time charge in the results from operations.
- General and administrative expenses were \$11.1 million for the third quarter of 2016 compared to \$7.8 million for the same period of 2015, an increase of \$3.3 million or 42%. The increase was primarily due to legal costs associated with the Dr. Reddy's settlement, RTU intregration costs, restructuring related costs and the inclusion of RTU.
- Selling and marketing expenses were \$0.7 million for the third quarter of 2016 compared to \$0.4 million for the same period of 2015. Fluctuation was due to the inclusion on R-Tech Ueno related commercial activities.
- Included in other income during the quarter is a one-time gain of \$9.3 million related to the termination of a loan from the Japan Agency for Medical Research & Development (AMED) for development of unoprostone, which was discontinued in early 2015.
- The effective tax rate for the third quarter of 2016 was 47.8%, compared to 37.5% in the same period of 2015. The increase 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 net income, 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 September 3			
	2016			2015
Adjusted Non-GAAP Income				
GAAP net income		8,092		7,205
Amortization Intangibles		6,672		-
Intangible Impairment		7,286		-
Legal Settlement		(9,260)		-
Restructuring Costs		208		-
Acquisition Related Expenses		605		943
Amortization of Financing Costs		875		-
Tax Effect of Adjustments		(2,107)		(313)
Adjusted Net Income		12,371		7,835
Adjusted Net Income Per Share:				
Diluted	\$	0.28	\$	0.17
		2016		2015
EBITDA				
GAAP net income		8,092		7,236
Income Tax Provision		7,410		4,327
Interest income		(31)		(30)
Interest payable		5,899		243
Depreciation		223		201
Amortization of Acquired Intangibles		6,672		-
Intangible Impairment		7,286		_
EBITDA		35,551		11,977
Non-GAAP Adjustments Share Based Compensation Expense		1,722		1,718
Restructuring Costs		208		1,/10
Acquisition Related Expenses		605		943
Legal settlement		(9,260)		5 <del>4</del> 5
Adjusted EBITDA		28,826		14,638
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Consolidated Statements of Operations and Comprehensive Income (unaudited)

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

At September 30, 2016, cash, cash equivalents, restricted cash and investments were \$153.7 million compared to \$163.5 million at
December 31, 2015. This change is primarily due to payments of the outstanding notes and related interest, offset by an increase in
cash flow from operating activities. At September 30, 2016 and December 31, 2015, notes payable were \$218.7 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 September 30, 2016 is \$65 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 September 30, 2016 and 2015 were as follows

	Three months ended September 30, 2016				Three m	onths end	led September	30, 2015
			Rest of the	_			Rest of the	
(In thousands)	USA	Japan	World	Total	USA	Japan	World	Total
AMITIZA Product sales	10,919	17,422	792	29,133	-	10,286	-	10,286
AMITIZA Royalty	20,770	-	-	20,770	19,327	-	-	19,327
Rescula Product Sales	21	2,400	-	2,421	736	-	-	736
Total	31,710	19,822	792	52,324	20,063	10,286		30,349

#### Guidance

Sucampo today raised its earnings guidance for the full year ending December 31, 2016. Sucampo now expects total revenue of \$220.0 million to \$225.0 million, adjusted net income of \$50.0 million to \$55.0 million, adjusted EPS of \$1.20 to \$1.25, and adjusted EBITDA of \$110.0 million to \$115.0 million. Adjusted net income guidance excludes amortization of acquired intangibles of approximately \$17.6 million, restructuring related costs of \$1.9 million, debt financing related costs of \$3.5 million, CPP option related expenses of \$7.5 million, amortization of the remaining inventory step-up costs of approximately \$8.9 million, intangible asset impairment expense of \$7.3 million and one time gains associated with a legal settlement of \$9.3 million. Adjusted EBITDA guidance excludes stock option related expenses of \$7.3 million, one time restructuring related costs of \$1.9 million and CPP option related expenses of \$7.5 million. Guidance includes a one-time \$10.0 million milestone in the fourth quarter of 2016 related to the achievement of sales milestone from Mylan related to sales of AMITIZA in Japan.

