

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 10, 2011

**Sucampo Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

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Delaware

001-33609

30-0520478

(State or Other Juris-  
diction of Incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

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4520 East-West Highway, Suite 300  
Bethesda, Maryland

20814

(Address of Principal Executive Offices)

(Zip Code)

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 10, 2011, Sucampo Pharmaceuticals, Inc. will make a corporate update presentation at an investor conference in Phoenix, Arizona at the 2011 Credit Suisse Healthcare Conference that include written communication comprised of slides. 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 10, 2011

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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 10, 2011

By: /s/ THOMAS J. KNAPP

Name: Thomas J. Knapp

Title: Sr. VP, General Counsel & Corporate Secretary



**Applying scientific and medical  
leadership in prostheses to develop and  
commercialize therapeutics for an  
aging population**

*Stanley G. Miele*

*Senior Vice President, Sales & Marketing*

*November 10, 2011*

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# Forward-Looking Statements

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 disclaims 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 Investment Highlights

- **Proven technology:** Leadership in prostones -- key ion channel activators, with validated clinical utility
- **Commercial products focused on large patient populations:** AMITIZA® approved in the U.S.; RESCULA® was approved in the U.S. and was approved in 45 countries; on market in Japan
- **Clinical expansion:** AMITIZA label expansion strategies underway in the U.S., Europe and Asia; RESCULA label expansion strategies underway in the U.S. and Europe
- **Robust pipeline:** Revenue stream fueling advances in proprietary prostone-based portfolio

# Prostones

- Class of compounds derived from endogenous functional fatty acids with wound-healing and restorative properties\*
- Selectively activate ion channels that modulate key pathways
- Metabolize quickly into inactive form - useful for localized effect in specific organs
- Broad and validated therapeutic applicability - can be targeted to induce specific pharmacological effects\*\*

\*Bilkslager AT et al. Comparison of the chloride channel activator lubiprostone and the oral laxative Polyethylene Glycol 3350 on Mucosal Barrier Repair in ischemic-injured porcine intestine. *World J Gastroenterol* 2008 Oct 21;14(39):6012-7.

\*\*Cuppoletti J et al. SPI-0211 activates T84 cell chloride transport and recombinant human ClC-2 chloride currents *Am J Physiol Cell Physiol* 287:C1173-C1183, 2004

# Prostones

- Act as Selective Potassium Channel (BK) and/or Selective Chloride (ClC-2) Channel activators
- ClC-2 Channel stimulators (lubiprostone and cobiprostone)
  - Restore endothelial and epithelial barrier functions\*
  - Stimulate wound repair\*\*
  - Restore tight junction, restore membrane integrity and normal trans-membrane resistance
  - Restore normal fluid circulation and modulate fluid transit across cell membranes

\*Tsukita S et. Japanese BioChemical Society 2011 Meeting. *Lubiprostone, a ClC-2 chloride channel activator, down-regulates the DSS-induced inflammation.*  
\*\*Blikslager AT Am J Physiol Gastrointest Liver Physiol 2007 Feb;292(2):G647-56. Epub 2006 Oct 19



# Prostones

- BK Channel Stimulators (unoprostone isopropyl)
  - Down-regulate inflammation, hypoxia and edema\*
  - Block pro-apoptotic and excito-toxic effects\*\*
  - Block the vaso-constrictive and pro-inflammatory effects of endothelin in the microvasculature
  - Reduce normal fluid pressure in the eye\*\*\*
  - Demonstrate neuroprotective effects in preclinical ophthalmology models (light-induced injury)\*\*\*\*
  - Demonstrate dose-dependent neuroprotective effects in clinical studies in glaucoma (head to head longitudinal studies vs. latanoprost\*\*\*\*\* in Japan) and retinitis pigmentosa\*\*\*\*\* (phase 2b in Japan)

\* Yu DY et al. Invest Ophthalmol Vis Sci 1994; 35:4087-4099. Kern TS. Exp Diabetes Res. 2007; 2007: 95013. Hardy P et al. Prostaglandins Leukot Essent Fatty Acids. 2005; 72(5): 301-325

\*\*Sugiyama T et al. Arch Ophthalmol. 2009;127:454-459 \*\*\* Inoue K et al. Clinical Ophthalmology 2011;5 1003-1005

\*\*\*\*Hayami K et al. Ophthalmic Res. 2001 Jul-Aug;33(4):203-9 and Melamed S. Drugs Exp Clin Res 2002;28(2-3):63-73.

