
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

**Pre-Effective
Amendment No. 1
to
FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

CATALYST PHARMACEUTICAL PARTNERS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

76-0837053
(I.R.S. Employer
Identification Number)

**355 Alhambra Circle
Suite 1370
Coral Gables, Florida 33134
(305) 529-2522**
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

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(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

Copy to:

**Philip B. Schwartz, Esq.
Akerman Senterfitt
One Southeast Third Avenue
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Miami, Florida 33131
(305) 982-5604**

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that the registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a) may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the Registration Statement containing this prospectus, which was filed with the Securities and Exchange Commission, is effective. The prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED DECEMBER 15, 2010

PROSPECTUS

\$ 30,000,000



Common Stock

We may, from time to time, sell shares of our common stock and warrants to purchase shares of our common stock, or a security consisting of a combination of these securities, in one or more offerings in amounts, at prices and on terms that we determine at the time of the offering, with an aggregate initial offering price not to exceed \$30,000,000. We will provide you of the specific terms of such securities to be sold in supplements to this prospectus. However, in no event will we sell more than $\frac{1}{3}$ of our public float in any 12-month period. You should read this prospectus and any prospectus supplement carefully before you invest.

INVESTING IN OUR SECURITIES INVOLVES RISKS. THE RISKS ASSOCIATED WITH AN INVESTMENT IN OUR SECURITIES WILL BE DESCRIBED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND IN OUR FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION THAT ARE INCORPORATED BY REFERENCE HEREIN, ALL AS MORE PARTICULARLY DESCRIBED UNDER THE CAPTION “[RISK FACTORS](#)” ON PAGE 6 OF THIS PROSPECTUS.

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol “CPRX”. On December 14, 2010, the last reported sale price for our common stock on the Nasdaq Capital Market was \$0.97 per share.

Shares of common stock or warrants to purchase shares of common stock, or securities consisting of a combination of these securities, may be sold by us to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled “Plan of Distribution” in this prospectus. If any underwriters are involved in the sale of any common stock or common stock purchase warrants or securities consisting of a combination of these securities, with respect to which this prospectus is delivered, the names of such underwriters and any applicable discounts or commissions, and any over-allotment options will be set forth in a prospectus supplement. The price to the public and the net proceeds we expect to receive from such sale will also be set forth in the prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the common stock or warrants to purchase common stock or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is December __, 2010

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the “SEC”), utilizing a “shelf” registration process. Under this shelf registration process, we may sell shares of our common stock, warrants to purchase shares of our common stock and securities consisting of a combination of these securities in one or more offerings. All such offerings will not exceed a total dollar amount of \$30,000,000. However, in no event will we sell more than 1/3 of our “public float” (the market value of our common stock held by non-affiliates) in any 12 month period. This prospectus provides you with a general description of our common stock. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of the applicable offering. The prospectus supplement may also add, change, or update information contained in this prospectus. You should read both this prospectus and any prospectus supplement, together with any additional information described under the heading “Incorporation by Reference.”

We have not authorized any dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

Reference in this prospectus to “we”, “our”, “us”, the “Company”, or “Catalyst” refer to Catalyst Pharmaceutical Partners, Inc., a Delaware corporation.

ABOUT THE COMPANY

We are a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting addiction and diseases of the central nervous system such as epilepsy. We have two products in development. We are currently evaluating our lead product candidate, CPP-109 (our version of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted “Fast Track” status by the U.S. Food & Drug Administration (“FDA”) for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective pharmacological treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and obsessive-compulsive disorders. Further, we are in the early stages of developing CPP-115, which is another GABA aminotransferase inhibitor that, based on non-clinical studies, we believe is more potent than vigabatrin but has reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including epilepsy, drug addiction and pain management. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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The successful development of CPP-109, CPP-115 or any other product we may acquire, develop or license is highly uncertain. We cannot reasonably estimate or know the nature, timing, or estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence due to the numerous risks and uncertainties associated with developing such products, including the uncertainty of:

- the scope, rate of progress and expense of our non-clinical and clinical trials, proof-of-concept studies, and other product development activities;
- the results of our non-clinical and clinical trials, and the number of clinical trials (and the scope of such trials) that will be required for us to seek and obtain approval of New Drug Applications (“NDAs”) for CPP-109 and CPP-115; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Recent Developments

CPP-109

On April 13, 2010, we signed a definitive Clinical Trial Agreement (“CTA”) with the National Institute on Drug Abuse (“NIDA”) to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the “Trial”). As part of the CTA, NIDA, under their agreement with the Veteran’s Administration Cooperative Studies Program, has agreed to provide substantial resources towards the completion of the Trial. It is anticipated that this double-blind, placebo-controlled trial, which will be conducted at twelve leading addiction research facilities across the United States, will recruit approximately 200 patients. The Trial, which will be overseen by the Veterans Administration (“V.A.”), was initiated in November 2010 and we expect to have top line data in the second quarter of 2012. The Trial is designed to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and if successful, we believe it will qualify to be one of the adequate and well controlled trials required to support approval of an NDA for CPP-109.

Pursuant to the CTA, we will provide the study drug (and matching placebo) for the Trial and materials required to package them suitably for use in the Trial. In conjunction with NIDA, we have developed the Trial protocol and informed consent and have submitted such documents to the FDA for approval. We will also be responsible for, among other duties, funding patient recruitment activities and advertising for the Trial, establishing and funding a contract with a vendor capable of decrypting and converting the visual field data obtained from study subjects into a format analyzable by the V.A. statisticians who will interpret the study data, and, if requested, funding the treatment costs of up to 25 of the study subjects. Further, pursuant to the CTA, NIDA has provided input on the protocol and informed consent and will, under their agreement with the Veteran’s Administration Cooperative Studies Program, solicit, recruit and fund qualified study sites and investigators and recruit and treat at least 175 of the study subjects. NIDA will also provide clinical monitoring for all sites.

