Catalyst Pharmaceutical Partners, Inc.
Form 8-K
February 23, 2010

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

February 22, 2010

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED)

Commission File No. 001-33057

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**76-0837053**
(State Or Other Jurisdiction Of Incorporation Or Organization)	**(IRS Employer Identification No.)**

355 Alhambra Circle, Suite 1370

Coral Gables, Florida 33134

(Address Of Principal Executive Offices)

(305) 529-2522

(Registrant s Telephone Number, Including Area Code)

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 8.01 Other Events

Development Plans for CPP-115

On February 22, 2010, the Company issued a press release reporting its development plans for CPP-115, which is the Company s compound for the treatment of epilepsy and addiction being developed under an exclusive worldwide license between the Company and Northwestern University.

CPP-115 has been shown to be at least 200 times more potent than CPP-109, Catalyst s version of vigabatrin, in both *in-vitro* and animal model studies. The increased potency could enable the development of superior or alternative dosage forms and routes of administration compared with the marketed version of vigabatrin, Sabril® (which is marketed in the U.S. by Lundbeck Inc. for infantile spasms and refractory complex partial seizures). It may also have superior specificity to GABA aminotransferase and, possibly, a better side effects profile (e.g. less visual field defects) compared with Sabril®. The Company believes that CPP-115 and other compounds that may be developed under the Northwestern University license are, in addition to vigabatrin, the only drugs currently in development or on the market having GABA aminotransferase inhibition as their primary mode of action.

Over the next year, the Company plans to advance the development of CPP-115 by completing a series of non-clinical studies designed to demonstrate critical safety and efficacy characteristics of CPP-115, as follows:

CPP-115 will be evaluated through the Anti-convulsant Screening Program at the U.S. National Institutes of Health using a variety of recognized and widely accepted animal models for the evaluation of the effectiveness of potential anti-epileptic drugs.

The visual safety of CPP-115 will be evaluated and compared to the only FDA approved GABA aminotransferase inhibitor drug, vigabatrin. The Company hopes to demonstrate that CPP-115 s enhanced mechanism of enzyme inactivation results in reduced or eliminated visual field defects compared to vigabatrin.

The Company will complete other safety evaluations including genotoxicity and cardiac safety.

The Company, through its CPP-109 collaborator, Stephen Dewey, Ph.D., of The North Shore LIJ Hospital, will conduct studies to demonstrate CPP-115 s effectiveness in extinguishing the reinstatement of addictive behavior. Dr. Dewey will also conduct a PET imaging study to establish the minimum effective dose of CPP-115 required to modulate cocaine-induced dopamine surges. These studies, including an already completed conditioned place preference study, are considered the most predictive studies of a drug s potential utility as a treatment for stimulant addiction. Vigabatrin performed well when previously evaluated in these same studies. The results of the CPP-115 conditioned place preference study referred to above have already been submitted to a peer-reviewed journal for publication.

By the end of the third quarter of 2010, most of the safety studies described above, including results from assessments of the comparative retinotoxicity of CPP-115 versus vigabatrin, are expected to be completed. Furthermore, during that same period, the Company expects to complete the above-described animal model efficacy screening of CPP-115 as a potential treatment for both epilepsy and drug addiction. The Company further expects that all of the above-described non-clinical studies, including evaluations after 90 days of dosing of visual safety including retinal histopathology, clinical chemistry, hematology, urinalysis and any necessary organ histopathology, will be completed by the end of the first quarter of 2011. The Company expects to spend approximately $1.5 million to complete all the non-clinical studies described herein.

The Company issued a press release on February 22, 2010 reporting the Company s development plans for CPP-115. A copy of that press release is attached hereto as Exhibit 99.1.

Upcoming study of CPP-109 to treat cocaine addiction

On February 22, 2009, the Company executed a non-binding letter of intent with the National Institute on Drug Abuse (NIDA) to conduct a U.S. Phase II(b) clinical trial evaluating CPP-109, the Company s formulation of vigabatrin, for the treatment of cocaine addiction. It is anticipated that NIDA, under their agreement with the Veteran s Administration Cooperative Studies Program, will provide substantial resources for the trial and that the Company will contribute approximately $2.5 million in resources as part of the estimated $10 million trial cost (including study medication, patient recruitment costs and certain trial expenses). The Company expects to execute a binding clinical trial agreement with NIDA regarding this trial in the near future.

It is anticipated that this double-blind, placebo-controlled clinical trial will enroll approximately 200 patients and will be conducted at eight leading addiction facilities across the United States. The trial will seek to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and is scheduled to commence in the early summer of 2010. The study is being designed to deal with issues related to poor medication compliance that the Company observed in its recently completed Phase II cocaine trial.

The Company issued a press release on February 23, 2010 reporting that the Company has entered into a non-binding letter of intent with NIDA to conduct this clinical trial. A copy of that press release is attached hereto as Exhibit 99.2.

Update on the Company s Capital Resources

The Company believes that its existing cash resources will allow it: (i) to fund the pre-clinical studies of CPP-115, which are estimated to be approximately $1.5 million, (ii) to fund its share of the costs of the clinical trial of CPP-109 that the Company intends to conduct with NIDA, which are estimated to be approximately $2.5 million over a two-year period, and (iii) to meet general corporate requirements through at least the first quarter of 2011.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

99.1 Press release issued by the Company on February 22, 2010

99.2 Press release issued by the Company on February 23, 2010

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/ Jack Weinstein
Jack Weinstein
Vice President, Treasurer and CFO

Dated: February 23, 2010

Exhibit Index

Exhibit No.	Description
99.1	Press release issued by the Company on February 22, 2010
99.2	Press release issued by the Company on February 23, 2010