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

May 21, 2012

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

355 Alhambra Circle, Suite 1500 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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

Enrollment of Phase II(b) Clinical Trial for CPP-109

On May 21, 2012, the Company issued a press release announcing that patient enrollment in its Phase II(b) clinical trial evaluating its product candidate, CPP-109, for the treatment of cocaine addiction has been completed. A copy of the Company's press release is Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Results of Phase I(a) Clinical Trial for CPP-109

On May 22, 2012 the Company reported positive results from its Phase I(a) clinical trial evaluating the safety, tolerability and pharmacokinetics profile of CPP-115. The study demonstrated that CPP-115 was well tolerated at all six doses administered in the study.

The study was a double-blind, placebo-controlled, single ascending dose of CPP-115 solution administered orally to 55 healthy volunteers in seven cohorts of eight subjects each (one had seven subjects) with six subjects randomized to CPP-115 and two subjects randomized to placebo and with doses ranging from 5 mg to 500 mg (a dose greater than ten times the predicted effective dose based on animal models of 15-30 mg per day).

The key findings of the study included:

- there were no serious or adverse events, and no cardiovascular or respiratory events were reported in the study;
- CPP-115 was rapidly absorbed (time to peak blood concentration was about 30 minutes);
- an elimination half-life of four to six hours; and
- peak serum concentration increased in a dose proportional basis over the range of doses studied, while there was a greater than proportional increase in AUC, a method of measurement of the bioavailability of a drug based on a plot of blood concentrations sampled at frequent intervals, on the dose range.

On May 22, 2012, the Company issued a press release announcing the above-described results of the Company's Phase I(a) clinical trial for CPP-115. A copy of the Company's press release is Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

- (d) <u>Exhibits</u>
- 99.1 Press release issued by the Company on May 21, 2012
- 99.2 Press release issued by the Company on May 22, 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: May 22, 2012



For Further Information Contact: Patrick J. McEnany Catalyst Pharmaceutical Partners Chief Executive Officer (305) 529-2522 <u>pmcenany@catalystpharma.com</u>

FOR IMMEDIATE RELEASE

Melody Carey Rx Communications Group Co-President (917) 322-2571 <u>mcarey@rxir.com</u>

Catalyst Pharmaceutical Partners Announces Completion of Enrollment in CPP-109 Phase II(b) Clinical Trial for the Treatment of Cocaine Addiction

Top-Line Data Expected Early First Quarter 2013

CORAL GABLES, FL, May 21, 2012 — Catalyst Pharmaceutical Partners, Inc. (Nasdaq: CPRX) today announced that patient enrollment in its CPP-109 vigabatrin Phase II(b) clinical trial has reached its goal of 200 cocaine dependent subjects. The Company anticipates that screening of all remaining subjects will be completed this week and the total number enrolled will be approximately 210. Top-line results of the clinical trial are expected to be available early in the first quarter of 2013.

"We are pleased to have accomplished this important milestone in the development of CPP-109 by completing enrollment in the CPP-109 Phase II(b) clinical trial within the expected timeframe," said Patrick J. McEnany, Chief Executive Officer of Catalyst. "There is a major need for effective and well-tolerated treatments for patients with cocaine addiction, and CPP-109 potentially represents a breakthrough product for them. I would like to thank our partners at the National Institute on Drug Abuse and the Veterans Administration, the clinical investigators and study site personnel for their dedication, as well as the subjects and their families who are participating in the trial."

About the CPP-109 Phase II(b) Clinical Trial

The 24-week CPP-109 Phase II(b) clinical trial is randomized, double-blind and placebo-controlled. It is designed to demonstrate that the rate of cocaine dependent subjects treated with CPP-109, who abstain from cocaine use in the last two weeks of the trial's treatment phase (weeks 8 and 9), will be higher than patients treated with placebo. Other outcomes include: i) reduction in cocaine use days; ii) increase in clean urines collected; and iii) durability of abstinence among those subjects who were abstinent during weeks 8 and 9.

About CPP-109 and Fast Track Status

CPP-109 is a GABA analog that is Catalyst's designation for vigabatrin. Catalyst licensed CPP-109 from Brookhaven National Laboratory for the treatment of cocaine and other addictions, and has been granted "Fast Track" status by the U.S. Food and Drug Administration (FDA) for cocaine addiction. Under the Federal Food, Drug, and Cosmetic Act, the FDA is directed to facilitate the development and expedite review of drugs and biologics intended to treat serious or life-threatening conditions, and that demonstrate the potential to address unmet medical needs. Fast Track designation emphasizes communication between Catalyst and the FDA, and provides Catalyst benefits that may help to expedite the approval process. For example, Fast Track designation affords Catalyst the potential to submit an NDA for CPP-109 on a rolling or modular basis, allowing the FDA to review sections of the NDA in advance of receiving a full submission. The designation also means that Catalyst may have increased communications with the FDA regarding the design of its clinical studies, which may expedite the development and review of Catalyst's application for the approval of CPP-109 for cocaine addiction and may provide greater certainty overall in the regulatory pathway.

