

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): June 27, 2011

**Sucampo Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction  
of Incorporation)

001-33609

(Commission  
File Number)

30-0520478

(IRS Employer  
Identification No.)

4520 East-West Highway, 3<sup>rd</sup> Floor  
Bethesda, Maryland

(Address of Principal Executive Offices)

20814

(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))

**Item 7.01. Regulation FD Disclosure.**

On June 27 and 28, 2011 Sucampo Pharmaceuticals, Inc. will make corporate update presentation to shareholders, an analyst and an investor 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 June 27, 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: June 27, 2011

By: /s/ THOMAS J. KNAPP  
Name: Thomas J. Knapp  
Title: Sr. VP, General Counsel & Corporate Secretary



# Corporate Update

Stanley G. Miele

*Senior Vice President, Sales & Marketing, Sucampo Pharmaceuticals, Inc.*

*President, Sucampo Pharma Americas, Inc.*

Cary J. Claiborne

*Interim Chief Financial Officer*

*June 27, 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: An International Biopharmaceutical Company

## **RESCULA® (unoprostone isopropyl)**

- 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
- Await FDA approval of a scientifically accurate, enhanced, commercially-viable label for re-launch
- In-licensed clinical development and commercial rights in April 2009
- Designing trials for additional indications, based on partner's phase 2 results in RP

## **AMITIZA® (lubiprostone)**

- 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.

## **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
- A proprietary platform technology generating additional prostones in preclinical development

## **Strong financial position**

- \$115.0 million in cash, restricted cash and investments as well as \$45.0MM in long term debt as of March 31, 2011

# Prostones Fuel Sucampo's Growth and Deep Product Pipeline

Fatty Acids

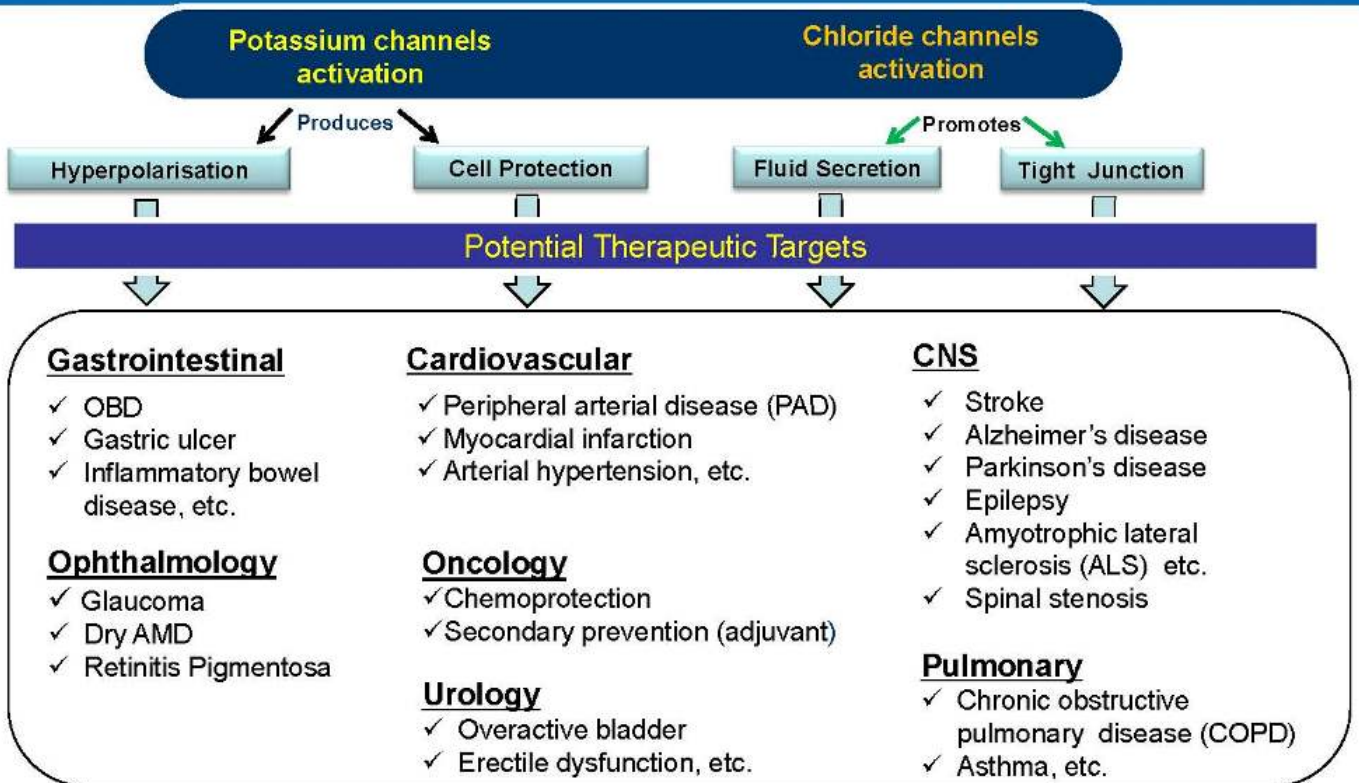


Prostones

AMITIZA (lubiprostone)	RESCULA (unoprostone isopropyl)	cobiprostone	Other Prostones
CIC (24 mcg) approved January 2006	FDA approved in 2000 Now planning re-launch in U.S.	Prevention of NSAID- induced ulcers in phase 2	Several compounds selected for preclinical development
IBS-C (8 mcg) approved April 2008	Approved in EU 5 and Switzerland Filing re-activation applications in 2011	Chronic Obstructive Pulmonary Disease (COPD) Preclinical development	
	Phase 2 protocols for dry AMD under development	Oral Mucositis in Cancer Patients Preclinical Development	



# Prostones Work As Potassium and Chloride Channel Activators





# 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 MM people in the U.S and ~1/3 or ~19 MM have IBS-C
  - Approx. 15% of IBS patients seek medical attention
- **OBD**
  - Approx. 4.3 MM of U.S. adults use opioids to control pain
  - 41% of non-cancer pain patients experience constipating side effects



## 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

OBD: Kalso, et al, PAIN 2004

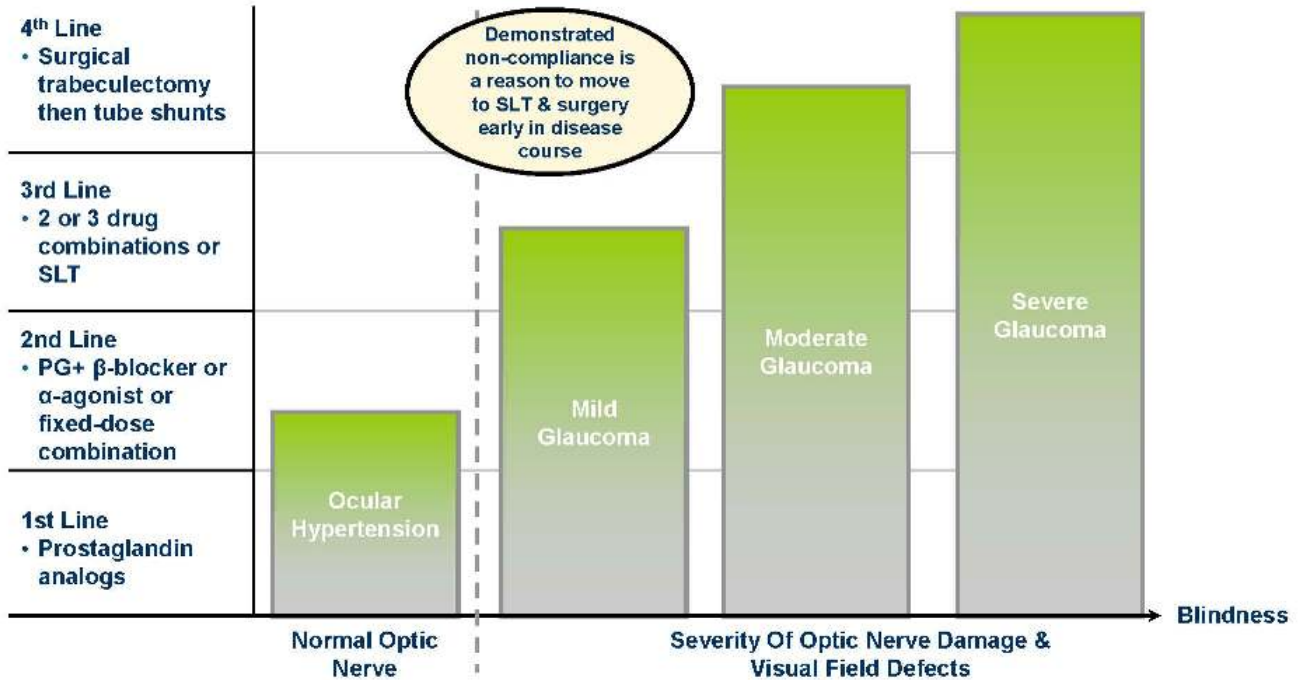
# RESCULA:

