

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): September 7, 2012

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware

001-33609

30-0520478

(State or Other Juris-
diction of Incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

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

20814

(Address of Principal Executive Offices)

(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 7.01. Regulation FD Disclosure.

On September 7, 2012, Sucampo Pharmaceuticals, Inc. will meet with investors and analysts and make a corporate update presentation at an investor conference in New York City, NY at the 19th Annual NewsMakers in the Biotech Industry Conference being sponsored by BioCentury and Thomson Reuters 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 September 7, 2012.

SIGNATURE

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

SUCAMPO PHARMACEUTICALS, INC.

Date: September 7, 2012

By: /s/ Thomas J. Knapp

Name: Thomas J. Knapp

Title: Corporate Secretary



BioCentury
Thomson Reuters
NewsMakers 2012 in the BioTech Industry

Ryuji Ueno, MD, PhD, PhD, Chair, CEO, CSO

Cary J. Claiborne, CFO

Stanley G. Miele, SVP, Sales & Marketing

Silvia Taylor, SVP, IR, PR & Corporate Communications

September 7, 2012

Forward-Looking Statements

This presentation contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential, future financial and operating results, and other statements that are not historical facts. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the impact of pharmaceutical industry regulation and health care legislation; Sucampo’s ability to accurately predict future market conditions; dependence on the effectiveness of Sucampo’s patents and other protections for innovative products; the risk of new and changing regulation and health policies in the US and internationally and the exposure to litigation and/or regulatory actions.

No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Sucampo undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this presentation should be evaluated together with the many uncertainties that affect Sucampo’s business, particularly those mentioned in the risk factors and cautionary statements in Sucampo’s Form 10-K for the year ended Dec. 31, 2011, which the Company incorporates by reference.

Sucampo Snapshot

A commercial-stage, global biopharmaceutical company since 1996

- **2 FDA-approved drugs based on our proprietary prostone technology**
 - AMITIZA® (lubiprostone) in Gastroenterology market
 - RESCULA® (unoprostone isopropyl) in Ophthalmology market
- **The therapeutic potential of prostones was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' chairman and chief executive officer. Dr. Ueno and Sachiko Kuno, Ph.D., founded Sucampo Pharmaceuticals in 1996**
- **AMITIZA has helped 6 million patients over 6 years combat the effects of chronic idiopathic constipation and irritable bowel syndrome with constipation**
- **New indications for current areas**
- **New global markets and diseases**
- **Deep and promising pipeline**

Second Quarter 2012 and Recent Highlights

AMITIZA[®]

- Approved in Japan June 2012
- Filed OIC sNDA July 2012

RESCULA[®]

- US: Anticipate approval of sNDA for glaucoma indication in US (new label/updated MOA)
- EUROPE: Re-approval filings in EU and Switzerland

Research and Development

- Pipeline prioritized

Financial/Corporate

- **Cash, cash equivalents, and investments**
 - Ended Q2 2012 with \$89M
- **Revenue**
 - Q2 \$16.7M up 19%, 1H \$31.1M up 19%
 - 1H 2012 - Net Operating Cash Flow Positive
 - Dual class of Common Stock Eliminated

Proprietary Prostone Technology

- **Prostones are naturally occurring compounds that act locally to restore injured cells and tissues**
 - Prostones possess a unique mechanism of action as potent and specific activators of ion channels.
 - Ion channels regulate the flow of specific ions into and out of cells. This regulation is key to the functioning of cells, such as metabolic processes and cell survival
 - There is evidence that prostones have anti-inflammatory properties, prevent cell death, and restore cells and organs
- **Ion channels are ubiquitous in the body, and targeted dosing of prostones may have broad applicability in many degenerative diseases**
- **Sucampo has pioneered the field of prostones**
 - Broad patent estate (>580 issued patents)
 - Developed synthetic analogs of naturally occurring prostones, which are more potent, selective and stable than naturally occurring prostones, enabling their use as drugs
- **The safety profile of prostone compounds is excellent, as demonstrated by the clinical safety record of AMITIZA and RESCULA**