\*\*\*\*\*Ishida T et al. *Topical Monotherapy for Normal Tension Glaucoma-Comparison of Long-term Monotherapies in Maintaining Visual Field* Ophthalmology 47:1107-1112,2005.

\*\*\*\*\*ARVO 2011, Poster#4992, A416

# Prostones' Therapeutic Potential

- Vast therapeutic targeting potential
  - GI\*
  - Ophthalmology\*\*
  - CV
  - Oncology \*\*\*
  - Urology
  - CNS
  - Pulmonary\*\*\*\*

\*Cryer B et al. *Cobiprostone demonstrates protective effects against non-steroidal anti-inflammatory drug-induced gastrointestinal injury.* Gastroenterology 138(5 Suppl 1):S-64 [abstract 475F].

\*\*Cuppoletti J et al. *Cellular and molecular effects of unoprostone as a BK channel activator.* BioChem Biophys Acta 1768(5):1083-82.

\*\*\*Cuppoletti J et al. *Lubiprostone suppresses growth of colon cancer cells in vitro and in vivo.* Am J Gastroenterol 105 (Suppl 1):S76-77 [abstract 203].

\*\*\*\*Cuppoletti J. et al. *SPI-8811 activates human bronchial epithelial cell chloride transport and recombinant human ClC-2 chloride currents.* Pediatr Pulmonol 38(Suppl 27):245-6 [abstract 167].

# Deep and Validated Clinical Pipeline

Clinical Focus	Stage of Development					
	Discovery	Pre-Clinical	Phase 1	Phase 2	Phase 3	Filed
<b>lubiprostone</b>						
Chronic Idiopathic Constipation (CIC)						(Switzerland + UK)
(CIC)						(Japan)
Opioid-induced Bowel Dysfunction (OBD) in chronic pain patients without cancer				(U.S. and E.U.)		
OBD in cancer pain patients						
Inflammatory Bowel Disease (IBD)						
<b>unoprostone isopropyl</b>						
Lowering IOP in glaucoma and ocular hypertension patients intolerant of or insufficiently responsive to other IOP-lowering medications						(U.S.)
						(E.U.)
Dry Age-related Macular Degeneration (Dry AMD)						
Retinitis Pigmentosa (RP) conducted by RTU						
<b>cobiprostone</b>						
Prevention of NSAID-Induced Ulcers						
Chronic Obstructive Pulmonary Disease (COPD)						
IBD						
Oral Mucositis in cancer patients						
<b>SPI-017</b>						
Spinal stenosis (pain management)						
<b>SPI-3608</b>						
Spinal stenosis (pain management)						

# AMITIZA (lubiprostone)



24 mcg for CIC



8 mcg for IBS-C



# AMITIZA (lubiprostone)

## A differentiated mechanism of action

- **Small intestine fluid secretion:** Chloride ions enter intestinal lumen following CLC-2 activation
- **Small intestine fluid secretion:** Sodium ions follow chloride ions into lumen to maintain isoelectric neutrality
- **Small intestine fluid secretion:** Ion transport also draws water into lumen to maintain osmotic neutrality
- **Lubiprostone activates intestinal CLC-2 channels:** Works through 'facilitated diffusion' and/or 'passive transport'
- **Increases tight junction** integrity and function to maintain normal transepithelial resistance.