## Terms of Agreements with R-Tech Ueno

- SPA licensed Rescula's US and Canadian rights from R-Tech Ueno (RTU) in April 2009 and SMR licensed additional rights in April 2011 that expand Sucampo's rights to all other countries except Japan, Korea, Taiwan and the People's Republic of China
- Sucampo holds rights to develop, use, make, have made, export, commercialize, promote, offer for sale and sell unoprostone isopropyl
- RTU is responsible for clinical and commercial supplies of Rescula to Sucampo
- Sucampo has paid a total of \$6.5 million in upfront payments to RTU for both licenses and is responsible for an additional upfront and milestone payments
- Sucampo responsible for development, regulatory and commercialization activities and expenses within its territories
- Sucampo now moving to reactivate licenses in the U.S., European Union and Switzerland for glaucoma and ocular hypertension

# RESCULA: Glaucoma Treatment Pathway

Goal: Slow the Progression of Visual Field Defects



SLT = Selective Laser Trabeculopasty

# RESCULA: A Differentiated Ophthalmic Drug

## A unique mechanism of action

- Rescula (unoprostone isopropyl) 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 (unoprostone isopropyl) eye-drops are a prostone drug, not a prostaglandin
- Awaiting a scientifically accurate, and thus enhanced, commercially-viable label from FDA in order to complete U.S. launch plans for approved indication
- 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.
- Unoprostone isopropyl is approved for glaucoma and ocular hypertension in more than 45 countries, but licenses have lapsed. Now preparing to submit reactivation filing for EU 5 and Switzerland later this year.
- Potential indications include Dry Age-related Macular Degeneration (dry AMD) and Retinitis Pigmentosa (RP)



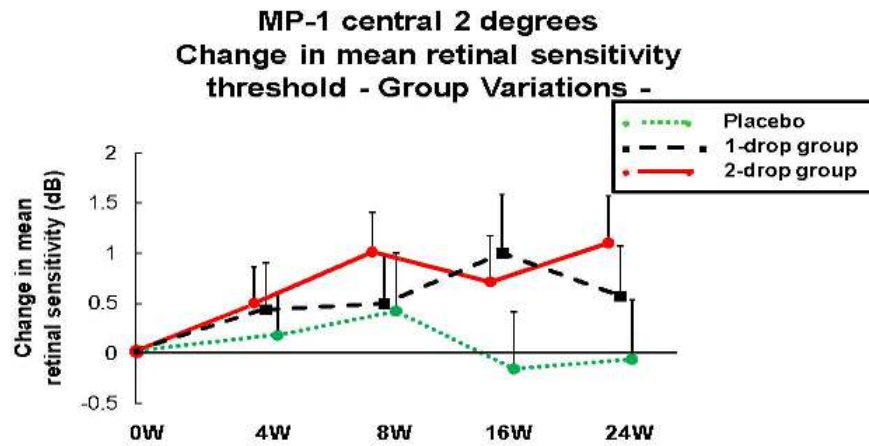
# RESCULA: Phase 2 Clinical Trial Design -- Retinitis Pigmentosa

## Design of Phase 2 Trial Conducted by R-Tech Ueno (RTU)

- A multi-center, randomized, double-blind, three parallel group, placebo-controlled trial conducted by our partner 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
- Purpose: To test the effects of UF-021 in protecting and improving the central vision in mid- to late-stage RP patients
- 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: Phase 2 Efficacy Data – Microperimetry-1 (MP-1) Measurements\*

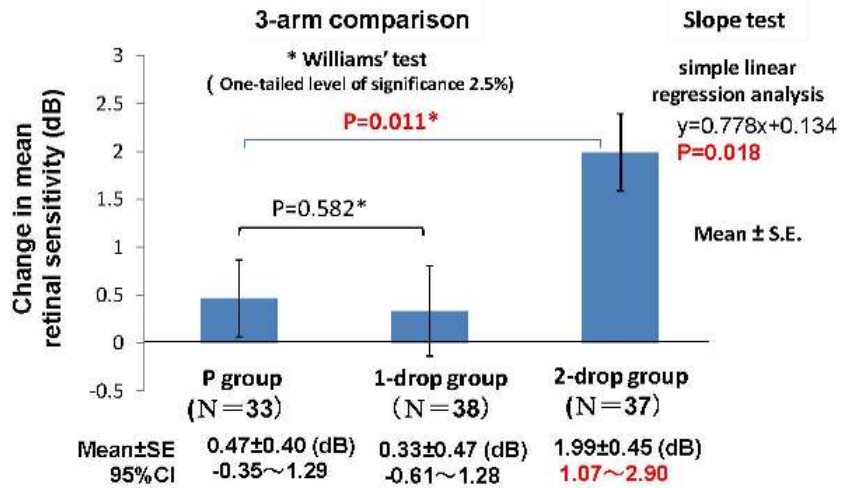


The 2-drop group met the primary endpoint ( $p=0.018$ ) of change from baseline in retinal sensitivity threshold in the central 2 degrees, as measured by Microperimeter-1.



# RESCULA: Phase 2 Efficacy Data: Humphrey 10-2 Measurements\*

## HFA 10-2 Central 2 degrees Change in mean retinal sensitivity threshold — Dose responsiveness —



\*ARVO 2011, Poster # 4992, A416

# Unoprostone isopropyl

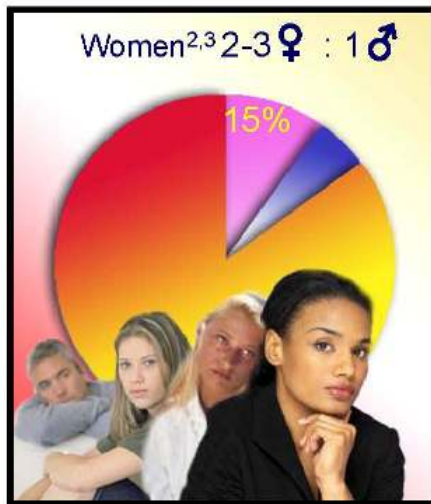
## Proof of concept phase 2a study in dry AMD

- Purpose: to study choroidal blood flow and the progression from dry AMD to choroidal neo-vascularization to wet AMD following administration of unoprostone isopropyl vs. placebo
- A single-center, double-masked, randomized, placebo-controlled 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, expect results in late 2011/early 2012

# 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>

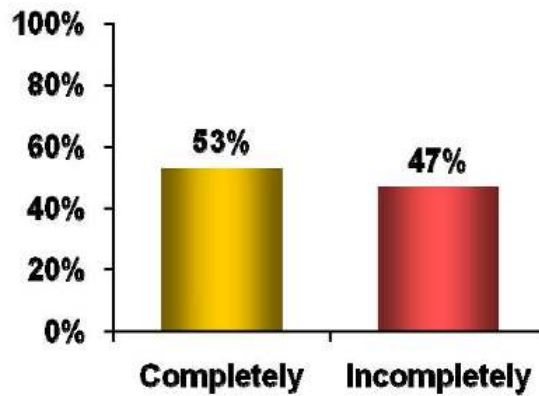
Frequency-based  
(bowel movement  
no more than  
every  
3 to 4 days)