Sucampo Is a Leader in Gastroenterology: AMITIZA

Gastroenterology

Areas of Focus: Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome (IBS)

• **CIC**

- Constipation is characterized by infrequent stools, difficult stool passage, or both¹
- CIC affects an estimated 14% of the US adult population (33 million)²
- Constipation accounts for 92,000 hospitalizations in the US each year³
- Studies have found that severe constipation is associated with increased cardiovascular risk in women^{4,5}

• **IBS**

- IBS is defined as abdominal pain or discomfort that occurs in association with altered bowel habits over a period of at least 3 months¹
- IBS affects an estimated 15% of the adult population (45 million)⁶
 - IBS with constipation (IBS-C) affects approx. 5% of the adult population (12 million)⁶
- Direct and indirect costs of IBS care in the US are estimated at about \$20 billion per year⁶
- Studies have documented that patients with IBS consume more than 50% more health care resources than those without IBS⁷

Sucampo Is an Emerging Player in Ophthalmology: RESCULA

Ophthalmology

Area of Focus: Glaucoma

- **Glaucoma is a group of ocular diseases with various causes that ultimately are associated with a progressive optic neuropathy leading to loss of vision function⁸**
- **Glaucoma is an age-related disease**
 - Glaucoma is the second leading cause of bilateral blindness worldwide⁹
 - It will affect an estimated 79.6 million people worldwide by 2020⁹
- **As of 2009, 120,000 people in the United States were blind because of glaucoma¹⁰**
- **An estimated 2.2 million people had the most common form of glaucoma – OAG – expected to increase to 3.36 million in 2020¹¹**

Sucampo's Prostone Technology Has Resulted in Two FDA-Approved Products

AMITIZA[®] (lubiprostone) for Chronic Idiopathic Constipation (CIC) in adults and Irritable Bowel Syndrome with Constipation (IBS-C) in adult women



- Product Overview
 - AMITIZA is a chloride ion channel activator
 - FDA approved and marketed for CIC in adults and IBS-C in adult women; sNDA for OIC filed July 2012
 - Activation of this channel in cells within the intestinal tract results in fluid secretion and repair of epithelial cell barriers which are essential to the normal function of the digestive track

RESCULA[®] (unoprostone isopropyl) 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

- Product Overview
 - RESCULA is a potassium ion channel activator
 - FDA approved for the lowering of intraocular pressure (IOP) in primary open-angle glaucoma and ocular hypertension
 - Activation of this channel relaxes contractile cells, resulting in decreased intraocular pressure which is a known risk factor for glaucoma-associated vision loss

 **SUCAMPO**
PHARMACEUTICALS, INC.

Key Facts

Trading Symbol	SCMP
Corporate Headquarters	Bethesda, MD
Stock Price (9-4-2012), 52-Week Range	\$4.52, \$8.50 to \$2.96
Shares Outstanding (9-4-2012)	41.9 M (1 class of common stock)
Daily Volume (90-day average at 9-4-2012)	61,111
Market Capitalization (9-4-2012)	\$189 M
Debt (6-30-12)	\$60.4 M
Cash (6-30-12)	\$88.6 M
Enterprise Value	\$188.1M
YTD Total Revenue (6-30-2012)	\$31.1 M
Full-time Employees (12-31-2011)	~110
Fiscal Year Ends	December 31
Accounting Firm	PricewaterhouseCoopers, LLP

Management

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

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

Cary J. Claiborne, Chief Financial Officer

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

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

- Abbott Laboratories
- Millennium Pharmaceuticals (COR Therapeutics)

