

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): November 12, 2010

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Sucampo Pharmaceuticals, Inc.  
(Exact Name of Registrant as Specified in Charter)

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Delaware	001-33609	30-0520478
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
4520 East-West Highway, Suite 300 Bethesda, Maryland		20814
(Address of Principal Executive Offices)		(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 7.01. Regulation FD Disclosure.**

On November 12, 2010, Sucampo Pharmaceuticals, Inc. will make a corporate update presentation at the 2010 Credit Suisse Healthcare Conference that will include written communication comprised of slides. This presentation will be webcast and may be accessed at [www.sucampo.com](http://www.sucampo.com). The slides from the presentation are being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 9.01. Financial Statements and Exhibits.**

(d) Exhibits

99.1 The corporate update presentation slides dated November 12, 2010.

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SIGNATURE

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

SUCAMPO PHARMACEUTICALS, INC.

Date: November 12, 2010

By: /s/ JAN SMILEK

Name: Jan Smilek

Title: Chief Financial Officer



# Credit Suisse 2010 Healthcare Conference

James J. Egan  
Chief Operating Officer  
*November 12, 2010*

## Forward-Looking Statement

Forward-looking statements contained in this presentation are based on Sucampo's assumptions and expectations concerning future events. They are subject to significant business, economic and competitive risks and uncertainties that could cause actual results to differ materially from those reflected in the forward-looking statements. Sucampo's forward-looking statements could be affected by numerous foreseeable and unforeseeable events and developments such as regulatory delays, the failure of clinical trials, the inability to fund drug development initiatives, competitive products and other factors identified in the "Risk Factors" section of Sucampo's Annual Report on Form 10-K and other periodic reports filed with the Securities and Exchange Commission. While Sucampo may elect to update these statements at some point in the future Sucampo specifically disclaim any obligation to do so, whether as a result of new information, future events or otherwise. In light of the significant uncertainties inherent in the forward-looking information in this presentation, you are cautioned not to place undue reliance on these forward-looking statements.

# Sucampo: A Biopharmaceutical Company

## **Rescula®**

- FDA approved for lowering intra-ocular pressure (IOP) in glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications
- In-licensed US + Canadian development and marketing rights in April 2009
- Awaiting FDA approval of label-enhancing supplemental NDA (sNDA) to re-launch in U.S.
- Designing trials for additional indications, based on partner's breakthrough clinical results

## **Amitiza®**

- Only FDA approved drug for chronic idiopathic constipation (CIC) in adults
- Only FDA approved drug for irritable bowel syndrome with constipation (IBS-C) in adult women
- Marketing authorization approved (Nov 2009) in Switzerland for CIC indication
- Phase 3 trial in opioid-induced bowel dysfunction (OBD) to initiate late 2010
- U.S + Canadian commercial rights held by Takeda, commercial rights in Japan held by Abbott

## **A deep pipeline leveraging prostone technology, expertise**

- Cobiprostone for prevention of NSAID-induced gastric ulcers in Phase 2
- SPI-017 for peripheral arterial disease going into Phase 2
- Additional prostones in preclinical development, such as SPI-3608

## **Strong financial position**

- \$110.7 million in cash and investments as of Sept. 30, 2010

## Rescula: In-Licensed from R-Tech Ueno

- Sucampo licensed Rescula's US and Canada rights from R-Tech Ueno (RTU) in April 2009
- Sucampo gained exclusive rights to commercialize Rescula in the U.S. and Canada for approved indication and right of first refusal to additional indications for which RTU develops Rescula
- Also received the right to develop Rescula for additional ophthalmic indications
- RTU is responsible for clinical and commercial supply of Rescula to Sucampo
- Sucampo paid an upfront payment of \$3 million to RTU and is responsible for additional milestone payments
- Sucampo responsible for development, regulatory and commercialization activities and expenses in the U.S. and Canada