The CTA terminates on April 13, 2015 or upon the completion of the Trial, whichever comes first, except that the CTA may be extended for two further periods of two years each by agreement of the parties if it is necessary to complete the Trial. Either party may terminate the CTA upon 60 days’ notice without cause, or upon 30 days’ written notice for cause. Both NIDA and us have continuing rights under the CTA if the CTA is terminated. Among other obligations, this includes an obligation of each party to continue their respective obligations under the CTA until all study subjects enrolled in the trial at the time of such termination have completed the study and continuing duties of confidentiality.

During July 2010, we announced that the European Patent Office granted to Brookhaven National Laboratory (“Brookhaven”) a European patent for the use of vigabatrin for the prevention of addiction to opioids (e.g. oxycodone, hydrocodone) used in pain management. By dampening dopamine release and thus, the euphoria associated with opioids, the opioid/vigabatrin combination may lower or prevent addictive liability without adversely affecting pain relief. We license this patent from Brookhaven.

We also announced on December 9, 2010 that the Canadian Intellectual Property Office has granted to Brookhaven a patent for the use of vigabatrin for the prevention of addiction in pain management. The patent is broad and includes the use of vigabatrin/ CPP-109 in combination with opioids (e.g., oxycodone, hydrocodone) for pain management. We license this patent from Brookhaven.

CPP-115

On November 1, 2010 we announced key results for an initial series of safety and efficacy evaluations in a number of animal and in-vitro laboratory tests:

- In visual safety testing of treated rats exposed for 90 days to CPP-115, vigabatrin, and placebo, CPP-115 caused substantially less retinal damage than vigabatrin at well above the expected therapeutic doses.
- The oral pharmacokinetic behavior of CPP-115 in rats supports further development as an orally delivered pharmacotherapy.
- CPP-115 was found to not inhibit or induce metabolic enzymes and is not itself metabolized. As a result, drug-drug interactions or other metabolism-related side effects are unlikely. Additionally, non-metabolized drugs are advantageous for treating drug addicts; a population that often has impaired liver function.
- With the exception of its biochemical target, GABA-aminotransferase, CPP-115 did not show any clinically significant binding to 111 of the most prevalent receptors, proteins and transporters. Additionally, CPP-115 showed no binding to other GABA-related targets (GABA receptors and transporters). Therefore, CPP-115 is very specific and is not likely to induce drug-drug interactions or unintended side effects.
- CPP-115 did not show any interference with the hERG channel and is therefore not likely to induce heart arrhythmias.
- CPP-115 did not show any abnormalities in an in-vitro battery of genotoxicity tests and thus is not likely to be carcinogenic.
- CPP-115 did not show any inhibition of AST and ALT at doses far above the expected therapeutic dosage. This is in contrast to vigabatrin's known inhibition at therapeutic doses of these key liver transaminase enzymes.
- CPP-115, like vigabatrin, was found to significantly reduce seizures in accepted animal models of epilepsy, as evaluated by the National Institutes of Health's Anticonvulsant Screening Program, at lower doses than vigabatrin.
- CPP-115 was found to eliminate cocaine-related conditioned place preference and significantly reduced cocaine-induced dopamine surge, key tests needed to demonstrate a drug's effectiveness as a potential treatment for stimulant addiction. These effects were observed at doses more than 100 times lower than that needed by vigabatrin to achieve the same effect.

We are currently advancing the development of CPP-115 by undertaking the remainder of the non-clinical studies necessary to file an Investigational New Drug Application ("IND") with the FDA.

Additionally, on September 1, 2010, CPP-115 was granted orphan drug designation by the FDA for the treatment of infantile spasms.

There can be no assurance that CPP-115 will ultimately be proven to be safe and effective to treat epilepsy, drug addiction or for use in pain management, or that CPP-115 will be determined not to have a similar visual field defect profile to vigabatrin.

Update on non-clinical and clinical studies that we support

We have been advised that one of our clinical collaborators received a \$1.2 million grant from the U.S. Department of Defense to conduct an animal study of the use of vigabatrin in combination with opiates to effectively manage pain while reducing the potential for opiate addiction. This research is being conducted by a research team led by Wynne K. Schiffer, Ph.D. and Stephen L. Dewey, Ph.D. of The Feinstein Institute for Medical Research at the North Shore LIJ Hospital and by Jonathan D. Brodie, M.D., Ph.D. from the Department of Psychiatry at New York University's School of Medicine. Drs. Dewey and Brodie are the co-inventors on the vigabatrin-related patents that we have licensed from Brookhaven and are members of our Scientific Advisory Board.

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The study is being conducted at the Feinstein Institute. Opioid abuse is one of the many substance addiction indications covered under our exclusive license of Brookhaven's vigabatrin use patent portfolio. We have supplied CPP-109 (our version of vigabatrin) to facilitate this study.

We have been advised that a clinical researcher at the University of Pennsylvania expects to commence an investigator-sponsored proof-of-concept study of CPP-109 in patients dependent on both cocaine and alcohol by early 2011. We expect to supply CPP-109 (our version of vigabatrin), placebo and approximately \$50,000 in funding to facilitate the conduct of this study.

