

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): February 19, 2009

**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))
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**Item 1.01. Entry into a Material Definitive Agreement.**

***Agreements with R-Tech Ueno, Ltd.***

On April 23, 2009, Sucampo Pharma Americas, Inc., or SPA, a wholly-owned subsidiary of the Registrant, entered into an Exclusive Manufacturing and Supply Agreement and an NDA Transfer, Patent and Know-how Licensing, and Data Sharing Agreement with R-Tech Ueno, Ltd., or RTU, to acquire rights to Rescula® (unoprostone isopropyl) in the United States and Canada.

Under the terms of these agreements, SPA is licensing from RTU all patents and other intellectual property rights related to Rescula in the United States and Canada and holds the exclusive rights to commercialize Rescula in those countries for the treatment of glaucoma and ocular hypertension and any other indication that SPA may develop. SPA also will have the right of first refusal to negotiate with RTU for the rights to develop and commercialize in the United States and Canada any additional indications for which unoprostone isopropyl is developed by RTU. Similarly, RTU will have the right of first refusal to negotiate with SPA for the rights to develop and commercialize outside the United States and Canada any additional indications for which unoprostone isopropyl is developed by SPA.

Rescula eye drops have been approved by the U.S. Food and Drug Administration for the treatment of open-angle glaucoma and ocular hypertension.

RTU will have the exclusive right and responsibility to manufacture and supply unoprostone isopropyl to SPA for the United States and Canada at specified prices.

SPA will make an upfront payment to RTU of \$3.0 million and will be responsible for additional milestone payments of up to \$5.5 million based on the achievement of specified development and commercialization milestones. SPA will be responsible for the development, regulatory, and commercialization activities and expenses for Rescula in the United States and Canada.

The term of the agreements will end, and the licensed rights will revert back to RTU, if SPA does not place an initial order for Rescula from RTU within two years or if SPA does not initiate a clinical trial for an additional indication for Rescula in the same period or does not launch the product.

SPA plans to re-launch Rescula in the United States for the treatment of glaucoma and ocular hypertension in 2010 and to initiate a phase 2 clinical trial for Rescula for treatment of dry aged-related macular degeneration in 2010.

As of April 1, 2009, RTU held approximately 6% of the Registrant's outstanding common stock, including approximately 16% of its class A common stock. Dr. Ryuji Ueno, Chairman and Chief Executive Officer of the Registrant, and his wife, Dr. Sachiko Kuno, directly and indirectly own a majority of the capital stock of RTU. Dr. Ueno and Dr. Kuno do not hold any management or board positions with RTU. Dr. Ueno and Dr. Kuno are both members of the board of directors of the Registrant and together directly or indirectly hold a substantial majority of the Registrant's common stock.

The Registrant intends to file a copy of the Unoprostone Exclusive Manufacturing and Supply Agreement and the Unoprostone NDA Transfer, Patent and Know-how Licensing, and Data Sharing Agreement as exhibits to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.

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**Item 7.01. Regulation FD Disclosure.**

On April 23, 2009, the Registrant issued a press release announcing the agreements with RTU, a copy of which is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) 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 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

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1 Press release issued by the Registrant on April 23, 2009

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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: April 27, 2009

By: /s/ Jan Smilek

Name: Jan Smilek

Title: Chief Financial Officer

## Sucampo Acquires Rights to Rescula for U.S. and Canada

### *Strengthens Sucampo's Prostone Product Portfolio Potential for Label Expansion in Dry AMD*

BETHESDA, Md. & TOKYO--(BUSINESS WIRE)--April 23, 2009--Sucampo Pharmaceuticals, Inc., (NASDAQ:SCMP) and R-Tech Ueno, Ltd. (RTU) (Osaka Exchange Hercules code: 4573), today announced that Sucampo Pharma Americas, Inc. (SPA), a wholly owned subsidiary of Sucampo Pharmaceuticals Inc., licensed from RTU the commercialization rights to Rescula<sup>®</sup> (unoprostone isopropyl) in the United States and Canada, including all associated patents and other intellectual property. In addition, RTU will be the exclusive supplier of finished product to Sucampo.

Rescula was approved by the U.S. Food and Drug Administration (FDA) for the treatment of open-angle glaucoma and ocular hypertension in 2000. In addition to these approved indications, Sucampo management believes that Rescula has the potential to be a treatment for dry age-related macular degeneration (dry AMD). As a result, Sucampo plans to initiate a phase 2 clinical trial with Rescula for dry AMD in 2010.