# Rescula: Phase 2 Clinical Trial Design -- Retinitis Pigmentosa

## Design of Phase 2 Trial

- A multi-center, randomized, double-blind, three parallel group, placebo-controlled trial
- Enrolled 112 mid- to late-stage Retinitis Pigmentosa (RP) patients with visual acuity of 0.5 or more in a narrow visual field
- Conducted at 6 sites in Japan
- Patients received either one or two drops of active drug or placebo twice a day for 24 weeks
- Primary endpoint : change from baseline in the mean retinal sensitivity of the central 2-degrees of the ocular fundus as measured with an MP-1 microperimeter
- Secondary endpoints included
  - Retina sensitivity measured by Humphrey perimeter (10-2)
  - Visual acuity
  - Contrast sensitivity
  - Health related Quality of Life (measured by VFQ-25)



# Rescula: A Differentiated Ophthalmic Drug

## A unique mechanism of action:

- Rescula activates Maxi K channels in neurons and contractile cells
- Lowers IOP by increased outflow of aqueous humor through trabecular meshwork and uveoscleral pathway
- Increases both retinal and choroidal components of ocular blood flow to optic nerve
- Maintains visual field in glaucoma patients; inhibits apoptosis of retinal neurons and ischemia-induced degeneration of optic nerve fibers in non-clinical studies

## Leads to future opportunities in retinal diseases

- Dry Age-related Macular Edema (dry AMD)
- Diabetic Macular Edema (DME)

## Rescula: Current Status

- Rescula eye-drops are a prostone-based drug, not a prostaglandin
- FDA-approved for lowering of intra-ocular pressure (IOP) in primary open-angle glaucoma (POAG) and ocular hypertension patients who are intolerant of or are insufficiently responsive to other IOP lowering medications; not currently available in U.S.
- Sucampo submitted data developed after Rescula's FDA approval in 2000 in an sNDA (August 2009)
- Will complete label discussions with FDA before finalizing US launch plans

# Amitiza Answers Unmet Medical Needs

- **Represents a major market opportunity**

- More than 14 million (CIC and IBS-C) office visits each year in U.S.
- 4.5 million U.S. office visits seeking relief of opioid-induced bowel dysfunction (OBD)

- **Offers proven safety and efficacy for long-term usage**

- Efficacy + tolerability are similar for both genders + across age groups for CIC
- 90% of nausea events diminish after first week of use
- Competing products recommended for short-term use only

- **Provides quick and predictable relief of symptoms**

- Between 57%-63% of CIC patients respond within 24 hours and remain responsive
- IBS-C patients were twice as likely to achieve overall response than those receiving placebo

- **Differentiated mechanisms of action**

- In CIC, Amitiza activates chloride ion channels, promoting fluid secretion
- In IBS-C, Amitiza activates chloride ion channels and promotes mucosal barrier protection

## Phase 3 pivotal trial design

- 2 multicenter trials, both randomized, parallel-group, enrolled 479 patients
- Administered 24 mcg gel capsule of Amitiza or placebo twice daily
- 4 week treatment period preceded by 2 week baseline period
- Entry criteria: modified Rome II criteria for functional constipation
- Primary efficacy endpoint: change from baseline in number of spontaneous bowel movements (SBMs) after 1 week of treatment
- Secondary endpoints included:
  - SBMs at weeks 2, 3 and 4
  - Percentage of patients with a SBM within 24 hours of first dose
  - Time to first SBM

•Barish CF. *Dig Dis Sci* 2010; 55: 1090-1097

•Johanson JF et al *Am J Gastroenterol*. 2008;103:170-177

## Phase 3 Trials Results

Amitiza met the primary endpoint with statistical significance ( $p < 0.0001$ ), as Amitiza patients experienced statistically significantly greater mean numbers of SBMs at Week 1 as compared to placebo patients (5.5 / 5.9 vs. 3.5 / 4.0)

Secondary endpoint results:

- In each week of the trials, Amitiza patients had significantly higher frequency of SBMs at all weeks except week 2
- Significantly higher percentage of Amitiza patients experienced a SBM within 24 hours of first dose as compared to placebo (57-61.3% vs. 32-37%)
- Time to first SBM was significantly shorter in Amitiza patients than with placebo