We are also collaborating with other investigators by providing CPP-109 and access to our CPP-109 IND for studies that we believe will add value to our own research and development. Future potential studies include studies evaluating CPP-109 for the treatment of alcohol, nicotine, cocaine and methamphetamine addiction.

Discussions with potential strategic partners

We periodically have discussions with potential strategic partners interested in working with us on the development of CPP-109 and/or CPP-115. Such discussions may not result in relationships that we determine to pursue, and no agreements have been entered into to date.

NASDAQ Listing

Our common stock currently trades on the Nasdaq Capital Market. On November 13, 2009, we were informed by the Nasdaq Stock Market ("Nasdaq") that, as a result of our common stock no longer meeting the requirement that it trade at a bid price of at least \$1.00 per share, our common stock would be delisted from the Nasdaq Capital Market if, by May 12, 2010, we did not regain compliance with the requirement by our common stock trading at a bid price of at least \$1.00 per share for a period of at least ten consecutive trading days. On April 26, 2010, we received notice from Nasdaq confirming that we had regained compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as a result of our common stock closing with a bid price of at least \$1.00 for at least ten consecutive trading days.

Addition to Scientific Advisory Board

On November 15, 2010, we announced that Dr. Richard B. Silverman has joined our Scientific Advisory Board. Dr. Silverman is the inventor of CPP-115.

INFORMATION REGARDING FORWARD LOOKING STATEMENTS

Some of the statements provided in or incorporated by reference by this prospectus contain “forward-looking statements,” including statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words, “believes,” “anticipates,” “proposes,” “plans,” “expects,” “intends,” “may” and similar expressions are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements made in this prospectus are based on current expectations that involve numerous risks and uncertainties.

The successful development of CPP-109, CPP-115 or any other product we may acquire, develop or license is highly uncertain. We cannot reasonably estimate or know the nature, timing, or estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence due to the numerous risks and uncertainties associated with developing such products, including the uncertainty of:

- the scope, rate of progress and expense of our non-clinical and clinical trials, proof-of-concept studies, and other product development activities;
- our ability to complete our trials and studies on a timely basis and within the budgets we establish for such trials;
- whether our trials and studies will be successful;
- the results of our non-clinical and clinical trials, and the number and scope of such trials that will be required for us to seek and obtain approval of NDA's for CPP-109 and CPP-115;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- whether others develop and commercialize products competitive to our products;
- changes in the laws and regulations affecting our business including changes that may result from any future healthcare reform legislation that may become law;
- our ability to attract and retain skilled employees; and
- changes in general economic conditions and interest rates.

Our current plans and objectives are based on assumptions relating to the development of our current product candidates. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements made herein, which reflect our views only as of the date of this prospectus, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

RISK FACTORS

Before making an investment decision, you should carefully consider the risks described under “Risk Factors” in the applicable prospectus supplement and in our most recent Annual Report on Form 10-K, or any updates in subsequent Quarterly Reports on Form 10-Q, together with all of the other information appearing in this prospectus or incorporated in this prospectus by reference and any applicable prospectus supplement, in light of your particular investment objectives.

USE OF PROCEEDS

Except as may otherwise be provided in a prospectus supplement, we will use the net proceeds from sales of the securities to fund non-clinical and clinical studies with respect to our two product candidates, CPP-109 and CPP-115, and for general working capital purposes. When particular securities are offered, the prospectus supplement relating to that offering will set forth our intended use of the net proceeds received from the sale of these securities. Pending the application of the net proceeds for these purposes, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock trades on the Nasdaq Capital Market under the symbol CPRX. Previously, from November 8, 2006 to September 2, 2009, our common stock traded on the Nasdaq Global Market under the same symbol. There was no public market for our common stock before November 8, 2006. The following table sets forth the high and low closing sales prices per share of our common stock as reported on the Nasdaq Global Market or the Nasdaq Capital Market for the period indicated.

	<u>High</u>	<u>Low</u>
Year Ending December 31, 2010		
Fourth Quarter (through December 14, 2010)	\$1.19	\$0.97
Third Quarter	\$1.32	\$0.90
Second Quarter	\$2.00	\$0.71
First Quarter	\$0.87	\$0.56
Year Ended December 31, 2009		
Fourth Quarter	\$1.17	\$0.60
Third Quarter	\$1.39	\$0.41
Second Quarter	\$2.25	\$0.61
First Quarter	\$2.75	\$1.25

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

GENERAL DESCRIPTION OF OUR COMMON STOCK AND WARRANTS

The following summary of the material features of our common stock and our warrants to purchase shares of common stock does not purport to be complete and is subject to, and qualified in its entirety by the provisions of our Certificate of Incorporation, our Bylaws and other applicable law. See “Where You Can Find Additional Information”.

Our authorized capital currently consists of 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. As of the date of this prospectus, we had 19,394,737 shares of our common stock outstanding. There are no shares of preferred stock outstanding.

We are a Delaware corporation, and were incorporated on July 24, 2006. We are the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation, which was incorporated in January 2002.

Common Stock

Each holder of common stock is entitled to one vote for each share held of record on all matters presented to our stockholders, including the election of directors. In the event of our liquidation, dissolution, or winding-up, the holders of common stock are entitled to share ratably and equally in our assets, if any, that remain after paying all debts and liabilities and the liquidation preferences of any outstanding preferred stock. The common stock has no preemptive or cumulative rights and no redemption or conversion provisions.