See the table below for a comparison of the Company's previous 2016 guidance to the updated 2016 guidance:

Measure	Previous 2016 Guidance	Updated 2016 Guidance
Total Revenue	\$195.0 million to \$205.0 million	\$220.0 million to \$225.0 million
Adjusted Net Income	\$45.0 million to \$50.0 million	\$50.0 million to \$55.0 million
Adjusted EPS	\$0.97 to \$1.07	\$1.20 to \$1.25
Adjusted EBITDA	\$100.0 million to \$105.0 million	\$110.0 million to \$115.0 million

Sucampo is also providing preliminary earnings guidance for the full year ending December 31, 2017. Sucampo expects total revenue of \$220.0 million to \$230.0 million, adjusted net income of \$75.0 million to \$85.0 million, and adjusted EBITDA of \$145.0 million to \$155.0 million. Adjusted net income guidance excludes amortization of acquired intangibles of approximately \$22.58 million and debt financing related costs of \$3.1 million. Adjusted EBITDA guidance excludes stock option related costs of \$6.0 million.

#### Non-GAAP Financial Measures

This press release contains non-GAAP earnings and adjusted EBITDA 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, November 9, 2016 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: 94640075

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

Conference call replay:

Dates: Starting at 11:30 AM ET, November 9, 2016 a replay of the teleconference and webcast will be available

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

Passcode: 94640075

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

#### About AMITIZA® (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. and Israel 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. and Israel 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. 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.

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 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 financial results, 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 (unaudited)**

(in thousands, except per share data)

(In thousands, except per share data)	Three	e Months En	ded S	eptember 30,	Nin	e Months End	led Se	ptember 30,
		2016		2015		2016		2015
Revenues:								
Product royalty revenue	\$	20,771	\$	19,328	\$	56,222	\$	51,209
Product sales revenue		31,554		11,022		86,538		36,678
Research and development revenue		3,172		2,714		9,971		7,468
Contract and collaboration revenue		2,376		384		4,301		2,457
Total revenues		57,873		33,448		157,032		97,812
Costs and expenses:								
Costs of goods sold		15,586		5,286		59,278		18,656
Research and development		9,976		8,368		35,580		22,285
Impairment of in-process research and development		7,286		-		7,286		-
General and administrative		11,061		7,752		32,411		22,363
Selling and marketing		696		385		2,094		1,617
Total costs and expenses		44,605		21,791		136,649		64,921
Income from operations Non-operating income (expense):		13,268		11,657		20,383		32,891
Interest income		31		62		67		155
Interest expense		(5,899)		(243)		(18,141)		(784)
Other income, net		8,102		87		5,216		1,947
Total non-operating income (expense), net		2,234		(94)		(12,858)		1,318
Income before income taxes		15,502		11,563		7,525		34,209
Income tax provision		(7,410)		(4,327)		(4,321)		(10,989)
Net income	\$	8,092	\$	7,236	\$	3,203	\$	23,220
Net income per share:								
Basic	\$	0.19	\$	0.16	\$	0.08	\$	0.52
Diluted	\$	0.19	\$	0.16	\$	0.07	\$	0.51
Weighted average common shares outstanding:	Ψ	0.13	Ψ	0.10	Ψ	0.07	Ψ	0.51
Basic		42,813		44,731		42,704		45,576
Diluted		43,443		46,309		43,334		45,939
Comprehensive income								
Net income	\$	8,092	\$	7,236	\$	3,203	\$	23,220
Other comprehensive income (expense):	Ψ	0,032	Ψ	,,250	Ψ	3,203	Ψ	20,220
Unrealized gain on pension benefit obligation		12		57		37		38
Unrealized gain (loss) on investments, net of tax effect		-		(6)		-		6
Foreign currency translation gain	-	4,635		264		40,890		102
Comprehensive income	\$	12,739	\$	7,551	\$	44,130	\$	23,366
Comprehensive income	Ψ	14,700	Ψ	,,,,,,,	Ψ	77,100	Ψ	20,000

#### Sucampo Pharmaceuticals, Inc.

#### **Consolidated Balance Sheets (unaudited)**

(in thousands, except share and per share data)

(in thousands, except share and per share auta)	September 30 2016	), December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 128,465	\$ 108,284
Product royalties receivable	20,771	22,792
Accounts receivable, net	20,684	22,759
Restricted cash	25,213	55,218
Inventories	24,202	33,121