Ryuji Ueno, M.D., Ph.D., Ph.D., Chairman and Chief Executive Officer of Sucampo Pharmaceuticals, said, "We are very pleased to add Rescula to Sucampo's product portfolio, alongside Amitiza<sup>®</sup>. We look forward to re-launching Rescula for its currently approved indications and to developing it as a potential treatment for dry AMD. We believe Rescula will be an important and integral part of our product portfolio. Both Rescula and Amitiza are created from the prostone technology whose therapeutic potential I discovered in the 1980s and is also the basis for Sucampo's clinical and preclinical pipeline compounds. Rescula targets disorders caused by the aging process, which is consistent with the commercial focus of Sucampo and one of my abiding passions."

Ms. Yukiko Miyake-Hashitera, President and Chief Executive Officer of R-Tech Ueno Ltd., said, "I am very pleased with this agreement as it provides an opportunity for Rescula to significantly impact the quality of vision and quality of life of patients both in the U.S. and Canada. I have the utmost confidence that the potential of Rescula will be fully maximized."

Gayle Dolecek, P.D., M.P.H., Senior Vice President of Research & Development, Sucampo Pharmaceuticals, said, "Rescula's safety profile and novel mechanism of action are two of its product attributes that provide a rationale for new indications. Its existing FDA approval status and safety profile should facilitate entry into clinical trials for dry AMD patients. If those trials are successful, Rescula will provide us the opportunity to meet the unmet medical needs of a substantial patient population."

Stanley G. Miele, Senior Vice President of Sales & Marketing, Sucampo Pharmaceuticals, said, "This agreement provides Sucampo's sales team with a second prostone product. As part of our future re-launch of Rescula, we will continue focusing on the Amitiza market segments we now serve, while establishing relationships and a collaborative approach with specialists who treat ocular disorders. This is a very nice fit for our commercial team."

### **Terms of the Agreement**

Under the terms of the agreement, Sucampo will hold the exclusive rights to commercialize Rescula in the U.S. and Canada for the treatment of glaucoma and ocular hypertension. Sucampo also will have the right to develop Rescula for additional indications. Sucampo also will have the right of first refusal to commercialize in the U.S. and Canada any additional indications for which Rescula is developed by RTU. RTU will be exclusively responsible for supply of Rescula to Sucampo for the U.S. and Canada.

Sucampo will make an upfront payment to RTU of \$3.0 million and will be responsible for additional milestone payments based on the achievement of specified development and commercialization goals. Sucampo will be responsible for the development, regulatory, and commercialization activities and expenses for Rescula in the U.S. and Canada.

As of April 1, 2009, RTU held six percent of the outstanding common stock of Sucampo Pharmaceuticals' outstanding shares. Dr. Ueno, Chairman and Chief Executive Officer of Sucampo Pharmaceuticals, Inc., and his wife, Dr. Sachiko Kuno directly and indirectly own a majority of the capital stock of RTU. Dr. Ueno and Dr. Kuno do not hold any management or board positions with RTU. Dr. Ueno and Dr. Kuno are both members of the board of directors of Sucampo Pharmaceuticals and together directly or indirectly hold a substantial majority of the common stock of Sucampo Pharmaceuticals.

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## **About Rescula (unoprostone isopropyl)**

Rescula (unoprostone isopropyl) is a synthetic docosanoid that is administered topically as a liquid eye drop that activates the BK channels in cells within the retina. Sucampo management believes that this activation of BK channels lowers intraocular pressure (IOP) by increasing the outflow of aqueous humor. Clinical studies have shown that in patients with a mean baseline IOP of 23 mm Hg, unoprostone isopropyl lowers IOP by approximately 3 to 4 mm Hg throughout the day.

In clinical and preclinical studies Rescula has: increased ocular blood flow to the optic nerve and in the choroid; maintained visual field; delayed retinal degeneration induced by rhodopsin by inhibiting apoptosis; inhibited topographic and blood changes in an ischemic optic nerve head; and lowered intraocular pressure. SPA believes that these clinical effects suggest that Rescula could potentially be effective in the treatment of other ocular diseases.

Rescula received its first marketing approval in Japan in 1994 for the treatment of glaucoma and ocular hypertension.

Rescula is a registered trademark of RTU and has been licensed to Sucampo for use in the U.S. and Canada.

Amitiza is a registered trademark of Sucampo Pharmaceuticals, Inc.

## **About dry age-related macular degeneration (dry AMD)**

More than 8 million people in the U.S. currently have age-related macular degeneration (AMD), a disease which causes damage to the retina resulting in loss of vision. AMD is the leading cause of irreversible blindness in adults, worldwide. The prevalence of AMD in the U.S. is expected to increase by more than 50 percent, to approximately 12 million by 2020. More than 85 percent of all people with intermediate and advanced AMD have the dry form, [1]

AMD is a disease associated with aging that gradually destroys sharp, central vision. Central vision is needed for seeing objects clearly and for common daily tasks such as reading and driving. AMD affects the macula, the part of the eye that allows the seeing of fine detail. The macula is located in the center of the retina, the light-sensitive tissue at the back of the eye. The retina instantly converts light, or an image, into electrical impulses or nerve signals, which are sent to the brain. Dry AMD occurs when the light-sensitive cells in the macula slowly break down, gradually blurring central vision in the affected eye. As dry AMD progresses, patients may see a blurred spot in the center of their vision. Over time, as less of the macula functions, central vision is gradually lost in the affected eye. The most common symptom of dry AMD is slightly blurred vision and a need for more light to read and do other tasks. Dry AMD generally affects both eyes, but vision can be lost in one eye while the other eye seems unaffected. [2] Currently, no drugs have been approved by regulatory authorities for the treatment of dry AMD.

