

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): March 7, 2011

Sucampo Pharmaceuticals, Inc.

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(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

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(State or Other Jurisdiction  
of Incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

4520 East-West Highway, Suite 300  
Bethesda, Maryland

20814

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(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))
-

**Item 7.01. Regulation FD Disclosure.**

On March 7, 2011, Sucampo Pharmaceuticals, Inc. will discuss a corporate update presentation at an investor conference in Boston, MA at the Cowen and Company 31<sup>st</sup> Annual Health Care Conference that will 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 March 7, 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: March 7, 2011

By: /s/ ANDREW P. SMITH

Name: Andrew P. Smith

Title: Principal Accounting Officer



# Cowen and Company 31<sup>st</sup> Annual Health Care Conference

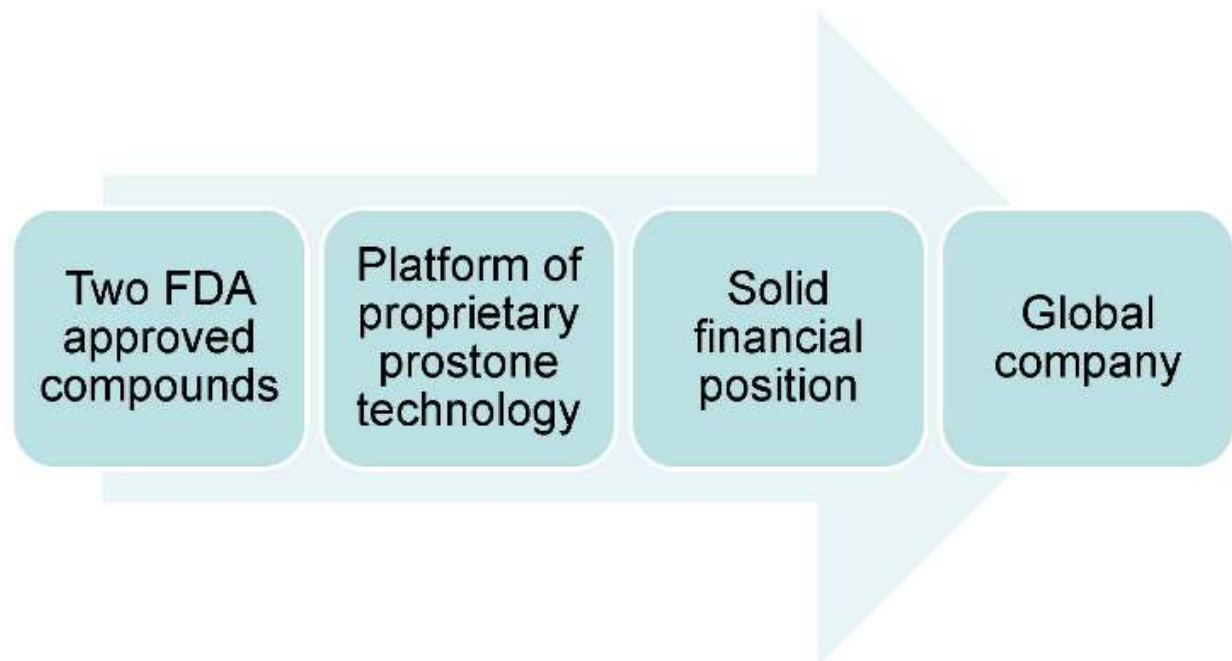
Stanley G. Miele  
*President, Sucampo Pharma Americas*

*March 7, 2011*

# 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 Has a Solid Foundation



# Unmet Medical Needs

## Gastroenterology

- **Constipation**
  - One of the most common GI complaints in the U.S.
  - Up to 42MM, of U.S. adults experience constipation
- **IBS-C**
  - IBS affects 58 million people in the U.S and ~1/3 or ~19 million IBS-C
  - Approximately 15% of IBS patients seek medical attention



## Ophthalmology

- **Glaucoma**
  - One of the leading causes of blindness in the U.S
  - Prevalence of 4.4MM U.S. Patients
  - 1.3MM diagnosed with POAG
  - 1.8MM diagnosed with Ocular Hypertension



NDDC. Constipation. Available at <http://www.digestive.niddk.nih.gov/diseases/pubs/constipation>. Accessed Dec. 3,2009

Higgins PD, et al. Am Journal of Gastroenterology. 2004; 99: 758

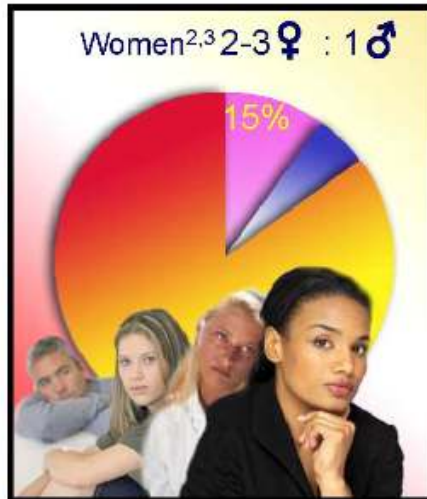
Freeman, Cathleenan, Cleveland Clinic, monograph. Aug 1, 2010

Arch of Ophthalmology (2004) 122: 532-538

# Prevalence of Chronic Constipation

## *Most Common in Elderly Females*

- Prevalence up to 28% with most studies falling between 12-19%<sup>1</sup>
- Prevalence is higher in:



1 – Brandt LJ, et al. *Am J Gastroenterol*. 2005;100(suppl 1):S5-S22.  
2 – Sonnenberg A, Koch TR. *Dis Colon Rectum*. 1989;32:1-8.  
3 – Everhart JE, et al. *Dig Dis Sci*. 1989;34:1153-1162  
4 – Talley NJ, et al. *Am J Gastroenterol*. 1996;91:19-25.



# Perceptions of Chronic Constipation

## *Patient vs. Physician Perceptions*

### Patient Perception<sup>1</sup>

Symptom-based  
(eg, straining,  
hard stools, and  
incomplete  
evacuation)

### Physician Perception<sup>2</sup>

Frequency-based  
(bowel movement  
no more than  
every  
3 to 4 days)

1 – Sandler RS, Drossman DA. Dig Dis Sci. 1987;32:841-845.  
2 – Herz MJ, et al. Fam Pract. 1996;13:156-159.

# Treatment of Constipation

## Traditional Pharmacological Options

Class	Examples	Mechanism of Action	Usage Guidelines
Fiber	Psyllium (Metamucil®)	Increases stool volume and restores regularity	Relief of <b>occasional</b> constipation; Powder mixed in 8 oz. fluid*
Bulking Agents	Methylcellulose (Citrucel®)	Promotes elimination by increasing (bulking) stool volume	Relief of <b>occasional</b> constipation; With at least 8 oz. fluid*
Stool Softeners	Mineral oil, Docusate (Colace®), Surfak®	Detergent allows water to react with stool to soften	Relief of <b>occasional</b> constipation*
Saline/Osmotic Laxatives	Polyethylene glycol (MiraLax™), Lactulose, Sorbitol, Magnesium Citrate/Hydroxide, MOM, Fleet	Draws water into intestines by osmotic gradient to stimulate peristalsis; alters electrolytes	Relief of <b>occasional</b> constipation; Mix PEG in 4-8 oz. fluid*
Stimulant Laxatives	Ex-Lax®, Castor oil®, Senna®, Bisacodyl®, Dulcolax®	Increases intestinal motility by secretion of water and ions; alters electrolytes	Relief of <b>occasional</b> constipation*

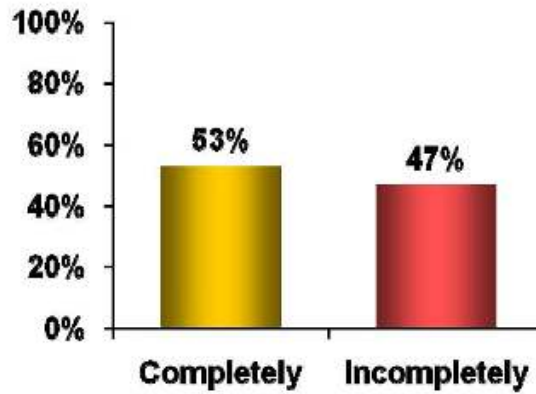
Brandt L, et al. *Am J Gastroenterol*. 2005;100(suppl 1):S5-S22.  
 Lembo A, Camilleri M. *N Engl J Med*. 2003;349:1360-1368.  
 Physicians' Desk Reference. 61st Ed. Montvale, NJ: Thomson PDR; 2007.  
 PDR for Nonprescription Drugs. 28<sup>th</sup> Ed. Montvale, NJ: Thomson PDR; 2007.