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

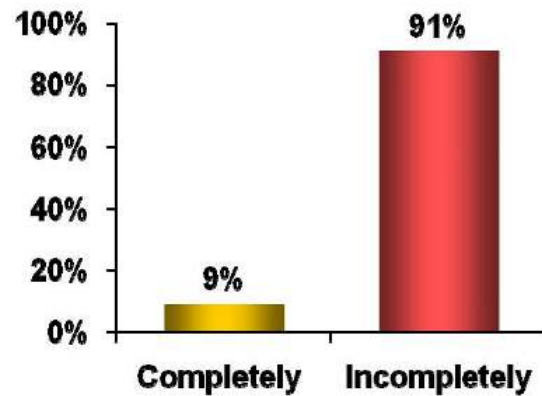
*Dissatisfaction with OTC and Prescription Treatment Options (Before AMITIZA's approval)*

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>

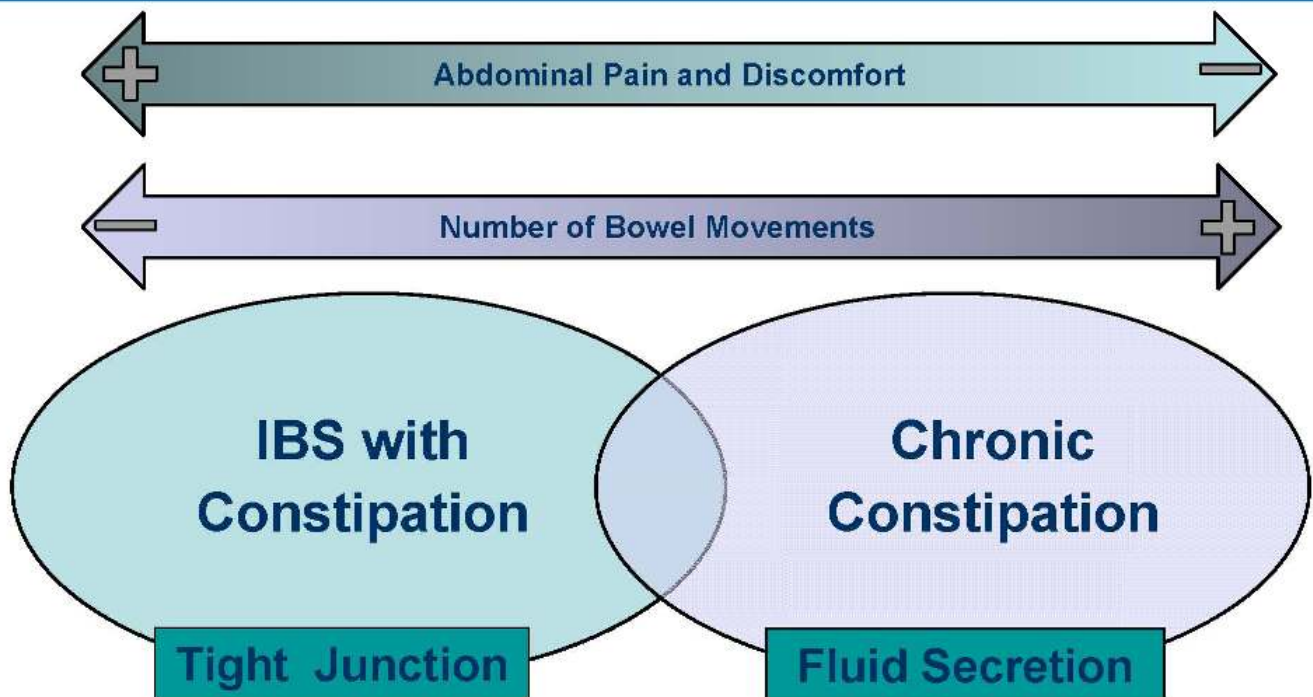


- 60% of physicians agreed that they do not have adequate products
- 91% of physicians wanted better treatment options

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



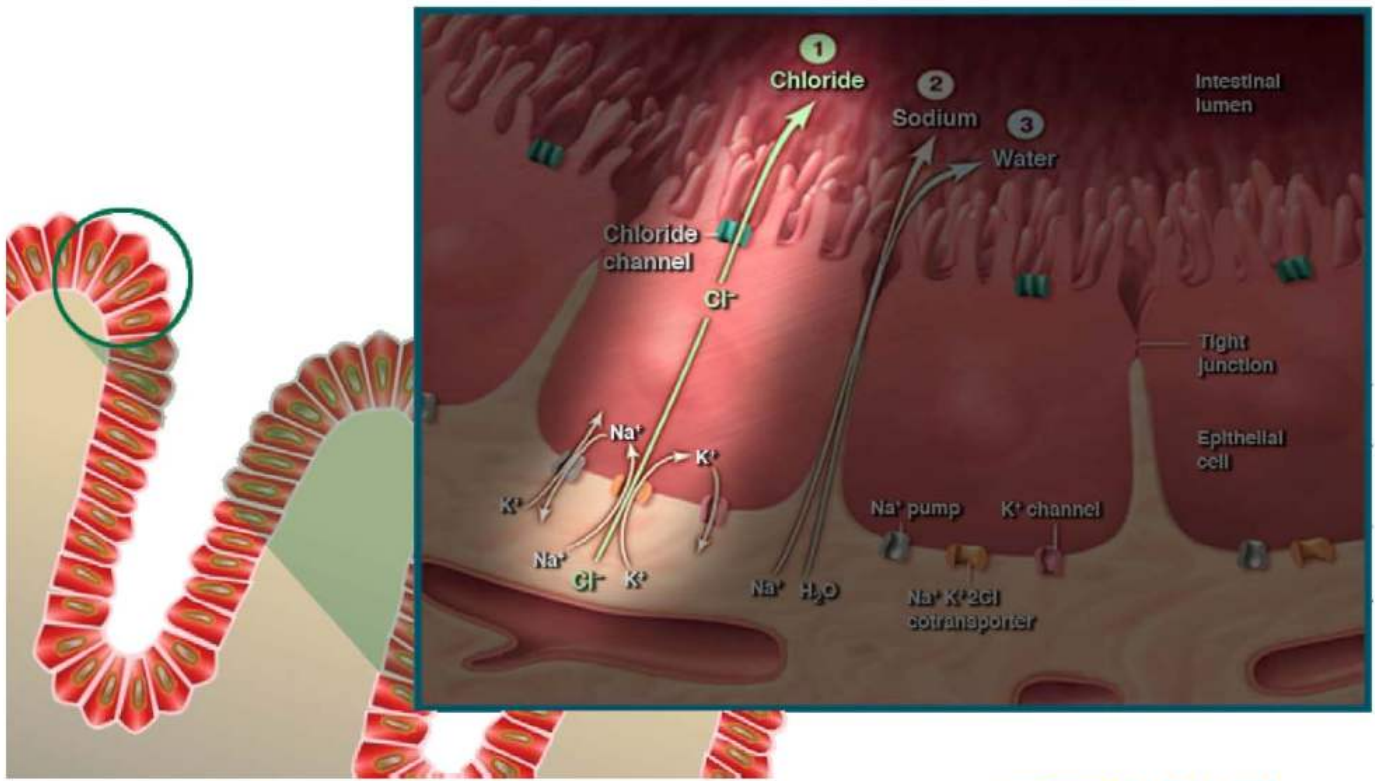
# AMITIZA Answers Unmet Medical Needs

- **Represents a major market opportunity**
  - More than 14 million (CIC and IBS-C) office visits each year in U.S.
- **Offers proven safety and efficacy for long-term usage**
  - Efficacy + tolerability are similar for both genders + across age groups for CIC, no ischemic bowel or bowel permeability
  - 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



