# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): January 9, 2016

### Sucampo Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u>

(State or other jurisdiction of incorporation)

001-33609

(Commission File Number)

30-0520478

(IRS Employer Identification No.)

805 King Farm Boulevard, Suite 550 Rockville, MD 20850

(Address of principal executive offices, including zip code)

(301) 961-3400

(Registrant's telephone number, including area code)

(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:

- [] 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 1.01. Entry into a Material Definitive Agreement.

On January 9, 2016, Sucampo Pharmaceuticals, Inc. ("we") entered into a strategic alliance for the development and commercialization of CPP-1X/sulindac combination with Cancer Prevention Pharmaceuticals, Inc. ("CPP"). Pursuant to the terms of a Securities Purchase Agreement, dated January 9, 2016, Sucampo AG, our wholly-owned Swiss subsidiary, made a loan to CPP evidenced by a promissory note in the aggregate principal amount of \$5,000,000 (the "Note"). The Note bears interest at the rate of 5.0% per annum and matures on January 31, 2019 unless earlier converted or prepaid. The Note is automatically convertible into shares of capital stock of CPP in the event CPP consummates a firm commitment underwritten public offering of its common stock or a private placement of debt, equity, preferred or convertible securities with aggregate gross proceeds of at least \$10.0 million, excluding any investment by us in such offering (such a transaction, a "Qualified Financing"). Upon a Qualified Financing, the outstanding principal amount and accrued and unpaid interest on the Note will automatically convert at a discount of 10% or 20%, as specified in the Note, below the lowest issuance price of the securities in the Qualified Financing and will convert into the same securities issued in such Qualified Financing. If a Qualified Financing or a Sale (as defined below) does not occur before the maturity date of the Note, then, at our election, we can convert the outstanding principal amount and accrued and unpaid interest on the Note upon 10 business days' notice into common stock of CPP at a conversion rate equal to the price per share set forth in the Company's most recent 409A valuation. In addition, in the event of the sale of all or substantially all of CPP's assets or CPP's consolidation or merger (a "Sale") prior to the maturity date of the Note or the consummation of a Qualified Financing, we can convert the outstanding principal amount and accrued and unpaid interest on the Note, at our election, into shares of CPP's c

Pursuant to the Securities Purchase Agreement, we have also agreed, at CPP's sole discretion, to (i) purchase up to \$5,000,000 of CPP's securities (the "Additional Investment") on the same terms and conditions as the other investors in a Qualified Financing, or (ii) if a Qualified Financing has not occurred before the successful completion of futility analysis of CPP's ongoing FAP Phase 3 trial studying CPP-1X/sulindac combination, subject to certain conditions to be met by CPP, to invest in the form of an additional convertible note in the principal amount of \$5,000,000 under the same terms and conditions as the Note.

We also entered into an exclusive option and collaboration agreement (the "Option and Collaboration Agreement") under which CPP has granted us the right to obtain (the "Option") an exclusive license, with the right to sublicense, develop, make, have made, use, import, offer for sale and sell the CPP-1X/sulindac combination product (the "Product") in North America (the "Territory") for the treatment, prevention and diagnosis of human diseases and conditions (the "Field"). We have agreed to pay CPP a fee of \$7,500,000 for the Option. The first tranche of this option fee has been paid; under certain conditions relating to the clinical development of the Product, we will be required to pay the remainder of the option fee (the "Second Option Fee Tranche") in order to retain the Option. If we exercise the Option, we have the right to negotiate and execute a definitive license agreement (the "License Agreement") within a defined period.

The Option expires if (i) it is not exercised within thirty 30 days after the acceptance for filing by the FDA of the first NDA filed by CPP for the Product; (ii) we are required to make the Additional Investment in accordance with the Securities Purchase Agreement, but we fail to do so; (iii) we are required to pay the Second Option Fee Tranche described above, but we fail to do so; or (iv) either party terminates the Option and Collaboration Agreement. Each party has the right to terminate the Option and Collaboration Agreement for material breach of the other party. In addition, CPP may terminate the Option and Collaboration Agreement, or if we assist any affiliate or third party of ours in such a challenge, other than as required by law.