*Basavappa S., et al Journal of Cellular Physiology 2005;202(1):21-31*

## AMITIZA (lubiprostone)

**Indications:** Approved by FDA for the treatment of IBS-C in women aged 18 years and older and for the treatment of CIC in adults

**Global status:** Marketed by Takeda in US, Abbott holds marketing rights to CIC in Japan, ROW owned by Sucampo

**U.S. Sales (net):** \$220 million in 2010

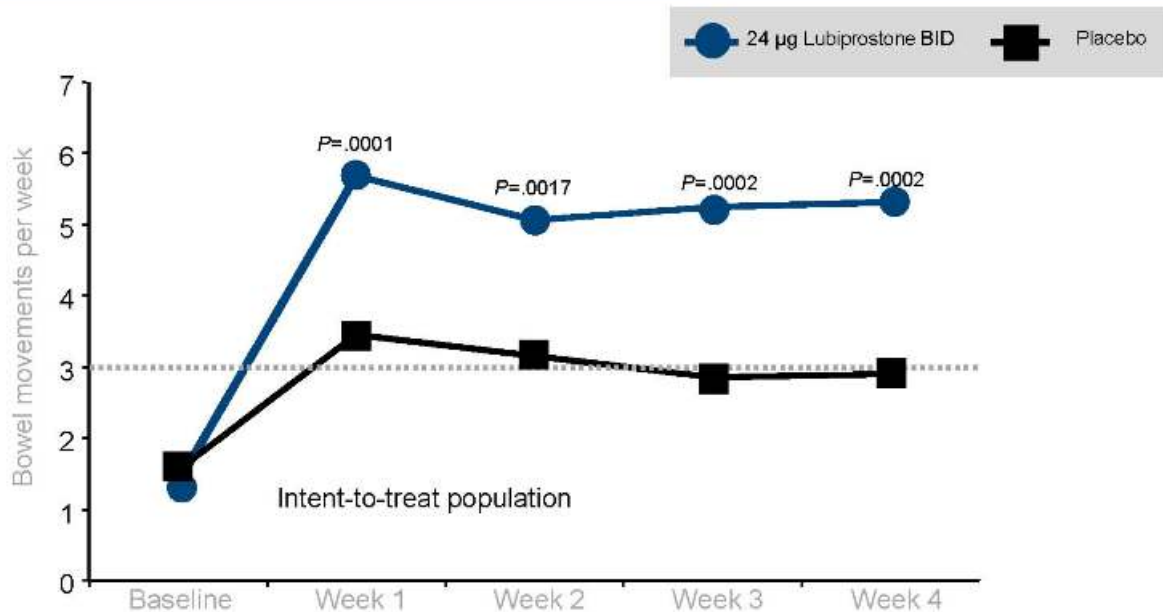
**Patent Life:** May extend effective exclusivity to 2022

# AMITIZA (lubiprostone)

## Key Events

- Label expansion
- Phase 3 OBD trial results
- Swiss pricing
- Japanese NDA decision
- MAA approval in the U.K.
- E.U. pricing
- Japanese pricing
- Decision in Takeda arbitration

# AMITIZA Phase 3 Trial Results in CIC: Highly Statistically Significant Results in SBM Frequency



**Primary Endpoint:** Average SBMs go from 1.5/Week to 5/Week  
Normal SBMs/week range from >3 to >8, but most patients consider 5 SBMs/week as “normal”



## In a 48 Week trial of high-dose AMITIZA, taken with food, CIC patients

- 1.08 reports/1,000 patient days with a reported nausea event
- 58.2% of all nausea events were “Mild”, i.e., noticeable but no effect on daily activities, and “acceptable”
- 38.8% of all nausea events were Moderate, noticeable, some effect on daily activities, and “acceptable”
- 3% of all nausea events, or 0.03 reports/100,000 patient days, were “Severe”, i.e., noticeable, had a significant effect on daily activities, and “unacceptable”. All of these “Severe” patients were on concomitant medicines, many with label warnings for nausea.
- Time of patients’ discontinuation for nausea:
  - 9 patients (3.6%) discontinued during weeks 0-12
  - 4 patients (1.6%) discontinued during weeks 13-48

\* Lembo, AJ, et al. *Long-Term Safety and Effectiveness of Lubiprostone, a Chloride Channel (ClC-2) Activator, in Patients with Chronic Idiopathic Constipation*. Dig Dis Sci (2011) 56:2639-2645