Amitiza approved by FDA for treatment of CIC in adults with no upper age limit in January 2006

\* Barish CF, et al *Dig Dis Sci* 2010; 55: 1090-1097 and Johanson JF, et al *Am J Gastroenterol*. 2008;103:170-177

## Phase 3 Results in CIC: Amitiza\* + Zelnorm\*\*

### Amitiza

Mean Number of SBMs/Week	24 mcg bid	Placebo
Study 0131	5.69	3.46
Study 0232	5.89	3.99

### Zelnorm

SBMs/Week	2 mg bid	6 mg bid	Placebo
Study 2301	1.6	2.0	0.9
Study 2302	2.0	1.9	1.0

\* Barish CF, et al *Dig Dis Sci* 2010; 55: 1090-1097  
Johanson JF et al *Am J Gastroenterol*. 2008;103:170-177

\*\*Zelnorm FDA GI Adv Cmte Briefing Document

# Amitiza: Irritable Bowel Syndrome with Constipation\*

## Design of two Phase 3 trials

- 2 multicenter trials identically designed, randomized, parallel-groups
- 1,171 U.S. patients received 8 mcg Amitiza gel capsule or placebo twice daily
- 12 week treatment period following a 2 week baseline period
- Entry criteria: all patients met Rome II criteria for Constipation-Predominant IBS
- To measure relief, patients responded to a weekly question: "How would you rate your relief of IBS symptoms over the past week compared to how you felt before you entered the study?"
- 7-point scale used to rate relief: "significantly relieved," "moderately relieved," "a little bit relieved," "unchanged," "a little bit worse," "moderately worse," "significantly worse"

## Endpoint

- Primary endpoint was percentage of overall responders in drug and placebo groups
- An overall responder was a monthly responder for at least 2 of the 3 months of the study

\* Drossman DA, Chey WD, Johanson JF et al, Aliment Pharmacol Ther 2009 Feb;29(3):329-41

## Amitiza: Phase 3 IBS-C Overall Responder Rate\*

Overall Responders	8 mcg bid	Placebo	p value
Study '431	13.8%	7.8%	0.029
Study '432	12.1%	5.7%	0.023
Pooled	13.0%	6.8%	0.001

Amitiza approved by FDA for treatment of IBS-C  
in adult women in April 2008

*\*Drossman DA, Chey WD, Johanson JF et al, Aliment Pharmacol Ther  
2009 Feb;29(3):329-41*



# IBS-C phase 3 Results: Overall Responders Amitiza\* + Zelnorm\*\*

<b>Amitiza</b>	<b>Study</b>	<b>8 mcg bid</b>	<b>Placebo</b>	
	'431	13.8	7.8	p=0.029
	'432	12.1	5.7	p=0.023

<b>Zelnorm</b>	<b>Study</b>	<u>Original Responder Definition</u>			<u>Changed Responder Definition</u>		
		<b>4 mg</b>	<b>12 mg</b>	<b>Placebo</b>	<b>4 mg</b>	<b>12 mg</b>	<b>Placebo</b>
	'301	28.8	26.2	20.5	38.8	38.4	30.2
	<i>p value</i>	<i>0.056</i>	<i>0.116</i>		<i>0.033</i>	<i>0.033</i>	
	'307	25.5	26.5	28.2	38.3	42.2	37.0
	<i>p value</i>	<i>0.703</i>	<i>0.703</i>		<i>0.837</i>	<i>0.284</i>	
	'351	29.4	26.2	22.1	38.9	45.7	33.3
	<i>p value</i>	<i>0.200</i>	<i>0.370</i>		<i>0.314</i>	<i>0.016</i>	