\*Use for greater than one (1) week only under physician direction.

# Treatment of Constipation

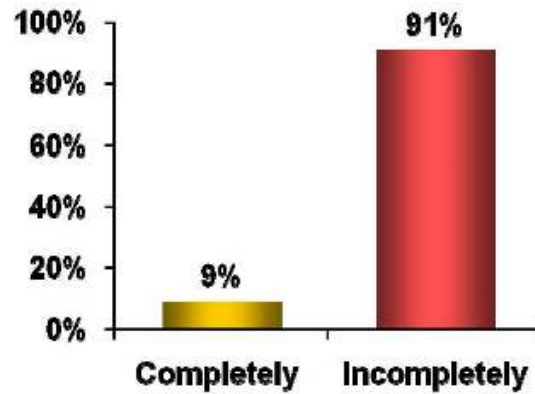
## *Dissatisfaction with Treatment Options*

Patient Satisfaction<sup>1</sup>



- Failure to result in regular bowel movements
- Unpredictable results
- Did not resolve bloating and gas

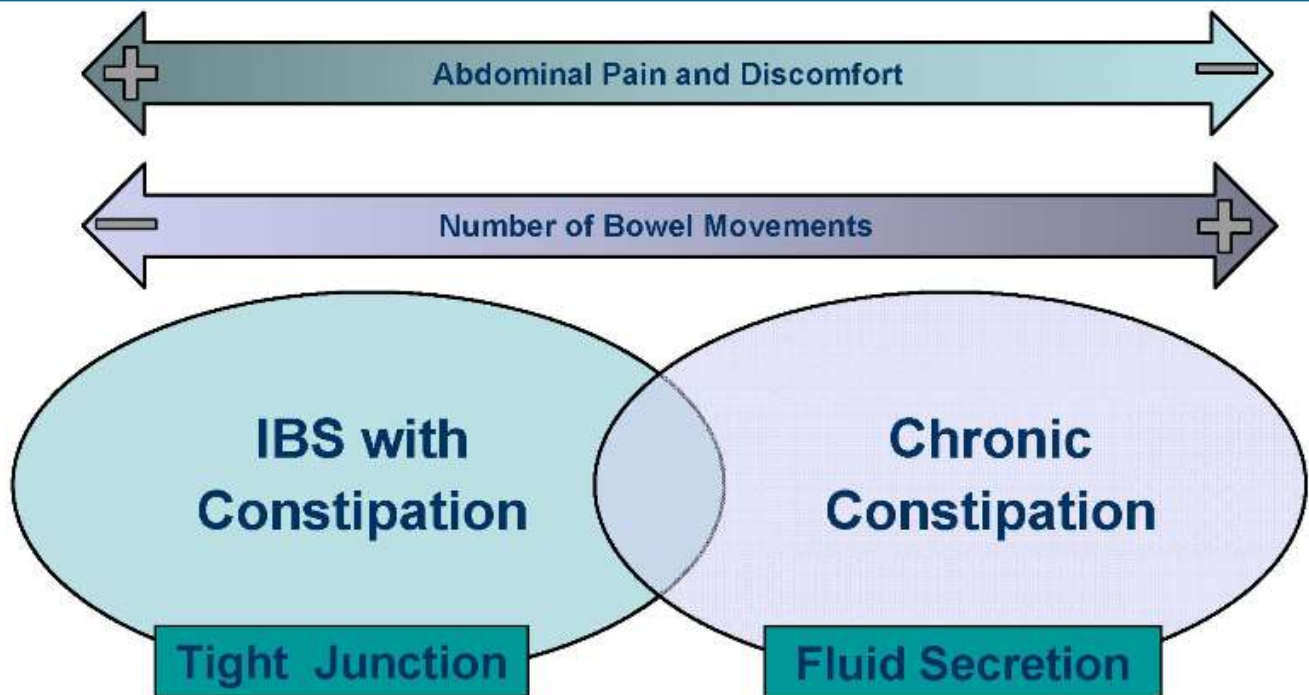
Physician Satisfaction<sup>2</sup>



- 60% of physicians agreed that they do not have adequate products
- 91% of physicians wanted better treatment options

1. Schiller LR, et al. *Am J Gastroenterol.* 2004;99(suppl):S234. Abstract 723.  
2. Schiller LR, et al. *Am J Gastroenterol.* 2004;99(suppl):S234-S235. Abstract 724.

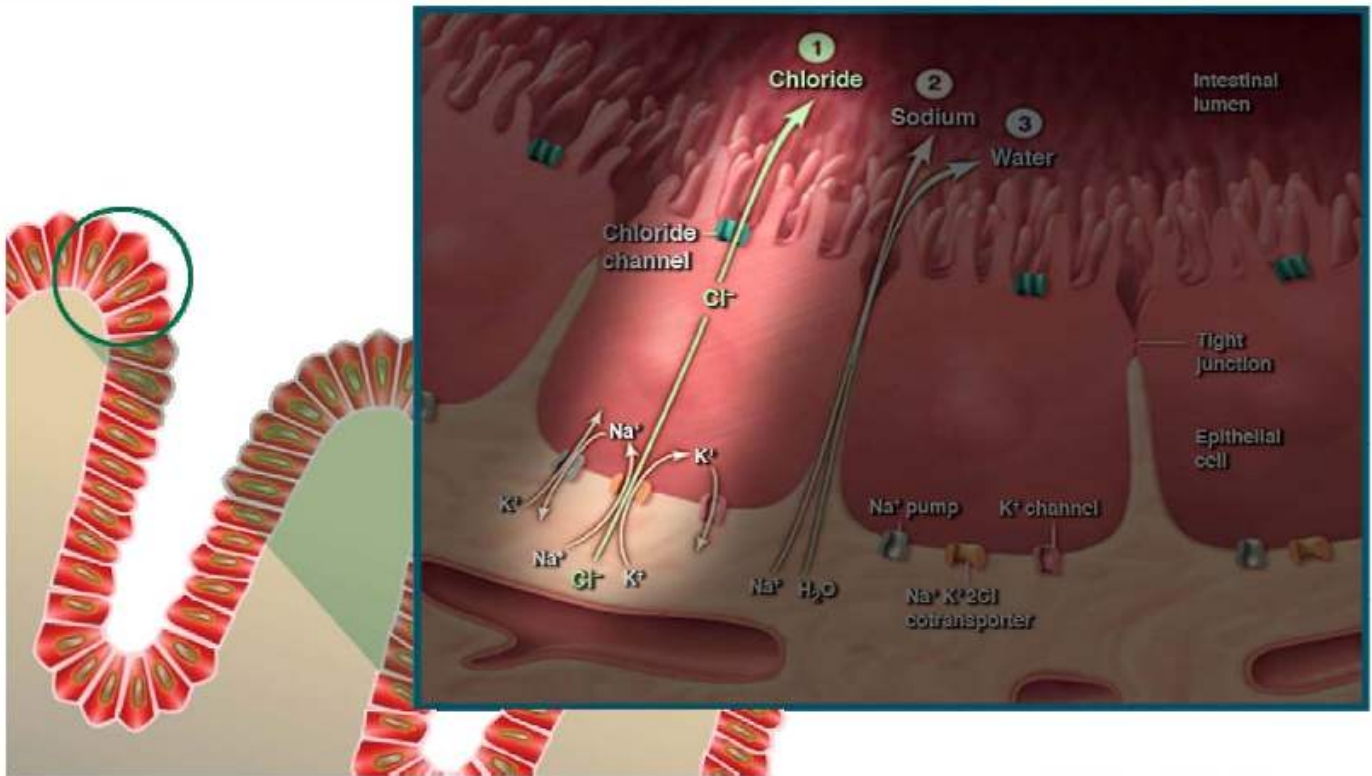
# Differentiating Between Chronic Constipation and Irritable Bowel Syndrome with Constipation





