

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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 28, 2012

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Jurisdiction
of Incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

4520 East-West Highway, 3rd Floor
Bethesda, Maryland

20814

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: (301) 961-3400

(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 7.01. Regulation FD Disclosure.

On December 4 and 5, 2012, Sucampo Pharmaceuticals, Inc. (the “Company”) will make a corporate update presentation with one-on-one meetings with investors in Boston, MA that will include written communication comprised of slides.

The information in this Item 7.01 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 (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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

The Company announced today that the U.S. Food and Drug Administration (“FDA”) has extended the Prescription Drug User Fee Act (“PDUFA”) goal date for the Agency’s priority review of the supplemental new drug application filing seeking approval for an additional indication for lubiprostone for the treatment of opioid-induced constipation in patients with chronic, non-cancer pain. Sucampo was notified that its November 16, 2012 submission of FDA-requested –supporting analyses has been designated as a major amendment to the application. Since the receipt date of this additional information is within three months of the PDUFA date, the FDA has decided to extend the goal date by three months to provide time for a full review of the submission. The extended user fee goal date is late April, 2013. No new clinical trials or studies have been requested by the FDA.

The information in this Item 8.01 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 of 1933, as amended, 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 8.01 shall be deemed to be furnished, and not filed:

- 99.1 The corporate update presentation slides dated December 4-5, 2012.
 - 99.2 Press Release issued by the registrant on November 30, 2012.
-

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 30, 2012

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: EVP, Chief Legal Officer and Corporate Secretary



Corporate Update

*Cary J. Claiborne, CFO
Stanley G. Miele, SVP, Sales & Marketing
Silvia Taylor, SVP, IR, PR & Corporate Communications
December 4-5, 2012*

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; 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 US 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 Form 10-K for the year ended Dec. 31, 2011, which the Company incorporates by reference.

Sucampo Snapshot: Prostone Pioneers

Sucampo Mission

To develop and commercialize prostone-based medicines to meet the major unmet medical needs of patients on a global basis

Commercial-stage, global biopharmaceutical company

- 2 FDA-approved drugs based on our proprietary prostone technology
 - AMITIZA® (lubiprostone) in gastroenterology market
 - RESCULA® (unoprostone isopropyl) in ophthalmology market

Prostone pioneers

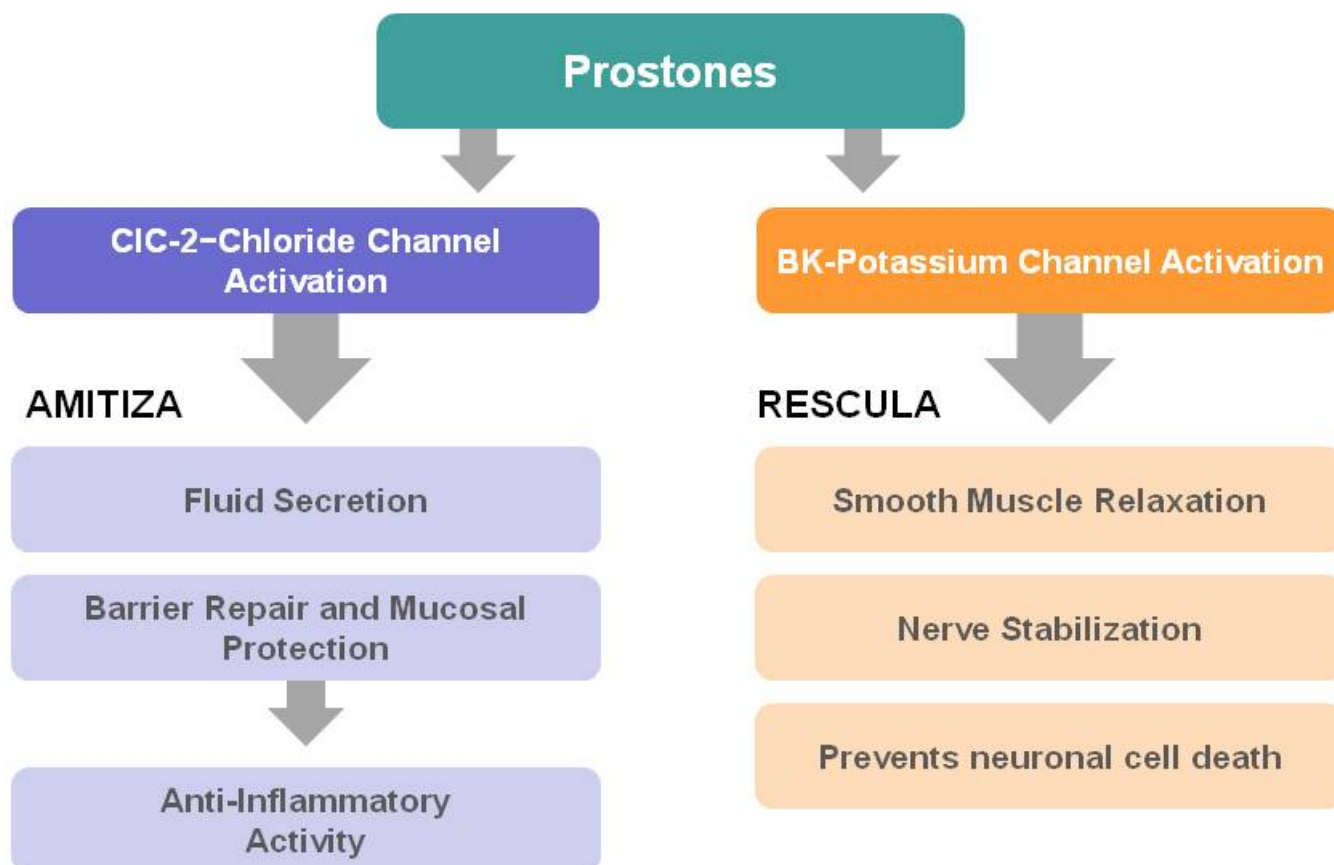
- Therapeutic potential 1st identified by Sucampo's founders, Drs Ryuji Ueno and Sachiko Kuno

Sucampo Has Pioneered the Field of Prostones

- Prostones:
 - Functional fatty acids naturally occurring in the human body
 - Selective ion-channel activators
 - Physiological mediators of restoration of cellular homeostasis and tissue regeneration
- Clinical safety profile of prostones is excellent, as demonstrated by the clinical safety record of AMITIZA in GI and RESCULA in ophthalmology
- Clinical potential of prostones is broad and applicable to various therapeutic fields beyond GI and ophthalmology

Sucampo is the only company developing and commercializing prostone compounds globally

