

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

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FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): May 7, 2014

Sucampo Pharmaceuticals, Inc.

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(Exact Name of Registrant as Specified in Charter)

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Delaware  
(State or Other Juris-  
diction 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 May 7, 2014, Sucampo Pharmaceuticals, Inc. (“the Company”) announced its consolidated financial results for the quarter ended March 31, 2014. 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 slides from the presentation will be referenced below are incorporated by reference.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, 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 May 7, 2014, the Company will host a conference call with investors to discuss the Company's financial and operating results for the quarter ended March 31, 2014. 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 Exhibits 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 exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

- 99.1 Press Release issued by the Company on May 7, 2014.
  - 99.2 The corporate update presentation slides dated May 7, 2014.
-

SIGNATURE

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

SUCAMPO PHARMACEUTICALS, INC.

Date: May 7, 2014

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and  
Corporate Secretary

## Sucampo Pharmaceuticals, Inc., Reports First Quarter 2014 Financial and Operating Results

### *Strong Financial Performance Driven by Year over Year Income and Revenue Growth*

#### *Company to host conference call today at 5:00 pm Eastern*

BETHESDA, Md., May 7, 2014 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (Nasdaq:SCMP) today reported consolidated financial results for the first quarter ended March 31, 2014. Sucampo reported year over year revenue growth of 31% and fully-diluted earnings per share of \$0.02 during the first quarter of 2014.

"I am pleased with the progress Sucampo made in the first quarter," said Peter Greenleaf, Chief Executive Officer of Sucampo. "Our financial results are solid, with 31% revenue growth year-over-year driven by the continued solid performance of AMITIZA in the U.S. in the face of aggressive competition. Our global expansion efforts also continued, led by an increase of AMITIZA sales in Japan of 177% year over year and solid progress in Europe. Our pipeline assets also showed progress, and we have five compounds in various stages of clinical development. I believe that we have an incredibly strong foundation to build upon, and my priority in the months to come will be completing a comprehensive strategic review of our proprietary technology, our products and our partnerships to create a plan for Sucampo's continued evolution."

#### **First Quarter 2014 Operational Review**

##### AMITIZA

- In the United States (U.S.), AMITIZA<sup>®</sup> (lubiprostone) total prescriptions were 315,828, an increase of 3%, compared to the first quarter of 2013. Net sales of AMITIZA, reported by Takeda Pharmaceuticals U.S.A., Inc. (Takeda) for royalty calculation purposes, increased 16% to \$75.0 million in the first quarter of 2014, compared to \$64.9 million in the same period of 2013.
- In Japan, Sucampo's revenue from sales of AMITIZA to Abbott was \$6.1 million, an increase of \$3.9 million compared to the first quarter of 2013.
- In Switzerland, the Bundesamt für Gesundheit revised several reimbursement limitations, allowing all Swiss physicians to prescribe AMITIZA and increasing its maximum treatment duration from 12 to 52 weeks. We are awaiting a decision by Swissmedic on our application for adding opioid-induced constipation (OIC) to our label.
- In the United Kingdom (U.K.), the National Institute for Health and Care Excellence submission for chronic idiopathic constipation (CIC) was completed in the first quarter of 2014. Additionally, the Medicines and Healthcare Products Regulatory Agency did not approve the OIC indication. Sucampo is exploring all available options for a path forward.

##### Research and Development

- The first patients were enrolled into a follow-on safety extension study of a global phase 3 clinical trial of lubiprostone in patients 6 to 17 years of age for pediatric functional constipation.
- The new drug application for the liquid formulation of lubiprostone will not be filed in the second half of 2014, as the U.S. Food and Drug Administration will require additional data to characterize pharmacokinetics (PK) of the new formulation. Additionally, a pharmacodynamics, PK and tolerability study of the reformulation showed directional improvement, but not statistical significance, in spontaneous bowel movement frequency. Takeda has agreed to fund 100% of the cost for additional reformulation work for lubiprostone.
- Results from a phase 1b trial evaluating the safety and PK of an oral spray formulation of cobiprostone, a compound in clinical development for the prevention and/or treatment of oral mucositis, showed that cobiprostone was well-tolerated overall and had low systemic exposure. The next phase of clinical development, a phase 2a trial, is expected to begin in the second half of 2014.
- A phase 1b study to evaluate the safety and PK of an orally administered ion channel activator was initiated. This compound is in clinical development for lumbar spinal stenosis (LSS), a degenerative disease of the lumbar spine. This trial is expected to conclude in the third quarter of 2014.
- In May, "*Efficacy of lubiprostone for the treatment of opioid-induced constipation according to opioid class*" (Webster et al.) was presented at the American Pain Society Conference, and five abstracts on lubiprostone were presented at Digestive Disease Week.
- "*A Randomized Study of Lubiprostone for Opioid-Induced Constipation in Patients with Chronic Noncancer Pain*" (Cryer et al.), outlining results from one of the well-controlled, pivotal studies of AMITIZA conducted in support of the OIC indication, was published online in the medical journal, *Pain Medicine*.