# Nausea rates in trials of high-dose AMITIZA, taken with food, in CIC patients

Study	CIC 4 week safety studies - 24mcg twice a day (2 studies)	CIC 4 week safety studies - 24mcg twice a day (2 studies)	CIC 48 Week safety study - 24mcg twice a day*
# of patients	240	239	248
Treatment	Placebo	Lubiprostone	Lubiprostone
Rate of Nausea events per 1000 patient days	1.4 reports/1000 days (15 events in 10,807 patient days)	7.9 reports/1000 days (81 events in 10,278 patient days)	1.08 reports/1000 days (67 events in 62,325 patient days)
% of Nausea events reported as Mild i.e., noticeable, but no effect on daily activities and "acceptable"	53.3% (8/15)	64.2% (52/81)	58.2% (39/67)
% of Nausea events reported as Moderate i.e., noticeable, some effect on daily activities and "acceptable"	46.7% (7/15)	27.2% (22/81)	38.8% (26/67)
<b>Total Mild/Moderate</b>	<b>100.0% (15/15)</b>	<b>91.4% (74/81)</b>	<b>97.0% (65/67)</b>
Rate of severe Nausea events per 1000 patient days	0	0.6 reports/1000 days (6 events in 10,278 patient days)	0.03 reports/1000 days (2 events in 62,325 patient days)
% of Nausea events reported as Severe i.e., noticeable, major effect on daily activities and "not acceptable"	0%	8.6% (7/81)	3.0% (2/67)
Severe Nausea events weeks 0 to 2	0	6	2
Severe Nausea events weeks 3 to 48	0	0	0
Patients reporting an event of nausea	6.3% (15/240)	29.7% (71/239)	(21.0%) 52/248
Patients Discontinued because of Nausea in 48 Week Trial	N/A	N/A	5.2% (13/248)
Time of patient Discontinuation because of Nausea	N/A	N/A	3.6% (9/248) in weeks 0-12 1.6% (4/248) weeks 13-48
Number of Severe patients of Nausea	0	4	2
Number of severe patients with concomitant medication	0	4	2
Percentage of severe patients with concomitant medication	0%	100.0% (4/4)	100.0% (2/2)
Percentage of nausea patients reporting only 1 event	100% (15/15)	88.7% (63/71)	75.0% (39/52)
Percentage of nausea patients reporting 2-3 events	0%	11.3% (8/71)	25.0% (13/52)
Percentage of nausea patients reporting >3 events	0%	0%	0%

\* Lembo, AJ, et al. Long-Term Safety and Effectiveness of Lubiprostone, a Chloride Channel (ClC-2) Activator, in Patients with Chronic Idiopathic Constipation. Dig Dis Sci (2011) 56:2639-2645

## Growth Strategy: AMTIZA in OBD

Clinical program of three phase 3 trials of AMITIZA for the treatment opioid-induced bowel dysfunction (OBD)

- Reported positive results of AMITIZA phase 3 trial (OBD0631) at DDW 2010
- Patients 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 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

\*Cryer B., et al. A phase 3, randomized, double-blind, placebo-controlled clinical trial of lubiprostone for the treatment of opioid-induced bowel dysfunction in patients with chronic non-cancer pain. *Gastroenterology* 138(5 Suppl 1):S-129 [abstract 906]

# AMTIZA Expansion Strategy Well Underway

- Third phase 3 trial of AMITIZA for the treatment of OBD fully enrolled
- Trial design
  - Primary endpoint: change from baseline in SBM frequency at Week 8 without reduction in dose of study pain medication
  - Randomized, placebo-controlled, multi-center trial
  - Almost the same protocol as used in the successful phase 3 trial (OBD0631) reported at DDW 2010, except exclusion of patients on methadone
  - One 24-mcg gel capsule of lubiprostone or placebo twice each day
  - 12 week treatment period
  - Permitted concomitant pain medications include fentanyl, morphine and oxycontin but exclude methadone
  - Enrolled more than 420 patients in the U.S. and Europe
- Sucampo and Takeda will share trial costs equally
- Top-line phase 3 results expected by year-end 2011