The Option and Collaboration Agreement provides that a joint steering committee (the "JSC") will be established to plan, administer, evaluate and carry out the development of the Product. Until the License Agreement is negotiated and executed, final decision making authority with regard to issues presented to the JSC will rest with CPP. Prior to execution of the License Agreement, CPP will be responsible for any expenses incurred in the development of the Product, and CPP will retain the right to develop the Product for any indication.

If we enter into the License Agreement, we would be responsible for and control the development, manufacture and commercialization of the Product in the Field and Territory at our own expense. Upon the execution of the License Agreement, we would be required to pay a license issue fee in the amount of \$5.0 million, if we enter into the License Agreement prior to the completion of CPP's FAP Phase 3 trial, or \$10.0 million, if we enter into the License Agreement after the completion of CPP's FAP Phase 3 trial. We may also be required to make additional payments of up to an aggregate of \$180,000,000 upon the achievement of specified development and sales milestones. In addition, we would be obligated to split equally with CPP any net profits generated by us from the sale of the Product, subject to certain adjustments.

The foregoing summary of the Securities Purchase Agreement, the Note and the Option and Collaboration Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by, the full text of each such agreement, a copy of which will be filed with our Quarterly Report on Form 10-Q for the quarter ending March 31, 2016.

#### Item 7.01. Regulation FD Disclosure.

On January 11, 2016, the Company issued a press release announcing the execution of the Option and Collaboration Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information set forth in this Item 7.01 and contained in the press release furnished as Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release issued by the Company on January 11, 2016.

#### **SIGNATURES**

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.

By: /s/ Matthias Alder

Matthias Alder

Executive Vice President, Business Development and Licensing, General Counsel and Corporate Secretary

Date: January 14, 2016

#### EXHIBIT INDEX

Exhibit No. Description

99.1 Press release issued by the Company on January 11, 2016.

## Sucampo Enters Into Exclusive Option and Collaboration Agreement With Cancer Prevention Pharmaceuticals for Development of Late-Stage CPP-1X/Sulindac Combination for Familial Adenomatous Polyposis

Addresses Significant Patient Need

Aligned With GI Expertise, Strategic Focus

Phase 3 Study Expected to be Complete in 2018

ROCKVILLE, Md., Jan. 11, 2016 (GLOBE NEWSWIRE) -- Sucampo Pharmaceuticals, Inc. (Sucampo) (NASDAQ:SCMP), a global biopharmaceutical company, today announced an option and collaboration agreement under which Cancer Prevention Pharmaceuticals, Inc. (CPP) has granted Sucampo the sole option to acquire an exclusive license to commercialize CPP-1X/sulindac combination product in North America. This product is currently in a Phase 3 clinical trial for the treatment of familial adenomatous polyposis (FAP).

"We are very excited to enter into this agreement with Cancer Prevention Pharmaceuticals, as it aligns with our vision to acquire late-stage programs with the potential to have a significant impact on patient lives," said Peter Greenleaf, Chairman and Chief Executive Officer of Sucampo. "We believe that this product represents a substantial market opportunity and, given clinical results to date, could be a valuable asset for Sucampo that leverages our gastrointestinal expertise and strategic focus."

There are currently no approved treatments for FAP and no other products in late-stage development. A genetic disease, FAP typically develops into colon cancer if left untreated. Current treatment paradigms require patients to undergo the progressive removal of colon and rectum, ongoing endoscopies of the GI tract, and additional surgery throughout life. As a result, patients with FAP experience poor quality of life, inconvenience and significant cost. FAP has been designated an orphan indication in the U.S. and Europe, with a prevalence of about 1 in 10,000, and approximately 30,000 cases currently in the United States.