# Small Intestine Fluid Secretion

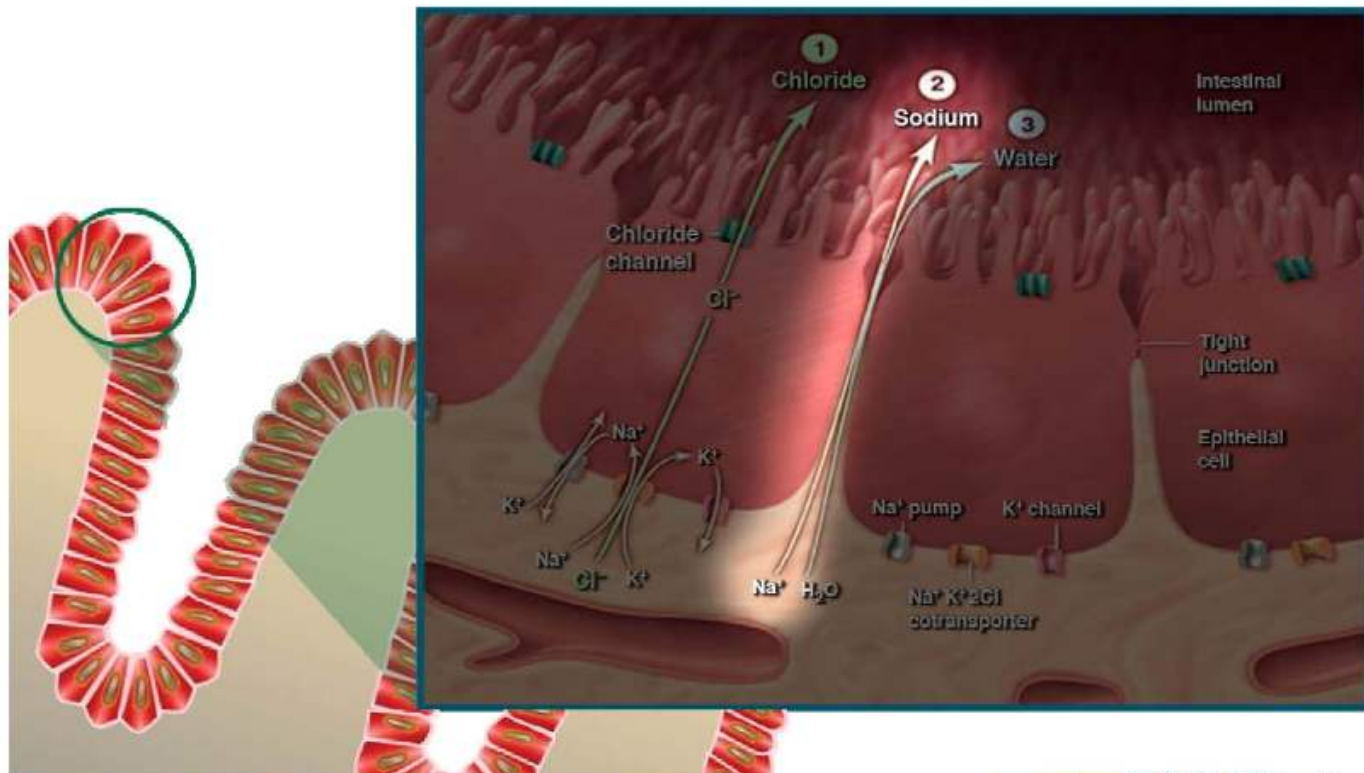
*Chloride Enters Intestinal Lumen Following CLC-2 Activation*



Basayappa S, et al. *J Cell Physiol.* 2005;202(1):21-31.

# Small Intestine Fluid Secretion

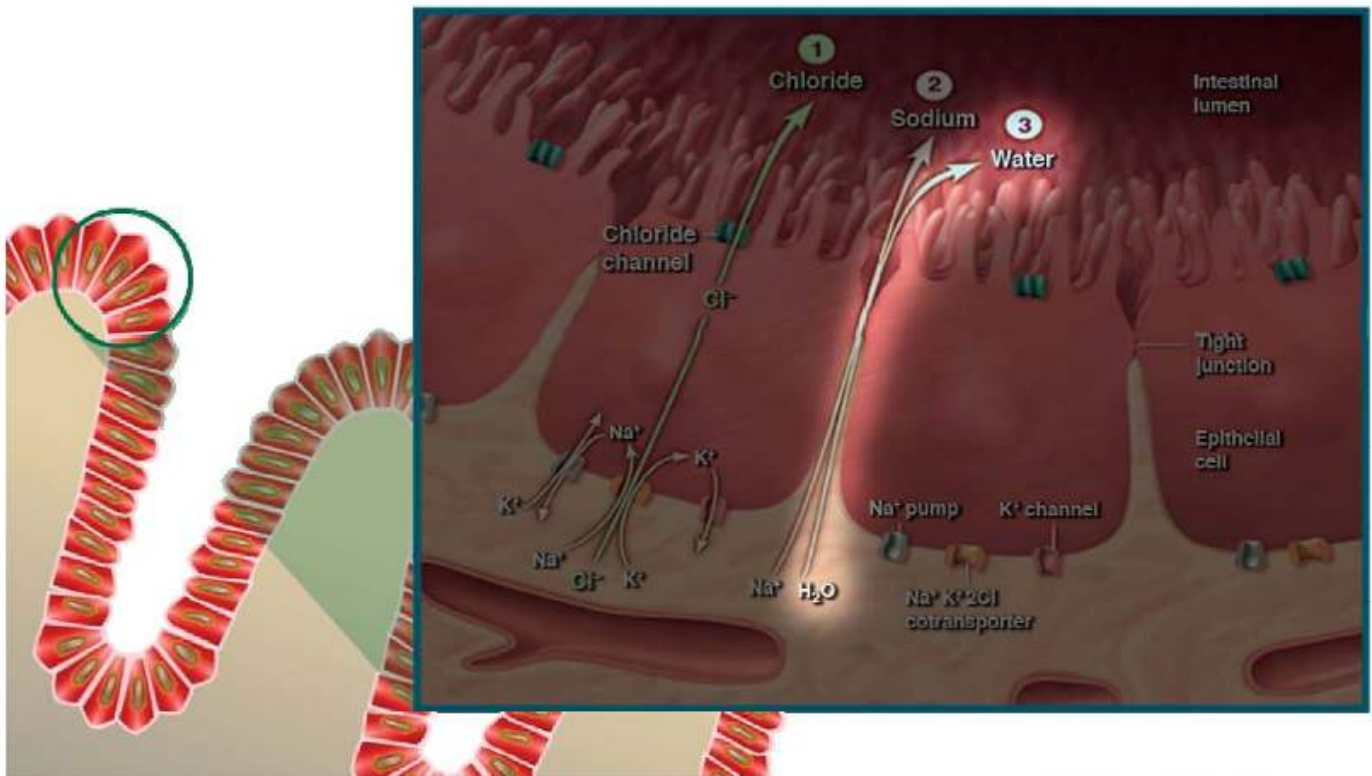
*Sodium Ions Follow Chloride To Maintain Electrical Neutrality*



Basayappa S, et al. *J Cell Physiol.* 2005;202(1):21-31.