Prepaid expenses and other current assets		18,146	 9,186
Total current assets		237,481	251,360
Property and equipment, net		6,563	6,393
Intangible assets		134,886	130,315
Goodwill		73,022	60,937
In-process research and development		-	6,171
Deferred charge, non-current		1,400	1,400
Convertible note receivable		5,182	-
Other assets	_	1,030	 605
Total assets	\$	459,564	\$ 457,181
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$	7,869	\$ 11,213
Accrued expenses		14,380	10,886
Collaboration obligation		1,438	5,623
Income tax payable		16,587	6,507
Notes payable, current		21,730	39,083
Other current liabilities		4,805	14,815
Total current liabilities		66,809	 88,127
Notes payable, non-current		196,984	213,277
Deferred revenue, non-current		913	1,088
Deferred tax liability, net		41,757	52,497
Other liabilities		8,291	15,743
Total liabilities		314,754	 370,732
Preferred stock, \$0.01 par value; 5,000,000 shares authorized at September 30, 2016 and December 31,			
2015; no shares issued and outstanding at September 30, 2016 and December 31, 2015		-	-
Class A common stock, \$0.01 par value; 270,000,000 shares authorized at September 30, 2016 and			
December 31, 2015; 45,828,775 and 45,509,150 shares issued and outstanding at September 30, 2016 and		450	455
December 31, 2015, respectively		458	455
Class B common stock, \$0.01 par value; 75,000,000 shares authorized at September 30, 2016 and December 31, 2015; no shares issued and outstanding at September 30, 2016 and December 31, 2015		-	-
Additional paid-in capital		113,440	99,212
Accumulated other comprehensive income		54,339	13,412
Treasury stock, at cost; 3,009,942 shares at September 30, 2016 and December 31, 2015		(46,269)	(46,269)
Retained earnings		22,842	 19,639
Total stockholders' equity		144,810	 86,449
Total liabilities and stockholders' equity	\$	459,564	\$ 457,181

Contact:

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



# Third Quarter 2016 Corporate Update and Financial Results

November 9, 2016

## Introductions and Forward-Looking Statements

Silvia Taylor, SVP Investor Relations & Corporate Affairs



Introductions and Forward-Looking Statements	Silvia Taylor
Corporate Update	Peter Greenleaf
Pipeline Update	Peter Lichtlen, M.D., Ph.D.
Financial Update	Andrew Smith
Closing Remarks	Peter Greenleaf

### Forward Looking Statement



This presentation contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, 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.

## Q3 2016 Corporate Update

Peter Greenleaf, Chairman and CEO

## Continued Financial and Operational Performance



- Strong financial performance driven by global performance of AMITIZA
  - Increased guidance for 2016
  - Preliminary 2017 guidance
- Resolution of AMITIZA patent litigation with Dr. Reddy's Laboratories
- · Results from Phase 3 trial of AMITIZA in children 6 to 17 years of age

#### Solid Overall Q3 Financial Results



#### REVENUE

- Overall revenue grew 73% YoY to \$57.9M
  - Increased royalties for AMITIZA in the U.S.
  - Sales of AMITIZA in Japan
  - Inclusion of RTU results
- Revenue grew 33% when excluding \$13.3M RTU-related revenue

### **EARNINGS\***

Summary of Results	Q3-16	% Increase/ (Decrease) over Q3-15
Net Income GAAP	\$8.1M	12%
EPS GAAP - diluted	\$0.19	19%
EBITDA	\$35.6M	197%
Adjusted Net Income*	\$12.4M	58%
Adjusted EPS – diluted*	\$0.28	68%
Adjusted EBITDA**	\$28.8M	97%

<sup>\*</sup>Adjusted figures exclude non-cash , one time items, and items associated with RTU acquisition

<sup>\*\*</sup> Adjusted EBITDA includes stock-based compensation expenses and other one time items

## Strong U.S. AMITIZA Performance



- Takeda's AMITIZA net sales for royalty calculation purposes
  - Q3 grew 7% YoY to \$109M
- Royalty revenue grew 7% YoY to \$21M
  - Driven by price increase in January 2016 and volume
- U.S. AMITIZA product sales to Takeda of \$10M
- Total U.S. revenue of \$32M
- AMITIZA TRX
  - Q3 IMS: ~374,000 TRx, decrease of 1.4% YoY
  - 9 months of 2016 IMS: TRx growth of 2% YOY

## Expected AMITIZA U.S. Growth Drivers



- Key formulary wins (effective 1/1/17):
  - · Added back to CVS Caremark preferred formulary
  - · Elevated to High Performance formulary status for Express Scripts
  - · Additional key formulary wins
- Highly-targeted DTC television campaign in select key markets
  - Launched earlier in October