About Cocaine Addiction

Cocaine binds to the dopamine reuptake transporter protein of the pre-synaptic neurons, preventing the reuptake and eventual breakdown of dopamine, resulting in enhanced and prolonged stimulation of dopamine on post-synaptic receptors, and causing a feeling of prolonged euphoria for the user. Cocaine addiction is caused by a neurological process called desensitization. Because the brain senses an unnaturally high level of dopamine, it responds by reducing the amount of dopamine released and the number of dopamine receptors created. Consequently, when the cocaine wears off, the user has a lower amount of dopamine and fewer functioning dopamine receptors, which results in a depressed mood. This desensitization process creates a lowering of mood each time the user takes more of the drug, causing them to seek additional cocaine to restore normal feelings, and requiring them to take an increasing amount of cocaine to achieve the same feeling of euphoria as before. According to the National Institute on Drug Abuse (NIDA), there are no pharmacologic treatments for cocaine addiction currently approved for marketing by the FDA.

According to the most recent Substance Abuse and Mental Health Services Administration (SAMHSA) survey, an estimated 1.5 million people, or 0.6% of the population aged 12 or over, had used cocaine in the month preceding the survey. Additionally, in 2010, approximately 637,000 people aged 12 or over had used cocaine for the first time within the preceding 12 months, an average of approximately 1,700 new users per day. In addition, approximately 699,000 patients received treatment for cocaine abuse in 2010.

Cocaine addiction is not only a U.S. health problem. In 2009, according to the United Nations Office on Drugs and Crime, there were 4.3 million - 4.7 million users of cocaine between the ages of 15 and 64 across Europe who had used it within the past year. Catalyst believes that the direct and indirect costs of cocaine use are indicative of a global public health problem, representing a significant unmet medical need for which no adequate pharmaceutical therapies exist.

About Catalyst Pharmaceutical Partners

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting

diseases and disorders of the central nervous system, including addiction and epilepsy. Catalyst has two products in development, CPP-109 and CPP-115. It is currently evaluating its lead product and first-in-class GABA aminotransferase inhibitor candidate, CPP-109, for the treatment of cocaine addiction. Both CPP-109 and CPP-115 have been granted "Fast Track" status by the FDA for the treatment of cocaine addiction. Catalyst is also planning to evaluate CPP-109 for the treatment of other addictions. Catalyst believes that it controls all current intellectual property for drugs that have a mechanism of action related to the inhibition of GABA aminotransferase. For more information about Catalyst, go to www.catalystpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause the Company's actual results in future periods to differ materially from forecasted results. A number of factors, including whether CPP-109 will be safe and effective for the treatment of addiction, whether the CPP-109 Phase II(b) clinical trial will be successful, whether CPP-109 will ever be approved for commercialization, and those other factors described in the Company's filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect the Company. Copies of the Company's filings with the SEC are available from the SEC, may be found on the Company's website or may be obtained upon request from the Company. The Company does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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For Further Information Contact: Patrick J. McEnany Catalyst Pharmaceutical Partners Chief Executive Officer (305) 529-2522 <u>pmcenany@catalystpharma.com</u>

FOR IMMEDIATE RELEASE

Melody Carey Rx Communications Group Co-President (917) 322-2571 <u>mcarey@rxir.com</u>

Catalyst Pharmaceutical Partners Reports Positive Results from Phase I(a) Clinical Study of CPP-115 CPP-115 Safe and Well Tolerated Across All Dose Levels

CORAL GABLES, FL, May 22, 2012 — Catalyst Pharmaceutical Partners, Inc. (Nasdaq: CPRX) today announced positive results from a Phase I(a) study to evaluate the safety, tolerability and pharmacokinetic (PK) profile of CPP-115, a novel small molecule drug candidate for the potential treatment of epilepsy (initially infantile spasms), cocaine addiction and other select CNS indications. The study results demonstrated that CPP-115 was well tolerated at all six doses administered. This Phase I(a) study is also the first step of an infantile spasms clinical development plan that was discussed with the U.S. Food and Drug Administration's (FDA) Division of Neurology Products during a pre-IND meeting in October 2011.

"The positive results of our CPP-115 first-in-man study mark an important initial milestone toward our goal of becoming a leading CNS specialty pharmaceutical company," said Patrick J. McEnany, Chief Executive Officer of Catalyst. "The results of the study are promising and are consistent with our preclinical findings. We believe that CPP-115 has the potential to address important unmet needs in both epilepsy and addiction, highlighted by its orphan designations in the United States (infantile spasms) and European Union (West Syndrome), as well as its Fast Track status for cocaine addiction in the United States."