# Small Intestine Fluid Secretion

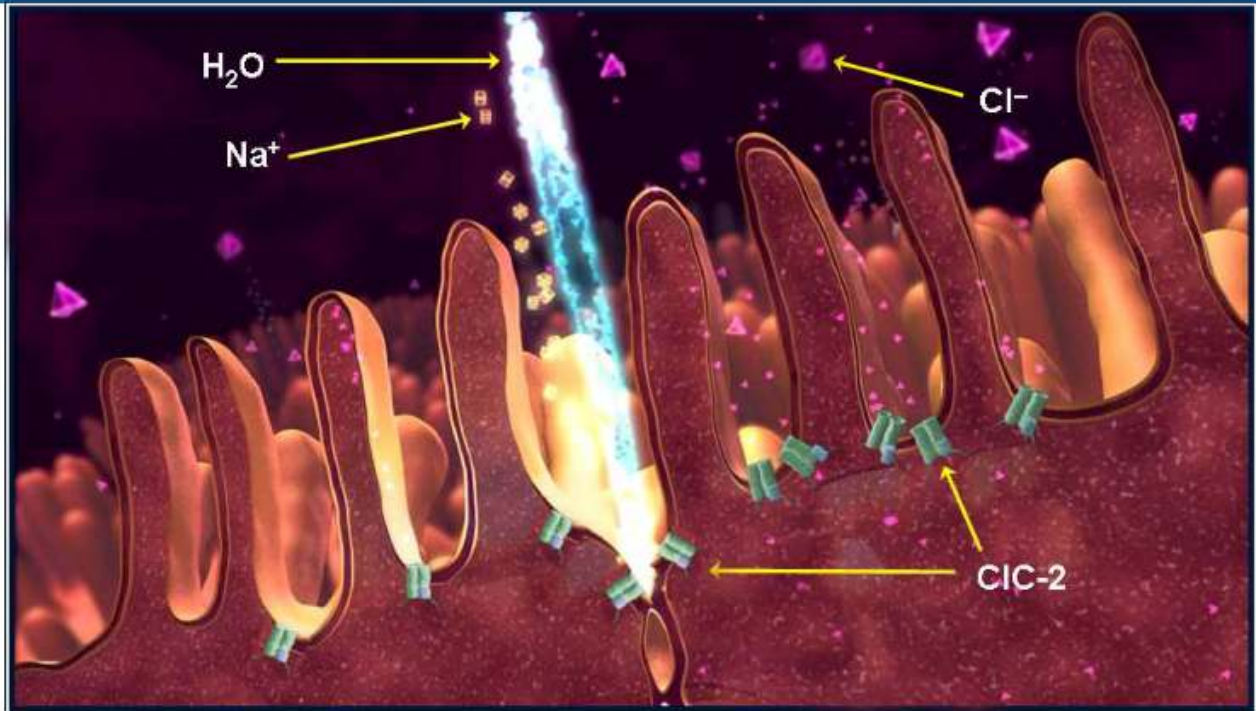
*Water Passively Enters Lumen To Maintain Osmotic Neutrality*



Basayappa S, et al. *J Cell Physiol.* 2005;202(1):21-31.



# AMITIZA<sup>®</sup> (lubiprostone) Activates Intestinal CIC-2 Channels

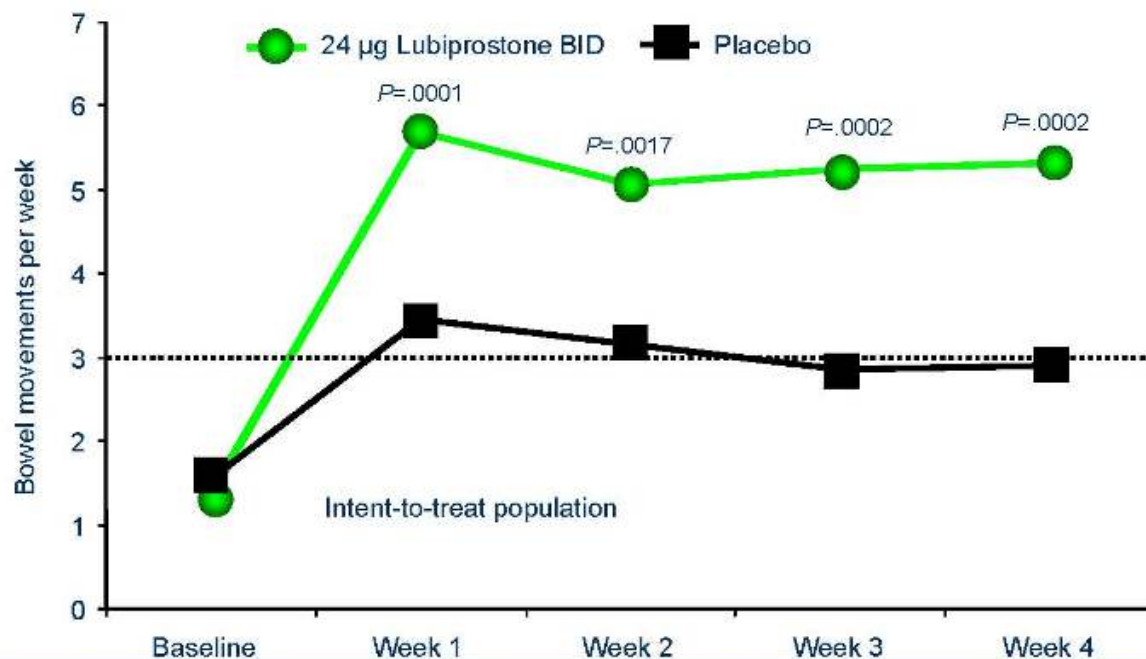


Works through 'facilitated diffusion' or 'passive transport'



# AMITIZA Efficacy: Phase 3 Trial Results Chronic Idiopathic Constipation

## Spontaneous Bowel Movement (SBM) Frequency



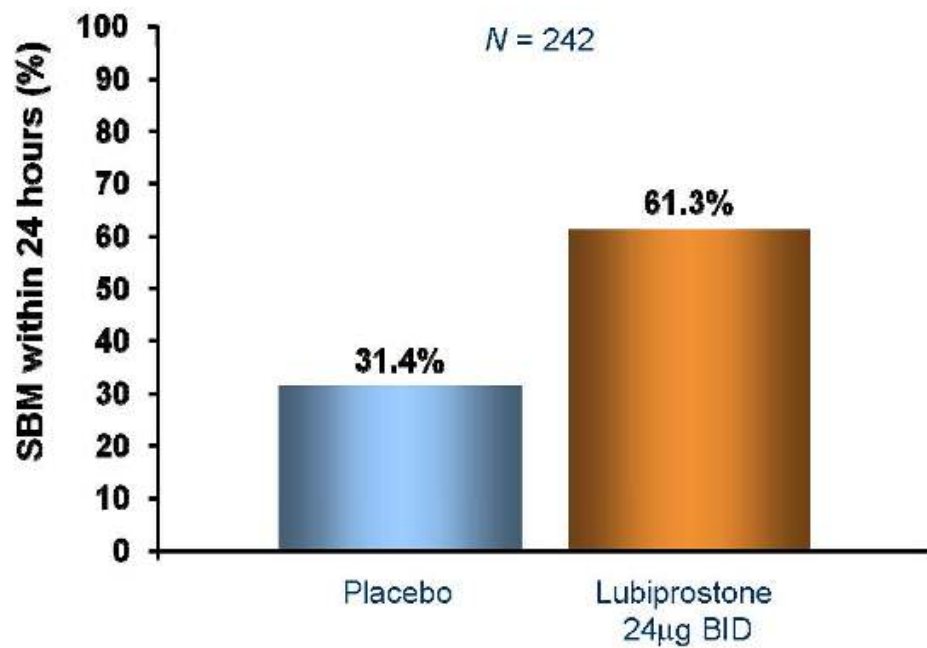
**Primary Endpoint. Average 2X the bowel movements with AMITIZA in a given week**