## Japan AMITIZA Performance



- Sucampo Q3 revenue: \$17.4M, growth of 69% YoY
- · Driven by volume
  - Increased by more than 40% for first nine months of 2016
- Growth drivers:
  - Strong market growth
  - Only branded constipation prescription medicine
  - Broad label of constipation

#### 2016 Guidance Increased



Total revenue: \$220 million to \$225 million

Adjusted net income: \$50 million to \$55 million

Adjusted EPS: \$1.20 to \$1.25

Adjusted EBITDA: \$110 million to \$115 million

Adjusted net income guidance excludes amortization of acquired intangibles of approximately \$17.6 million, restructuring related costs of \$1.9 million, debt financing related costs of \$3.5 million, CPP option related expenses of \$7.5 million, amortization of the remaining inventory step-up costs of approximately \$8.9 million, intangible asset impairment expense of \$7.3 million and one time gains associated with a legal settlement of \$9.3 million. Adjusted EBITDA guidance excludes stock option related expenses of \$7.3 million, one time restructuring related costs of \$1.9 million and CPP option related expenses of \$7.5 million. Guidance includes a one-time \$10.0 million milestone in the fourth quarter of 2016 related to the achievement of sales milestone from Mylan related to sales of AMITIZA in Japan.

## Settlement and License Agreement with Dr. Reddy's



- Resolves litigation in U.S. related to AMITIZA
  - Provides much greater certainty on future value of AMITIZA franchise
  - Significantly de-risks AMITIZA business in later years
- Dr. Reddy's granted non-exclusive license to market generic in U.S.
  - Does not begin until more than 6 years from today's date
  - Dr. Reddy's would pay Sucampo a share of net profits of generic lubiprostone products sold
  - Dr. Reddy's may elect to buy generic lubiprostone products from Sucampo
- Follows earlier agreement with Par Pharmaceuticals
  - Dr. Reddy's launch would reduce Sucampo's share of gross profits
- Agreement secures significant portion of initial profit split, ensures continued revenue from both Par and Dr. Reddy's
- Additional profit split arrangement with Takeda for branded product in 2021+



Peter Lichtlen, M.D., Ph.D., CMO

#### Pediatric Phase 3 Results with Current Formulation



- Phase 3 trial of AMITIZA vs. placebo in children 6 to 17 years of age
- Evaluated doses of 12 and 24 mcg over 12 weeks
- · Primary endpoint of overall spontaneous bowel movement (SBM) response
  - Never tested in pediatric population with functional constipation
- Largest trial ever run in pediatric functional constipation
  - Different population versus adult CIC population
- Conducted under PREA commitment

#### Pediatric Phase 3 Results with Current Formulation



- · Did not achieve primary endpoint of overall SBM response
- Did show trend in favor of efficacy
- Achieved statistical significance for key secondary endpoints
  - Overall SBM frequency
  - Straining
  - Stool consistency
- Well-tolerated
- Data warrants continuation of pediatric program and development of sprinkle formulation – subject to discussions with FDA

## Pediatric Phase 3 Results: Next Steps



- Review data with FDA
- Continue clinical development of sprinkle formulation for very young patients and adults who may not be willing or able to take the current formulation
- Initiate Phase 3 program aimed at adult patients with CIC by the end of this year
  - Expect to report results by mid-2017
- Based on positive sprinkle formulation data and discussions with FDA, initiate a phase 3 program in very young children using sprinkle formulation in mid-2017

## Product Pipeline



Program	Target	First Indication	Development Stage	(s)NDA / MAA Filing	Approval
GI/Metabolic/ Inflamation			,	1	
AMITIZA	CIC2	Pediatric functional constipation (6-17 yrs.)	P3	2017	2017
Lubiprostone Sprinkle Formulation	CIC2	Pediatric functional constipation 6 mos- 5 yrs (1); adult CIC (2)	P3	2018(1); 2017 (2)	2019 (1); 2018 (2)
CPP-1X/sulindac combination product	Polyamines	Familial Adeneomatous Polyposis	P3	2018	2019
Other					
RTU-009	Vap-1 inhibitor	Chronic Inflammatory Conditions	Preclinical		