##### Corporate

- On March 3, Peter Greenleaf joined as Chief Executive Officer (CEO) and Board member, replacing Ryuji Ueno, M.D., Ph.D., Ph.D., who resigned as CEO, Chairman, Chief Scientific Officer, and Board member in March.
- Dan Getman, Ph.D., became Chairman of the Board.

- Today, Sucampo received the District Court's favorable ruling adopting our claim construction of one term and the parties agreed to construction of two other terms after the March 31<sup>st</sup> *Markman* hearing in our patent infringement lawsuit against Anchen Pharmaceuticals, Inc., Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc., which involves our marketed product, AMITIZA.

## **First Quarter 2014 Financial Review**

- Net income was \$0.7 million, or \$0.02 per diluted share, compared to a net loss of \$3.1 million, or \$0.08 per diluted share, in the same period in 2013.
- Total revenues were \$22.2 million compared to \$16.9 million in the same period in 2013, an increase of 31%. The increase was primarily due to the higher royalty revenue on AMITIZA net sales in the U.S. and the growth of AMITIZA sales in Japan, partially offset by lower reimbursements from Takeda on our clinical development studies.
- Cost of goods sold were \$3.5 million compared to \$1.3 million for the same period of 2013. The increase was primarily due to greater volume of AMITIZA sales in Japan.
- R&D expenses were \$5.1 million compared to \$5.6 million for the same period of 2013, a decrease of 9%. The decrease was primarily due to the conclusion of our lubiprostone liquid formulation clinical trial, lower costs associated with our LSS trials, as well as our terminated collaboration agreement with Numab AG.
- G&A expenses were \$7.3 million compared to \$7.2 million for the same period of 2013. The increase includes legal fees from prosecuting our patent infringement lawsuit filed in February 2013, partially offset by reduced pharmacovigilance costs.
- Selling & Marketing expenses were \$3.6 million compared to \$5.4 million for the same period of 2013, a decrease of 32%. The decrease was primarily due to RESCULA<sup>®</sup> (unoprostone isopropyl) launch costs in last year's first quarter that did not reoccur in the first quarter of 2014.

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

At March 31, 2014, cash, cash equivalents, restricted cash and investments were \$106.0 million compared to \$95.9 million at December 31, 2013. At March 31, 2014, notes payable were \$53.2 million, compared to \$52.7 million at December 31, 2013, including current notes payable of \$27.3 million at March 31, 2014 and \$26.9 million at December 31, 2013.

## Stock Repurchase Plan

During the first quarter of 2014, Sucampo made no share repurchases under this program. Since inception, Sucampo has repurchased approximately \$2.3 million of its common stock.

## "At the Market" Sales Agreement

During the first quarter of 2014, Sucampo sold through this agreement an aggregate of 538,521 shares of Sucampo's class A common stock and received net proceeds of approximately \$5.3 million, before deducting issuance expenses. Since inception, Sucampo sold 1,287,904 shares and received gross proceeds of approximately \$10.6 million.

## **Guidance**

Sucampo announced today its specific earnings guidance for 2014. Sucampo now expects full year 2014 GAAP net income to be in the range of \$3.0 million to \$5.0 million, or \$0.06 to \$0.11 per diluted share.

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

Sucampo will host a conference call and webcast today at 5:00 pm Eastern. To participate on the live call, please dial 877-280-4958 (domestic) or 857-244-7315 (international), and provide the participant passcode 74434680, 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 31633726. Investors interested in accessing the live audio webcast of the teleconference may do so at <http://investor.sucampo.com> and should log on before the teleconference begins in order to download any software required. The archive of the teleconference will remain available for 30 days.