\*Sucampo press releases, Jan. 7, 2011 and Aug. 4, 2011

## Terms of Sucampo's AMITIZA Agreement with Takeda

- Takeda shall exert best efforts to promote, market, and sell AMITIZA and to maximize net sales revenue in the U.S. and Canada
- Sucampo's tiered royalty rate: 18% to 26% of annual net sales
- Sucampo earned \$20 million in upfront and \$130 million in development milestone payments, as of June 30, 2011
- We are disappointed by our partner's performance
- Arbitration hearing set for December 2011 but it is not known if the arbitration will remain on schedule or how long thereafter the arbitration proceedings will conclude

## AMITIZA Japanese Strategy

- Sucampo granted Abbott exclusive rights to commercialize AMITIZA 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 has received a total of \$22.5 million in upfront and milestone payments from Abbott, as of June 30, 2011
- Sucampo designed and managed the recently reported successful phase 3 efficacy trial and long-term safety trial in Japanese CIC patients
- NDA submitted September 2010
- Next Steps: Japanese regulatory decision

# RESCULA

**Compound:** Unoprostone isopropyl

**Indication:** FDA approved for the lowering of intraocular pressure (IOP) in open-angle glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP-lowering medications

**Global status:** Updating US label via sNDA; conducting trials to drive label expansion in dry AMD; reactivating and updating labels and licenses in EU

**Patent Life (Registered formulated drug product patent):**  
Extends to 2018

# RESCULA

## Upcoming Milestones:

- Data from exploratory dry AMD trial
- sNDA for glaucoma indication in US
- Reactivated licenses and revised labels in certain EU countries and Switzerland



# RESCULA: Broad Therapeutic Potential

## A demonstrated, but not yet labeled, unique mechanism of action

- Rescula (unoprostone isopropyl) activates Maxi K (BK) channels in neurons and contractile cells\*
- Blocks effect of endothelin \*
- 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\*\*\*
- Exploring AMD potential suggested by increased choroidal blood flow and endothelin blockade
- Maintains visual field in glaucoma patients; inhibits apoptosis of retinal neurons and ischemia-induced degeneration of optic nerve fibers in non-clinical studies\*\*\*\*

\* Yu DY et al. *Invest Ophthalmol Vis Sci.* 1994;35:4067-4099. Kern TS. *Exp Diabetes Res.* 2007;2007:95013. Hardy P. et al. *Prostaglandins Leukot Essent Fatty Acids.* 2005;72(5):301-325.

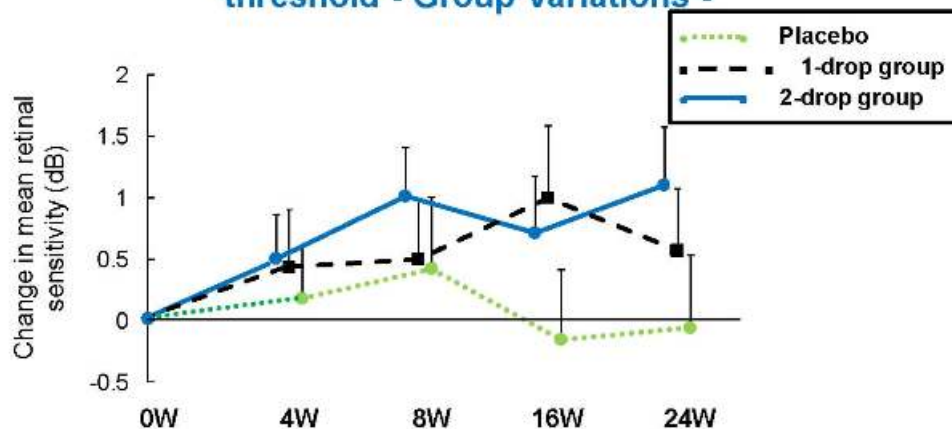
\*\* Alm A et al. *Exp Eye Res.* 2009;88:760-768. Toris CB et al. *Arch Ophthalmol.* 2004;122:1782-1787. Llobet A et al. *News Physiol Sci.* 2003;18:205-209

\*\*\* Kojima S et al. *Nippon Ganka Bakkai Zasshi.* 1997;101;605-610. Makimoto Y et al. *Jpn J Ophthalmol.* 2002;46:31-35. Kimura I et al. *Jpn J Ophthalmol.* 2005;49:287-293

\*\*\*\* Sugiyama T et al. *Arch Ophthalmol.* 2009;127:454-459

# RESCULA: High Dose Achieved Primary Endpoint in Phase 2a RP Study

MP-1 central 2 degrees  
Change in mean retinal sensitivity  
threshold - Group Variations -



The 2-drop group met the primary endpoint ( $p=0.018$ ) of change from baseline in retinal sensitivity threshold in the central 2 degrees, as measured by Microperimeter-1.