Holders of our common stock are entitled to receive dividends if, as, and when declared by our board of directors out of funds legally available therefor, subject to the dividend and liquidation rights of any preferred stock that may be issued and outstanding, all subject to any dividend restrictions in our credit facilities. No dividend or other distribution (including redemptions and repurchases of shares of capital stock) may be made, if after giving effect to such distribution, we would not be able to pay our debts as they come due in the usual course of business, or if our total assets would be less than the sum of our total liabilities plus the amount that would be needed at the time of a liquidation to satisfy the preferential rights of any holders of preferred stock.

Common Stock Purchase Warrants

We may issue warrants to purchase shares of our common stock. We may issue the warrants independently or together with the underlying common stock, and the warrants may be attached to or separate from the underlying common stock. We may also issue warrants under separate warrant agreements to be entered into between us and each of the initial holders of such warrants.

The following description is a summary of selected provisions relating to the warrants that we may issue. The summary is not complete. When warrants are offered in the future, a prospectus supplement will explain the particular terms of those securities and the extent to which these general provisions may apply. The specific terms of the warrants as described in a prospectus supplement will supplement and, if applicable, may modify or replace the general terms described in this section.

This summary and any description of warrants in the applicable prospectus supplement is subject to and is qualified in its entirety by reference to all of the provisions of any specific warrant document or agreement which we will file with the SEC for incorporation by reference into any prospectus supplement we may file. See “Where You Can Find Additional Information” and “Incorporation by Reference” for information on how to obtain a warrant document when it is filed.

Terms

The applicable prospectus supplement may describe the terms of any warrants that we may offer, including, but not limited to:

- the title of the warrants;
- the total number of warrants;
- the price or prices at which the warrants will be issued;
- the date on which the right to exercise the warrants will commence and the date on which the right will expire;
- if applicable, the minimum or maximum number of warrants that may issued at any one time;
- if applicable, the date on and after which the warrants and the related underlying common stock will be separately transferable;
- if applicable, a discussion of material United States income tax considerations;
- if applicable, the terms of redemption of the warrants;
- the procedures and conditions relating to the exercises of the warrants; and
- any other terms of the warrants, including terms, procedures, and limitations relating to the exchange and exercise of the warrants.

We may issue warrants under one or more Warrant Agreements, each to be entered into between us and each initial holder of such warrants.

We may issue warrants in non-global form, i.e. bearer form. If any warrants are issued in non-global form, warrant certificates may be exchanged for new warrant certificates of different denominations, and holders may exchange, transfer or exercise their warrants subject to the terms indicated in the applicable prospectus supplement or other offering material.

Prior to the exercise of their warrants, holders of warrants will not have any rights of holders of common stock purchasable upon their exercise and will not be entitled to dividend payments, if any, or voting rights of the common stock purchasable upon their exercise.

A warrant will generally entitle the holder thereof to purchase for cash an amount of common stock at an exercise price that will be stated in, or that will be determinable as described in, the applicable prospectus supplement or other offering material. After the close of business on the expiration date, unexercised warrants will become void. Warrants may be redeemed as set forth in the applicable prospectus supplement or other offering material.

Warrants may be exercised as set forth in the applicable prospectus supplement or other offering material. Upon receipt of payment and the warrant certificate properly completed and duly executed as indicated in the prospectus supplement or other offering material, we will forward, as soon as practicable, the common stock purchasable upon such exercise. If less than all of the warrants represented by such warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

Provisions of the Certificate and Bylaws

A number of provisions of our certificate of incorporation and bylaws concern matters of corporate governance and the rights of stockholders. Certain of these provisions, as well as the ability of our board of directors to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof, may be deemed to have an anti-takeover effect and may discourage takeover attempts not first approved by the board of directors (including takeovers which certain stockholders may deem to be in their best interests). To the extent takeover attempts are discouraged, temporary fluctuations in the market price of the common stock, which may result from actual or rumored takeover attempts, may be inhibited. These provisions, together with the ability of the board to issue preferred stock without further stockholder action, also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders, even if such removal or assumption would be beneficial to our stockholders. These provisions also could discourage or make more difficult a merger, tender offer or proxy contests, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of the common stock. The board of directors believes that these provisions are appropriate to protect our interest and the interests of our stockholders.

Issuance of Rights. The certificate authorizes the board of directors to create and issue rights (the “rights”) entitling the holders thereof to purchase from us shares of capital stock or other securities. The times at which, and the terms upon which, the rights are to be issued may be determined by the board of directors and set forth in the contracts or instruments that evidence the rights. The authority of the board of directors with respect to the rights includes, but is not limited to, the determination of (1) the initial purchase price per share of the capital stock or other securities of Catalyst Pharmaceutical Partners, Inc. to be purchased upon exercise of the rights, (2) provisions relating to the times at which and the circumstances under which the rights may be exercised or sold or otherwise transferred, either together with or separately from, any other securities of Catalyst Pharmaceutical Partners, Inc., (3) antidilutive provisions which adjust the number or exercise price of the rights or amount or nature of the securities or other property receivable upon exercise of the rights, (4) provisions which deny the holder of a specified percentage of the outstanding securities of Catalyst Pharmaceutical Partners, Inc. the right to exercise the rights and/or cause the rights held by such holder to become void, (5) provisions which permit Catalyst Pharmaceutical Partners, Inc. to redeem the rights, and (6) the appointment of a rights agent with respect to the rights.

Meetings of Stockholders. The bylaws provide that a special meeting of stockholders may be called only by the board of directors unless otherwise required by law. The bylaws provide that only those matters set forth in the notice of the special meeting may be considered or acted upon at that special meeting, unless otherwise provided by law. In addition, the bylaws set forth certain advance notice and informational requirements and time limitations on any director nomination or any new business which a stockholder wishes to propose for consideration at an annual meeting of stockholders.