Amitiza: Drossman DA et al, Aliment PharmacolTher 2009 Feb;29(3):329-41

Zelnorm: FDA GI AdvCmteBriefing Document

### Management of Opioid-induced Bowel Dysfunction in non-malignant pain (OBD) patients

- 4.5 million office visits in U.S. annually, seeking relief from OBD
- Sucampo conducted two phase 3 trials, one reached statistical significance for primary endpoint
- Sucampo to conduct another phase 3 trial, Takeda to share costs
- Design of successful Phase 3 trial:
  - Randomized, placebo-controlled, multi-center trial in 443 OBD patients
  - One 24-mcg gel capsule of lubiprostone or placebo twice each day
  - 12 week treatment period
  - Permitted concomitant pain medications included: fentanyl, methadone, morphine and oxycontin
  - Primary endpoint: change from baseline in SBM frequency at Week 8 without reduction in dose of study pain medication

## Management of Opioid-induced Bowel Dysfunction in non-malignant pain (OBD) patients

- Reported results phase 3 trial (OBD0631) at DDW 2010
- Patients in '631 trial taking lubiprostone achieved a statistically significant ( $p=0.02$ ) greater increase in the mean number of SBMs per week in 8 of the 12 weeks of the trial as compared to placebo patients
- The percentage of patients in '631 trial who achieved a SBM within 24 hours and 48 hours was significantly higher with lubiprostone as compared to placebo ( $p=0.0126$  at 24 hours, and  $p=0.0360$  at 48 hours)
- Statistical significance was achieved for the overall change from baseline in constipation-associated symptom secondary endpoints in '631 trial

\* DDW 2010, Abstract #780958

## Amitiza: Solid Cardiovascular Safety Data\*

- No clinically significant QTc prolongation was observed when healthy volunteers were administered lubiprostone at a single 24 or 144 mcg dose
- No clinically significant QTc prolongation was reported when constipated patients were dosed daily for 3 weeks with varying doses of lubiprostone
- These findings indicate that lubiprostone treatment does not increase the risk of TdP associated with QTc prolongation
- Cumulative safety information for lubiprostone administered to patients with chronic constipation or irritable bowel syndrome with constipation are consistent

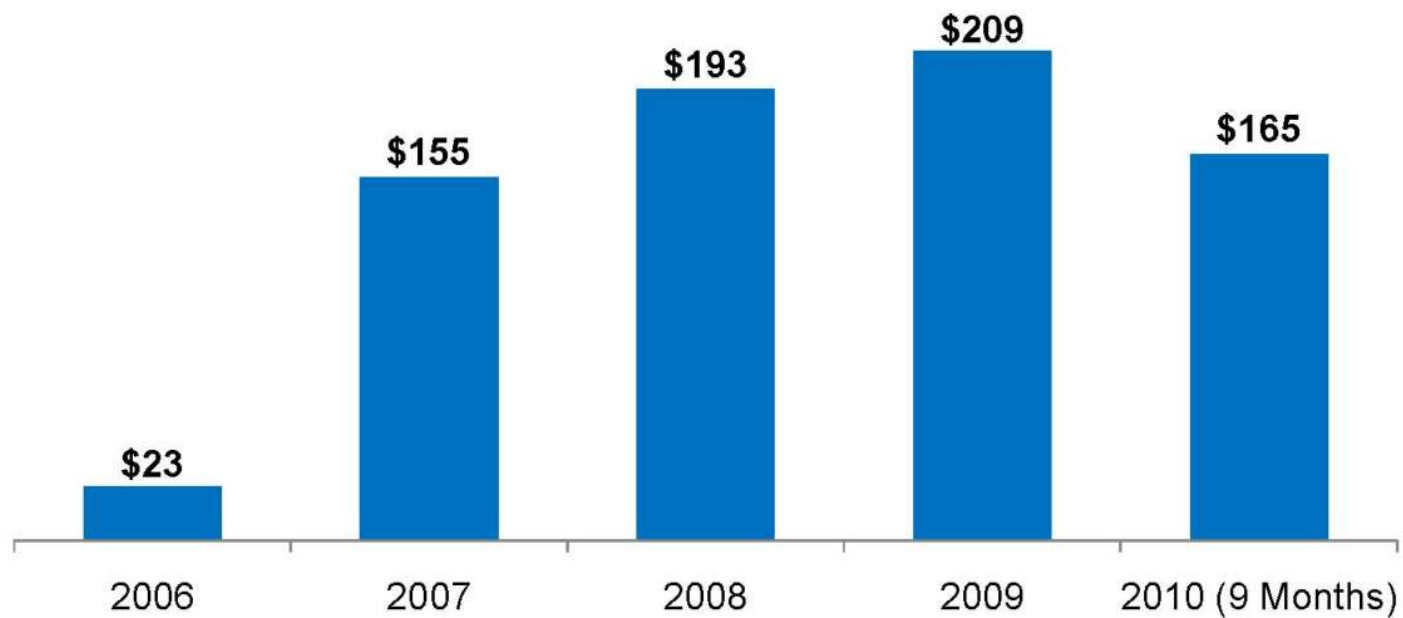
**No serious cardiac adverse events attributable to lubiprostone have been reported to date**