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

**SUCAMPO**  
PHARMACEUTICALS, INC.

# AMITIZA

Rapid Onset of Action - Spontaneous Bowel Movements (SBM)



# AMITIZA: Phase 3 IBS-C Pivotal Study Results

## Overall Responder Rate\*

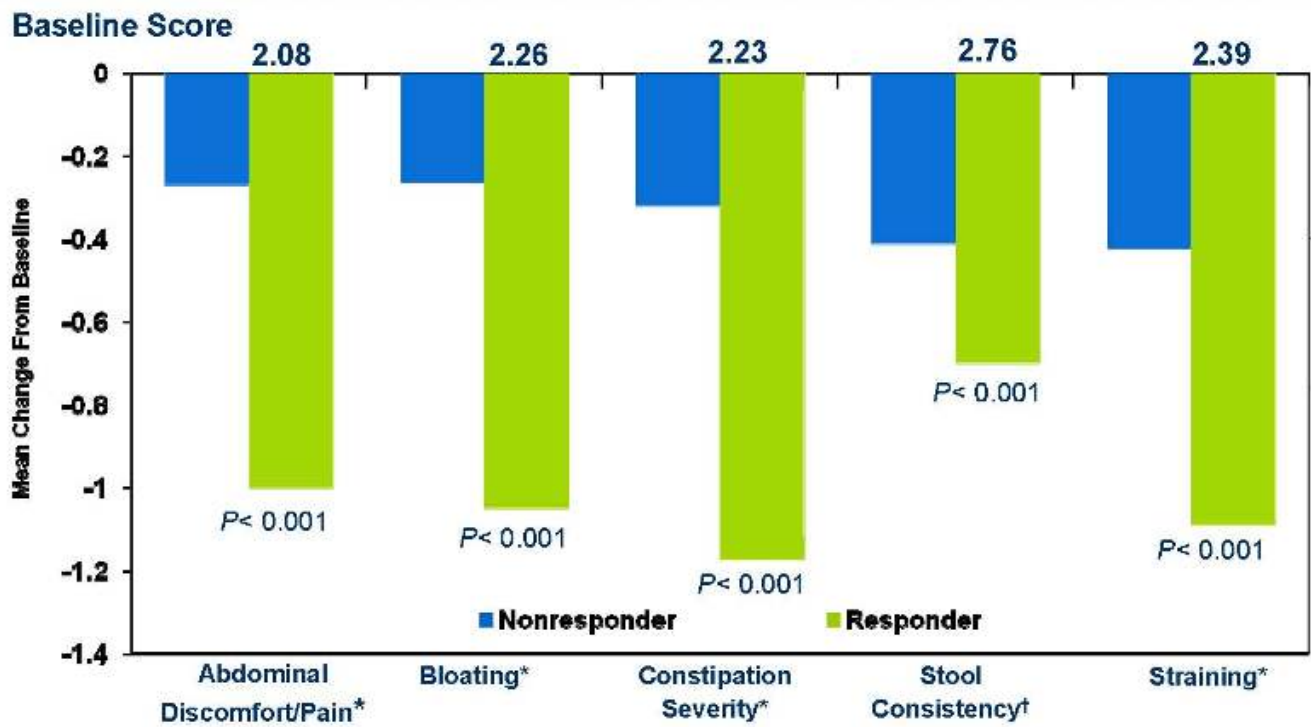
Overall Responders	8 mcg bid	Placebo	p value
Study '431	13.8%	7.8%	0.029
Study '432	12.1%	5.7%	0.023
Pooled	13.0%	6.8%	0.001



AMITIZA approved by FDA for treatment of IBS-C in women aged 18 years and older in April 2008 on achieving statistical significance in 2 well-controlled trials that adopted a higher standard of proof and endpoints to minimize placebo effects as directed by the FDA.

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

# Amitiza IBS-C Symptom Change: Responder versus Non-responder

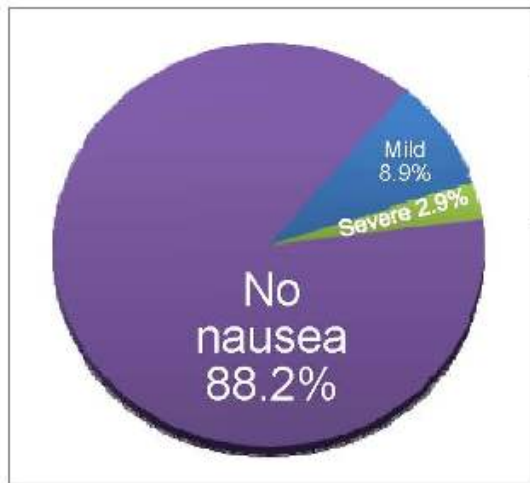


\*0 (absent), 1 (mild), 2 (moderate), 3 (severe), 4 (very severe)

†0 (very loose [watery]), 1 (loose), 2 (normal), 3 (hard), 4 (very hard [little balls])

# AMITIZA

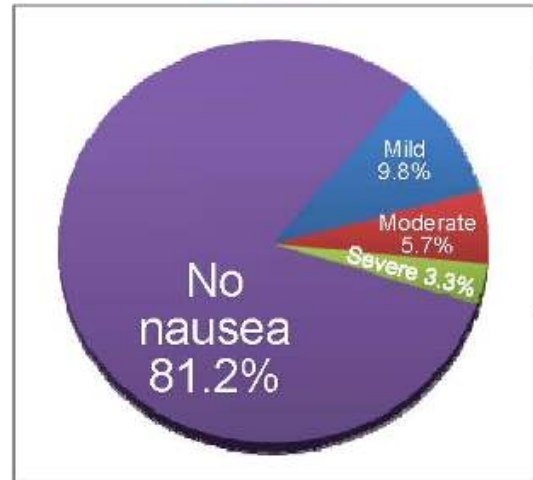
## Tolerability in Patients $\geq 65$ Years of Age



Nausea  
11.8%

Phase 3  
Efficacy Studies

Phase 3  
Open-Label  
Studies



Nausea  
18.8%

# AMITIZA Safety Profile

## Chronic Idiopathic Constipation & IBS-C

Treatment-related Adverse Events	CIC studies			IBS-C studies	
	Placebo N = 316	AMITIZA 24 mcg Once Daily N = 29	AMITIZA 24 mcg Twice Daily N = 1113	Placebo N = 435	AMITIZA 8 mcg Twice Daily N = 1011
<i>Abdominal Distension</i>	2%	-	6%	2%	3%
<i>Abdominal Pain</i>	3%	3%	8%	5%	5%
<i>Diarrhea</i>	<1%	7%	12%	4%	7%
<i>Nausea*</i>	3%	17%*	29%*	4%	8%

\*Nausea is significantly reduced with course of repeat treatment and/or when taken with food

**AMITIZA Has An Excellent Tolerability And Safety Profile  
No Habituation, No Abuse, No Fecal Incontinence,  
No Encopresis, No Urgent Defecation**



# AMITIZA Maintains Electrolyte Balance

Proper electrolyte balance is essential for muscle coordination, heart function, fluid absorption and excretion, nerve function, and concentration.