## **About glaucoma**

Glaucoma is a group of diseases that can damage the eye's optic nerve, or retina, resulting in vision loss and blindness. Glaucoma occurs when the normal fluid pressure inside the eyes slowly rises. However, with early treatment, one can often protect one's eyes against serious vision loss.

It is estimated that over 4 million Americans have glaucoma and that it accounts for 9 to 12 percent of all cases of blindness in the U.S. [3]

For more information visit: <http://nei.nih.gov/health> and <http://www.glaucoma.org>

## **Sources:**

1. Retina Today, January/February 2007
2. National Eye Institute, Facts about Age-Related Macular Degeneration [NEI Health Information]
3. Glaucoma Research Foundation, Glaucoma Facts and Stats

## **About Sucampo Pharmaceuticals**

Sucampo Pharmaceuticals, Inc., a biopharmaceutical company based in Bethesda, Maryland, focuses on the development and commercialization of medicines based on prostones. The therapeutic potential of prostones, which are bio-lipids that occur naturally in the human body, was first identified by Ryuji Ueno, M.D., Ph.D., Ph.D., Sucampo Pharmaceuticals' Chairman and Chief Executive Officer. Dr. Ueno founded Sucampo Pharmaceuticals in 1996 with Sachiko Kuno, Ph.D., founding Chief Executive Officer and currently Advisor, International Business Development and a Director.

Sucampo markets Amitiza® (lubiprostone) 24 mcg in the U.S. for chronic idiopathic constipation in adults and Amitiza 8 mcg in the U.S. to treat irritable bowel syndrome with constipation in adult women. Sucampo also is developing the drug for additional gastrointestinal disorders with large potential markets. In addition, Sucampo has a robust pipeline of compounds with the potential to target underserved diseases, inclusive of age-related diseases, affecting millions of patients worldwide. Sucampo Pharmaceuticals, Inc. has three wholly owned subsidiaries: Sucampo Pharma Europe, Ltd., located in the UK; Sucampo Pharma, Ltd., located in Japan; and, Sucampo Pharma Americas, Inc., located in Maryland. To learn more about Sucampo Pharmaceuticals and its products, visit [www.sucampo.com](http://www.sucampo.com).

## **About R-Tech Ueno**

R-Tech Ueno was founded in 1989 by Ryuji Ueno, M.D. Ph.D., Ph.D., and has been a pharmaceutical venture corporation focusing on research, development, manufacturing and sales promotion of prescription drugs mainly in the area of ophthalmic diseases. Products which we manufacture are Rescula eye drops, glaucoma and ocular hypertension drug and Amitiza capsules, Chronic Idiopathic Constipation and Irritable Bowel Syndrome drug. Utilizing the highest level of expertise in the field of ophthalmology, our “physicians oriented new drug innovation” is making advances into the development of new drugs that target ophthalmic diseases with no currently effective medications. We also offer comprehensive support services to venture companies which seek new drug development. R-Tech Ueno was listed on the Hercules, Osaka Stock Exchange on April 9, 2008. R-Tech Ueno contributes to the society and progress by developing effective pharmaceutical products which are derived from our own innovative ideas.

To learn more about R-Tech Ueno Ltd. and its products, visit <http://www.rtechueno.com/en/index.php>

## **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Sucampo Pharmaceuticals are forward-looking statements made under the provisions of The Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the words “project,” “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “should,” “would,” “could,” “will,” “may” or other similar expressions. Forward-looking statements include statements about potential growth in the prevalence of particular diseases or conditions, including dry AMD, the commercial relaunch of Rescula and the ability of Sucampo to commercialize and market it, the potential utility of Rescula to treat additional indications and future clinical trials. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including those described in Sucampo Pharmaceuticals’ filings with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K for the year ended December 31, 2008 and other periodic reports filed with the SEC. Any forward-looking statements in this press release represent Sucampo Pharmaceuticals’ views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Sucampo Pharmaceuticals anticipates that subsequent events and developments will cause its views to change. However, while Sucampo Pharmaceuticals may elect to update these forward-looking statements publicly at some point in the future, Sucampo Pharmaceuticals specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise.

### **CONTACT:**

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