\* Sprenger C, Copa A, Morganroth J, Panas R, Ueno R. Effect of lubiprostone, a unique agent for the treatment of chronic idiopathic constipation, on clinical electrocardiographic results. *Gastroenterology* 2007; 132(4 Suppl 2): A-3225 [abstract S2136]

## Key Terms of Agreements with Takeda

- Takeda shall exert best efforts to commercialize and market Amitiza in the U.S. and Canada to maximize net sales of Amitiza
  - Currently covers two indications: CIC in adults and IBS-C in adult women
  - Takeda holds right of first refusal to additional GI indications
  - Takeda records all U.S. sales, Sucampo receives a royalty
  - Sucampo retains all other rights
  - Takeda also has rights to Amitiza in Canada, but not yet launched
- Sucampo's tiered royalty rate: 18% to 26% of annual net sales
- Sucampo reimbursed for majority of GI clinical development costs
- Sucampo has received a total of \$150 million in upfront and development milestone payments as of Sept. 30, 2010

## Net Sales of Amitiza Since Launch in April 2006



## Amitiza: Agreement with Abbott Japan

- A key element in Sucampo's international growth strategy for Amitiza
- Abbott received exclusive rights to commercialize lubiprostone in Japan for CIC, and right of first refusal for additional indications in Japan
- If successfully developed, Sucampo will supply finished product to Abbott
- Sucampo retains right to co-promote Amitiza in Japan and to develop Amitiza for additional indications
- Sucampo has received a total of \$22.5 million in upfront and milestone payments from Abbott, as of Sept. 30, 2010
- Sucampo designed and managed the recently reported successful phase 3 efficacy trial and interim data from long-term safety trial in Japanese CIC patients

## Japanese Phase 3 efficacy trial

- Primary efficacy endpoint reached statistical significance (p=0.001)\*
- Double-blind, placebo-controlled multi-center trial, evaluated 124 patients
- Dose: Placebo or lubiprostone 24-mcg soft gel capsule, twice daily, for 28 days
- Results filed with Japanese authorities in marketing application (Sept. 2010)