	<u>n</u>	<u>Baseline</u>	<u>Week 24</u>	<u>Week 48</u>	<u>Significant Change?</u>
Sodium, mEq/L	873	141.0	140.0	139.0	No
Potassium, mEq/L	873	4.2	4.1	4.1	No
Chloride, mEq/L	873	103.0	103.0	103.0	No
Calcium, mg/dL	873	9.7	9.7	9.7	No
Magnesium, mEq/L	872	1.7	1.7	1.7	No
Phosphorus, mg/dL	872	3.6	3.6	3.6	No

Orr KK. *Formulary*. 2006;41(3):118-129. Ueno R, Osama H, Habe T, Engelke K, Patchen M. *Gastroenterology*. 2004;126(suppl 2):A-100.

# AMITIZA: Further Opportunities -- A Third Indication

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

- Reported results of successful AMITIZA phase 3 trial (OBD0631) at DDW 2010\*
- 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

\*DDW 2010, Abstract #780958



# AMITIZA: Further Opportunities – A Third Indication

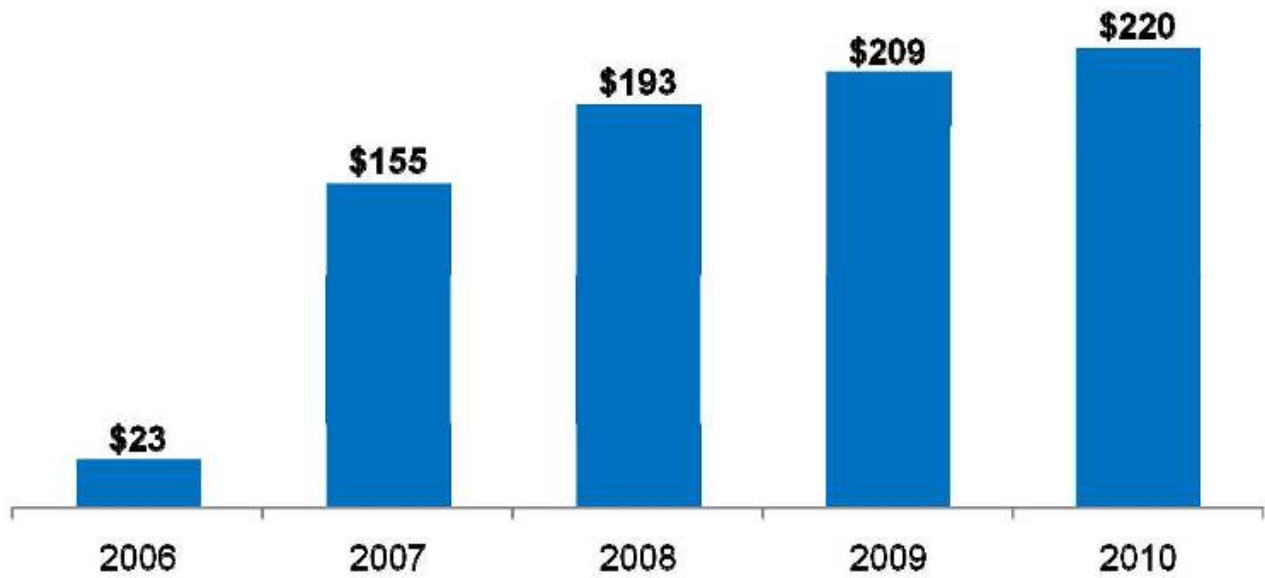
- Sucampo initiated a third phase 3 randomized, placebo-controlled, multi-center trial of AMITIZA for OBD in December 2010\*
- Trial design:
  - Almost the same protocol as used in the successful phase 3 trial (OBD0631) reported at DDW 2010, except exclusion of patients on methadone
  - One 24-mcg gel capsule of lubiprostone or placebo twice each day
  - 12 week treatment period
  - Permitted concomitant pain medications include: fentanyl, morphine and oxycontin but exclude methadone
  - Goal is to enroll 420 patients in the U.S. and Europe
  - Primary endpoint: change from baseline in SBM frequency at Week 8 without reduction in dose of study pain medication
- Sucampo and Takeda to share trial costs 50-50

\*Sucampo press release, Jan. 7, 2011

# Key Terms of Agreements with Takeda For U.S. and Canadian Marketing and Commercialization

- Takeda shall exert best efforts to promote, market and sell and to maximize net sales revenue
  - Currently covers two indications: CIC in adults and IBS-C in women aged 18 years and older
  - Takeda holds right of first refusal to additional GI indications in US and Canada
  - 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 Dec. 31, 2010

## Net Sales of AMITIZA Since Launch in April 2006



# AMITIZA – Future Global Opportunities

## Key Terms of Agreement with Abbott Japan

- Key element in Sucampo's growth strategy: increase the number of international market approvals 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 December 31, 2010
- Sucampo designed and managed the recently reported successful phase 3 efficacy trial and long-term safety trial in Japanese CIC patients

# AMITIZA: Future Global Opportunities -- Japan

## **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
- Results demonstrate lubiprostone is safe and well tolerated
- These results were added to marketing application (Dec. 2010)

Data from phase 3 trials to be  
presented at DDW in May 2011

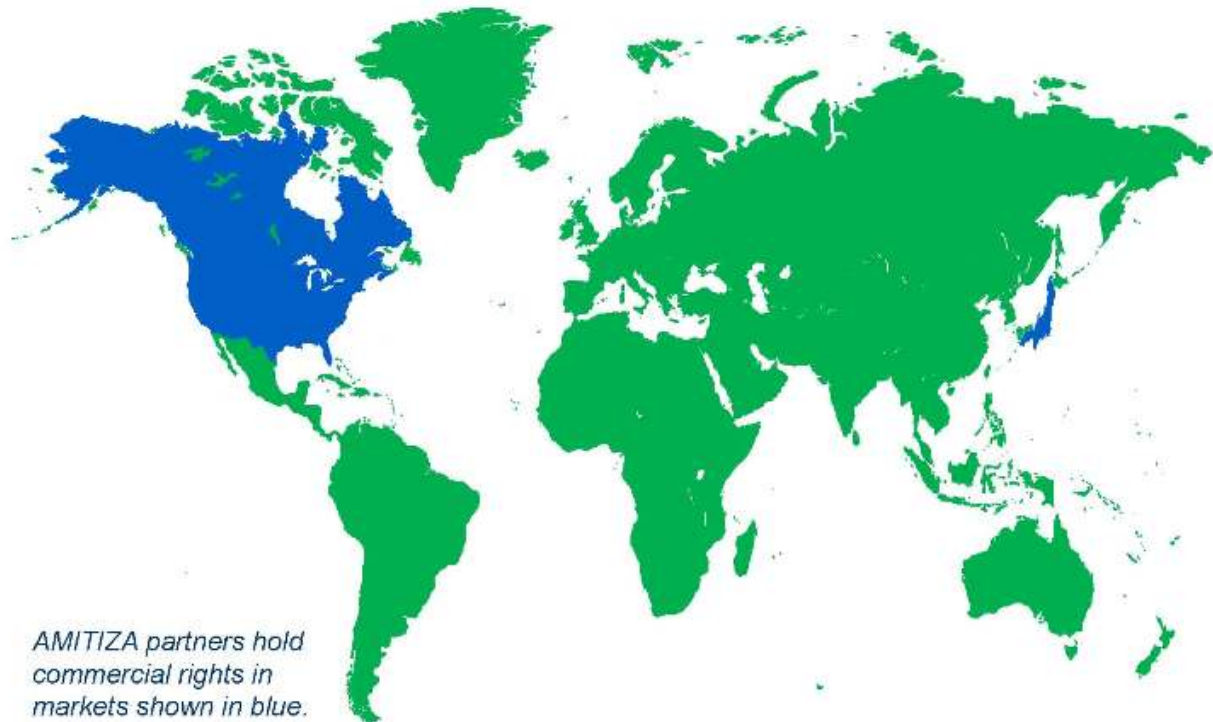
*Sucampo Press Releases:*

\* August 5, 2010

\*\* Nov. 30, 2010



# AMITIZA Future Opportunities -- Global Market Expansion



# RESCULA<sup>®</sup>: A Differentiated Ophthalmic Drug

## A unique mechanism of action

- RESCULA activates Maxi K (BK) 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\*\*\*\*

\* 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.