# Small Intestine Fluid Secretion

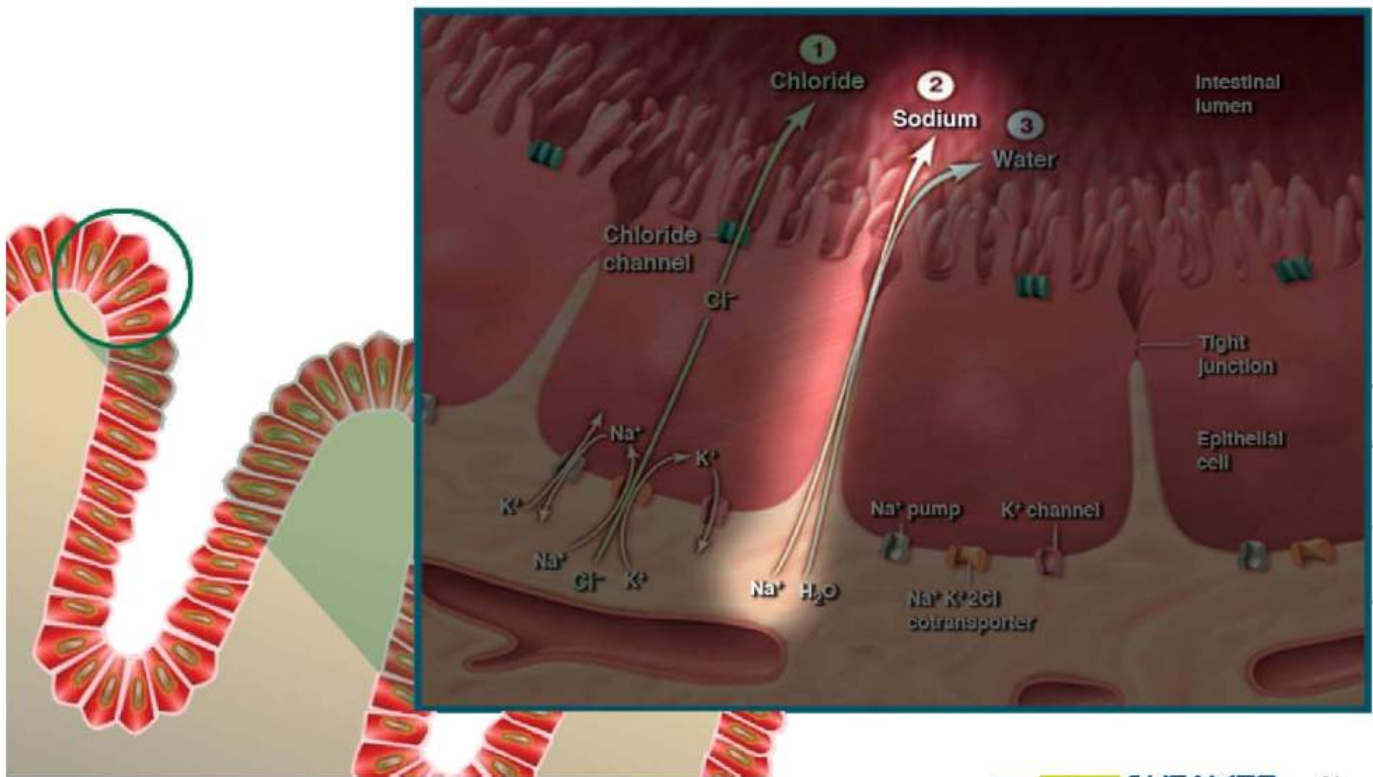
*Chloride Enters Intestinal Lumen Following CLC-2 Activation*



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

# Small Intestine Fluid Secretion

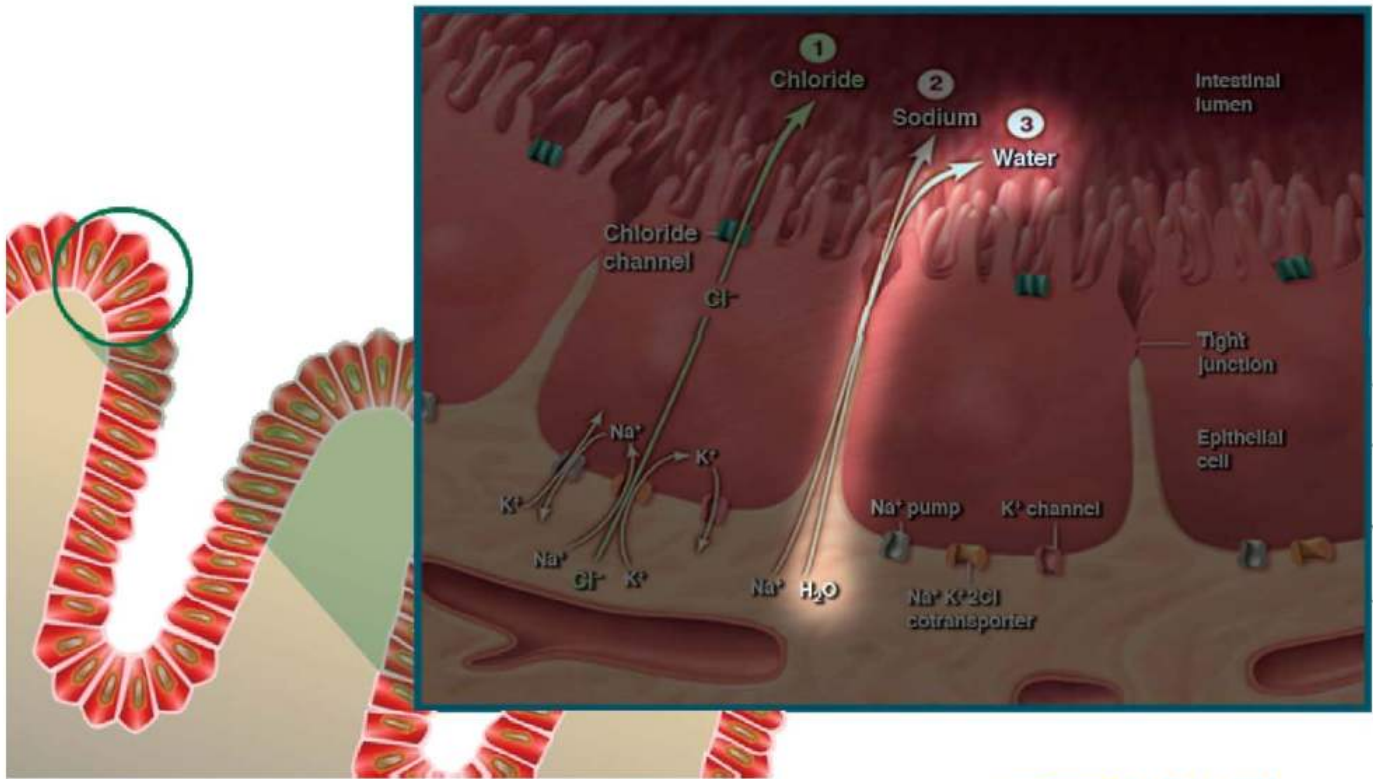
*Sodium Ions Follow Chloride To Maintain Electrical Neutrality*