Greg Deener, Senior Vice President, Marketing Strategy and Implementation

- GTX, Inc.
- GlaxoSmithKline

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

- NorthWestern Corporation, General Counsel and Corporate Secretary
- Boeing

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



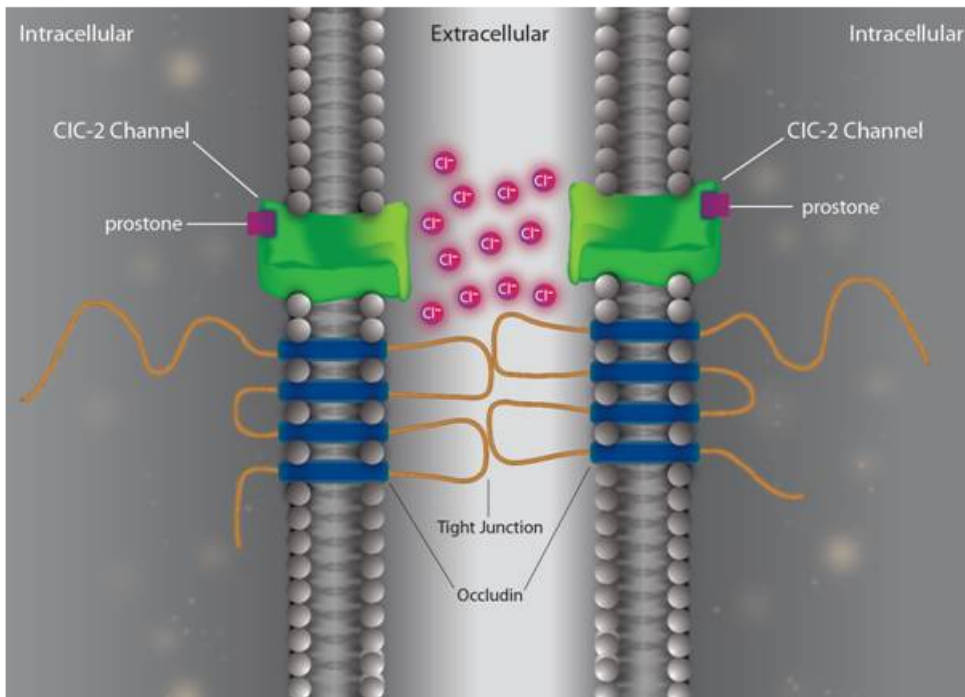
Amitiza® (lubiprostone)

AMITIZA® (lubiprostone)

- **Approved in**
 - US for CIC in adults (2006) and IBS-C in adult women (2008)
 - Partnered with Takeda Pharmaceuticals in US
 - Royalty revenue of \$41.5 M on net sales of \$226.4M in 2011
 - Switzerland for CIC (2009)
 - Limited marketing
 - Japan for chronic constipation (2012)
 - 4Q 2012 launch
 - Partnered with Abbott Japan
- **Filed in**
 - US for OIC (July 2012)
 - UK for CIC (August 2011)
 - Expect UK approval 3Q 2012
- **Sucampo plans to commercialize AMITIZA in Europe**