No Stockholder Action by Written Consent. The certificate provides that any action required or permitted to be taken by our stockholders at an annual or special meeting of stockholders must be effected at a duly called meeting and may not be taken or effected by a written consent of stockholders in lieu thereof.

Amendment of the Certificate. The certificate provides that an amendment thereof must first be approved by a majority of the board of directors and (with certain exceptions) thereafter approved by the holders of a majority of the total votes eligible to be cast by holders of voting stock with respect to such amendment or repeal; provided, however, that the affirmative vote of 80% of the total votes eligible to be cast by holders of voting stock, voting together as a single class, is required to amend provisions relating to the establishment of the board of directors and amendments to the certificate.

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Amendments of Bylaws. The certificate provides that the board of directors or the stockholders may amend or repeal the bylaws. Such action by the board of directors requires the affirmative vote of a majority of the directors then in office. Such action by the stockholders requires the affirmative vote of the holders of at least two-thirds of the total votes eligible to be cast by holders of voting stock with respect to such amendment or repeal at an annual meeting of stockholders or a special meeting called for such purposes, unless the board of directors recommends that the stockholders approve such amendment or repeal at such meeting, in which case such amendment or repeal shall only require the affirmative vote of a majority of the total votes eligible to be cast by holders of voting stock with respect to such amendment or repeal.

Certain Anti-Takeover Matters

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Delaware law, regulating corporate takeovers. In general, these provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholders for a period of three years following the date that the stockholder became an interested stockholder, unless:

- either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder is approved by our board of directors before the date the interested stockholder attained that status;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after that date, the business combination is approved by our board of directors and authorized at a meeting of stockholders, and not by written consent, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines “business combination” to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

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- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any of these entities or persons.

A Delaware corporation may opt out of this provision either with an express provision in its original certificate of incorporation or in an amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. The statute could prohibit or delay mergers or other takeover or change in control attempts and, accordingly, may discourage attempts to acquire us.

Limitation of Liability and Indemnification Matters

Our certificate of incorporation limits the liability for monetary damages for breach of fiduciary duty by members of our board of directors, except for liability that cannot be eliminated under Delaware law. Under Delaware law, our directors have a fiduciary duty to us which is not eliminated by this provision in our certificate of incorporation. In addition, each of our directors is subject to liability under Delaware law for breach of their duty of loyalty for acts or omissions which are found by a court of competent jurisdiction to be not in good faith or which involve intentional misconduct or knowing violations of law for actions leading to improper personal benefit to the director and for payments of dividends or approval of stock repurchases or redemptions that are prohibited by Delaware law. This provision does not affect our directors' responsibilities under any other laws, such as federal securities laws.

Delaware law provides that the directors of a company will not be personally liable for monetary damages for breach of their fiduciary duty as directors, except for liability for any of the following:

- any breach of a director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Delaware law provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which our directors and officers may be entitled to under our bylaws, any agreement, a vote of stockholders or otherwise. Our certificate of incorporation and bylaws eliminate the personal liability of directors to the maximum extent permitted by Delaware law. In addition, our certificate of incorporation and bylaws provide that we may fully indemnify any person who is or was a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was one of our directors, officers, employees or other agents, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding.

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Listing

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol “CPRX”.

Transfer Agent and Registrar

Our transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. They are located at 17 Battery Park, 8th Floor, New York, New York 10004. They can be reached via telephone at (212) 509-4000.

PLAN OF DISTRIBUTION

We may sell the securities from time-to-time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities: (1) through underwriters or dealers, (2) through agents, and/or (3) directly to one or more purchasers. However, in any given 12-month period, we may sell only one third ($\frac{1}{3}$) of our “public float.” We may distribute the securities from time to time in one or more transactions at:

- a fixed price or prices, which may change;
- market prices prevailing at the time of sale;
- prices relating to the prevailing market prices;
- varying prices determined at the time of sale; or
- negotiated prices.

The applicable prospectus supplement with respect to a particular offering of securities will describe the terms of the offering of the securities, including:

- the name or names of any underwriters, and if required, any dealers or agents;
- the purchase price of the securities and the proceeds we will receive from the sale;
- any underwriting discounts and other items constituting underwriters’ compensation;
- any discounts or concessions allowed or reallocated or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

We may solicit directly offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in a prospectus supplement any agent involved in the offer or sale of our securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the

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underwriter at the time of sale and we will provide the name of any underwriter in the prospectus supplement which the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

With respect to underwritten public offerings, negotiated transactions and block trades, we will provide in the applicable prospectus supplement any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments they may be required to make in respect thereof.

To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in other transactions with us, or perform other services for us, in the ordinary course of their business.

LEGAL MATTERS

Certain legal matters in connection with any offering of securities made by this prospectus will be passed upon for us by Akerman Senterfitt.

EXPERTS

The audited financial statements incorporated by reference in this Prospectus have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing in giving said report.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC-0330 for further information on the operating rules and procedures for the public reference room.

This prospectus does not contain all of the information included in the registration statement. We have omitted certain parts of the registration statement in accordance with the rules and regulations of the SEC. For further information, we refer you to the registration statement, including its exhibits and schedules. Statements contained in this prospectus and any accompanying prospectus supplement about the provisions or contents of any contract, agreement or any other document referred to are not necessarily complete. Please refer to the actual exhibit for a more complete description of the matters involved.

INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be a part of this prospectus, except for any information superseded by information in this prospectus or by any information in a prospectus supplement accompanying this prospectus.