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

# Small Intestine Fluid Secretion

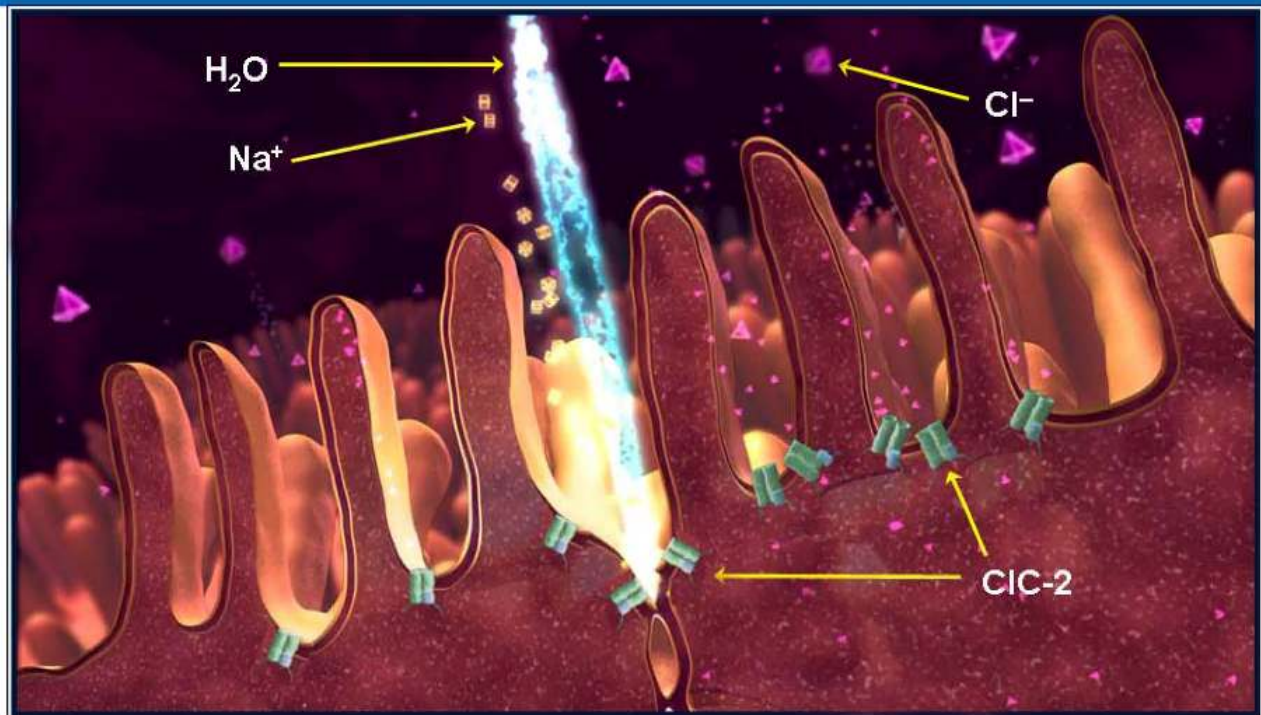
*Water Passively Enters Lumen To Maintain Osmotic Neutrality*



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



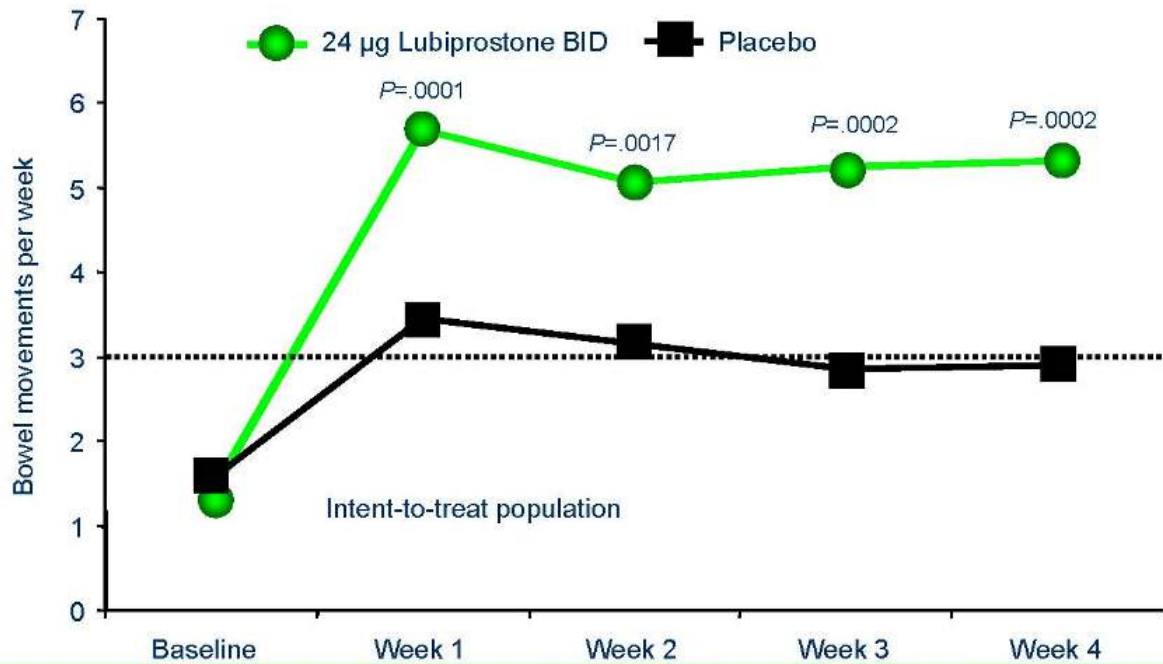
# AMITIZA Activates Intestinal ClC-2 Channels



Works through 'facilitated diffusion' or 'passive transport'

# AMITIZA Efficacy: Phase 3 Trial Results Chronic Idiopathic Constipation

## Spontaneous Bowel Movement (SBM) Frequency

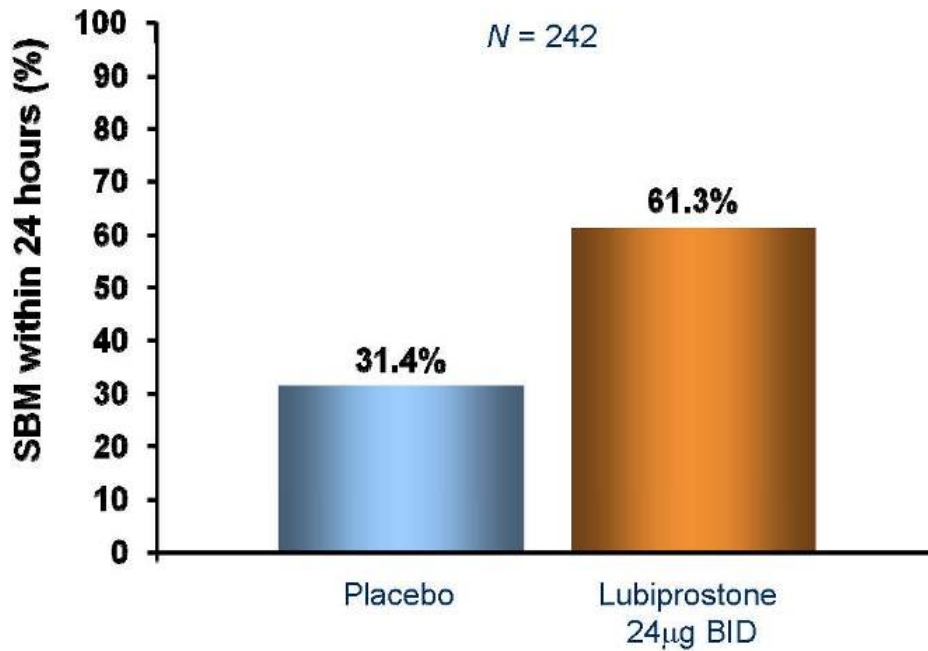


**Primary Endpoint: Average SBMs go from 1.5/Week to 5/Week**

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

# 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	Treatment Effect
Study '431	13.8%	7.8%	0.029	176%
Study '432	12.1%	5.7%	0.023	212%
Pooled	13.0%	6.8%	0.001	191%