\*\* 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: Current Status and Potential Opportunities

- 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) and updated it in December 2010
- Awaiting a commercially viable label from FDA in order to complete U.S. launch plans
- Potential indications include Dry Age-related Macular Edema (dry AMD) and Retinitis Pigmentosa (RP)



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

## Design of Phase 2 Trial Conducted by Partner

- A multi-center, randomized, double-blind, three parallel group, placebo-controlled trial conducted by R-Tech Ueno (RTU) at 6 Japanese sites
- Enrolled 112 mid- to late-stage Retinitis Pigmentosa (RP) patients with visual acuity of 0.5 or more in a narrow visual field
- Patients received either one or two drops of active drug or placebo twice a day for 24 week
- 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
  - Change in retinal sensitivity measured by Humphrey perimeter (10-2)
  - Visual acuity
  - Contrast sensitivity
  - Health-related Quality of Life (measured by VFQ-25)

*\* R-Tech Ueno press releases of June 3, 2010 and July 15, 2010*

# RESCULA: Results of Phase 2 Clinical Trial\*

- RESCULA met primary endpoint (change from baseline in retinal sensitivity, as measured by MP-1) with statistically significant, dose-dependent improvement in visual function in the high dose group vs. placebo group
  - No severe adverse effects
  - Sub-analysis showed these changes from baseline in retinal sensitivity of more than 4dB:

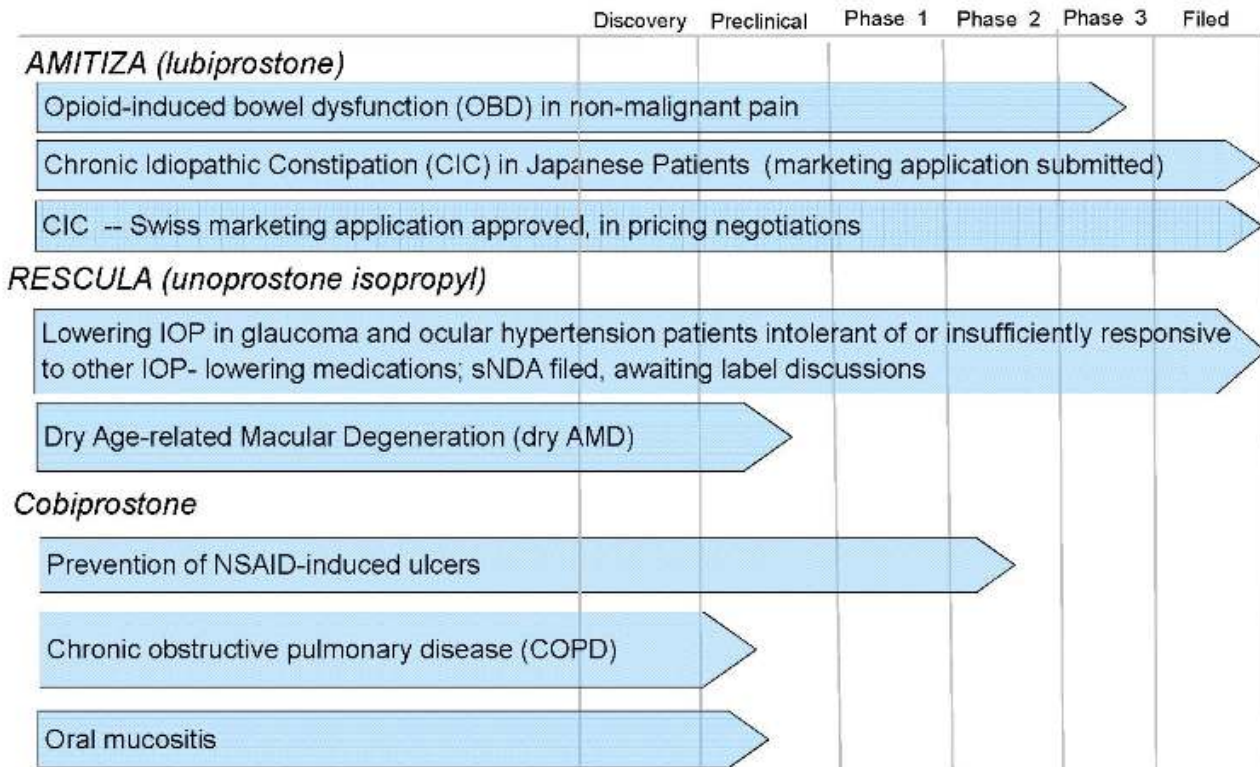
	Increased sensitivity	Decreased sensitivity
Placebo	15.2%	21.2%
Low dose	7.9%	15.8%
High dose	18.4%	2.6%

*RP trial data to be presented at ARVO in May 2011*

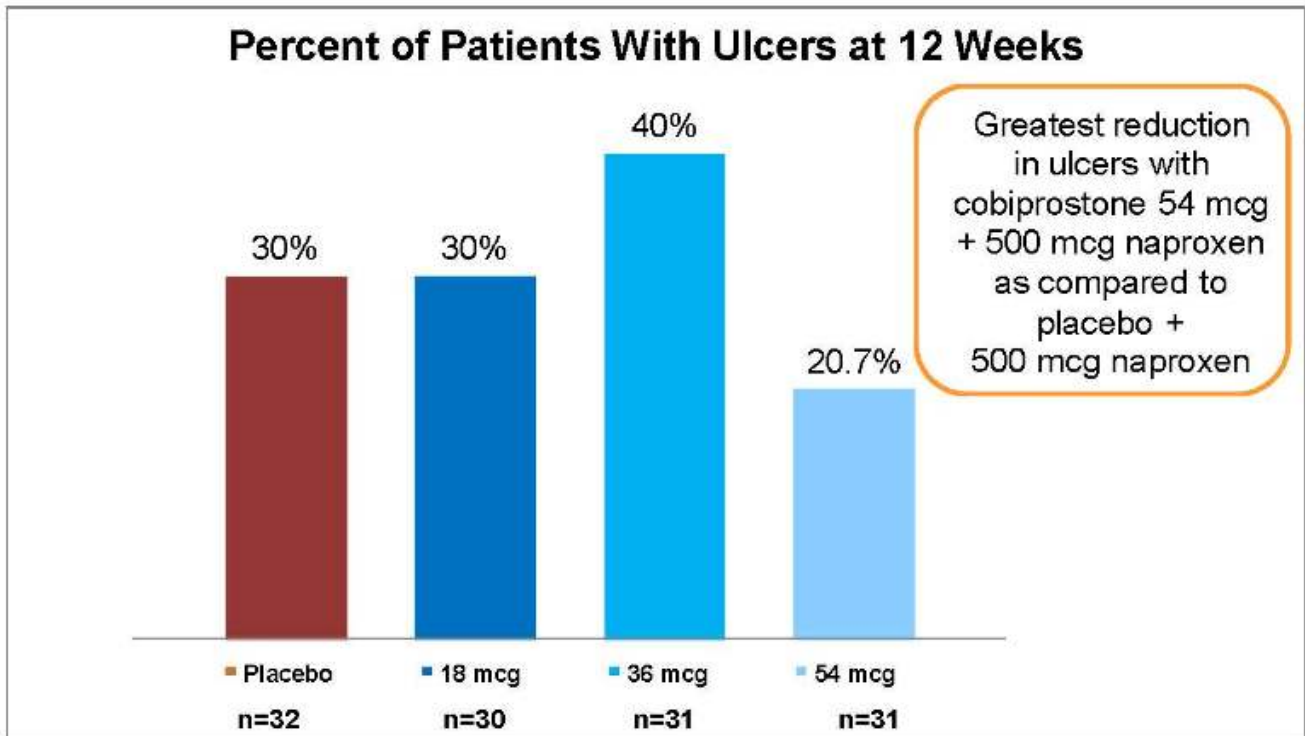
- Secondary endpoint, changes in retinal sensitivity from baseline to Week 24, as measured by Humphrey perimeter, met with statistical significance in high dose group compared to placebo