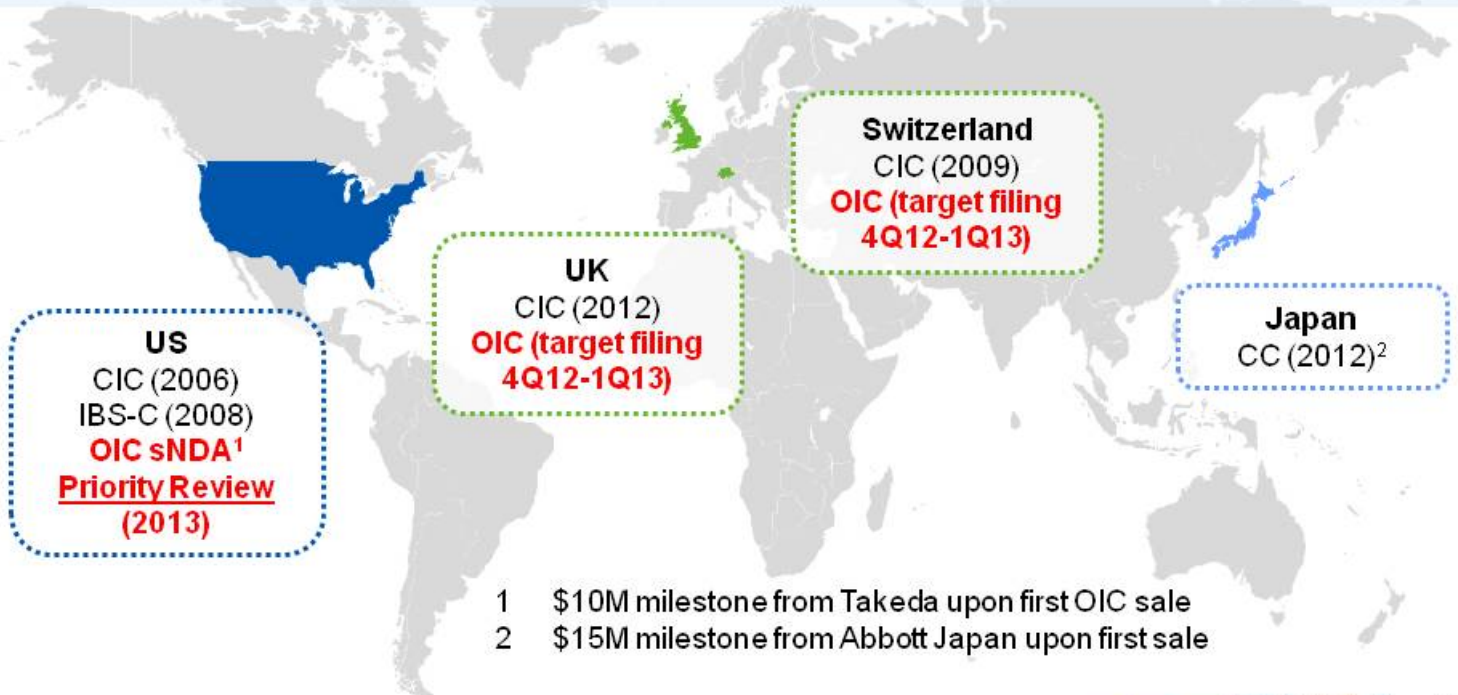
Proprietary Platform Technology: Sucampo's Prostones Are Highly Potent Ion-Channel Activators



See Reference 1

Global AMITIZA Approvals and Regulatory Filings

AMITIZA has been used for >6 y with 6 million prescriptions by patients suffering from chronic idiopathic constipation and irritable bowel syndrome with constipation



See Reference 1

Sucampo: Leader in Gastrointestinal Disease Medication Development

- **Chronic Idiopathic Constipation (CIC)**

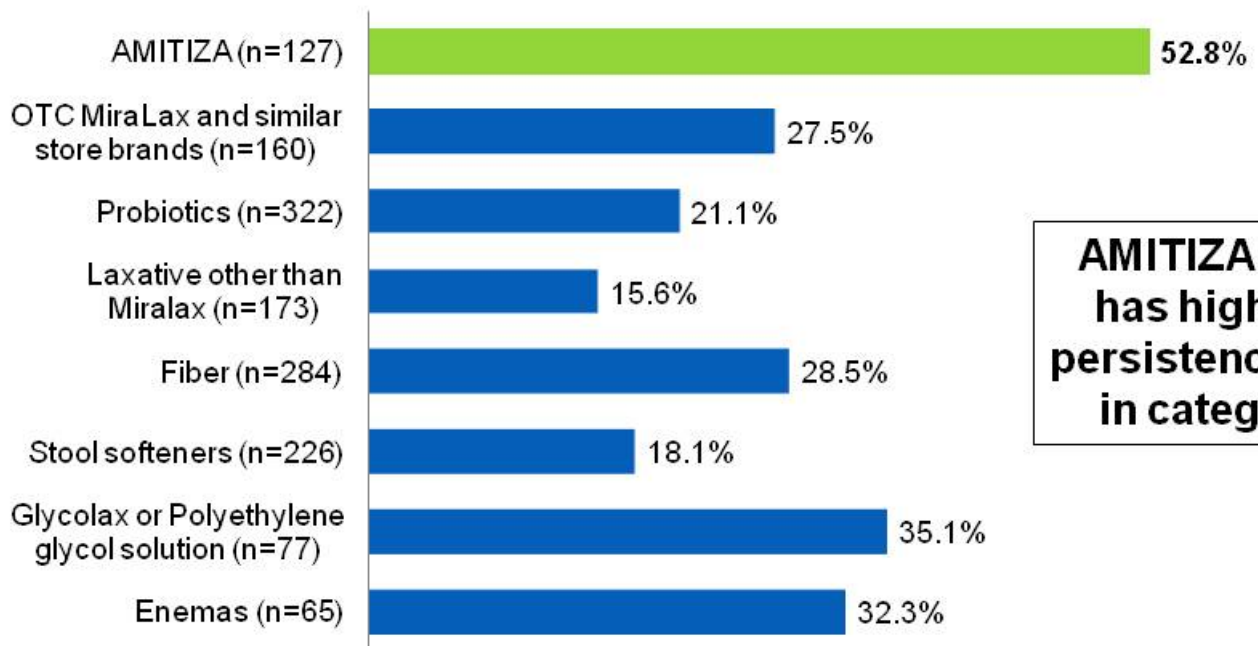
- Affects ~14%–16% of adult population globally
 - 33M in US (14%),² 41M in EU 5 (16%),² 15M in Japan (14.3%)³ – CC
- Accounts for 92,000 hospitalizations/yr in US⁴
- Severe constipation is associated with increased cardiovascular risk in women^{5,6}

- **Irritable Bowel Syndrome (IBS)**

- Affects ~15% of adult population globally, 1/3 of whom have IBS with constipation (IBS-C)⁷
 - 12M in US, 11M in EU^{7,8}, 3M in Japan^{7,9}
- Direct and indirect costs of IBS care in US: \$20 billion/yr⁷
- Patients with IBS consume >50% more healthcare resources than those without IBS¹⁰

AMITIZA Users Are the Most Satisfied With Their Treatment and Twice as Satisfied as MiraLAX Users