## Japanese Phase 3 long-term safety trial\*

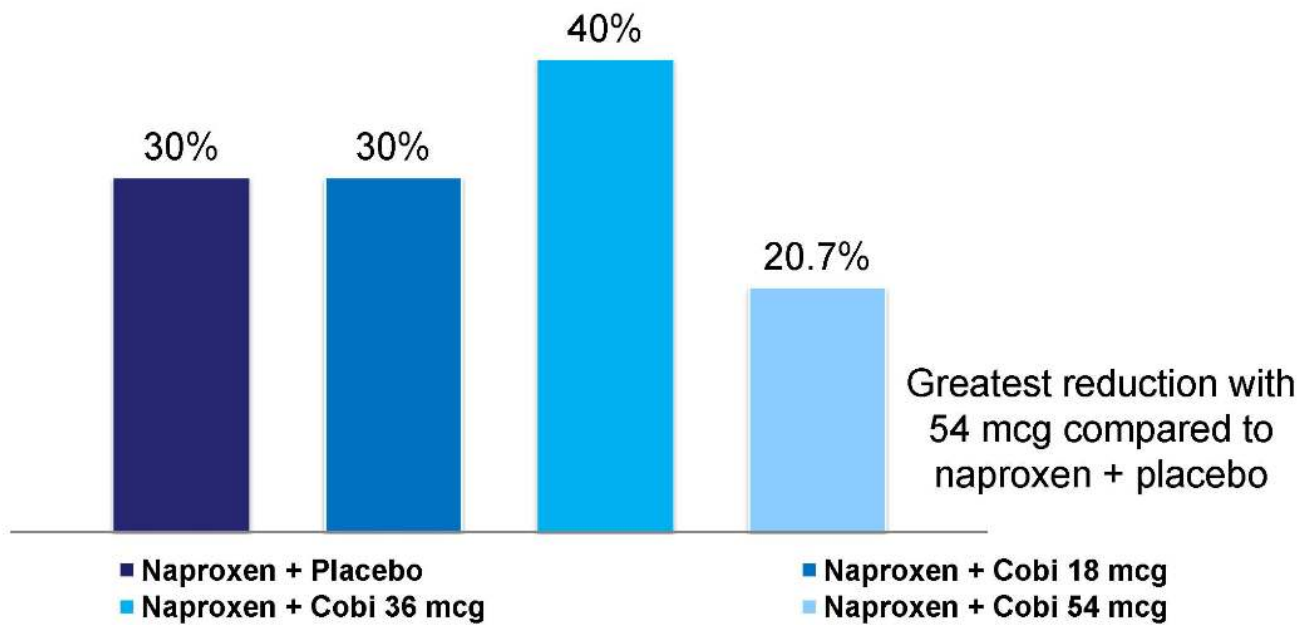
- An open-label, multi-center trial with 209 patients
- Dose: one lubiprostone 24-mcg gel capsule twice a day for 48 weeks
- Interim results through Week 24 of 48-week trial show lubiprostone is safe and well tolerated
- Interim safety results included in Japanese marketing application