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

AMITIZA (lubiprostone) is a prostone, a locally acting chloride channel activator, indicated for the treatment of CIC in adults and OIC in adults with chronic, non-cancer pain (24 mcg twice daily) and for irritable bowel syndrome with constipation (8 mcg twice daily) in women 18 years of age and older in the U.S. In Japan, lubiprostone (24 mcg twice daily) is indicated for the treatment of chronic constipation (excluding constipation caused by organic diseases). In Switzerland, lubiprostone (24 mcg twice daily) is indicated for the treatment of CIC. In the U.K., lubiprostone (24 mcg twice daily) is indicated for the treatment of CIC and associated symptoms in adults.

## **About unoprostone isopropyl (RESCULA<sup>®</sup>)**

In 2009 and 2011, Sucampo acquired development and commercialization rights to unoprostone isopropyl throughout the world except in Japan, Korea, Taiwan and the People's Republic of China. Unoprostone isopropyl 0.12% (trade named RESCULA) first received marketing authorization in 1994 in Japan and was subsequently approved in over 40 countries, including approval in 2000 by the FDA. RESCULA

(unoprostone isopropyl ophthalmic solution) 0.15% is indicated for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension in the U.S.

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

Sucampo Pharmaceuticals, Inc. is focused on the discovery, development and commercialization of drugs based on ion channel activators known as prostones. Prostons are naturally occurring fatty acid metabolites with unique physiological activities. Sucampo has two marketed products – AMITIZA and RESCULA – and a pipeline of prostone-based 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 is the registered trademark and the tagline, The Science of Innovation, is a pending trademark of Sucampo AG.

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

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

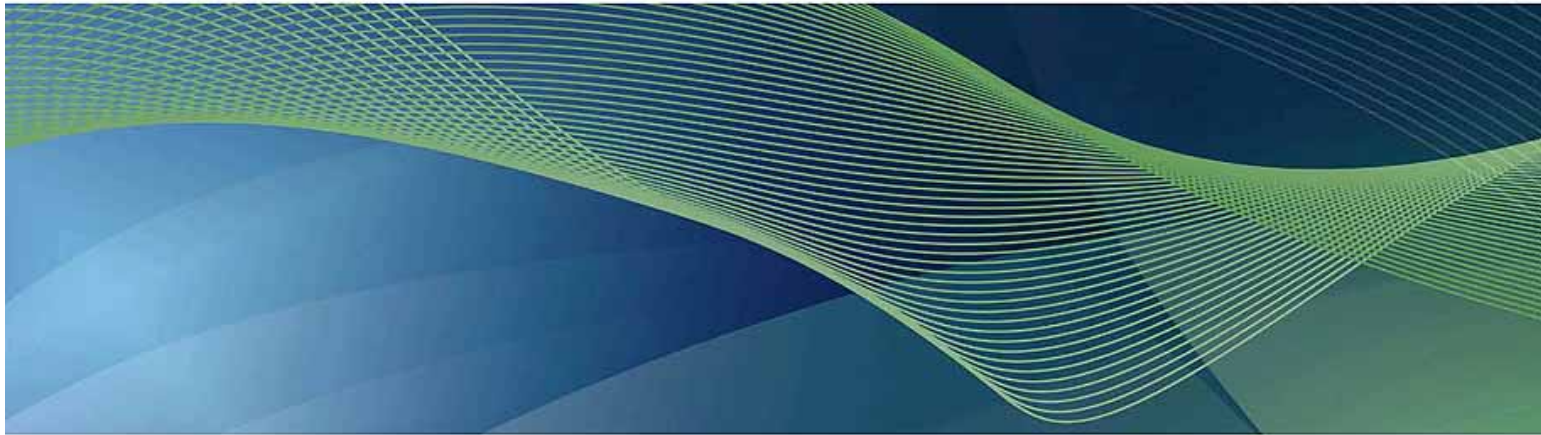
Twitter LinkedIn

### **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 product development, product potential, future financial and operating results, 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 develop and commercialize existing and pipeline products; 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 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 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 12, 2014 as well as its filings with the Securities and Exchange Commission on Form 10-Q and 8-K, which Sucampo incorporates by reference.