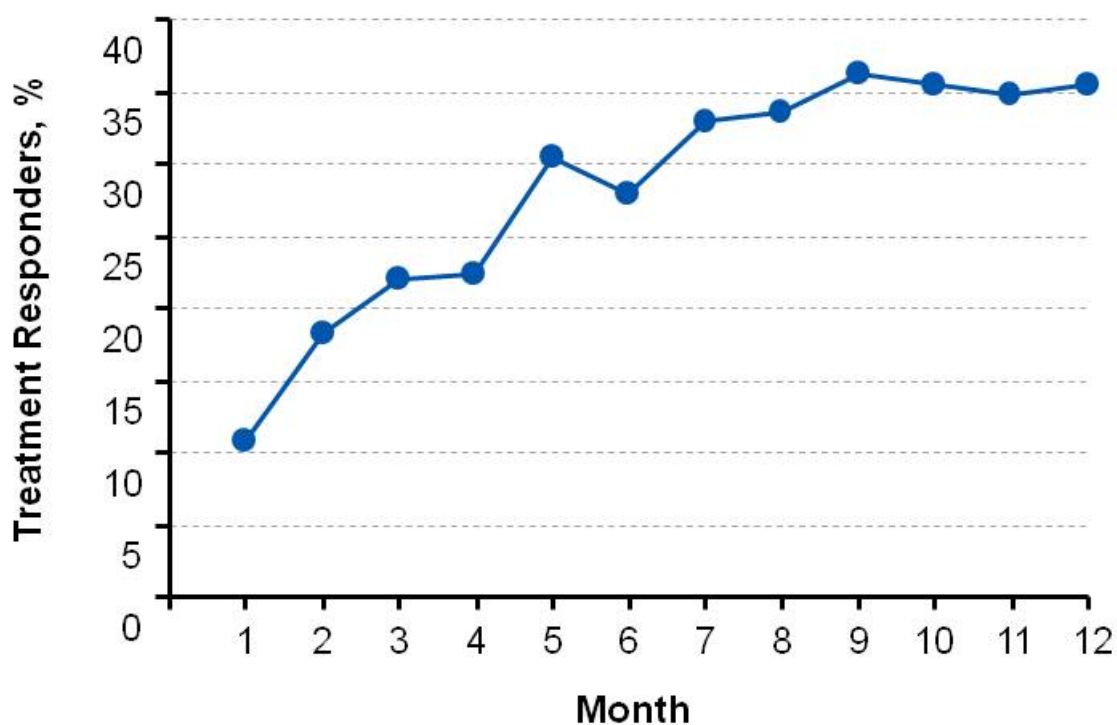
Satisfaction with Current Treatments



AMITIZA also has highest persistency rate in category

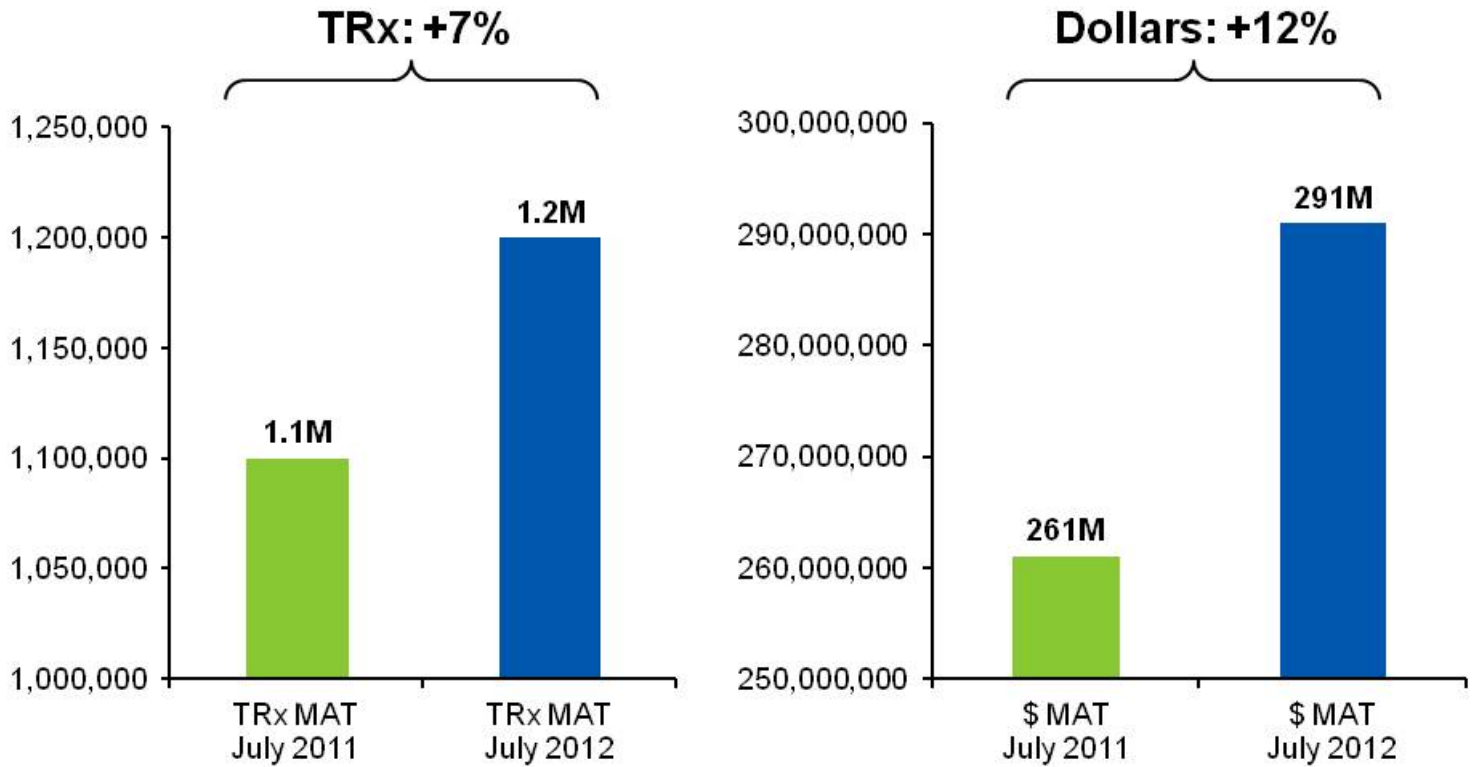
Positive Long-term Treatment Response: Phase 3 Studies of AMITIZA 8 μ g BID in IBS-C

Long-term Efficacy



See Reference 1

Positive Clinical Experience Translating to Consumption Growth: \$291M on Annualized Basis



AMITIZA has 1-2% share of ~250M units for Constipation

See Reference 12

AMITIZA Has Time-Tested Safety Profile and Positive Clinical Experience Valued by Physicians

Criteria	AMITIZA	Linacotide
MOA	CIC-2; mucosal barrier protection	GC-C receptor
Black box warning	No	Yes
Long-term safety profile	Established; 6 y, 6M prescriptions	No
Safety data in label for elderly with CIC	Yes; lower nausea rates	No; insufficient no. of subjects
Primary side effect	Nausea	Diarrhea
Efficacy in CIC and IBS-C	Yes	Yes
Satisfied patients in "real world"	Yes	No
Multisymptom benefit for CIC with abdominal discomfort/bloating in label	Yes	No
Dosing	BID with food and water	qd \geq 30 min before 1 st meal

See Reference 1

Opioid-Induced Constipation: Increase Potential Pool for AMITIZA and Strengthen Efficacy Positioning

- Moderate–severe OIC affects ~2.0M–2.5M patients
 - Currently no approved oral product for OIC
 - Most common reason for discontinuation of opioid therapy
 - OIC patients are viewed as “difficult to treat” and are dissatisfied
 - PCPs welcome 1 medicine indicated for multiple causes of constipation
- AMITIZA does not act on opiate receptors or inhibit analgesic activity of opioid therapy
- Mu-opioid–receptor agonist compounds under development may have cardiac safety concerns

FDA priority review action date: late April 2013

Summary and Outlook for AMITIZA

- Well positioned to serve expanding population of patients with CIC and IBS-C
 - Continue growth in US: over 6 million prescriptions used over past 6 yrs, with favorable benefit-risk profile
- Near-term goals
 - Seek approval for OIC indication in US and submit labeling applications for OIC abroad
 - Expand global approvals and launches for AMITIZA worldwide
 - Develop and seek approval for AMITIZA in pediatric constipation
 - Currently unmet medical need; no approved prescription medications
 - Develop liquid formulation of AMITIZA for long-term care market
 - Evaluate potential of AMITIZA for new indications, such as mixed irritable bowel syndrome