\* *Sucampo Press Release, August 5, 2010*



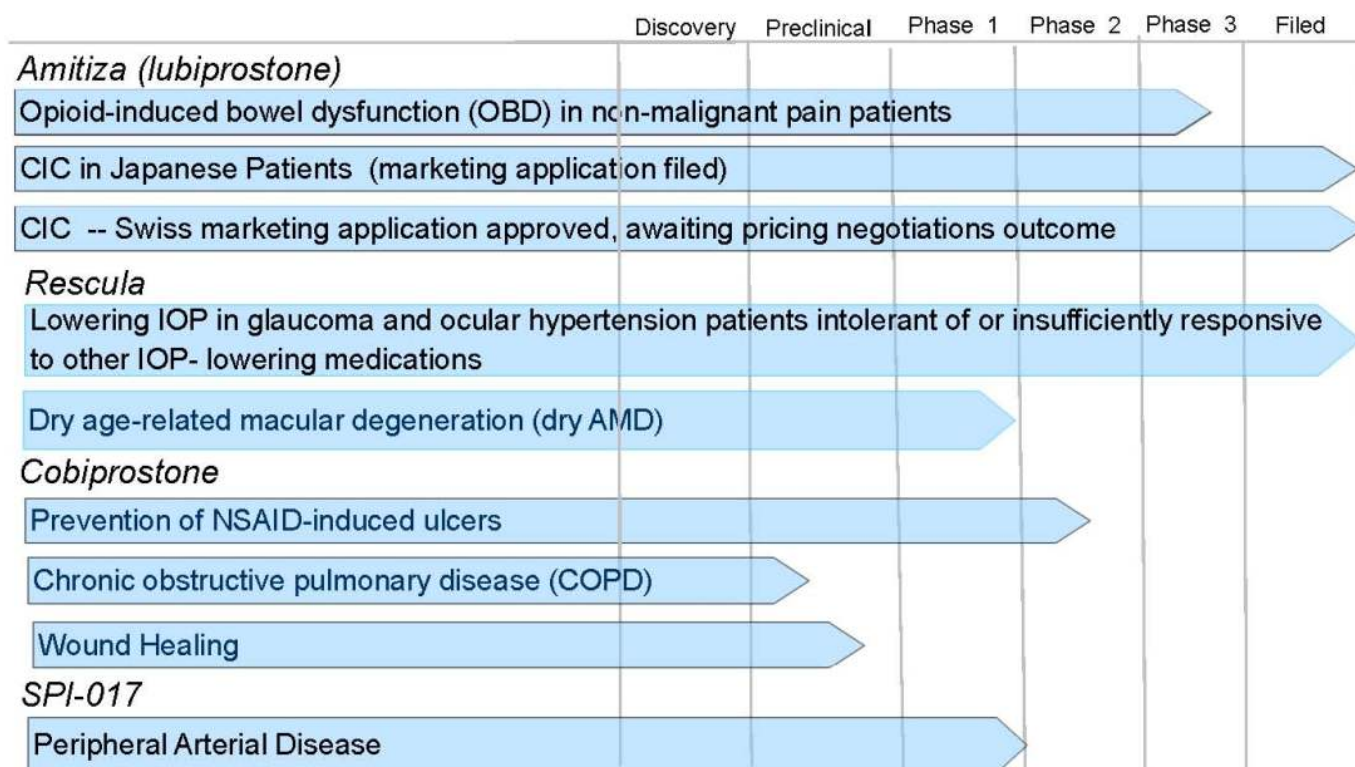
# Future Opportunities: Cobiprostone - Phase 2 Results \*