## RESCULA: Exploring Potential with Phase 2a Study in Dry AMD

- **Purpose:** to study choroidal blood flow following administration of unoprostone isopropyl vs. placebo
- **Design:**
  - A single-center, double-masked, randomized, placebo-controlled, cross-over designed study in 28 dry AMD patients
  - Administer two doses (Day 1 and 8); 14 day follow-up period
  - Choroidal blood flow measured by laser doppler flowmetry
- **Study initiated in May 2011**, expecting results in late 2011

## RESCULA Current Status

- Awaiting FDA label with mechanism of action language based on current scientific understanding
- Was approved in 45 countries for glaucoma and ocular hypertension and is still approved in Japan and U.S.
- Reactivating and updating label and licenses in certain E.U. countries and Switzerland
- Data from exploratory clinical study in dry AMD patients available 4Q 2011

## R&D Candidates

- Cobiprostone
  - Phase 2 for prevention of NSAID-induced gastric ulcers
  - Preclinical studies for oral mucositis
  - Preclinical studies for COPD
- SPI-3608
  - Preclinical development for pain associated with spinal stenosis
- Additional prostones in preclinical development generated by Sucampo's proven technology platform
- Generating additional pipeline candidates through Numab AG collaboration

# Key Financials

(In millions, except per share data)	2010*	2011* (6 months)
Product Royalty Revenue	\$40.3	\$30.7
R&D Revenue*	\$16.5	\$6.6
Total Revenue	\$61.9	\$40.5
Net Income/(Loss)	(\$2.7)	(\$20.0)
Earnings Per Share (diluted)	(\$0.07)	(\$0.48)
Cash, Restricted Cash and Investments	\$123.9**	\$104.6***

\* Results for 2010 and 2011 are consolidated to reflect the acquisition of Sucampo AG in Dec 2010

\*\* At Dec. 31, 2010, Sucampo had \$44.4 million in long-term debt and \$19.5 million in short-term debt

\*\*\* At Sept. 30, 2011, Sucampo had \$46.2 million in long-term debt and \$20.5 million in short-term debt

## 2011 Milestones

- ✓ Completion of enrollment into third phase 3 clinical trial of lubiprostone for OBD during third quarter
- ✓ Submit a Marketing Approval Application (MAA) for lubiprostone for CIC in the United Kingdom
- ✓ Integrate Sucampo AG into corporate structure to achieve operational efficiencies afforded by our December 2010 acquisition of SAG and its IP estate
  - Gain approval of a revised label (sNDA) for RESCULA to reflect the current state of scientific understanding of its mechanism of action to support a re-launch in the U.S. for the approved indication of lowering of intraocular pressure (IOP) in open-angle glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP-lowering medications
  - Make substantial progress towards successfully resolving our dispute with our U.S. partner (Takeda)

# Sucampo Investment Highlights

- **Proven technology:** Leadership in prostones -- key ion channel activators, with validated clinical utility
- **Commercial products focused on large patient populations:** AMITIZA is approved in the U.S.; and RESCULA is approved in the U.S. and was approved in 45 countries; on market in Japan
- **Clinical expansion:** AMITIZA label expansion strategies under way in the U.S., Europe and Asia; RESCULA label expansion strategies underway in the U.S. and Europe
- **Robust pipeline:** Revenue stream fueling advances in proprietary prostone-based portfolio





**Applying scientific and medical  
leadership in prostheses to develop and  
commercialize therapeutics for an  
aging population**