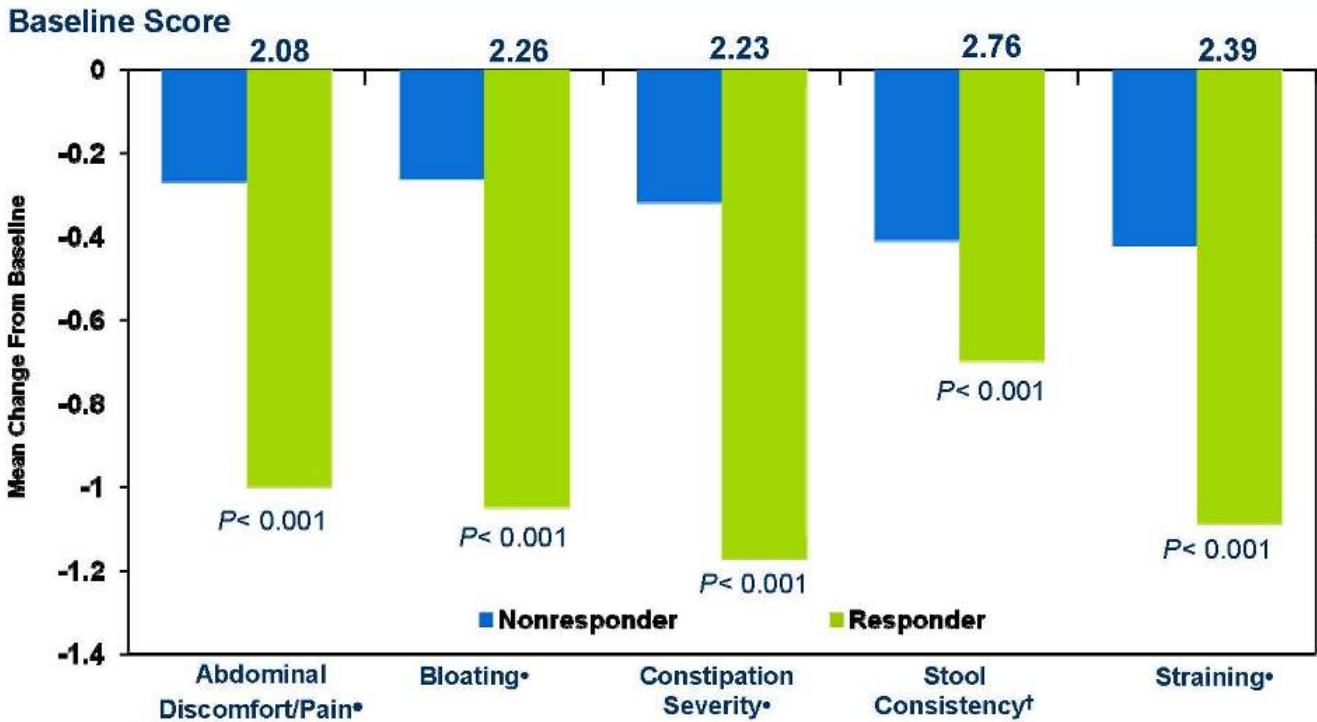


AMITIZA approved by FDA for treatment of IBS-C in women aged 18 years and older in April 2008 on achieving statistical significance in 2 well-controlled trials that adopted a higher standard of proof and endpoints to minimize placebo effects as directed by the FDA.

\*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



\*Drossman, D. et al. Lubiprostone significantly improves symptom relief rates in adults with Irritable Bowel Syndrome with constipation: data from two, twelve-week, randomized, placebo-controlled, double-blind trials. Abstract # 639f. Digestive Disease Week 2007, Washington, D.C.

\*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 Maintains Electrolyte Balance Through 48 Weeks of Treatment

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

	<b>n</b>	<b>Baseline</b>	<b>Week 24</b>	<b>Week 48</b>	<b>Significant Change?</b>
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. NDA, p96

# AMITIZA: Chronic Idiopathic Constipation\*

## 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

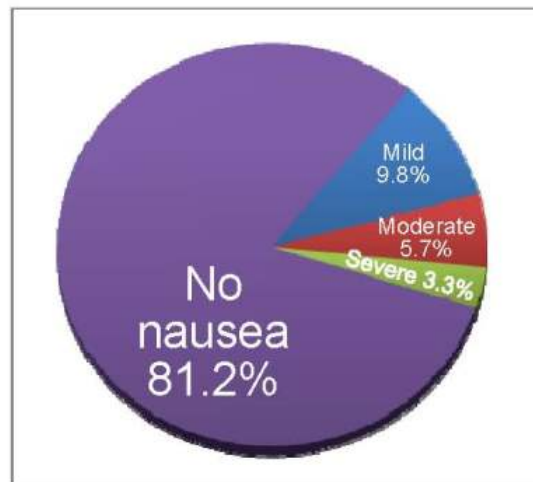
# AMITIZA

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



Phase 3  
Efficacy Studies  
(lubiprostone 24-mcg)

Phase 3  
Open-Label  
Studies  
(lubiprostone 24-mcg)



# AMITIZA: Irritable Bowel Syndrome with Constipation\*

## Design of Amitiza's two pivotal Phase 3 trials for IBS-C

- 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

# 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:

## Global Growth Strategies – 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 will share trial costs equally

\*Sucampo press release, Jan. 7, 2011

# AMITIZA:

## Data from a Successful Phase 3 OBD Trial\*

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

- Reported 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

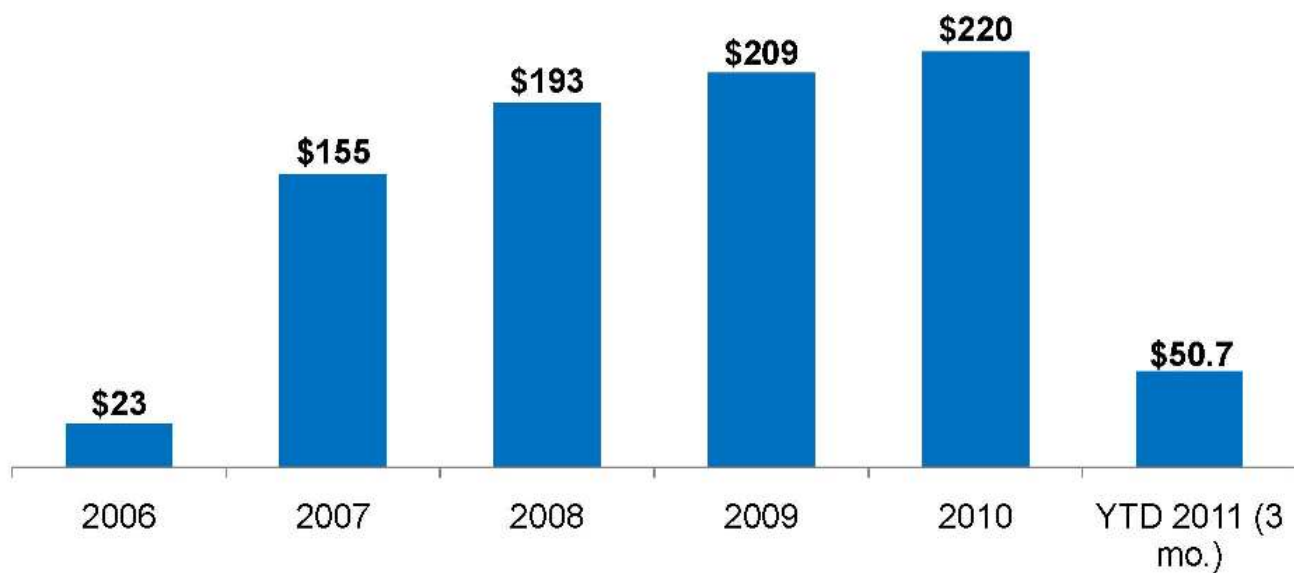
\* DDW 2010, Abstract #780958

## AMITIZA: A Third phase 3 trial of lubiprostone for OBD Initiated\*

- Sucampo initiated a phase 3 trial of lubiprostone (AMITIZA) for OBD in December 2010
- Sucampo and Takeda to share costs 50-50
- Phase 3 trial design:
  - Almost the same protocol as used in the phase 3 trial reported at DDW 2010, except exclusion of patients on methadone pain therapy
  - A randomized, placebo-controlled, multi-center trial in the U.S. and Europe
  - 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
  - Goal is to enroll 420 patients
  - Primary endpoint: change from baseline in SBM frequency at Week 8 without reduction in dose of study pain medication