## Percent of Patients With Ulcers at 12 Weeks



\*DDW 2010, oral presentation 780837

# Sucampo's Clinical Product Opportunities



# Prostones Fuel Sucampo's Growth and Deep Product Pipeline

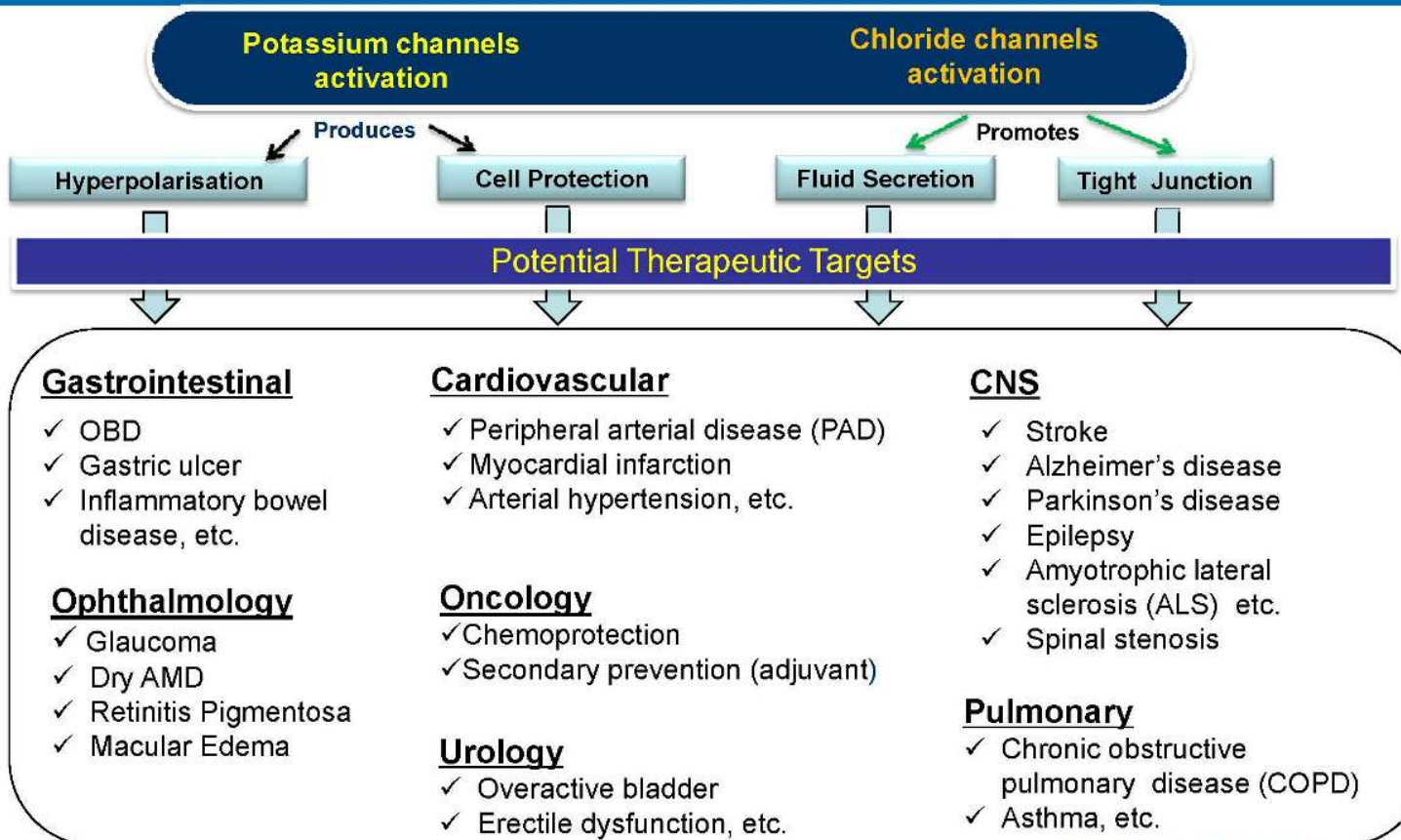
## Fatty Acids



## Prostones

Amitiza (lubiprostone)	Rescula (unoprostone isopropyl)	Cobiprostone (SPI-8811)	SPI-017	Other Prostones
CIC (24 mcg) approved January 2006	FDA approved in 2000 Now planning re-launch in U.S.	Reported phase 2 trial for prevention of NSAID-induced gastric ulcers	Planning phase 2 trial for peripheral arterial disease	Several compounds selected for preclinical development
IBS-C (8 mcg) approved April 2008	Phase 2 protocols for dry AMD under development			

# Prostones Work As Potassium and Chloride Channel Activators



## Sucampo's Financial Results and Position

<i>(In millions, except per share data)</i>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010 YTD</b> As of Sept 30 (9 months)
Product Royalty Revenue	\$27.5	\$34.4	\$38.3	\$29.8
R&D Revenue*	\$59.4	\$72.3	\$24.0	\$15.9
Total Revenue	\$91.9	\$112.1	\$67.4	\$49.5
Net Income/(Loss)	\$13.2	\$25.0	(\$0.8)	(\$0.1)
Earnings Per Share (diluted)	\$0.35	\$0.59	(\$0.02)	\$0.0
Cash and Investments	\$86.1	\$121.5	\$118.3	\$110.7

*\*R&D Revenue includes reimbursement of clinical trial expenses, and revenue recognized from milestone payments for filing and approval of sNDA for IBS-C (in 2007 and 2008, respectively).*

## Sucampo's 2010 Milestones

- √ Submit NDA in Japan with results to date of Amitiza in CIC program
- √ Report phase 3 efficacy trial results of Amitiza in Japanese CIC patients
- √ Complete phase 1 trial of SPL-017 for PAD in Japanese patients
- Initiate third pivotal phase 3 trial of Amitiza in OBD patients
- Initiate phase 2 trial of Rescula in dry AMD
- Plan Amitiza's Swiss commercialization based on outcome of pricing negotiations

# Credit Suisse 2010 Healthcare Conference

James J. Egan  
Chief Operating Officer  
*November 12, 2010*