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): October 29, 2010

Sucampo Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

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

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 October 29, 2010, Sucampo Pharmaceuticals, Inc. will make a corporate update presentation at the 2010 Mid-Atlantic BIO 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 October 29, 2010.

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: October 29, 2010

By: /s/ JAN SMILEK
Name: Jan Smilek
Title: Chief Financial Officer

SUCAMPO PHARMACEUTICALS, INC.

# 2010 Mid-Atlantic BIO

James J. Egan
Chief Operating Officer

October 29, 2010

# Forward-Looking Statement

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

# Sucampo: A Biopharmaceutical Company

- **Amitiza®**
  - Only FDA approved drug for chronic idiopathic constipation (CIC) in adults
  - Only FDA approved drug for irritable bowel syndrome with constipation (IBS-C) in adult women
  - Marketing authorization approved (Nov 2009) in Switzerland for CIC indication
  - Phase 3 trial in opioid-induced bowel dysfunction (OBD) to initiate late 2010
  - U.S + Canadian commercial rights held by Takeda, commercial rights in Japan held by Abbott
- **Rescula®**
  - FDA approved for lowering intra-ocular pressure (IOP) in glaucoma and ocular hypertension in patients who are intolerant of or insufficiently responsive to other IOP lowering medications
  - In-licensed US + Canadian development and marketing rights in April 2009
  - Awaiting FDA approval of label-enhancing supplemental NDA (sNDA) before re-launch in U.S.
  - Designing trials for additional indications, based on partner's breakthrough clinical results
- **A deep pipeline leveraging prostone technology, expertise**
  - Cobiprostone for prevention of NSAID-induced gastric ulcers in Phase 2
  - SPI-017 for peripheral arterial disease going into Phase 2
  - Additional prostones in preclinical development, such as SPI-3608
- **Strong financial position**
  - $114.4 million in cash and investments (as of June 30, 2010)

# Rescula: In-Licensed from R-Tech Ueno

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

SUCAMPO PHARMACEUTICALS, INC.

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

Design of Phase 2 Trial:

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

# Rescula: Phase 2 Results in Retinitis Pigmentosa*

Sucampo's partner, R-Tech Ueno, recently disclosed results of its recently completed Phase 2 clinical trial of UF-021 in mid- to late-stage RP patients

| | 4dB Improvement in Retina Sensitivity | 4dB Aggravation in Retina Sensitivity |
|---|---|---|
| Placebo | 15.2% | 21.2% |
| 1 drop twice a day | 7.9% | 15.8% |
| 2 drops twice a day | 18.4% | 2.6%** |

*** Statistically significant result when comparing 2 drops twice a day to placebo in aggravation of retinal sensitivity*

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

SUCAMPO PHARMACEUTICALS, INC.

# Rescula: A Differentiated Ophthalmic Drug

## A unique mechanism of action:

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

## Leads to future opportunities in retinal diseases

- Prevention of Choroidal Neo-Vascular (CNV) formation in dry Age-related Macular Edema (AMD)
- Diabetic Macular Edema (DME)

SUCAMPO PHARMACEUTICALS, INC.

# Rescula: Current Status

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

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

SUCAMPO PHARMACEUTICALS, INC.

# Amitiza Answers Unmet Medical Needs

- **Represents a major market opportunity**
  - More than 14 million (CIC and IBS-C) office visits in U.S. annually
- **Offers proven safety and efficacy for long-term usage**
  - Efficacy + tolerability are similar for both genders + across age groups for CIC
  - 90% of nausea events diminish after first week of use
  - Competing products recommended for short-term use only
- **Provides quick and predictable relief of symptoms**
  - Between 57%-63% of CIC patients respond within 24 hours and remain responsive
  - IBS-C patients were twice as likely to achieve overall response than those receiving placebo
- **Differentiated mechanisms of action**
  - In CIC, Amitiza activates chloride ion channels, promoting fluid secretion
  - In IBS-C, Amitiza activates chloride ion channels and promotes mucosal barrier protection

SUCAMPO PHARMACEUTICALS, INC.

# 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 (SBM's) after 1 week of treatment
  - Secondary endpoints included:
    - SMBs 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

SUCAMPO PHARMACEUTICALS, INC.

# 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 does 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 CIC in January 2006

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

SUCAMPO PHARMACEUTICALS, INC.

# Amitiza: Irritable Bowel Syndrome with Constipation*

- **Design of two pivotal phase 3 trials**
  - 2 multicenter trials identically designed, randomized, parallel-groups
  - 1,171 patients, all in U.S., received 8 mcg Amitiza gel capsule or placebo twice daily
  - 12 week treatment period after 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

SUCAMPO PHARMACEUTICALS, INC.

