CATALYST PHARMACEUTICAL PARTNERS, INC.
Form 8-K
October 31, 2012

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 26, 2012

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**001-33057**	**76-0837053**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
355 Alhambra Circle		**33134**

Suite 1500

Coral Gables, Florida
(Address of principal executive offices) **(Zip Code)**

Registrant s telephone number, including area code: (305) 529-2522

Not Applicable

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 CFR240.14d-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 October 26, 2012, Catalyst Pharmaceutical Partners, Inc. (the Company) entered into a strategic collaboration with BioMarin Pharmaceutical Inc. (BioMarin) for Firdapse (Firdapse or the Product), a Phase III orphan drug for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS), which is a rare, debilitating and sometimes fatal autoimmune disease with the primary symptoms of muscle weakness. The key components of the collaboration include Catalyst licensing the exclusive North American rights to the Product pursuant to the terms of a License Agreement, dated as of October 26, 2012, between the Company and BioMarin (the License Agreement) and BioMarin making a $5,000,000 investment in the Company pursuant to the terms of a Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012, between the Company and BioMarin (the Investment Agreement) to rapidly advance the development of Firdapse in the United States.

Investment Agreement

On October 26, 2012, the Company and BioMarin entered into the Investment Agreement pursuant to which BioMarin has invested $5,000,000 into the Company. Initially, such amount shall be treated as a loan to the Company. However, the amount of the loan shall automatically convert into shares of the Company s authorized but unissued common stock on the earlier of: (i) March 31, 2013, or (ii) the date that is thirty (30) days after the Company publicly releases top-line data from its Phase II(b) clinical trial evaluating the use of its product candidate, CPP-109, for the treatment of cocaine addiction (the Conversion Date), except in certain limited circumstances as more particularly described below and in the Investment Agreement. As previously reported, the Company currently expects to be in a position to release the top-line data from its Phase II(b) clinical trial during the first half of November 2012. The conversion price of the shares of the Company s common stock to be acquired by BioMarin upon conversion of its $5 million investment in the Company will be the dollar weighted average price (as defined in the Investment Agreement) of the Company s common stock for the fifteen (15) business day period prior to the Conversion Date, multiplied by 0.9, *provided, however,* that the conversion price shall not be less than $0.75 per share or more than $2.50 per share.

The Investment Agreement also provides that the Company will use the $5 million solely for the purpose of developing the Product and that for such period that BioMarin owns more than 10% of the Company s outstanding common stock, BioMarin will exclusively use the exemption from registration provided under Rule 144 to make sales of the Company shares acquired in the investment transaction. The Company also agreed in the Investment Agreement not to make certain asset sales or sales of the Company s securities during the period between the date of the Investment Agreement and the Conversion Date without the prior written consent of BioMarin. Finally, the Investment Agreement provides that the Company is obligated to repay the $5 million to BioMarin, with interest, if an event of default (as defined in the Investment Agreement) occurs prior to the conversion of the loan amount into shares of the Company s common stock.

The foregoing description of the Investment Agreement is qualified in its entirety by reference thereto. A copy of the Investment Agreement is Exhibit 10.1 to this Current Report on Form 8-K, and is incorporated fully herein by this reference.

The Product and Development Plans for the Product in the United States

Firdapse is a proprietary form of 3,4-diaminopyridine (amifampridine phosphate), or 3,4-DAP, for the treatment of LEMS. BioMarin acquired the rights to Firdapse in October 2009 as a result of its acquisition of Huxley Pharmaceuticals, Inc. (Huxley). Firdapse was granted marketing approval in the European Union (EU) in December 2009, which, because Firdapse had previously been granted orphan medicinal product designation in the EU, included ten year marketing exclusivity in the EU. BioMarin will continue to sell Firdapse in the EU following this transaction.

Pursuant to the License Agreement, the Company will license the rights to Firdapse in North America. At present, BioMarin is conducting a Phase III clinical trial of Firdapse (the Phase III Trial), which trial will be transferred to and continued by the Company pursuant to the License Agreement. The Phase III Trial began in the second quarter of 2011 and is a double-blind, placebo-controlled randomized discontinuation study followed by an open-label extension period in approximately 30 patients across 10 sites in the U.S. and Europe. The primary objective of the trial is to evaluate the efficacy and safety, including the long-term safety, of Firdapse . The primary endpoint is a change from baseline in the Quantitative Myasthenia Gravis score at 14 days and the secondary endpoint is change from baseline in the timed 25-foot walk test at 14 days. At present, the Company expects to complete the double-blind treatment portion of the Phase III trial in the second half of 2014.