The following documents filed with the SEC are incorporated by reference in this prospectus:

1. Our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 31, 2010;
2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on May 17, 2010, for the quarter ended June 30, 2010, filed with the SEC on August 12, 2010, and for the quarter ended September 30, 2010, filed with the SEC on November 15, 2010;
3. Our Current Reports on Form 8-K filed with the SEC on February 17, 2010, February 23, 2010, April 1, 2010, April 13, 2010, April 26, 2010, August 4, 2010, August 6, 2010, September 21, 2010, November 1, 2010, November 2, 2010, November 4, 2010, November 16, 2010, and November 18, 2010;
4. Our description of our common stock contained in our Registration Statement on Form 8-A, filed with the SEC on September 29, 2006, along with Amendment No. 1 thereto, filed with the SEC on October 18, 2006; and
5. All documents subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, from the date of filing of such documents, before the filing of a post-effective amendment to this Registration Statement which indicates that all securities offered hereunder have been sold or which deregisters all securities then remaining unsold.

You may obtain a copy of any of these documents at no cost by requesting them from us or by writing or calling: Catalyst Pharmaceutical Partners, Inc., 355 Alhambra Circle, Suite 1370, Coral Gables, Florida, 33134, Attn: Investor Relations, or by calling (305) 529-2522. Copies of each of these filings are also available for no cost on our website, www.catalystpharma.com, or on the SEC's web site, www.sec.gov.

PART II
INFORMATION NOT REQUIRED IN THIS PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution

The following table sets forth all expenses to be paid by the registrant, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the registration fee.

SEC registration fee	\$ 2,139
Legal fees and expenses	15,000
Accounting fees and expenses	5,000
Miscellaneous expenses	5,000
Total	<u>\$27,139</u>

Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law provides for the indemnification of officers, directors, and other corporate agents in terms sufficiently broad to indemnify such persons under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act. The registrant's Restated Certificate of Incorporation and the registrant's Amended and Restated Bylaws provide for indemnification of the registrant's directors, officers, employees and other agents to the extent and under the circumstances permitted by the Delaware General Corporation Law.

The registrant has also entered into agreements with its directors and officers that will require the registrant, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent not prohibited by law.

Item 16. Exhibits

(a) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
3.1	Certificate of Incorporation (1)
3.2	Amendment to Certificate of Incorporation (1)
3.3	By-laws (1)
4.1	Specimen stock certificate for common stock (1)
5.1	Opinion of Akerman Senterfitt (2)
10.1	Agreement, dated April 7, 2010, between Catalyst Pharmaceutical Partners, Inc. and the Division of Pharmacotherapies and Medical Consequences of Drug Abuse of the National Institute on Drug Abuse.
23.1	Consent of Grant Thornton LLP
23.2	Consent of Akerman Senterfitt (included in Exhibit 5.1)
24.1	Power of Attorney (2)

(1) Filed by reference to the Company's Registration Statement on Form S-1 (File No. 333-136039)

(2) Previously filed.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information to be included in a post-effective amendment by those paragraphs is contained in reports furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference into this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the

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information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is a part of the registration statement will, as to a purchaser with a time of contract sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was a part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act and (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the

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registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

AGREEMENT BETWEEN
CATALYST PHARMACEUTICAL PARTNERS, INC.
AND THE
DIVISION OF PHARMACOTHERAPIES AND MEDICAL CONSEQUENCES OF DRUG ABUSE
NATIONAL INSTITUTE ON DRUG ABUSE

This Agreement made this 7th day of April, 2010 by and between: Catalyst Pharmaceutical Partners, Inc. (hereafter referred to as “Collaborator”), a Delaware corporation, having its offices at 355 Alhambra Circle, Suite 1370, Coral Gables, FL 33134 and The Division of Pharmacotherapies and Medical Consequences of Drug Abuse (hereafter referred to as “DPMCD”) of the National Institute on Drug Abuse (hereafter referred to as “NIDA”), a part of the National Institutes of Health (hereafter referred to as “NIH”) of the U.S. Public Health Services (hereafter referred to as “PHS”), Department of Health and Human Services (hereafter referred to as “DHHS”), an agency of the United States Government, having its offices at 6001 Executive Boulevard, Room 4123, MSC 9551, Bethesda, Maryland 20892.

BACKGROUND

- A. DPMCD recognizes the importance of the role of the pharmaceutical industry in the clinical development of new agents to treat addiction to controlled substances. DPMCD wishes to foster collaboration with industry whenever possible. As part of its mission to improve treatment for drug dependence, DPMCD shares with industry the important goal of defining the contribution of a new drug or biologic in the treatment of drug dependence.
- B. DPMCD recognizes and supports the need for the private sector to focus at the appropriate time on clinical trials that lead to a New Drug Application (as hereafter defined, an “NDA”), since NDAs are the vehicles through which new pharmacotherapies become available to treat drug dependent persons.
- C. DPMCD considers it appropriate for investigators sponsored by DPMCD to do clinical trials of interest to, and partially supported by pharmaceutical firms, provided that the trials have scientific merit and the goals of the investigators and the pharmaceutical firm are consistent with the goals of DPMCD and meet U.S. legal and regulatory standards.
- D. Collaborator has developed a pharmaceutical product from a compound known as **Vigabatrin** (hereinafter referred to as the “Agent”) for the treatment of cocaine dependence. DPMCD has indicated an interest in the Agent and has expressed its willingness to Collaborator to conduct a clinical trial that may be used by Collaborator in support of an eventual NDA submission.
- E. Collaborator acknowledges that DPMCD coordinates a large volume of clinical research with products for the treatment of drug dependence and recognizes DPMCD’s need to be aware of industry’s plans for the clinical development of new drugs of mutual interest. Collaborator also recognizes the necessity of preserving the spirit of free and open inquiry among clinical investigators.