Sucampo Is an Emerging Player in Ophthalmology: RESCULA

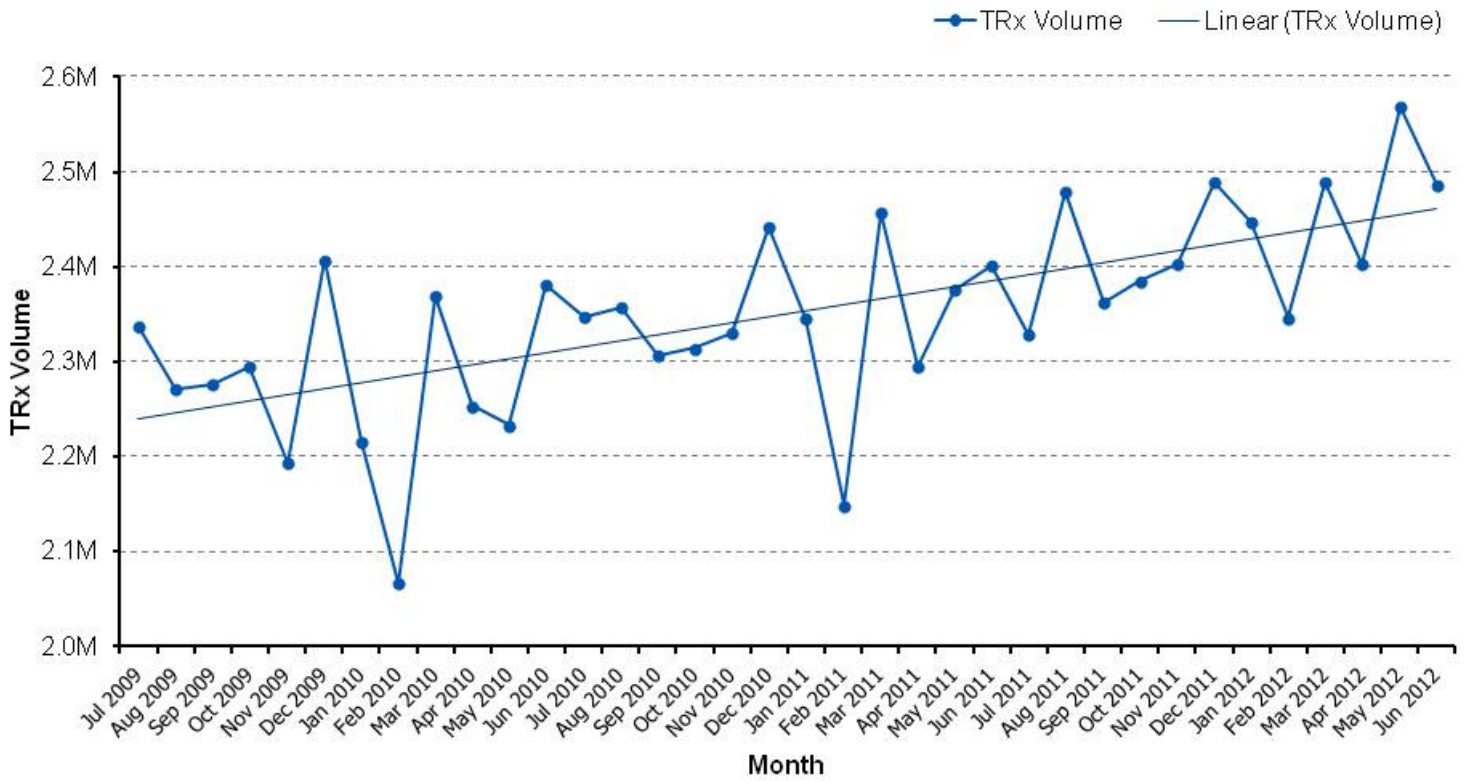
Ophthalmology

- **Glaucoma is a group of ocular diseases with various causes that ultimately are associated with a progressive optic neuropathy leading to loss of vision**
 - Age-related disease:
 - Second leading cause of bilateral blindness worldwide
 - Will affect an estimated 79.6 million people worldwide by 2020¹⁸
- Reduction in intra-ocular pressure (IOP) is currently the only modifiable risk factor for patients with glaucoma and ocular hypertension

US Glaucoma Market Overview

- **The US glaucoma market is 29.2M TRX's²²**
 - 4-5M potential patients^{21,22,24}
 - 67% of the market is generic²²
 - 80% of TRX's are by eye specialists²²
 - ~\$3B: US sales volume (2012)
 - ~\$1B: Japan sales volume (2011)
- **Compliance and adherence are unmet needs**
 - 50% of new patients drop off therapy within one year of initiation
- **Prostaglandins are inflammatory agents which depolarize cell membranes**
 - #1 reason for discontinuation of prostaglandins is hyperemia^{20,23,24}

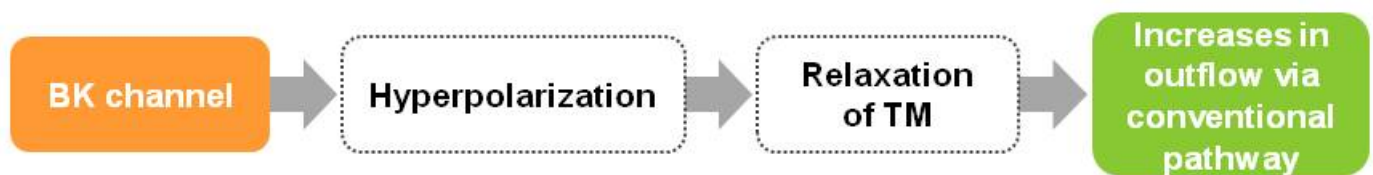
Over Past 3 Years, Category TRx Volume in US Has Increased 7% From 27.3M to 29.2M



See Reference 25

RESCULA has an alternate route to IOP Reduction

- In patients with primary open angle glaucoma or ocular hypertension, RESCULA
 - Reduces IOP throughout the day, alone or in combination
 - Has an excellent systemic safety profile and an established and ocular safety profile
 - MOA: ion channel activator promotes aqueous humor outflow through the trabecular meshwork
- Clinically meaningful results: glaucoma and intraocular hypertension



Opportunity for new option: differentiated product with a novel mechanism of action

RESCULA: Only Nonprostaglandin That Lowers IOP Throughout Day (12 h) With Excellent Systemic Safety Profile