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

| Overall Responders | 8 mg bid | Placebo | |
|---|---|---|---|
| Study '431 | 13.8% | 7.8% | p=0.029 |
| Study '432 | 12.1% | 5.7% | p=0.023 |
| Pooled | 13.0% | 6.8% | p=0.001 |

Amitiza approved by FDA for 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

SUCAMPO PHARMACEUTICALS, INC.

# Amitiza: Further Opportunities -- OBD

## Management of Opioid-induced Bowel Dysfunction in Non-malignant Pain Patients (OBD)

- 4.5 Million patients in U.S. suffer from OBD
- Conducted two phase 3 trials, one reached statistical significance for primary endpoint
- Sucampo to conduct another phase 3 trial to obtain approval, Takeda to share costs

- Design of Successful Phase 3 trial
  - Randomized, placebo-controlled, double-blinded, multi-center , ~450 OBD patients per trial
  - One 24-mcg gel capsule of lubiprostone or placebo twice each day
  - 12 week treatment period
  - Permitted concomitant pain medications included: fentanyl, methadone, morphine and oxycontin
  - Primary endpoint: change from baseline in SBM frequency at week 8 without reduction in dose of study pain medication

SUCAMPO PHARMACEUTICALS, INC.

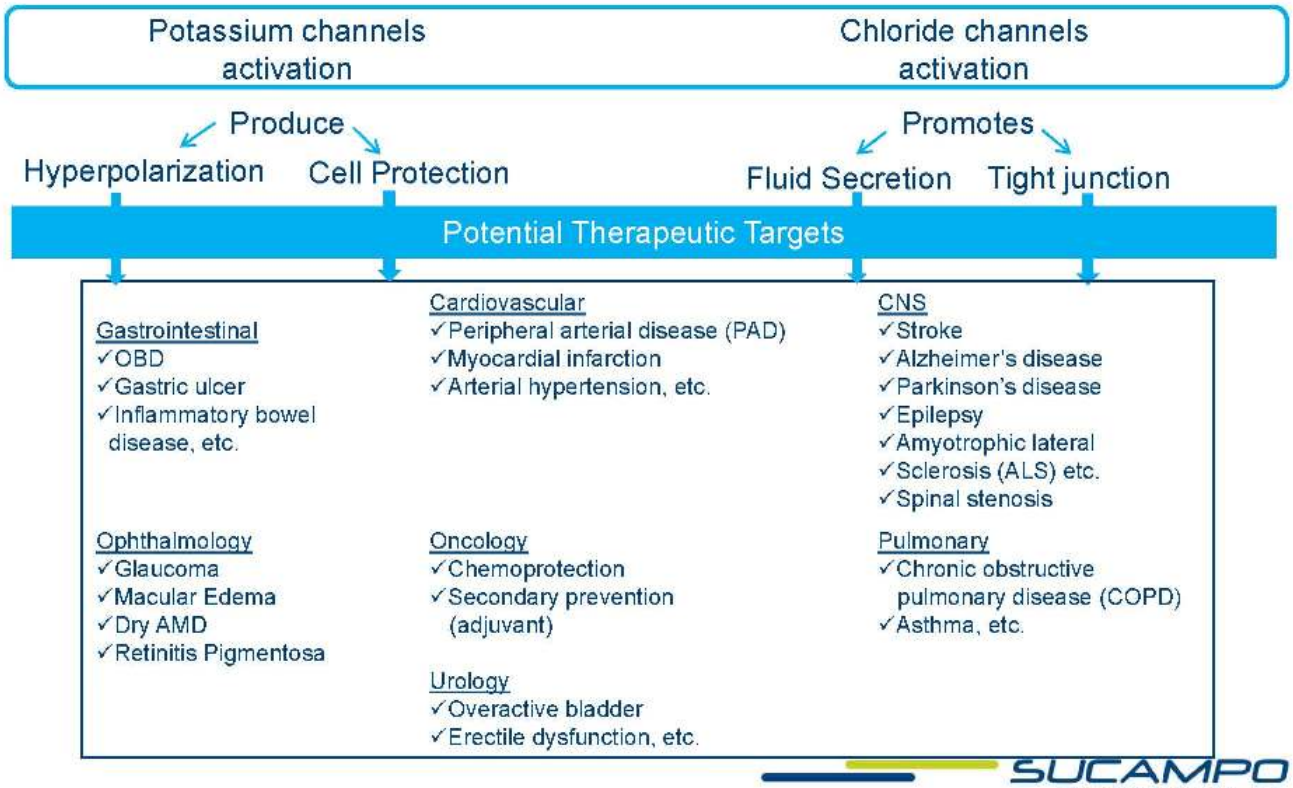
# Prostones Fuel Sucampo's Growth and Deep Product Pipeline