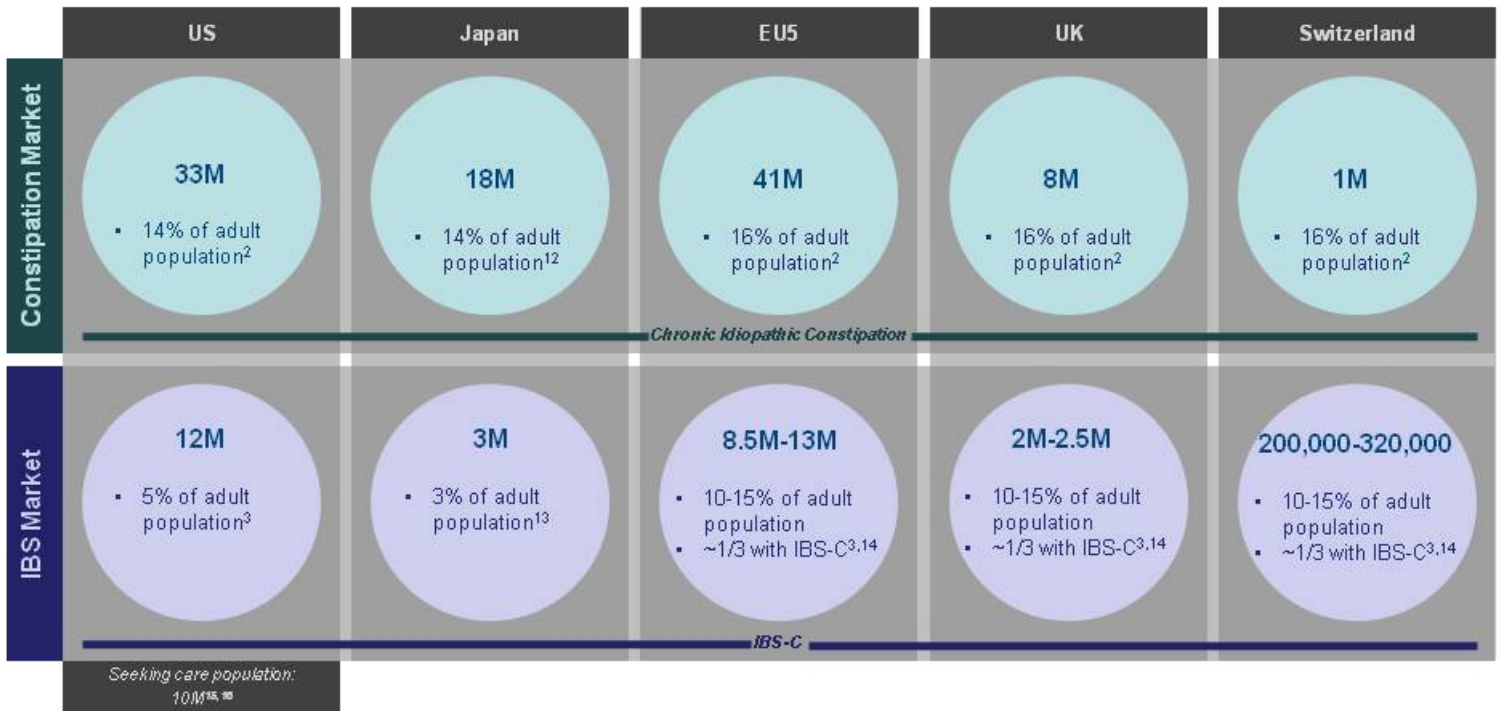
AMITIZA Mechanism of Action

CIC-2 Ion Channel Activation



- The mucosal barrier within the intestinal tract can be damaged by disease or injury (e.g., IBS) leading to symptomatic manifestations
- AMITIZA can help restore tight junctions by binding and activating CIC-2 channels
- The CIC-2 chloride channel allows chloride to flow out of cells, promoting fluid secretion