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Silvia Taylor  
Senior Vice President, Investor Relations  
and Corporate Communications  
1-240-223-3718  
[staylor@sucampo.com](mailto:staylor@sucampo.com)



# First Quarter 2014 Results

May 7, 2014



# 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>Highlights of the Quarter</b>	Peter Greenleaf
<b>AMITIZA® (lubiprostone) &amp; RESCULA® (unoprostone isopropyl) Commercial Update</b>	Stanley G. Miele
<b>Pipeline and R&amp;D Update</b>	Taryn Losch-Beridon
<b>Financial Performance</b>	Cary J. Claiborne
<b>Closing Remarks</b>	Peter Greenleaf

# Forward-Looking Statements

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, product potential, future financial and operating results, 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 develop and commercialize existing and pipeline products; 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 and the exposure to litigation and/or regulatory actions.

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# Q1 2014 Financial Highlights



**Peter Greenleaf**  
*Chief Executive Officer*

## 60 Day Areas of Emphasis

- Great **PEOPLE**
- Great **SCIENCE**
- Strong **FUNDAMENTALS**



# Q1 2014 Overview & Highlights

## **Comprehensive Review of Our Strategy**

- Operating structure, prostate technology platform, pipeline, partnerships, capital structure
- Plan to be shared in Q3

## **Strong Financial Performance**

- Reporting 31% YoY growth in revenues
  - In the U.S.: solid performance of AMITIZA
  - In Japan: significant growth of AMITIZA
  - In Europe: progress and increased access to AMITIZA

## **Pipeline Opportunities**

- Excited by the depth of our pipeline, opportunity to expand/refine it

# Commercial Update



## **Stanley G. Miele**

*President, Sucampo Pharma Americas, LLC  
and SVP, Sales and Marketing*



# AMITIZA U.S.



## Continued AMITIZA YOY Growth

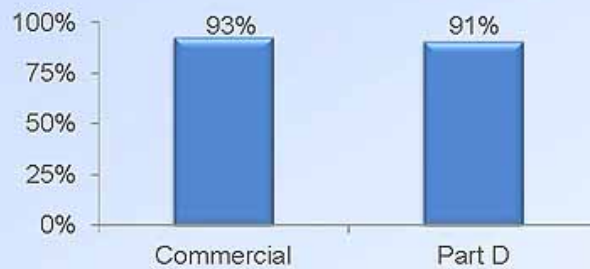
- Net sales growth of 16% for Q1 2014 compared to Q1 2013
- TRx growth of 3% for Q1<sup>1</sup>

## Market Growth Accelerating

- Class up 6% for Q1 2014 vs. Q1 2013

## Strong Partner Commercial Execution Driving Sales Growth

- Over 8M TRx's in  $\approx$  8 years<sup>2</sup>; heritage is driver of increased sales
- Managed care advantage and broad patient access vs. competition; increasing patient- focused efforts



AMITIZA is covered for 90% of lives nationally for all channels<sup>3</sup>

See References 1 - 3



# AMITIZA Global Snapshot

## Japan

- Continued success; sales continue to be above our and Abbott's expectations
- AMITIZA sales in Japan grew to \$6.1M (+177%)
- Abbott applying more than half of detailing efforts in Japan to AMITIZA
- 2 week limitation removed
- Available market is over 21M patients, making Japan a significant and growing driver of our revenue

## Europe

### Switzerland

- OIC decision ≈ 2H 2014
- Several reimbursement limitations revised

### U.K.

- CIC NICE\* submission; decision ≈ 2H 2014
- MHRA\*\* did not approve OIC; evaluating path forward

### E.U.

- Initiating MRP\*\*\*; anticipate approvals Q1 2015

\*National Institute for Health and Care Excellence \*\*Medicines and Healthcare Products Regulatory Agency;  
\*\*\*Mutual Recognition Procedure



# Pipeline and R&D Update



**Taryn Losch-Beridon**

*Vice President, Clinical Development*

# Clinical Pipeline & Product Development Highlights

CLINICAL FOCUS LEAD COMPOUNDS	STAGE OF CLINICAL DEVELOPMENT			
	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Lubiprostone Pediatric Functional Constipation				Began Q4 13
Lubiprostone Alternate Formulation CIC				Began Q3 13
Unoprostone Isopropyl Retinitis Pigmentosa*				Began Q1 13
Cobiprostone Oral Mucositis		P1b Q1 14	P2a 2H 14	
PO Ion Channel Activator Spinal Stenosis		P1b Began Q1 14		
IV Ion Channel Activator Spinal Stenosis			P2 Q4 13 P2a 2H 14	