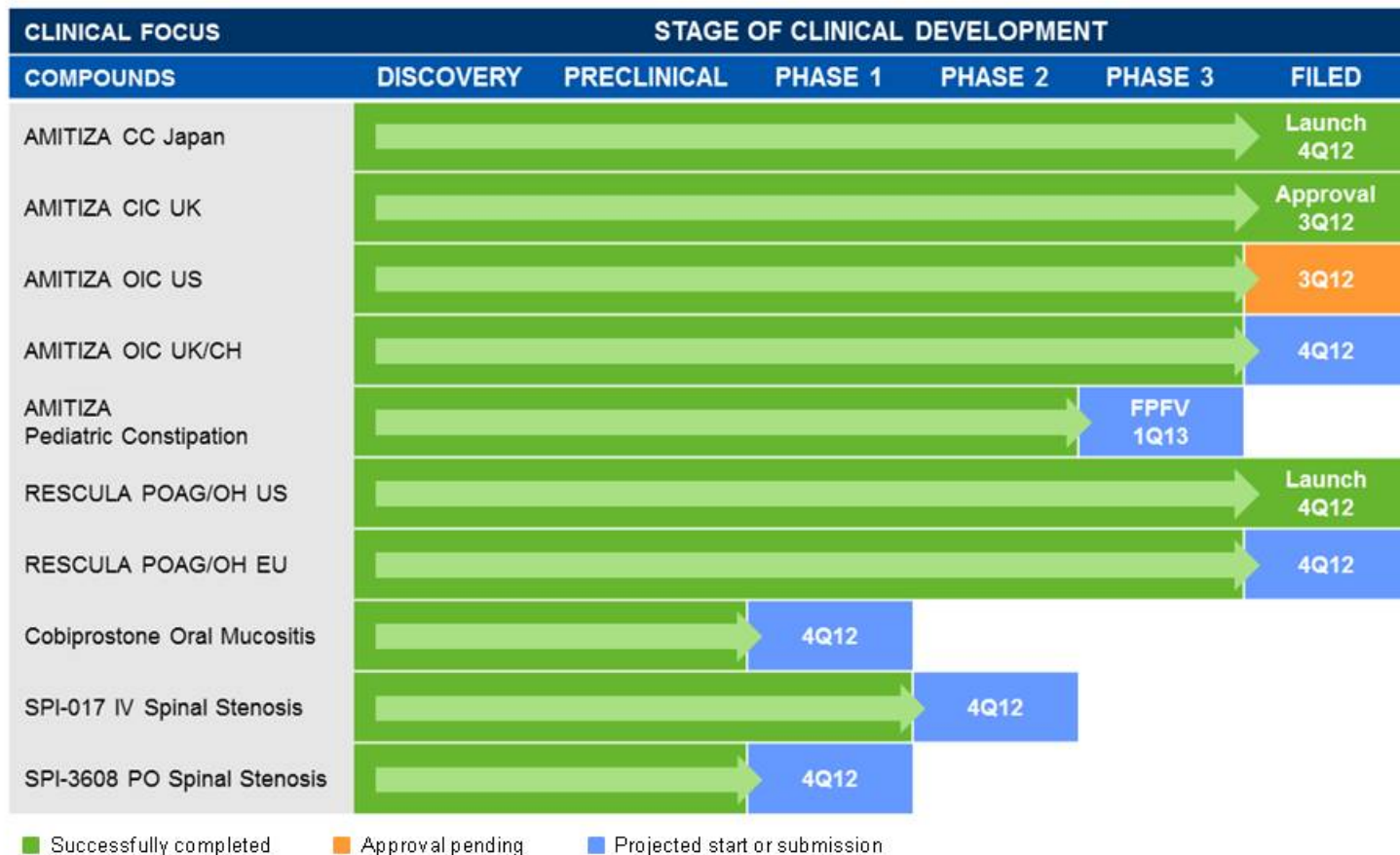
	RESCULA ²³	β-Blocker ²⁶	Alphagan-P ²⁷	Azopt ²⁸
Contraindicated in asthma/warning in COPD and diabetes	No	Yes	No	No
Drug interactions in label	No	Yes	Yes	Yes
Fatigue, muscle weakness, or drowsiness	No	Yes	Yes	No
Caution in using antihypertensives	No	Yes	Yes	No
Allergic reaction (10%–20%)	No	No	Yes	No
Care exercised in driving motor vehicles or hazardous activities	No	No	Yes	No
Bitter taste	No	No	No	Yes
Recommended dosing	BID	BID/QD	TID	TID

See References 23, 26-28

RESCULA US Launch Overview

- RESCULA was FDA-approved (2000) for the **lowering of intraocular pressure (IOP) in primary open-angle glaucoma (POAG) and ocular hypertension (OH)** in patients who are intolerant of or insufficiently responsive to other IOP-lowering medications
- sNDA Approval and Label update: reflect current scientific understanding of mechanism of action and be approved for first-line treatment
- Sucampo plans to launch RESCULA in US upon sNDA approval

Sucampo's Clinical Pipeline



Key Facts

Trading Symbol	SCMP (NASDAQ)
Corporate Headquarters	Bethesda, MD
Stock Price (11-29-2012), 52-Week Range	\$5.10, \$8.50 to \$3.67
Shares Outstanding (9-30-2012)	41.9 M (1 class of common stock)
Daily Volume (90-day average)	84,604
Market Capitalization (11-29-2012)	\$213.7 M
Debt (9-30-12)	\$61.2 M
Cash & Equivalents (9-30-12)	\$82.1 M
Enterprise Value	\$192.8 M
YTD Total Revenue (9-30-2012)	\$46.6 M
Full-time Employees (11-29-2012)	122
Fiscal Year Ends	December 31
Accounting Firm	PricewaterhouseCoopers, LLP

Key Value Drivers

✓ Completed In Process

AMITIZA	US	<ul style="list-style-type: none"> ✓ Filed OIC sNDA: 3Q 2012 <ul style="list-style-type: none"> • OIC filing accepted by FDA for priority review ✓ Decision in Takeda arbitration resolved dispute
	Switzerland	<ul style="list-style-type: none"> ✓ Reached agreement on reimbursement price <input type="checkbox"/> Begin active marketing 1Q 2013 <input type="checkbox"/> Submit for regulatory approval of OIC
	Japan	<ul style="list-style-type: none"> ✓ Approved in Japan for CC: 2Q 2012 ✓ Await pricing decision: Nov '12 ✓ Launch: 4Q 2012 (\$15M milestone upon first sale)
	EU	<ul style="list-style-type: none"> ✓ Approved in UK for CIC: 3Q 2012 <input type="checkbox"/> Launch 1Q 2013 <input type="checkbox"/> Submit for regulatory approval of OIC
RESCULA	US	<ul style="list-style-type: none"> <input type="checkbox"/> Obtain approval of sNDA (updated label) <input type="checkbox"/> Launch: shortly after approval of sNDA



Appendix

Terms of Sucampo's AMITIZA Agreements

- No gender restriction in CIC
- Approved for use in women with IBS-C in US
- Rapid onset in CIC: 57%–63% of patients respond within 24 h
- No black box warning
- Proven long-term safety profile in CIC and IBS-C
 - No serious safety concerns have arisen in post marketing use of AMITIZA
 - Safety in clinical-use setting has been a problem for other CIC and IBS-C medications, leading to withdrawal of marketing applications
 - Labeled risk-benefit ratio for AMITIZA is well supported by post marketing safety profile from over 6 million prescriptions over 6 yrs
- No limitation on duration of use in US, Japan, and Switzerland