## Appendix

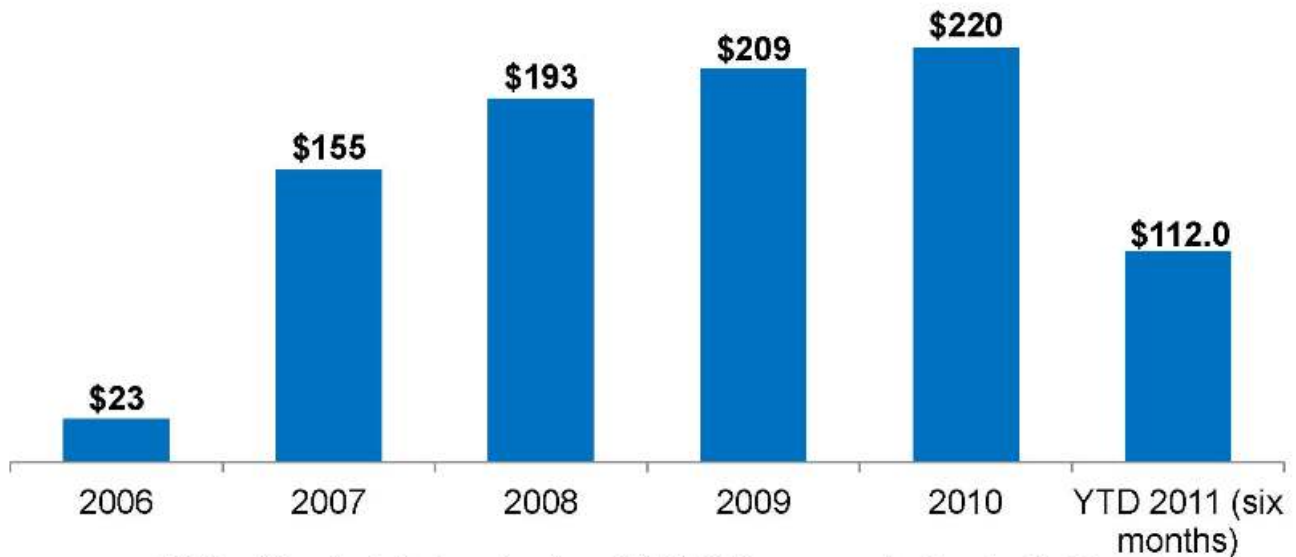
## Patents: Lubiprostone and Unoprostone

	U.S.	E.U.	Japan
Lubiprostone	US5284858 expires Jul. 2014	EP1220849 expires Oct. 2020	JP 4332316 expires Oct. 2020
	US6583174 and US7417067 expire Oct. 2020	EP1426361 expires Oct. 2020	
	US8026393 expires Oct. 2022		
Unoprostone	US5221763 expires Jul. 2012	EP289349 expires Apr. 2013	Unoprostone's commercial rights in Japan are held by another company.
	US6770675 expires Nov. 2018	EP969846 expires Mar. 2018	

Additional patents, covering formulation, use and manufacturing for lubiprostone, have been issued in the U.S., E.U. and Japan and provide coverage until 2021 or 2029.

Patent term extensions, of up to 5 years, are available for lubiprostone in EU and Japan upon receipt of marketing approvals there.

## Net Sales of AMITIZA Since Launch in April 2006



*\$912 million to date in net sales of AMITIZA on a product projected to sell \$800 million/year by 2012 in an IBS-C/CIC market to be shared with Zelnorm selling at \$1.2-1.8 billion/year*

## AMITIZA Net Sales of \$220 Million in US (2010)

- ▶ Only FDA approved prescription product currently in the market for CIC (2006) and IBS-C (2008)
- ▶ Over 5M prescriptions filled since 2006 with a favorable post-marketing safety profile

### AMITIZA product profile was better than Zelnorm's

	Zelnorm	AMITIZA
Peak US annual TRxs	3.1 million (year 4)	1.2 million (year 6)
Year 3 length of therapy (IMS)	132 days	156 days
Launch year audited details (IMS)	477,000	164,000
Commitment to DTC advertising	Yes	No
Unique MOA vs. OTC laxatives	Yes	Yes
Successfully differentiated unique MOA	Yes	No