■ COMPLETED ■ PROJECTED START ■ ONGOING

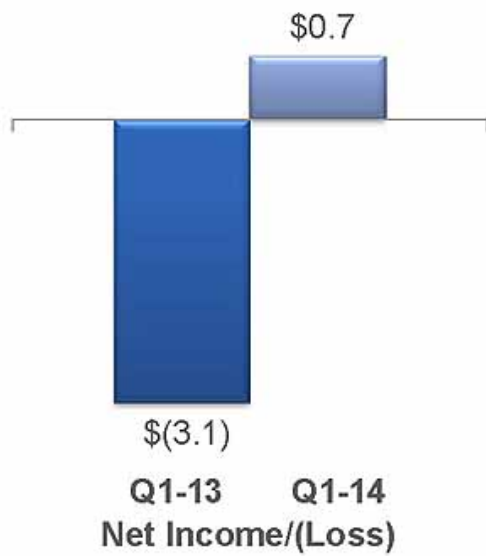
\*Co-developing with R-Tech Ueno, Ltd.

# Q1 2014 Performance Update



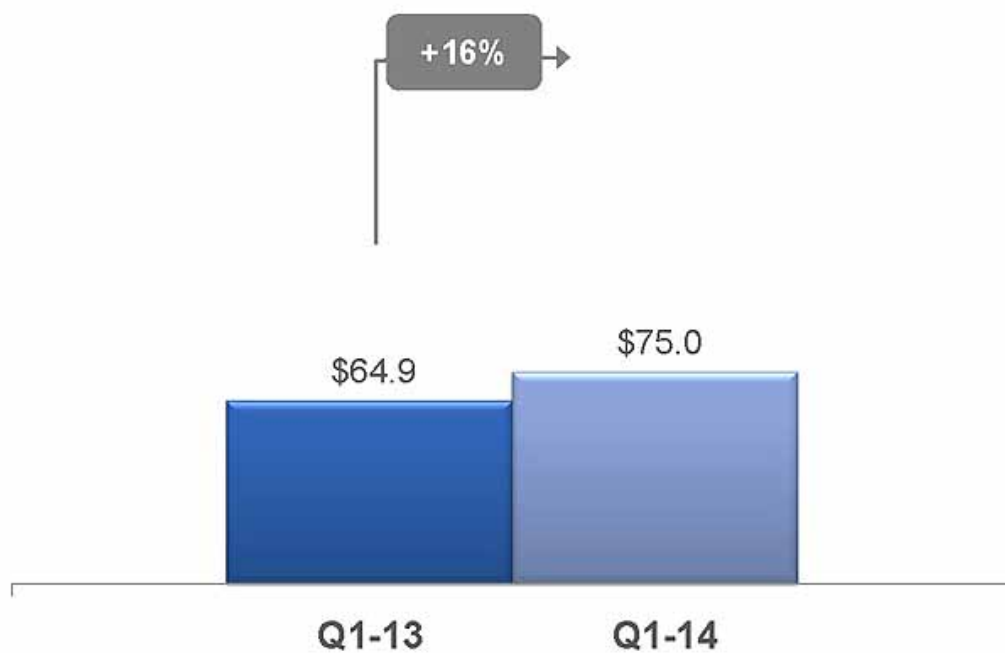
**Cary J. Claiborne**  
*Chief Financial Officer*