AMITIZA: Effective 1st-Line Therapy for CIC and IBS-C

- **Takeda Agreement**

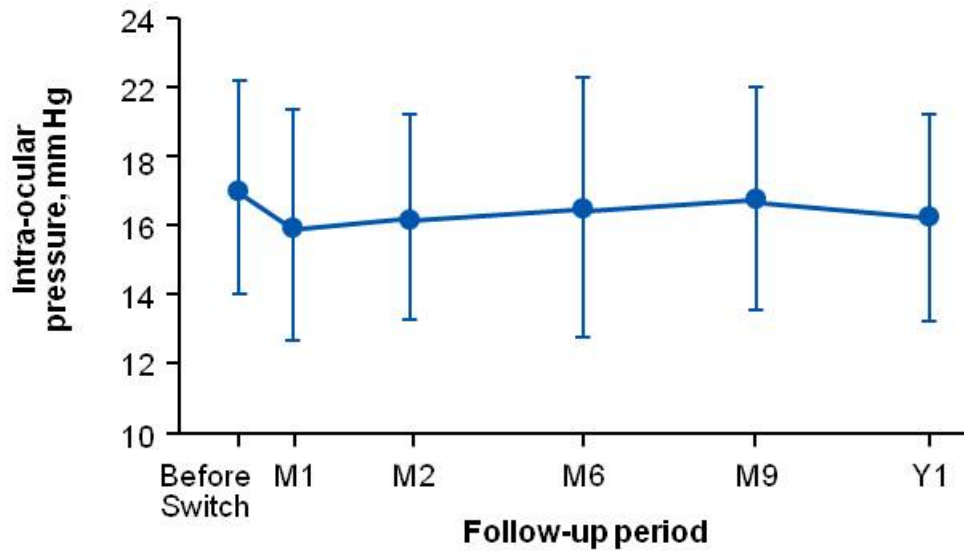
- Takeda shall promote, market, and sell AMITIZA in US and Canada
- Sucampo's tiered royalty rate: 18%–26% of annual net sales
- Sucampo earned \$20M in upfront and \$130M in development milestone payments as of 9/30/12
- Sucampo received \$106M in reimbursement for R&D expenses from Takeda

- **Abbott Japan Agreement**

- Abbott Japan shall promote, market, and sell AMITIZA in Japan
- Sucampo will sell product to Abbott Japan at discount to Abbott Japan's approved reimbursement price
- Sucampo earned \$10M in upfront and \$12.5M in development milestone payments as of 9/30/12
- Sucampo earned \$15M milestone payment on 1st commercial sale in Japan by Abbott Japan in 4Q12

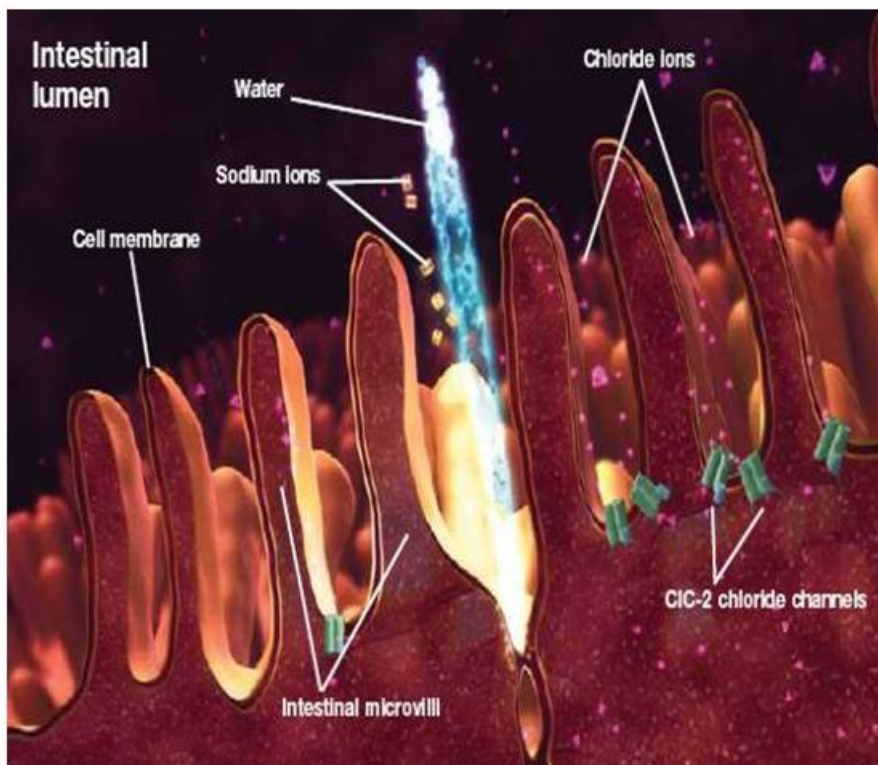
RESCULA 0.12% Has Been Shown to Maintain IOP in Patients Intolerant of Prostaglandins

IOP change in 23 eyes switched to RESCULA after mean 8 mo on prostaglandins, with mean initial IOP of 24.7 mm Hg and 17.2 mm Hg at treatment switch



- Changes over time in intra-ocular pressure (N = 23)
- ANOVA revealed no significant change ($P = 0.41$)

AMITIZA Mechanism of Action: ClC-2 Ion-Channel Activation and Fluid Secretion



Highly selective activation
of ClC-2 channels in
intestinal lumen



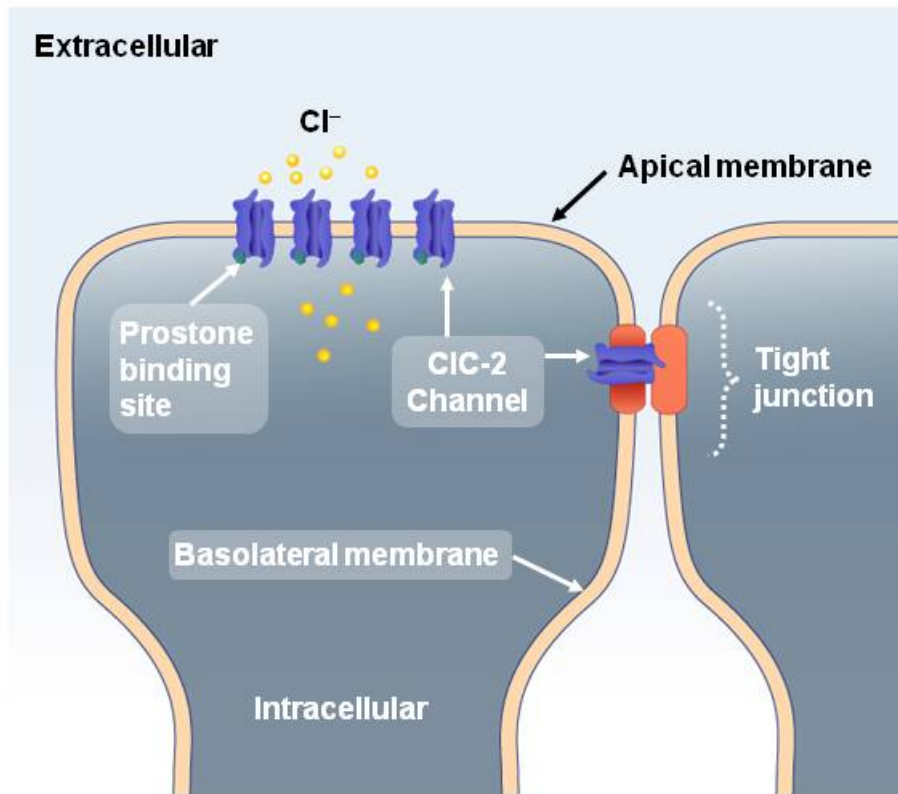
Chloride efflux followed by
passive efflux of sodium
into small intestine



Enhanced intestinal fluid
secretion without alteration
of serum electrolyte levels

See Reference 1

AMITIZA Mechanism of Action: Restores CIC-2-Mediated Barrier



Disease, injury, stress, or medications such as NSAIDs can damage epithelial barrier

Disorganized tight junctions and resulting intestinal permeability may be involved in pathogenesis of IBS

CIC-2 activation by AMITIZA enhances restoration of tight junctions and reduces intestinal permeability caused by stress or ischemia