AGREEMENT

In view of the foregoing background, the following Agreement serves as the basis for the co-development of Agent by Collaborator and DPMCDA.

1. DEFINITIONS

“Adverse Event (or Adverse Experience)” Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. AEs can also be identified as serious and/or unexpected. If there is a conflict, the Study protocol will prevail.

“Affiliate” means any corporation or other business entity controlled by, controlling or under common control with Collaborator. For purposes of this definition, “control” means direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock, or at least fifty percent (50%) interest in the income of such corporation or other business entity.

“Agent” or “Study Agent” means the Collaborator’s version of Vigabatrin, which the Collaborator has designated CPP-109.

“Annual Report” means the annual report of the progress of the IND for the Agent which the IND sponsor is required to submit to the FDA within 60 days of the anniversary of the submission of the IND (pursuant to 21 CFR 312.33).

“Audit” means a systematic, independent examination to determine whether the conduct of a clinical trial investigation complies with the agreed protocol and the data reported are consistent with the records on site.

“Biological Product” means any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man, as further defined in 21 CFR 600.3(h).

“CFR” means Code of Federal Regulations

“Collaborator” means company Catalyst Pharmaceutical Partners, Inc. and its Affiliates, Assignees, or Successors in Interest.

“Contract” means a Funding Agreement that is a research and development contract specifying services that a contractor performs for the benefit of the Government with an expectation of completion of the stated research goals and the delivery of a report, data, materials or other product. Generally, Contracts are administered under the Federal Acquisition Regulations (FAR), codified at 48 CFR Chapter 1.

“Cooperative Agreement” means a Funding Agreement that is a species of grant whereby the federal agency intends to be substantially involved in carrying out the research program. Cooperative Agreements may be used where the federal agency intends for its scientists to collaborate directly with

the researchers of the funded institution on a joint research project. The federal agency may then pay for the research of both its employees and those of the funded institution. (See 45 CFR Part 74).

“Data and Safety Monitoring Board (DSMB)” An independent group of experts that advises NIDA and the study investigators. The primary responsibilities of the DSMB are to 1) periodically review and evaluate the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and 2) make recommendations to NIDA concerning the continuation, modification, or termination of the trial. The DSMB considers study-specific data as well as relevant background knowledge about the disease, Study Agent, or patient population under study.

“DHHS” means the United States Federal Department of Health and Human Services.

“Drug Master Files (“DMFs”) means reference files submitted to the FDA that are used in the review of investigational and marketing applications for human drugs. Drug Master Files are submitted to the FDA to allow another party to reference this material without disclosing to that party the contents of the file.

“DPMCD” means the Division of Pharmacotherapies and Medical Consequences of Drug Abuse, National Institute on Drug Abuse.

“Extramural Principal Investigator” means a Principal Investigator funded by NIDA under a grant, Contract or Interagency Agreement.

“FDA” means the Food and Drug Administration, under the DHHS.

“Funding Agreement” means a Contract, grant, Cooperative Agreement or Interagency Agreement entered into between a federal agency and another party for the performance of experimental, developmental or research work funded in whole or in part by the federal government.

“Government” means the United States Government and any of its agencies.

“Human Subjects” means individual volunteers who are healthy or with a disease whose physiological or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations for the protection of human subjects, human subjects are defined as living individuals about whom an investigator obtains:

- a) data through intervention or interaction with the individual; or
- b) identifiable private information [45 CFR 46.102 (f)].

“Identifiable Private Information” means patient-identifying data from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to individual human subjects, either directly or through codes.

“IND” An investigational new drug application. “IND” is synonymous with “Notice of Claimed Investigational Exemption for a New Drug.” It is the legal mechanism that allows for experimental drugs to be shipped across state lines. INDs must comply with the requirements set forth under 21 CFR Part 312.

“IND Holder” means the person or organization filing an IND with the FDA. The IND Holder agrees to comply with all FDA regulations and obligations relevant to experimental clinical trials (synonymous with the term “sponsor”. The IND holder for purposes of this agreement is the Collaborator.

“Institutional Review Board (IRB)” means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

“Interagency Agreement” means an agreement between NIDA, NIH and another federal agency for the performance of experimental, developmental or research work funded in whole or in part by NIDA.

“Investigational New Drug” means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this agreement.

“Investigator” means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. “Sub-investigator” includes any other individual member of that team.

“Investigator’s Brochure (IB)” means a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration, and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial.

“Monitoring” means the act of overseeing the progress of a clinical investigation to ensure that it is conducted, recorded and reported in accordance with the clinical protocol and FDA Good Clinical Practices.

“NDA” means a New Drug Application. The NDA is the formal process by which the FDA approves a drug for commercial distribution.

“NIDA” means the National Institute on Drug Abuse, NIH, DHHS.

“NIH” means the National Institutes of Health, DHHS.

“Parties” means Collaborator and NIDA.

“PLA” means a Product License Application. The PLA is the formal process by which the FDA approves a biological for commercial distribution.

“PRC” means the DPMCDA Protocol Review Committee that reviews and approves all studies involving investigational compounds and/or activities supported by DPMCDA.

“Principal Investigator” means an individual who has organizational and fiscal responsibility for the use of federal funds to conduct a plan of research that frequently includes several clinical trials, e.g., Contract

Principal Investigator, Grant Principal Investigator or Interagency Principal Investigator.