CPP-1X/sulindac oral combination product has demonstrated robust Phase 2 data in sporadic colon adenoma, additional evidence of efficacy in FAP with CPP-1X combinations, and has shown to be well-tolerated. The ongoing Phase 3 study is a 150-patient, three-arm, double-blind, randomized trial of the combination agent and the single agent comparators. Enrollment in the study is expected to be complete in the first half of 2016 and the trial is expected to conclude in 2018, with potential for approval in 2019. In addition, co-formulation activities are ongoing. The product also has additional opportunities in sporadic colon adenoma therapy (CAT), which is currently in a Phase 3 clinical trial with the National Cancer Institute and SWOG (formerly Southwest Oncology Group), as well as other potential GI and oncology indications.

Under the terms of the agreement, Sucampo will invest \$5.0 million in CPP in the form of a convertible note, with a planned additional \$5.0 million equity investment in CPP's next qualified financing, which will be either an IPO or a private financing as defined by the agreement. In addition, Sucampo will pay CPP an option fee of up to \$7.5 million, payable in two tranches. CPP will complete the ongoing Phase 3 trial under the oversight of a joint steering committee. Upon exercise of its exclusive option, Sucampo would acquire an exclusive license to the product and would be obligated to pay CPP up to an aggregate of \$190 million in license fees and milestone payments upon the achievement of specified clinical development and sales milestones. Under the terms of the license, Sucampo and CPP would share equally in profits from the sale of approved products.

#### **About FAP**

**Familial Adenomatous Polyposis**(FAP) is a rare hereditary disease characterized by cancer of the colon and rectum. Patients with the classic presentation of FAP begin to develop multiple benign polyps in the colon in their early teenage years. Eventually, the colon becomes covered with hundreds to thousands of polyps that typically become cancerous if left untreated. Current medical practice recommends the removal of the colon and sometimes the rectum in the formative years for the typical FAP patient. CPP's lead product candidate, CPP-1X/sulindac, is being developed to minimize the occurrence and/or recurrence of polyps and tumors associated with FAP and offers the potential of a non-surgical pharmacopreventive therapy across the spectrum of FAP patients.

#### About Sucampo Pharmaceuticals, Inc.

Sucampo Pharmaceuticals, Inc. is focused on the development and commercialization of medicines that meet major unmet medical needs of patients worldwide. Sucampo has one marketed product – AMITIZA – and a pipeline of product candidates in clinical development. A global company, Sucampo is headquartered in Rockville, Maryland, and has operations in Japan, Switzerland and the U.K. For more information, please visit www.sucampo.com.

The Sucampo logo and the tagline, The Science of Innovation, are registered trademarks of Sucampo AG. AMITIZA is a registered trademark of Sucampo AG.

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Twitter LinkedIn

**About Cancer Prevention Pharmaceuticals, Inc. (CPP)** 

CPP is developing therapeutics designed to reduce the risk of cancer. CPP's approach has been used with great success in other disease categories such as cardiovascular, neurovascular and infectious disease. CPP is co-sponsoring a large Phase 3 trial in colon cancer survivors (with NCI and SWOG) and a Phase 3 clinical trial in patients with Familial Adenomatous Polyposis (FAP). CPP is also working collaboratively with non-profit groups to support their clinical trials in neuroblastoma (childhood cancer) for the prevention of relapse, in gastric cancer, and in early-onset type 1 diabetes.

#### **Sucampo Forward-Looking Statement**

This press release 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 include statements regarding Sucampo's option agreement with CPP, including financial terms of a potential license agreement, and the expected timing of clinical trials. 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; the ability of Sucampo to successfully develop and commercialize product candidates; Sucampo's ability to accurately predict future market conditions; 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 press release 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 most recent Form 10-K as filed with the Securities and Exchange Commission on March 9, 2015 as well as its filings with the Securities and Exchange Commission on Forms 8-K and 10-Q since the filing of the Form 10-K, all of which Sucampo incorporates by reference.

Contact:

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