See Reference 1

 **SUCAMPO**
PHARMACEUTICALS, INC.

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AMITIZA Safety Profile: Clinical Trials in Patients With CIC or IBS-C

- Nausea rated as mild-moderate by 89% and 96% of CIC and IBS-C patients, respectively, who experienced nausea
 - >93% of patients reporting nausea experienced only 1 event over course of treatment with AMITIZA
- In placebo-controlled, 12-wk IBS-C trials, diarrhea reported by 7% of AMITIZA patients vs 4% of placebo patients
- In IBS-C exposure up to 1 yr, dropout due to diarrhea accounted for <2% of patients

**AMITIZA has excellent tolerability and safety profile
as demonstrated in clinical studies**

AMITIZA Postmarketing Safety

- No serious safety concerns have arisen in postmarketing use of AMITIZA
- Safety in clinical-use setting has been a problem for other CIC and IBS-C medications, leading to withdrawal of marketing applications
- Labeled risk-benefit ratio for AMITIZA is well supported by postmarketing safety profile from 6 million prescriptions over 6 yr

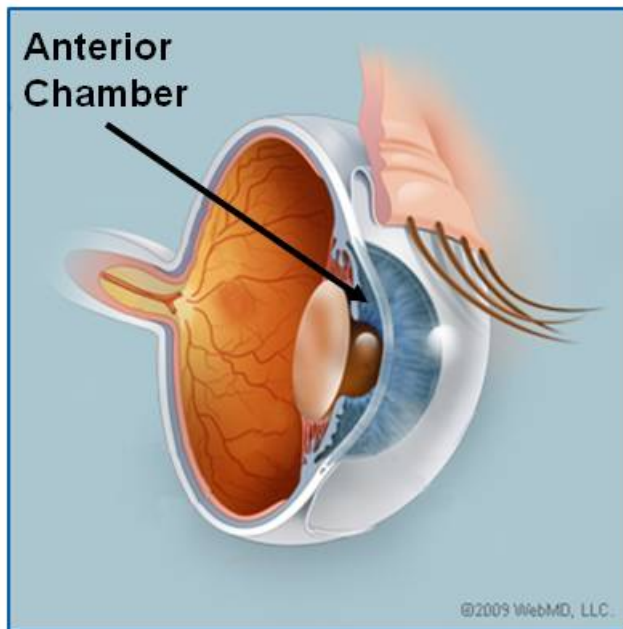
Substantial Abdominal Pain Improvement in IBS-C Patients Reporting at Least Severe Abdominal Pain at Baseline*

% Improvement	Placebo BID (n = 94)	Lubiprostone 8 µg BID (n = 183)	P Value†
≥10	53.9%	61.9%	<0.0001
≥20	40.1%	49.6%	<0.0001
≥30	24.2%	35.1%	<0.0001
≥40	14.5%	23.7%	<0.0001
≥50	9.4%	16.7%	<0.0001
≥60	4.7%	12.7%	<0.0001

*LOCF analysis; †P value from CMH test.
See Reference 31

Unoprostone – BK Channels – Trabecular Outflow

- Aqueous humor
 - Formed in ciliary processes from arterial blood
 - Secreted to posterior chamber
 - Reaches anterior chamber by crossing pupil



See Reference 18

- **BK channels are found in the trabecular meshwork (TM)²**
- **Unoprostone reduces IOP**
 - **Activation of BK channels** hyperpolarizes the cell and leads to relaxation of the TM
 - **Resulting in** increased outflow via **conventional pathway (through the TM)**

Management

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman, Chief Executive Officer, Chief Scientific Officer, and Co-Founder

- R-Tech Ueno, LTD, Co-Founder
- MD and Ph.D. (Medicinal Chemistry) from Keio University; Ph.D. (Pharmacology) from Osaka University

Cary J. Claiborne, Chief Financial Officer

- New Generation Biofuels, CEO, CFO, Director
- Osiris Therapeutics, CFO
- Constellation Energy Group, VP Financial Planning
- Senior leadership positions with General Electric (15 years), MCI and Home Depot

Stanley G. Miele, President, Sucampo Pharma Americas, LLC and Senior Vice President, Sales and Marketing, Sucampo Pharmaceuticals, Inc.

- Abbott Laboratories
- Millennium Pharmaceuticals (COR Therapeutics)

Greg Deener, Senior Vice President, Marketing Strategy and Implementation

- GTx, Inc.
- GlaxoSmithKline

Thomas J. Knapp, Executive Vice President, Chief Legal Officer and Secretary

- NorthWestern Corporation, General Counsel and Corporate Secretary
- Boeing

Other executive experience includes FDA/Center for Drug Evaluation and Research, Procter & Gamble, Pfizer, MedImmune, Allergan, Alcon and GlaxoSmithKline

Issued Lubiprostone Patents

<u>US Patent No.</u>	<u>Expires</u>	<u>Type of patent</u>
5,284,858	2014	Composition of matter
6,414,016	2020	Therapeutic use (treating conditions including constipation)
6,583,174	2020	Composition of matter
7,064,148	2022	Therapeutic use (treating conditions including constipation)
7,417,067	2020	Composition of matter
7,795,312	2024	Therapeutic use (treating conditions including IBS)
8,026,393	2027	Formulation
8,071,613	2020	Method for relieving constipation in IBS-C
8,088,934	2021	Composition of matter
8,097,649	2020	Composition of matter
8,097,653	2022	Therapeutic use (treating constipation)
8,114,890	2020	Composition of matter
4,332,316	2020	Composition of matter
4,332,353	2022	Therapeutic use
4,684,334	2021	Therapeutic use (treating conditions including constipation)
4,783,794	2027	Composition of matter
4,786,866	2022	Therapeutic use (treating constipation)

*For Orange Book-listed patents concerning lubiprostone, see for example:

http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021908&Product_No=001&table1=OB_Rx

Issued Lubiprostone Patents

Japanese

<u>Patent No.</u>	<u>Expires</u>	<u>Type of patent</u>
4,332,316	2020	Composition of matter
4,332,353	2022	Therapeutic use
4,684,334	2021	Therapeutic use (treating conditions including constipation)
4,783,794	2027	Composition of matter
4,786,866	2022	Therapeutic use (treating constipation)
4,852,229	2022	Therapeutic use (treating constipation)
4,889,219	2023	Therapeutic use (treating constipation)

European

<u>Patent No.</u>	<u>Expires</u>	<u>Type of Patent</u>
1,220,849	2020	Composition of matter
1,315,485	2021	Therapeutic use (treating constipation)
1,392,318	2022	Therapeutic use
1,426,361	2020	Composition of matter
1,443,938	2022	Therapeutic use (treating constipation)

*For Orange Book-listed patents concerning lubiprostone, see for example:

http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021908&Product_No=001&table1=OB_Rx

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3. Kantar Health Epi database <http://epidb.khapps.jp>
4. Lembo et al. *Sleisenger and Fordtran's Gastrointestinal and Liver Disease*. 2010
5. Salmoirago-Blotcher et al. *Am J Med*. 2011
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7. Saito et al. *Am J Gastroenterol*. 2002
8. Muller-Lissner S et al. *Digestion*. 2001
9. Kubo et al. *Neurogastroenterol Motil*. 2011
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13. IMS Health
14. Verispan PDDA
15. Physician Interviews
16. ClearView Analysis
17. RESCULA Package Insert
18. Quigley et al. *Br J Ophthalmol* 2006 Mar;90(3):252-7