\* R-Tech Ueno press releases of June 3, 2010 and July 15, 2010

# Sucampo's Clinical Product Opportunities



# Future Opportunities: Cobiprostone for Prevention of NSAID-induced Ulcers - Phase 2a Results \*



\*DDW 2010, abstract 780837

# Prostones Fuel Sucampo's Growth and Deep Product Pipeline

Fatty Acids

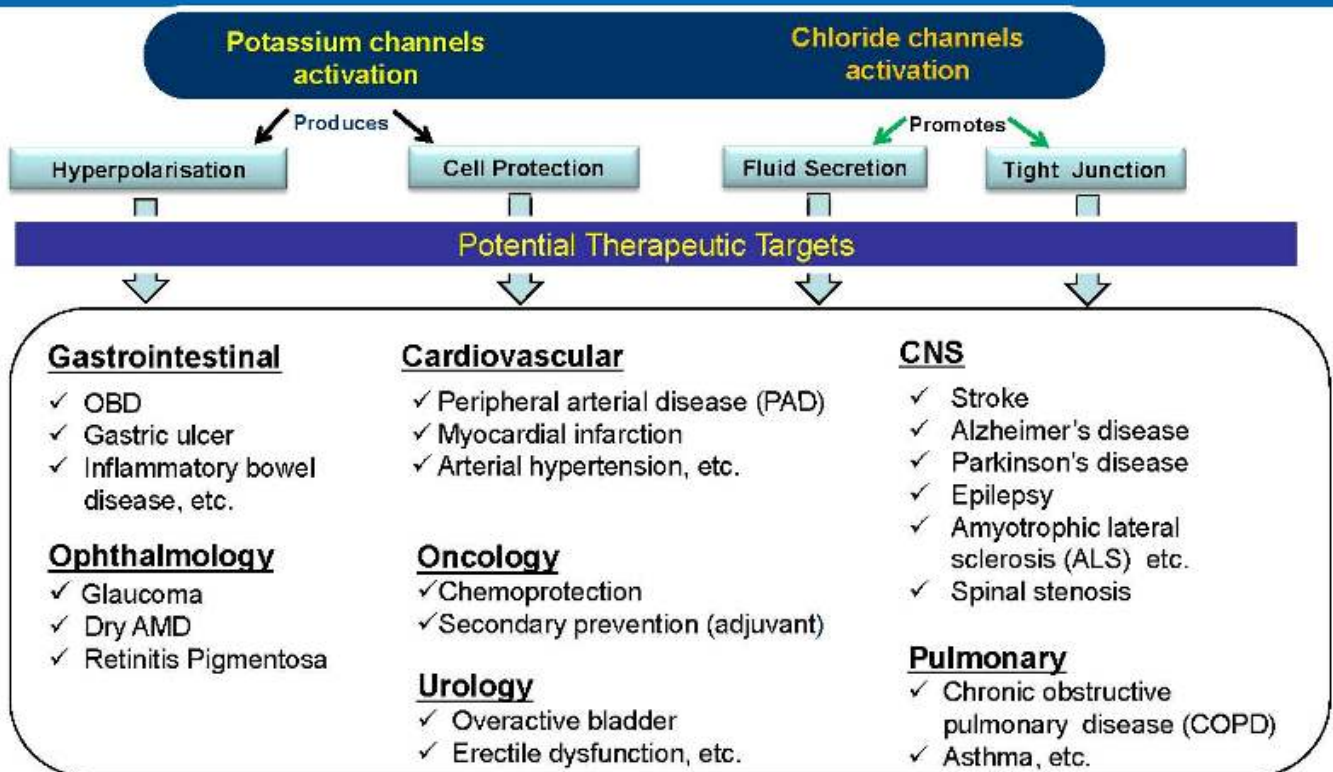


Prostones

AMITIZA (lubiprostone)	RESCULA (unoprostone isopropyl)	Cobiprostone (SPI-8811)	SPI-3608	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	Preclinical testing for spinal stenosis pain	Several compounds selected for preclinical development
IBS-C (8 mcg) approved April 2008	Phase 2 protocols for dry AMD under development	Conducting preclinical studies in COPD		



# Prostones Work As Potassium and Chloride Channel Activators



# Sucampo's Financial Results and Position

<i>(In millions, except per share data)</i>	<b>2009*</b>	<b>2010*</b>
Product Royalty Revenue	\$38.3	\$40.3
R&D Revenue*	\$24.0	\$16.5
Total Revenue	\$67.3	\$61.9
Net Income/(Loss)	\$4.8	(\$2.7)
Earnings Per Share (diluted)	\$0.11	(\$0.07)
Cash, Restricted Cash and Investments	\$153.0	\$123.9**

\*Results for 2009 and 2010 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.

# Sucampo's 2011 Milestones

- Completion of enrollment into third phase 3 clinical trial of lubiprostone for OBD during third quarter
- Gain approval of a commercially viable label (sNDA) for RESCULA 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
- 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 it
- Make substantial progress towards successfully resolving our dispute with our U.S. partner (Takeda)



# Sucampo: A Biopharmaceutical Company

## **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 women aged 18 years and older
- Marketing authorization approved in Switzerland for CIC, now in pricing negotiations there
- Filed NDA for CIC in Japan in Sept 2010
- Third Phase 3 trial in opioid-induced bowel dysfunction (OBD) initiated late 2010 in U.S.
- U.S + Canadian commercial rights held by Takeda; Abbott holds Japanese commercial rights

## **RESCULA®**

- FDA-approved for lowering intra-ocular pressure (IOP) in glaucoma and ocular hypertension patients who are intolerant of or insufficiently responsive to other IOP-lowering medications
- In-licensed clinical development and commercial rights in April 2009
- Await FDA approval of commercially viable label supplemental NDA (sNDA) to re-launch in U.S.
- Designing trials for additional indications, based on partner's breakthrough phase 2 results

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

- Cobiprostone for prevention of NSAID-induced gastric ulcers in Phase 2
- SPI-3608 in preclinical development for pain associated with spinal stenosis
- Additional prostones in preclinical development

## **Strong financial position**

- \$123.9 million in cash, restricted cash and investments as well as \$44.4MM in long term debt as of Dec. 31, 2010



# Cowen and Company 31<sup>st</sup> Annual Health Care Conference

Stanley G. Miele  
*President, Sucampo Pharma Americas*

*March 7, 2011*