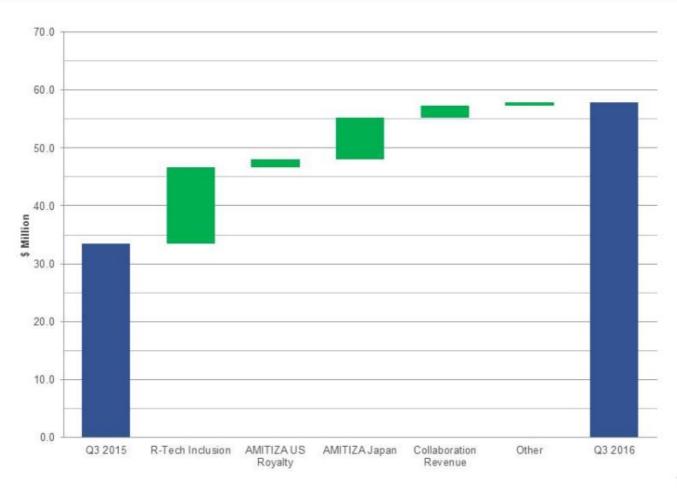
Sucampo Program	RTU Program	Option

## Financial Update

Andrew Smith, CFO

## Q3 Revenue

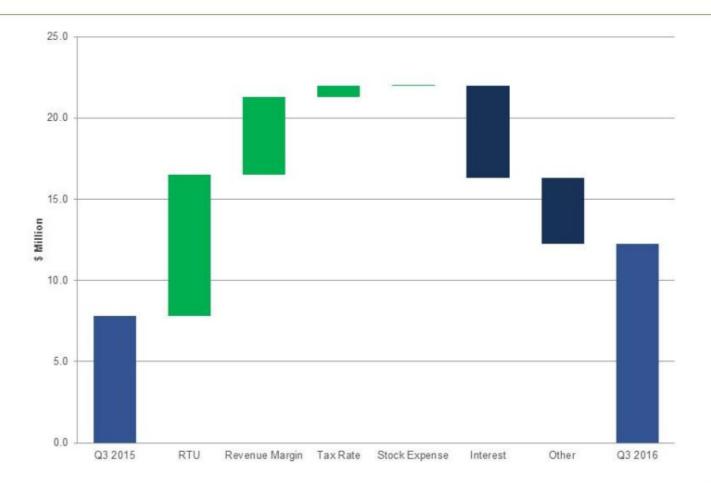




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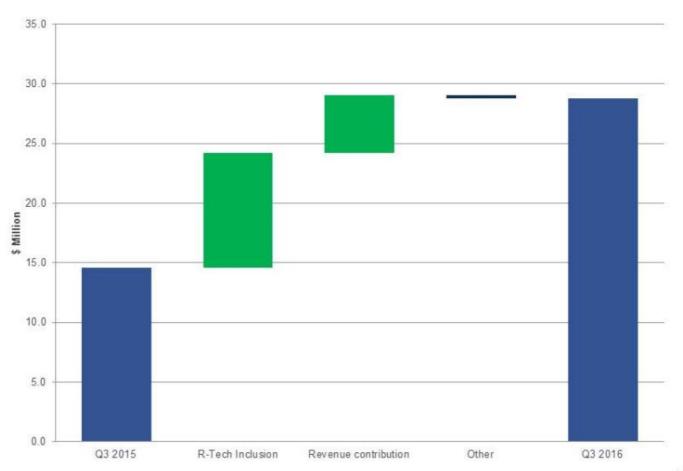
## Q3 Adjusted Net Income





## Q3 Adjusted EBITDA





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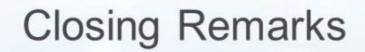
Item	As of 6/30/16	Change	As of 12/31/15
Cash, Cash Equivalents and Restricted Cash	\$153.7M	(\$9.8)	\$163.5M
Notes Payable	(\$218.7M)	\$33.7M	(\$252.4M)
Net Debt	(\$65.0M)	\$23.9M	(\$88.9M)

## 2017 Preliminary Guidance



- Total revenue: \$220 million to \$230 million
- Adjusted net income: \$75 million to \$85 million
- Adjusted EBITDA: \$145 million to \$155 million
- Revenue does not include any milestone payments

Adjusted net income guidance excludes amortization of acquired intangibles of approximately \$22.58 million, debt financing related costs of \$3.1 million. Adjusted EBITDA guidance excludes stock option related costs of \$6.0 million.



Peter Greenleaf, Chairman and CEO

### End of 2016/2017 Areas of Focus



- 1. Deliver outstanding financial performance, both top and bottom line
- Interactions with FDA regarding Phase 3 trial results for AMITIZA in the pediatric population and next steps
- 3. Evaluate and execute on additional opportunities for growth