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20. Friedman et al. Prevalence of Open-Angle Glaucoma Among Adults in the United States. [Arch Ophthalmol](#). 2004 Apr;122(4):532-8
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28. Azopt Prescribing information. 2000–2009. Alcon Laboratories Inc, Fort Worth, TX
29. Goseki T et al. *Jpn. J Clin Ophthalmol*. 2006;60:1227-30
30. AMITIZA Package Inserts (US and UK)
31. Joswick et al. Digestive Disease Week, 2012



Corporate Update

*Cary J. Claiborne, CFO
Stanley G. Miele, SVP, Sales & Marketing
Silvia Taylor, SVP, IR, PR & Corporate Communications
December 4-5, 2012*

Sucampo Announces Approval of a Supplemental Application for Updates to AMITIZA (lubiprostone) Pregnancy Labeling***Changes Related to Risk-Benefit Profile in Pregnancy and Nursing Mothers, and Update to Mechanism of Action Section*****Company Also Announces Extension of sNDA Priority Review for AMITIZA Submission Seeking Approval for Treatment of Opioid-Induced Constipation**

BETHESDA, Md.--(BUSINESS WIRE)--November 30, 2012--Sucampo Pharmaceuticals, Inc. (NASDAQ: SCMP) today announced that the Company received a supplement approval from the U.S. Food and Drug Administration (FDA) that removes pregnancy “warnings and precautions” and clarifies information regarding the use of AMITIZA[®] (lubiprostone) by pregnant and/or nursing women. In addition, the FDA expanded the labeling text of the Mechanism of Action section in the prescribing information for AMITIZA. AMITIZA is approved for the treatment of chronic idiopathic constipation (CIC) in adults (24 mcg twice daily) and irritable bowel syndrome with constipation (IBS-C) in women 18 years of age and older (8 mcg twice daily).

The Company also announced today that the FDA has extended the Prescription Drug User Fee Act (PDUFA) goal date for the Agency’s priority review of the supplemental new drug application (sNDA) filing seeking approval for an additional indication for lubiprostone for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain. Sucampo was notified that its November 16, 2012 submission of FDA-requested supportive analyses has been designated as a major amendment to the application. Since the receipt date of this additional information is within three months of the PDUFA date, the FDA has decided to extend the goal date by three months to provide time for a full review of the submission. The extended user fee goal date is late April, 2013. No new clinical trials or studies have been requested by the FDA.

“Sucampo’s scientific and regulatory teams are pleased with the FDA-approved changes to the AMITIZA label. We believe these changes will enable physicians and women of child-bearing age who are suffering from IBS-C or CIC to better evaluate the risk-benefit profile of AMITIZA. The details added to the mechanism of action section highlight AMITIZA’s ability to restore the mucosal barrier of the gut, which is important to further clarify clinician understanding of how AMITIZA may work in the treatment of IBS-C. Additionally, we look forward to completion of the FDA’s review of our sNDA for OIC,” said Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo.

Sucampo has accepted the following FDA-approved labeling changes, which will be effective immediately:

1. All pregnancy-related Warnings and Precautions (Section 5.1 of the label) have been removed. This includes deletion of the sentence: “Women who could become pregnant should have a negative pregnancy test prior to beginning therapy with AMITIZA and should be capable of complying with effective contraceptive measures.”
2. Section 8 of the product labeling, “Use in Specific Populations,” was updated to include additional animal data and a Clinical Consideration section, with the pregnancy category remaining unchanged.
3. Previous labeling statements regarding the potential for serious adverse reactions in nursing infants have been removed. The revised label states that caution should be exercised when AMITIZA is administered to a nursing mother and advises “lactating women to monitor their human milk-fed infants for diarrhea while taking AMITIZA.”
4. The Mechanism of Action section (Section 12.1) of the label now reads as follows: “Lubiprostone is a locally acting chloride channel activator. . .activation of ClC-2 by lubiprostone has been shown to stimulate recovery of mucosal barrier function and **reduce intestinal permeability** (bolding added to indicate label addition) via the restoration of tight junction complexes in *ex vivo* studies of ischemic porcine intestine.”

A recent study suggests that one of the contributing factors to abdominal pain in IBS may be increased intestinal permeability induced by disruption of the tight junctions. It has been previously established that activation of the ClC-2 chloride channel specifically, but not CFTR chloride channel, mediates reduction in intestinal permeability. Lubiprostone is the only product approved for use in IBS-C which includes a mechanism of action for reducing intestinal permeability.

For further information please see the complete Prescribing Information and visit www.amitiza.com.

About AMITIZA (lubiprostone) for Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C)

AMITIZA is a chloride channel activator indicated for the treatment of CIC (24 mcg twice daily) in adults and for IBS-C (8 mcg twice daily) in women 18 years of age and older.

Important Safety Information

AMITIZA (lubiprostone) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction. Patients with symptoms suggestive of mechanical gastrointestinal obstruction should be thoroughly evaluated by the treating healthcare provider to confirm the absence of such an obstruction prior to initiating AMITIZA treatment.

Patients taking AMITIZA may experience nausea. If this occurs, concomitant administration of food with AMITIZA may reduce symptoms of nausea. Patients who experience severe nausea should inform their healthcare provider.

AMITIZA should not be prescribed to patients that have severe diarrhea. Patients should be aware of the possible occurrence of diarrhea during treatment and inform their healthcare provider if the diarrhea becomes severe.

Patients taking AMITIZA may experience dyspnea within an hour of first dose. This symptom generally resolves within three hours, but may recur with repeat dosing. Patients who experience dyspnea should inform their healthcare provider. Some patients have discontinued therapy because of dyspnea.

In clinical trials of AMITIZA (24 mcg twice daily vs placebo; N=1113 vs N=316, respectively) in patients with Chronic Idiopathic Constipation (CIC), the most common adverse reactions (incidence > 4%) were nausea (29% vs 3%), diarrhea (12% vs <1%), headache (11% vs 5%), abdominal pain (8% vs 3%), abdominal distension (6% vs 2%), and flatulence (6% vs 2%).

In clinical trials of AMITIZA (8 mcg twice daily vs placebo; N=1011 vs N=435, respectively) in patients with Irritable Bowel Syndrome with Constipation (IBS-C), the most common adverse reactions (incidence > 4%) were nausea (8% vs 4%), diarrhea (7% vs 4%), and abdominal pain (5% vs 5%).

The safety of AMITIZA in pregnancy has not been evaluated in humans. Based on animal data, AMITIZA may cause fetal harm. AMITIZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when AMITIZA is administered to a nursing woman. Advise nursing women to monitor infants for diarrhea.

Reduce the dosage in CIC patients with moderate and severe hepatic impairment. Reduce the dosage in IBS-C patients with severe hepatic impairment.

For further information please see the complete Prescribing Information and visit www.amitiza.com.

About Sucampo Pharmaceuticals

Sucampo Pharmaceuticals, Inc. is a global pharmaceutical company focused on innovative research, discovery, development and commercialization of proprietary drugs based on prostones. The therapeutic potential of prostones was first discovered by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo's Chairman, Chief Executive Officer, and co-founder. Prostones, naturally occurring fatty acid metabolites that have emerged as promising compounds with unique physiological activities, can be targeted for the treatment of unmet or underserved medical needs. For more information, please visit www.sucampo.com.

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 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; 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 US 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 Form 10-K for the year ended Dec. 31, 2011, which the Company incorporates by reference.

CONTACT:

Sucampo Pharmaceuticals, Inc.
Silvia Taylor, 1-240-223-3718
staylor@sucampo.com