The U.S. Food and Drug Administration (FDA) has previously granted orphan drug designation to Firdapse for the treatment of LEMS, which means that if the Company is the first to obtain approval of the Product in the United States, it will be eligible to obtain seven year marketing exclusivity in the United States.

LEMS is a rare autoimmune disease with the primary symptoms of muscle weakness. The muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels leading to a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at approximately 3,000 patients in the United States and Canada. Approximately 50 percent of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. The weakness is generally more marked in the proximal muscles, particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with swallowing. Patients often report dry mouth, impotence, constipation and feelings of light headedness on standing. These problems can be life threatening when the weakness involves respiratory muscles. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyographic testing and the presence of autoantibodies against voltage gated calcium channels.

There are no approved drugs in the United States for the treatment of LEMS. Current options rely on intravenous immunoglobulin, plasmapheresis and/or immuno suppressant drugs. Firdapse is the only version of amifampridine phosphate (3,4-DAP) in Phase III trials for LEMS. However, the Company believes that another pharmaceutical company is conducting a Phase II clinical trial in the U.S. for its version of amifampridine (3,4-DAP) for the treatment of LEMS.

While the Company s initial efforts will be on seeking the approval of Firdapse for the treatment of LEMS in the United States, the Company also intends to explore other potential orphan central nervous system indications for Firdapse , such as Myasthenia Gravis and Congenital Myasthenic Syndrome.

License Agreement

On October 26, 2012, the Company and BioMarin entered into the License Agreement pursuant to which the Company licensed the North American rights to the Product. As part of the License Agreement, the Company will take over the Phase III Trial and will be obligated to use its diligent efforts to seek to obtain regulatory approval for and to commercialize the Product in the United States. The Company is obligated to use diligent efforts to complete the double-blind treatment phase of the Phase III trial within 24 months of entering into the License Agreement, and BioMarin has the right to terminate the License Agreement if such treatment phase has not been completed in such 24-month period (unless the Company is using diligent effort to pursue the completion of such treatment phase and has spent at least $5 million in connection with the conduct of the Phase III Trial during such 24 month period). The Company currently anticipates that the remaining development program costs required to file a New Drug Application (NDA) for the Product will be approximately $17 million.

Under the License Agreement, the Company has agreed to make: (i) certain royalty payments to BioMarin based on the Company s net sales in North America; (ii) certain royalty payments to a third-party licensor of the rights being sublicensed to the Company based on the Company s net sales in North America, and (iii) certain milestone payments to such third-party licensor and to the former stockholders of Huxley that BioMarin is obligated to make (which milestone payments are due, in part, upon acceptance by the FDA of a filing of an NDA for Firdapse for the treatment of LEMS, and, in part, on the unconditional approval by the FDA of an NDA for Firdapse for the treatment of LEMS). The Company has also agreed to share in the cost of certain post-marketing studies that are being conducted by BioMarin if such studies are required as a condition for approval of the Product by the FDA.

The Company is submitting, simultaneously with the filing of this Form 8-K a FOIA Confidential Treatment Request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the License Agreement. The omitted material will be included in the request for confidential treatment.

The foregoing description of the License Agreement is qualified in its entirety by reference to the License Agreement. A redacted copy of the License Agreement is attached as Exhibit 10.2 to this Current Report on Form 8-K.

Item 3.02 Unregistered Sales of Equity Securities

The information set forth in Item 1.01 of this Current Report on Form 8-K relating to the Agreement is incorporated by reference into this Item 3.02 in its entirety.

Item 8.01 Other Events

On October 31, 2012, the Company and BioMarin issued a press release announcing that they had entered into the License Agreement and the Investment Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1 Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012, between BioMarin Pharmaceutical, Inc. and Catalyst Pharmaceutical Partners, Inc.

10.2 License Agreement, dated as of October 26, 2012, between BioMarin Pharmaceutical, Inc. and Catalyst Pharmaceutical Partners, Inc.

99.1 Press release issued by the Company and BioMarin on October 31, 2012.

SIGNATURES

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

Catalyst Pharmaceutical Partners, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: October 31, 2012