*\*Sucampo press release, Jan. 7, 2011*

## Net Sales of AMITIZA Since Launch in April 2006



# AMITIZA – Key Terms of Development and Marketing Agreements with Takeda

- 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
  - 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 March 31, 2011

# AMITIZA: Global Growth Strategy – JAPAN

## Japanese Constipation Market Data (select)

- Current treatment options are laxatives – approximately \$326.0 million annually
- Magnesium oxide, alone, generated \$129.0 million in sales in 2009
- Market growth of 6% from 2008 to 2009
- Future market growth expected to continue due to increasingly older population and changes in lifestyle and eating habits



# AMITIZA – Global Growth Strategy

## 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 March 31, 2011
- Sucampo designed and managed the recently reported successful phase 3 efficacy trial and long-term safety trial in Japanese CIC patients

# AMITIZA: Global Growth Strategy-- 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)

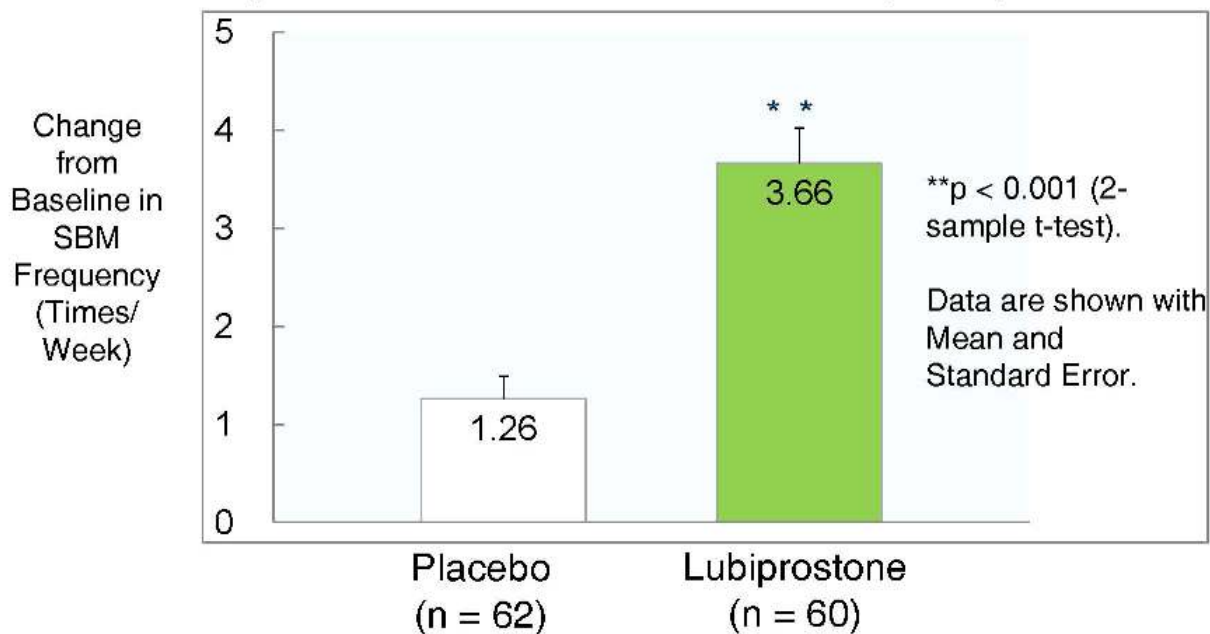
*Sucampo Press Releases:*

*\* August 5, 2010*

*\*\* Nov. 30, 2010*

# AMITIZA: Global Growth Strategy - JAPAN

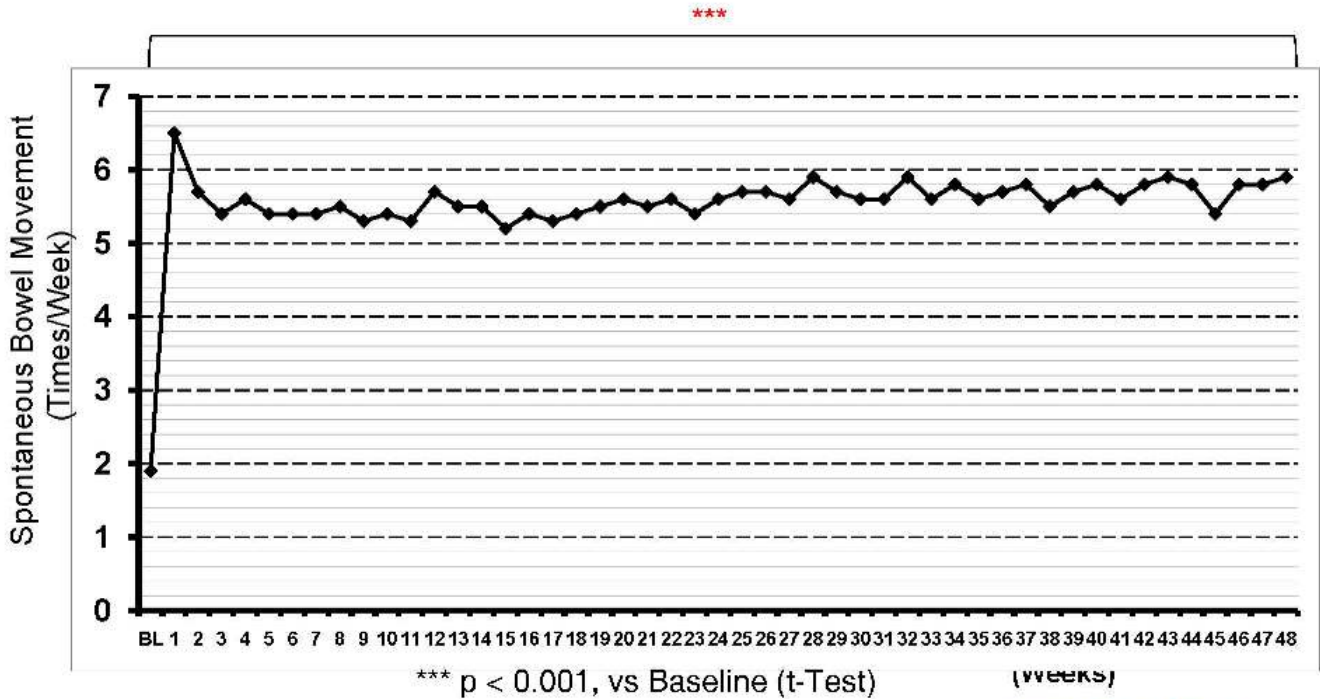
Primary Efficacy: Change from Baseline in Weekly Spontaneous Bowel Movement (SBM) at Week 1\*