Highlights from the CPP-115 Phase I(a) study include:

- Study Design
 - o Double-blind, placebo-controlled, single ascending dose of CPP-115 solution administered orally to healthy volunteers
 - o 55 subjects in 7 cohorts of 8 each (1 had 7); 6 subjects randomized to CPP-115 and 2 subjects randomized to placebo
 - o Dosing ranged from 5 mg to 500 mg

- Primary Outcome Measure
 - Safety of single oral doses, defined as number of subjects with clinically significant changes in vital signs, electrocardiogram abnormalities based on changes in cardiac rhythm, serious or severe adverse events, and/or clinically significant changes in clinical laboratory evaluations
- · Secondary Outcome Measures
 - Comparative PK profiles of single ascending oral doses, with profile comparisons based on plasma concentrations, including: i) C_{max} maximum observed plasma concentration; ii) T_{max} time to maximum observed plasma concentration; iii) AUC (0 ¥) area under the concentration-time curve from time zero extrapolated to infinite time; and iv) AUC (0 last) area under the concentration-time curve from time zero to the last measurable concentration
- Key Findings
 - o No serious or severe adverse events
 - o No cardiovascular or respiratory events
 - o Rapidly absorbed (time to peak blood concentration about 30 minutes)
 - o Elimination half-life of 4-6 hours
 - o C_{max} increases in a dose proportional manner over the range of doses studied, 5-500 mg; whereas there is a greater than proportional increase in AUCs in the dose range
 - o Top dose studied of 500 mg is greater than 10 times the predicted effective doses from animal models of 15-30 mg/day
- Future Development Plans (subject to funding)
 - o Preclinical studies in juvenile animals of sufficient duration to span Phase II study designs
 - o Double-blind, placebo-controlled multiple ascending dose Phase I(b) study to evaluate safety and PK, and to determine the effective dose using GABA magnetic resonance spectroscopy
 - o Phase II studies to evaluate the use of CPP-115 in the treatment of infantile spasms (West Syndrome) and cocaine addiction
- Advisors for CPP-115 Development to Treat Infantile Spasms
 - Dr. Jack Pellock and Dr. Donald Shields, who are world-renowned experts in the clinical development and treatment of infantile spasms; both of them attended Catalyst's pre-IND meeting and are medical consultants to Catalyst on the development of CPP-115 for the treatment of infantile spasms

"I am pleased that Catalyst has successfully completed the first study necessary to move CPP-115 forward into a pilot trial in babies diagnosed with infantile spasms, a serious disease that is in need of safer, more efficacious treatments," stated Dr. Jack Pellock, Professor and Chairman, Division of Child Neurology, Virginia Commonwealth University. "I look forward to working with Catalyst to advance CPP-115 expeditiously into a Phase II trial to determine its safety and efficacy in such patients."

About CPP-115

CPP-115 is a novel GABA aminotransferase inhibitor and vigabatrin analogue that, based on preclinical studies to-date, is greater than 100 times more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs and sedation) from those associated with vigabatrin. Catalyst licensed CPP-115 from Northwestern University where it was invented by Dr. Richard B. Silverman, the John Evans Professor of Chemistry, and a team of scientists. Dr. Silverman holds more than 40 patents and is the inventor of Pfizer's drug, pregabalin (Lyrica[®]). CPP-115's development progress was recently presented at the 2012 Epilepsy Pipeline Update Conference in San Francisco, CA. CPP-115 has been granted Orphan Drug Designation for the treatment of infantile spasms by the FDA, and has been granted Orphan Medicinal Product Designation for the treatment of West Syndrome by the European Commission. It has also been granted Fast Track status by the FDA for the treatment of cocaine addiction.

About West Syndrome / Infantile Spasms

An infantile spasm is a type of seizure seen in an epilepsy syndrome of infancy and childhood known as West Syndrome. The onset of infantile spasms is usually in the first year of life, typically between 4-8 months. Spasms often occur in clusters of up to 100 at a time, and infants may have dozens of clusters and several hundred spasms per day. Infantile spasms usually stop by age five, but may be replaced by other seizure types. Many underlying disorders, such as birth injury, metabolic disorders and genetic disorders can give rise to spasms, making it important to identify them (symptomatic IS). In some children, no cause can be found (cryptogenic IS). Mental retardation occurs in 70–90% of persons with infantile spasms, usually involving severe to profound retardation. Early control of seizures is critical for reducing developmental delays and levels of mental retardation, but ~5% of infants with this condition eventually die from complications caused by the seizures.

About Catalyst Pharmaceutical Partners

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system, including addiction and epilepsy. Catalyst has two products in development, CPP-109 and CPP-115, and is currently evaluating its lead product and first-in-class GABA aminotransferase inhibitor candidate, CPP-109, for the treatment of cocaine addiction. CPP-109 has been granted "Fast Track" status by the FDA for the treatment of cocaine addiction. Catalyst also plans to evaluate CPP-109 for the treatment of other addictions. Catalyst believes that it controls all current intellectual property for drugs that have a mechanism of action related to the inhibition of GABA aminotransferase. For more information about Catalyst, go to www.catalystpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause the Company's actual results in future periods to differ materially from forecasted results. A number of factors, including whether CPP-115 will be determined to be effective for the treatment of addiction, infantile spasms or other CNS indications, whether CPP-115 will have reduced side effects compared to CPP-109, whether the funding required for future studies of CPP-115 will be obtained, whether CPP-115 will ever be approved for commercialization, and those other factors described in the Company's filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect the Company. Copies of the Company's filings with the SEC are available from the SEC, may be found on the Company's website or may be obtained upon request from the Company. The Company does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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