Chronic Constipation and IBS-C are Large Markets with Unmet Medical Needs

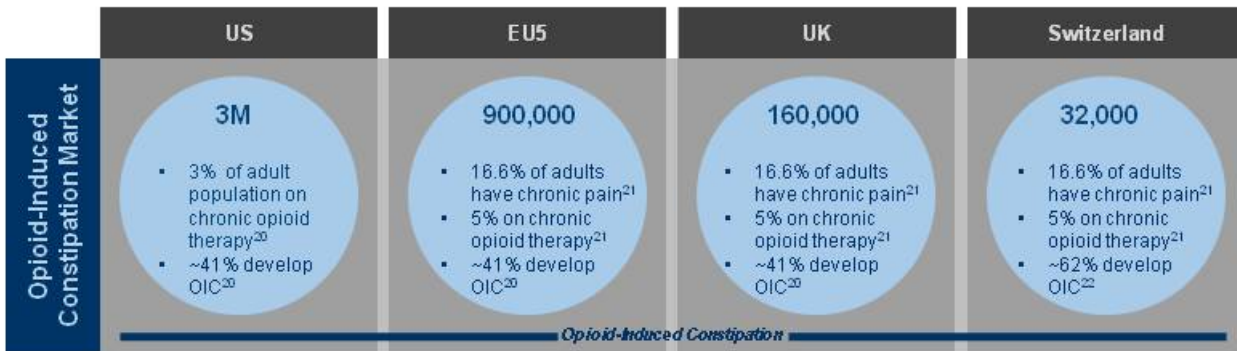


New Indication in OIC Will Expand the AMITIZA Franchise

- **Sucampo and Takeda announced filing of sNDA for OIC on July 26, 2012**
 - Seeking approval for a new indication for AMITIZA® (lubiprostone) for the treatment of opioid-induced constipation (OIC) in patients with chronic, non-cancer pain
 - Filing is based on results from three Phase 3, well-controlled studies of 12 weeks' duration in patients taking opioids chronically for non-cancer pain, as well as a long-term, open-label safety study, which provide additional support for use in this population
 - Global trials: 250 sites, 1,500 patients
 - Takeda funded the first \$50M and 50% of trial costs in excess of \$50 million

- **FDA decision expected 1H13**

A Significant Portion of Opioid Users Develop Opioid-induced Constipation



Amitiza Growth Opportunities

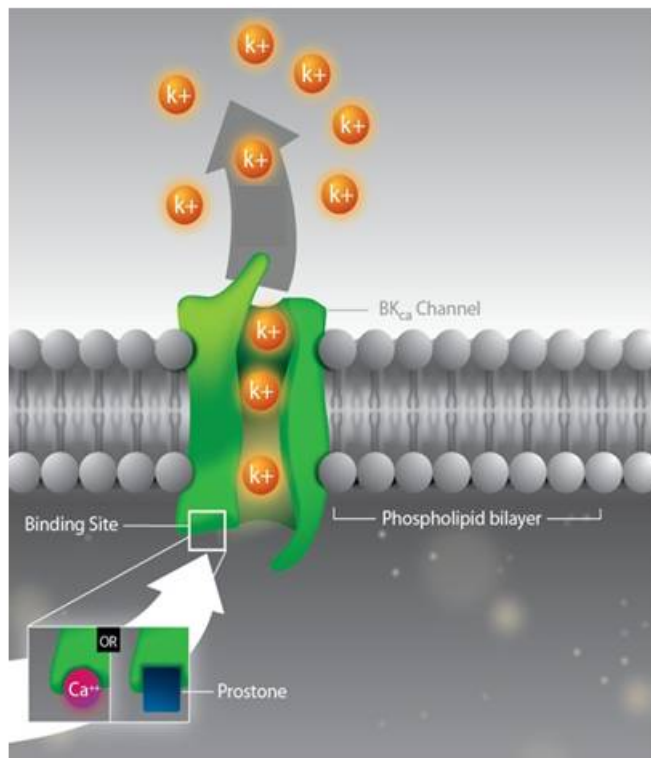
- **Expansion of the AMITIZA franchise**
 - New geographic markets
 - New indications
- **Growth in United States**
 - Increase CIC and IBS-C sales
 - Patient awareness
 - Customer targeting
 - Managed care access
 - Sales force efforts
 - Approval of sNDA for OIC
- **Growth in Japan and Europe**
 - Recent approval in Japan, partnered with Abbott Japan
 - Expect approval of an MAA for CIC in the UK
 - Anticipate filing for OIC in the UK with other European countries to follow

RESCULA® (unoprostone isopropyl)

RESCULA® (unoprostone isopropyl)