\* DDW 2011, poster DDW/AGA 1038006

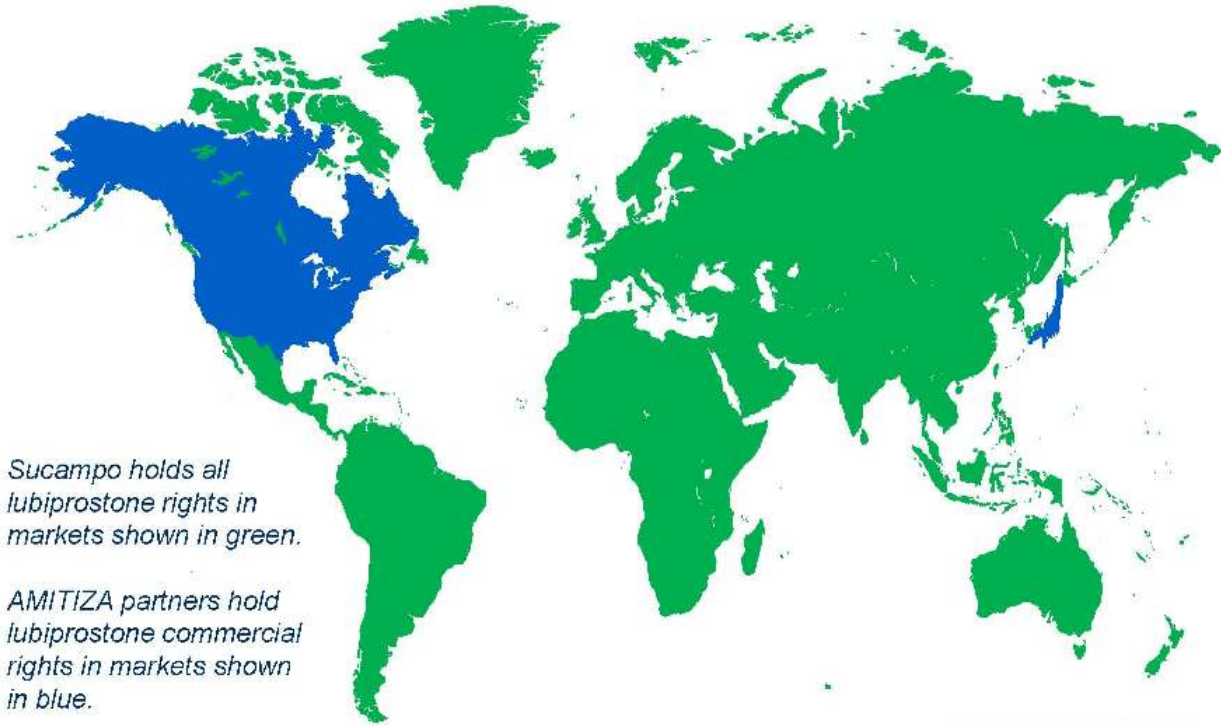
# AMITIZA: Future Global Opportunities - JAPAN

## Long-Term Effect of Lubiprostone on Weekly SBM Frequency



\* DDW 2011, poster DDW/AGA 1038006

## AMITIZA Future Opportunities – Global Market Expansion

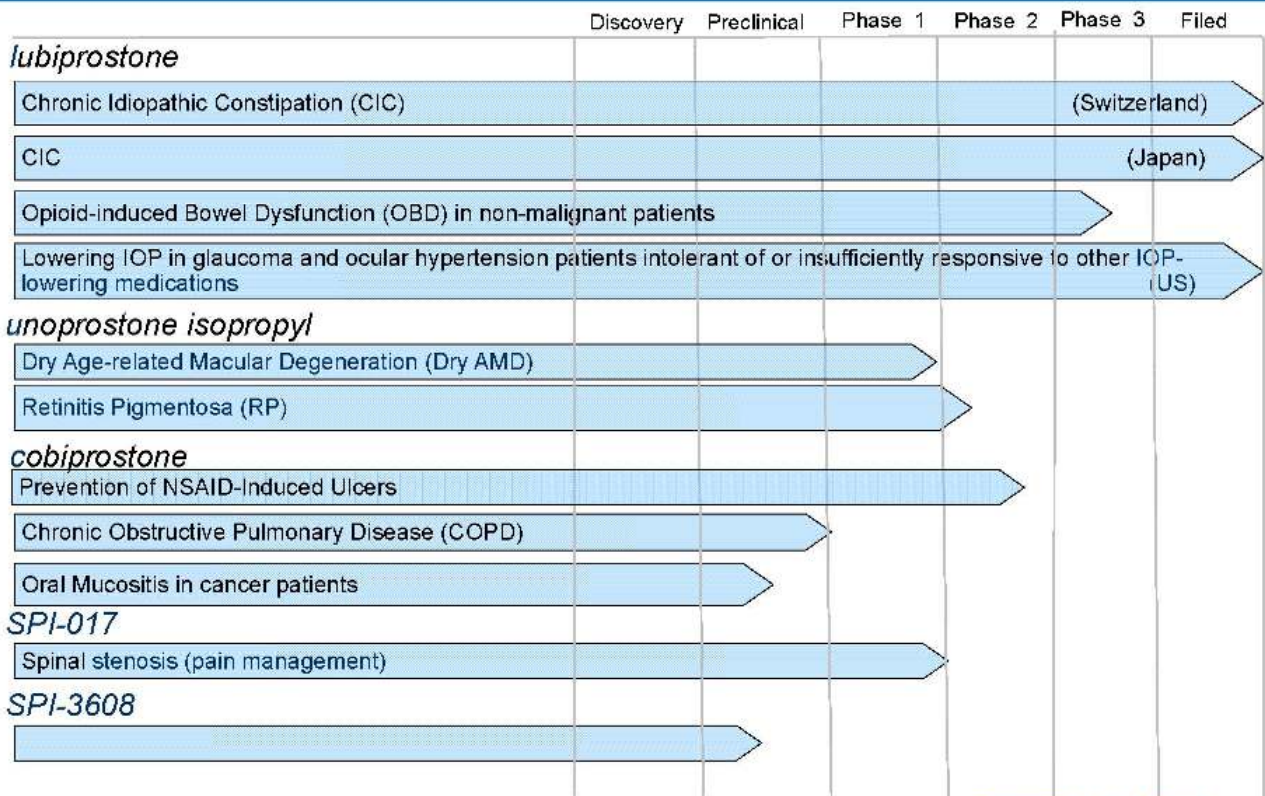


*Sucampo holds all  
lubiprostone rights in  
markets shown in green.*

*AMITIZA partners hold  
lubiprostone commercial  
rights in markets shown  
in blue.*



# Sucampo's Clinical Product Opportunities



# Sucampo's Financial Results and Position

<i>(In millions, except per share data)</i>	<b>2010*</b>	<b>2011* (3 months)</b>
Product Royalty Revenue	\$40.3	\$9.1
R&D Revenue*	\$16.5	\$2.0
Total Revenue	\$61.9	\$12.1
Net Income/(Loss)	(\$2.7)	(\$6.9)
Earnings Per Share (diluted)	(\$0.07)	(\$0.17)
Cash, Restricted Cash and Investments	\$123.9**	\$115.0***

\* 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

\*\*\* At March 31, 2011, Sucampo had \$45.0 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)



# Corporate Update

Stanley G. Miele

*Senior Vice President, Sales & Marketing, Sucampo Pharmaceuticals, Inc.*

*President, Sucampo Pharma Americas, Inc.*

Cary J. Claiborne

*Interim Chief Financial Officer*

*June 27, 2011*

48

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## Recent Development

### Sucampo Acquires Prostone Patent-Holding Company

- Sucampo Pharmaceuticals, Inc. (SPI) acquired Sucampo AG (SAG), a patent-holding company, in December 2010, from SPI's co-founders
- Secures control and ownership of the patents and other intellectual property underlying SPI's current and future prostone products including Amitiza, cobiprostone, SPI-017, SPI-3608 and other compounds
- Advances SPI toward goal of becoming a fully-integrated international pharmaceutical company
- Eliminates future royalty and milestone payments to SAG from future sales and development milestone payments from current and future products as well as mandatory funding requirements of early-stage compounds in order to maintain rights
- Terms: Upfront payment of \$28.1 million, and 7-year subordinated, unsecured promissory note of \$51.9 million. Potential earn-out: if SPI receives any cash in connection with current arbitration against Takeda, SAG holders will receive 15%, up to a maximum of \$40 million



# Amitiza: Chronic Idiopathic Constipation\*

## 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 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

## 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 Pharmacol Ther 2009 Feb;29(3):329-41

Zelnorm: FDA GI AdvCmte Briefing Document