# Strong Financial Performance in Q1 (\$M, except EPS)



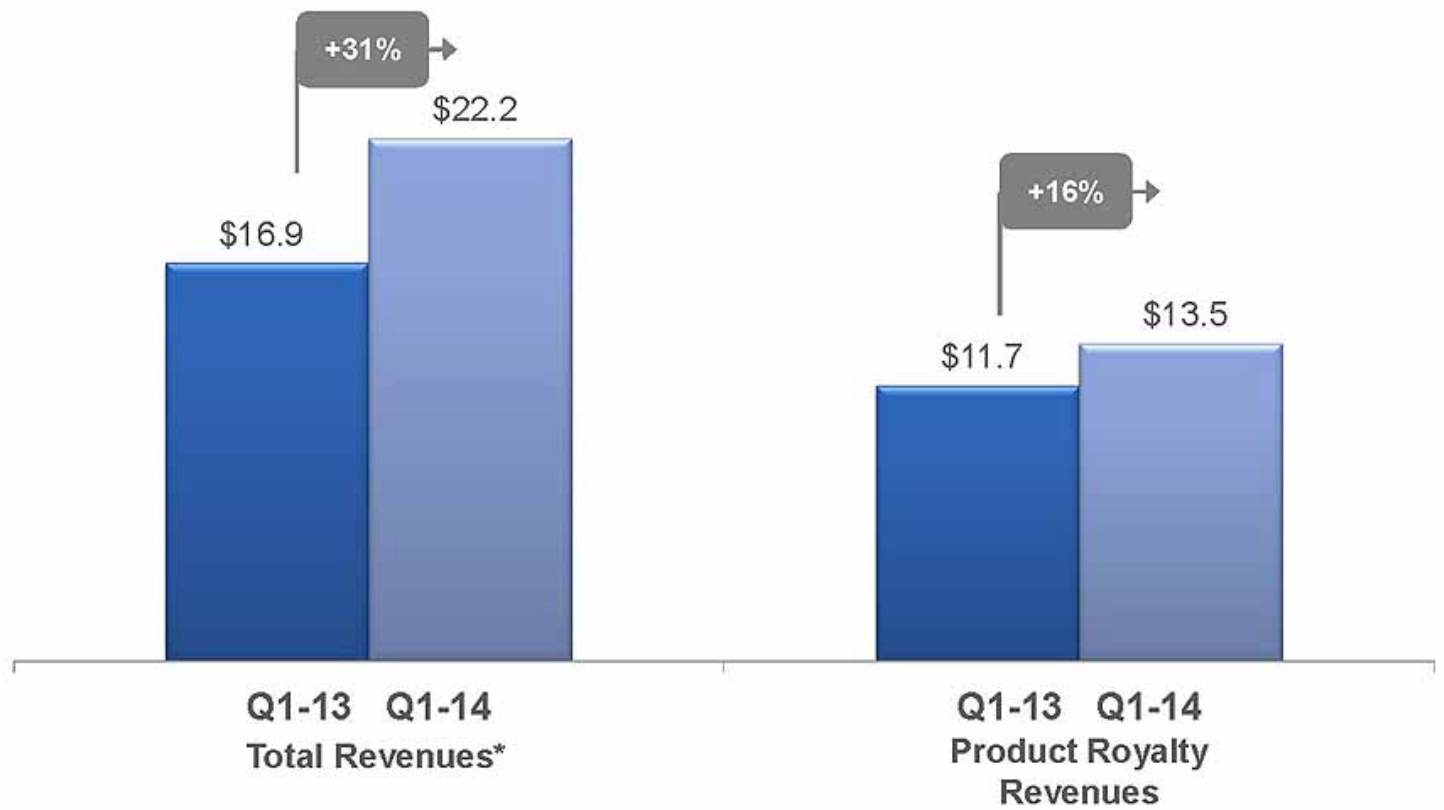


# Q1 AMITIZA U.S. Net Sales\* (\$M)



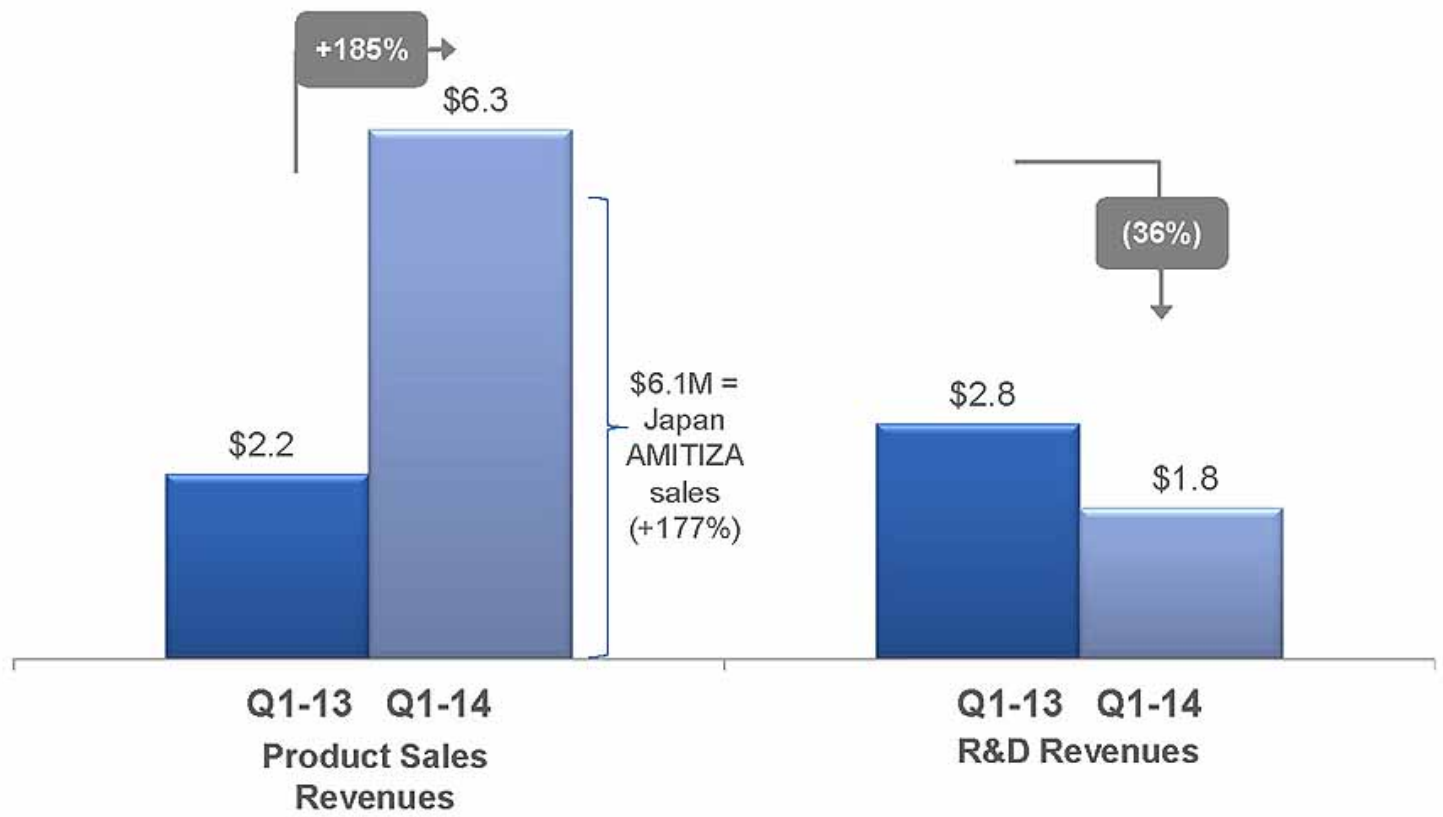
\*As reported by Takeda for royalty calculation purposes

# Q1 Revenue Highlights (\$M)



\*Co-promotion, contract and collaboration revenue also are components of revenue.

# Q1 Revenue Highlights (\$M) (cont.)



# Condensed Consolidated Statements of Operations (Unaudited)

(\$M, except EPS)*	Q1 2013	Q1 2014	\$ Change	% Change
Revenue	\$16.9	\$22.2	\$5.2	31.0%
Expenses:				
Cost of goods sold	\$1.3	\$3.5	\$2.2	174.3%
R&D expense	\$5.6	\$5.1	(\$0.5)	(8.8%)
G&A expense	\$7.2	\$7.3	---	0.4%
S&M expense	\$5.4	\$3.6	(\$1.7)	(32.3%)
Income/(loss) from operations	(\$2.6)	\$2.6	\$5.2	F
Non-operating income/(expense), net	\$0.6	(\$0.7)	(\$1.3)	U
Tax provision	(\$1.1)	(\$1.3)	(\$0.1)	10.7%
GAAP net income/(loss)	(\$3.1)	\$0.7	\$3.8	F

**COGS:** Increased volume of AMITIZA sales in Japan

**R&D expense:** Conclusion of clinical trial of our lubiprostone liquid formulation, lower costs of our LSS trials and the 2013-terminated collaboration with Numab AG, partially offset by increased spending with the first patients enrollment for the PFC program

**G&A expense:** Increased legal fees from prosecuting our patent infringement lawsuit, partially offset by lower PV costs in Japan

**S&M expense:** One-time RESCULA launch costs in 2013, partially offset by an increase from our co-promotion activities for U.S. AMITIZA and support for our European commercial activities

\*For chart, all numbers rounded



# 2014 Financial Guidance

## Financial Guidance

### Full Year 2014

GAAP Net Income

\$3M - \$5M

GAAP EPS

\$0.06 - \$0.11

# Conclusion



**Peter Greenleaf**  
*Chief Executive Officer*