- Approved in
 - US for the lowering of intraocular pressure (IOP) in primary open-angle glaucoma (POAG) and ocular hypertension (OH) in patients who are intolerant of or insufficiently responsive to other IOP-lowering medications (2000)
 - Many European and several South American and Middle Eastern countries for treatment of glaucoma (late 1990's)
 - In Japan for treatment of glaucoma (1994)
- Filings in
 - US to fully reflect current scientific understanding of mechanism of action, approval expected 3Q 2012 (label update)
 - MAAs to be filed in EU and Switzerland by year-end to fully reflect current scientific understanding of mechanism of action
- Licensed worldwide commercialization and development rights (except Japan, Korea, Taiwan and People's Republic of China) from R-Tech Ueno, Ltd. (2010, 2011)
- Sucampo to launch RESCULA in US by the end of 2012
- Will commercialize in Europe

BK (Maxi-K) Potassium Channel Activation RESCULA's Unique Mechanism of Action



- **RESCULA eye drops lower intra-ocular pressure (IOP)**
- **BK channel activation hyperpolarizes the cell and leads to the relaxation of the trabecular meshwork to increase the outflow of aqueous humor**

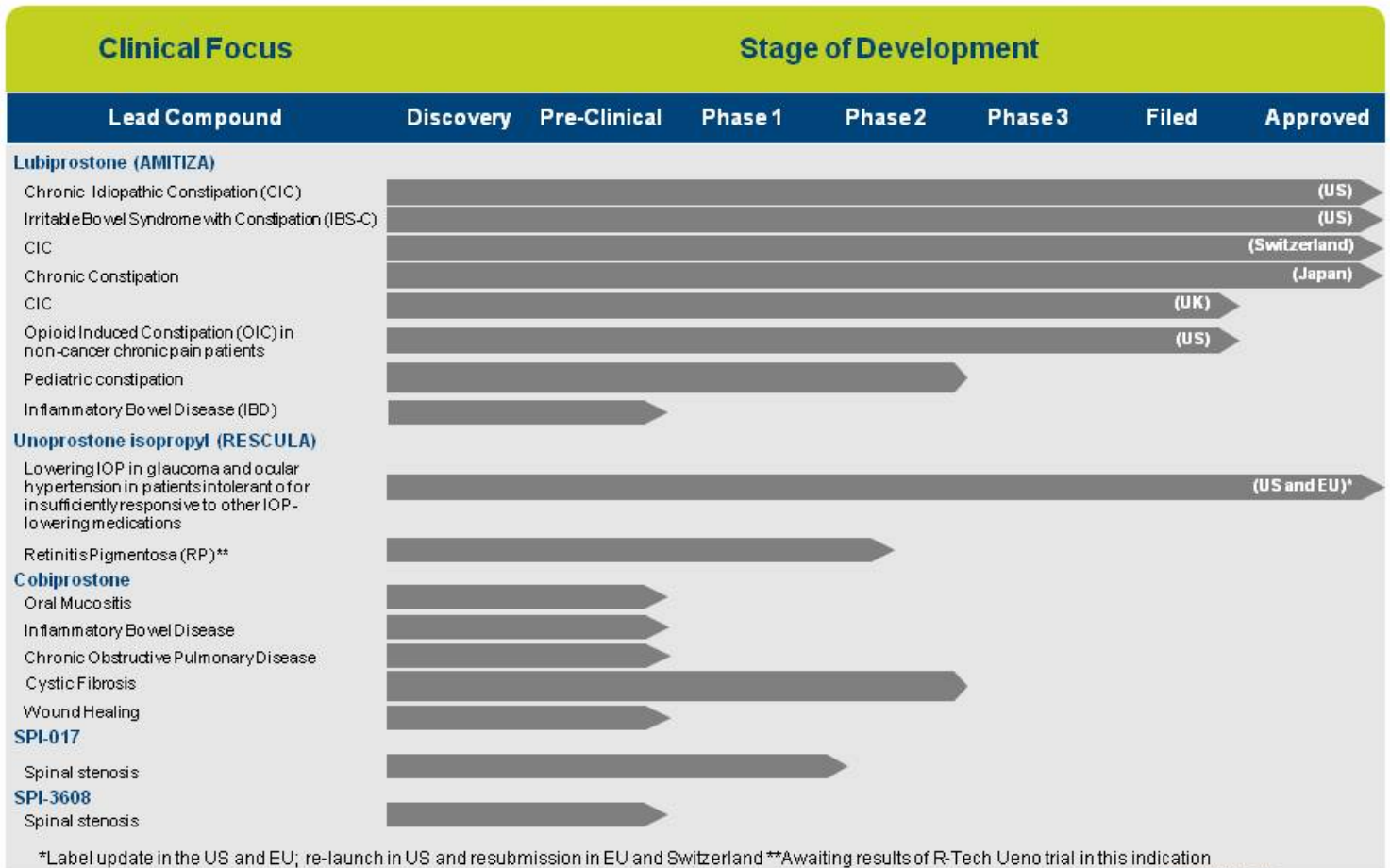
US Glaucoma Market Overview

- **The US glaucoma market is 29.2M TRx's⁴¹**
 - 4-5M potential patients^{40,41,43}
 - 67% of the market is generic⁴²
 - 80% of TRx's are by eye specialists⁴²
 - Limited new products vs. reformulations
- **Compliance and adherence are unmet needs**
 - 50% of new patients drop off therapy within one year of initiation
- **Prostaglandins are inflammatory agents which depolarize cell membranes**
 - #1 reason for discontinuation of prostaglandins is hyperemia^{39,43,44}
- **There is opportunity in this market for a differentiated product with a novel mechanism of action, such as Rescula**
- **Glaucoma sales volume (market opportunity):**
 - ~\$3B in US (2012)
 - ~\$1B in Japan (2011)

RESCULA Growth Opportunities

- Sucampo is seeking revisions to the label to more accurately reflect current scientific understanding