**Fatty Acids**

**Prostones**

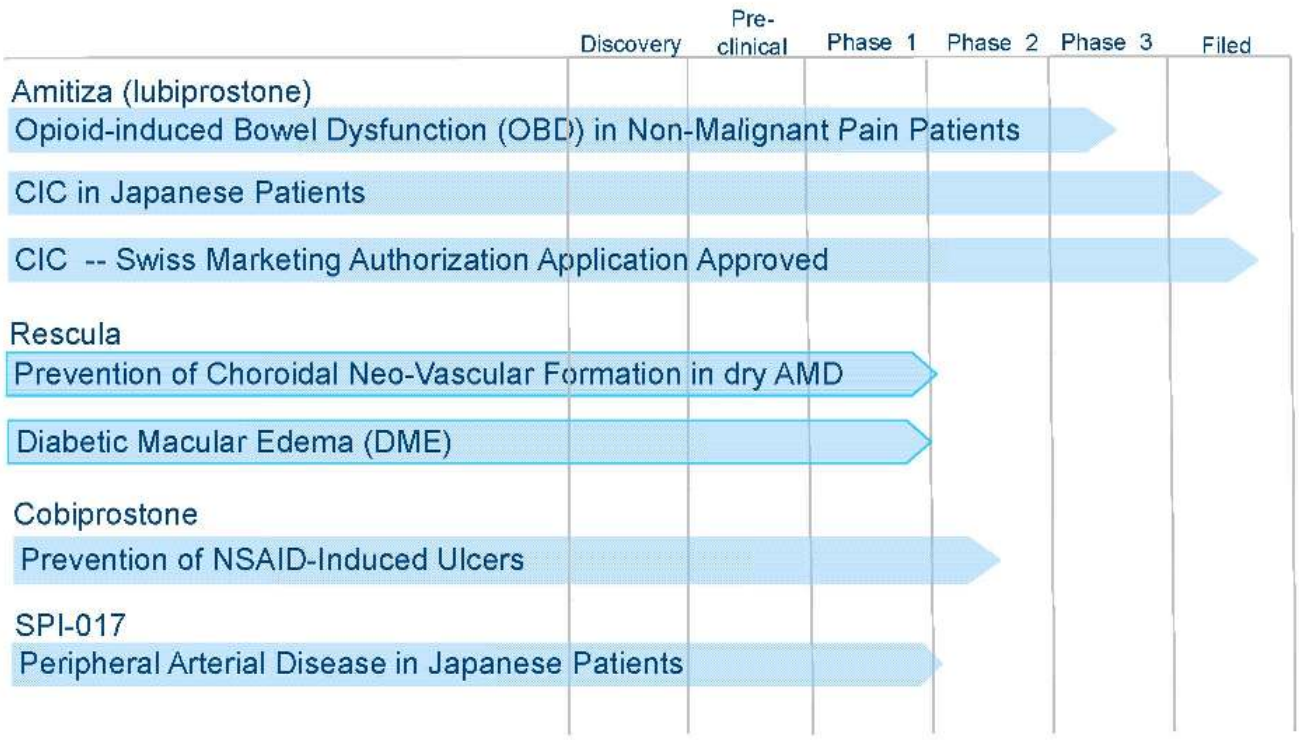
| Amitiza (lubiprostone) | Rescula (unoprostone isopropyl) | Cobiprostone (SPI-8811) | SPI-017 | Other Prostones |
|---|---|---|---|---|
| CIC (24 mcg) approved January 2006 | Re-launch in U.S. | Reported phase 2 trial for prevention of NSAID-induced gastric ulcers | Planning phase 2 trial for peripheral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

# Prostones Work as Potassium, and Chloride Channel Activators




SUCAMPO PHARMACEUTICALS, INC.

# Sucampo's Clinical Product Opportunities




SUCAMPO PHARMACEUTICALS, INC.

# Sucampo's Financial Results and Position

| In millions, except per share data | 2007 | 2008 | 2009 | 2010 YTD As of June 30 (6 months) |
|---|---|---|---|---|
| Product Royalty Revenue | $27.5 | $34.4 | $38.3 | $19.4 |
| R&D Revenue* | $59.4 | $72.3 | $24.0 | $6.8 |
| Total Revenue | $91.9 | $112.1 | $67.4 | $28.6 |
| Net Income/(Loss) | $13.2 | $25.0 | ($0.8) | ($2.3) |
| Earnings Per Share (diluted) | $0.35 | $0.59 | ($0.02) | ($0.05) |
| Cash & Investments | $86.1 | $121.5 | $118.3 | $114.4 |

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

SUCAMPO PHARMACEUTICALS, INC.

SUCAMPO PHARMACEUTICALS, INC.

# 2010 Mid-Atlantic BIO

James J. Egan
Chief Operating Officer

October 29, 2010