 - We anticipate agreement on the final RESCULA label during 3Q 2012
- Advantages of RESCULA
 - Reduces IOP throughout the day alone or in combination
 - Avoids side effects seen with other agents
 - Novel MOA: ion channel activator promotes aqueous humor outflow through the trabecular meshwork
- Sucampo plans to launch RESCULA by the end of 2012

Deep and Validated Clinical Pipeline



*Label update in the US and EU; re-launch in US and resubmission in EU and Switzerland **Awaiting results of R-Tech Ueno trial in this indication

PHARMACEUTICALS, INC.

Key Value Drivers

- **AMITIZA**

- **US**

- ✓ Filed OIC sNDA mid-year 2012
 - ✓ Decision in Takeda arbitration resolved dispute

- **Switzerland**

- **Pricing resolution in 4Q12**

- **Japan**

- ✓ Approved in Japan June 2012
 - **Await pricing decision in 3Q12**
 - **Launch in 4Q12**

- **EU**

- **Expect approval of MAA in UK for CIC in 3Q12**
 - **Submit OIC MAAs in UK and Switzerland**

- | | |
|---|-------------------|
| ✓ | Completed |
| • | In process |

- **RESCULA**

- **US**

- **Anticipate approval of sNDA for glaucoma indication in US (updated label)**
 - **Launch in 4Q12**

- **EU**

- **Re-approval filings in EU and Switzerland**

Appendix

Issued Lubiprostone Patents

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

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

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

Issued Lubiprostone Patents

Japanese

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

European

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

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

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

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41. July 2011-June 2012 MATTY IMS NPA data.
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43. Input from KOLs.



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Ryuji Ueno, MD, PhD, PhD, Chair and CEO

Cary J. Claiborne, CFO

Stanley G. Miele, SVP, Sales & Marketing

Silvia Taylor, SVP, IR, PR & Corporate Communications

September 7, 2012