“Project Officer” means the individual whose responsibilities include oversight of the activities of a government contract.

“Proprietary Data” means confidential scientific, business or financial data, excepting the following sets of data:

- data publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;
- data made available by the owners of the data to others without a confidentiality obligation;
- data already known or available to the receiving Party without a confidentiality obligation;
- data relating to potential hazards or cautionary warnings associated with the production, handling or use of the subject matter of this Agreement; and
- data required to be disclosed by law or court order, and
- an Annual Report to the FDA.

If the data is required to be disclosed by law or court order, the party disclosing the data will consult with the other party before making the disclosure. If any one or more of the above provisions of this definition is met, the relevant information shall no longer be considered Proprietary Data.

“Raw Data” means the primary quantitative and empirical data collected by the intramural and extramural investigators from experiments and clinical trials conducted under the scope of this Agreement. Raw data will not include any Identifiable Private Information.

“Regulatory Affairs Branch” means the Regulatory Affairs Branch of DPMCDCA.

“Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an application, including the ability to make available the underlying raw data from the investigation for FDA audit, if necessary.

“Serious Adverse Drug Experience” (SAE) shall be defined in the Study protocol. SAE means any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/ incapacity, or a congenital anomaly/birth defect. If there are any conflicts, the Study Protocol will prevail.

“Sponsor” means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator, which is synonymous with IND Holder.

“Sponsor-Investigator” means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.

“Subject Data” means all recorded information first produced in the performance of this Agreement by the parties. “Subject Data” shall specifically exclude “Identifiable Private Information.”

“Sub-investigator” may include any other designated individual of the group or team of persons performing duties under the trial but who is not the “Principal Investigator”.

“Summary Data” means a summary of the Raw Data which shall be made available to DPMCDA and which will be used by the IND Holder to prepare an Annual Report to the FDA.

“Unexpected Adverse Drug Experience” is any adverse drug experience, the specificity or severity of which is not consistent with the risk information described in the current investigator brochure, protocol, general investigational plan or elsewhere in the IND.

“Yearly Summary Report” means a report prepared by the NIDA relating to this Study for use by Collaborator in its Annual Reports to the FDA and for other administrative purposes. Such report shall contain the Summary Data from this Study and shall be available to the public in accordance with NIDA policy.

2. PLANNING OF CLINICAL TRIALS

The Parties agree that the Study Agent is of interest to DPMCDA and that the investigational plan for a clinical trial of the Study Agent shall be developed by DPMCDA and Collaborator. In addition to areas of mutual interest, DPMCDA and Collaborator may independently pursue clinical studies of particular interest to each. Because such independently sponsored studies have implications for commitment of resources by both DPMCDA and Collaborator, to the extent such plans exist, they shall be the subject of joint discussion and planning between DPMCDA and Collaborator. Each party shall provide those services set forth in the Scope of Work in accordance with this Agreement (Attachment C)

3. INDs

Collaborator is the Sponsor for the Vigabatrin IND under which this study shall be performed and by Letter of Authorization (LOA) or right of reference, NIDA may authorize Collaborator to cross-reference an existing IND, NDA, Drug Master File or data held by NIDA. All information in INDs will be fully shared between DPMCDA and Collaborator as described below. However, certain information pertaining to proprietary processes not required for conduct of the study may be held in confidence by Collaborator. The IND Sponsor assumes the responsibility for insuring that all FDA regulations are met regarding the IND and all subsequent filings.

For purposes of this Agreement, it is agreed that Collaborator shall be the IND Sponsor, and shall employ a suitably qualified physician to monitor and assess adverse events occurring in and across all studies relevant to Agent.

4. PROTOCOL(S)

A general investigational plan for the Phase II clinical trial of Study Agent shall be established by DPMCDA and the Collaborator (See Attachment B). Each clinical research protocol prepared by Collaborator shall be forwarded to DPMCDA for review and comment. Comments from DPMCDA received by Collaborator will be given due consideration and will be incorporated into the protocol absent good cause. Comments from either Collaborator or DPMCDA staff that are agreed upon will be formatted as a consensus review that is returned to the investigator(s) for necessary and/or suggested changes before the protocol can be given final approval and then submitted for approval by appropriate

Institutional Review Board(s). When all appropriate review and approval has occurred the IND Holder shall submit the protocol to the FDA. Both Parties will receive copies of the final approved protocol at the time it is submitted to the FDA.

Each protocol, and any subsequent amendments agreed to by Collaborator and NIDA and approved by the clinical site IRB, and the FDA shall be appropriately filed by the IND holder, and shall be incorporated as part of this agreement.

5. ADVERSE EVENTS, ANNUAL REPORTS, OTHER IND DATA

(a) Where DPMCDA monitors the clinical trial, DPMCDA shall provide Collaborator with copies of all adverse event reports for their submission to the FDA. Copies of any warning letters shall also be sent to Collaborator for timely review and comment prior to the time they are sent to participating investigators and to FDA. In addition, pertinent IND data (including, but not limited to: data for inclusion in the Clinical Investigator Brochure; safety data (including lists of deaths, adverse event and drop-outs); and formulation and pre-clinical data (including toxicology findings) shall be provided to Collaborator as they become available.

(b) Where Collaborator monitors the clinical trial, Collaborator shall provide DPMCDA with copies of all adverse event reports concurrently with their submission to the FDA. Copies of any warning letters shall also be sent to DPMCDA for timely review and comment prior to the time they are sent to participating investigators and to FDA. In addition, copies of Annual Reports and other pertinent IND data (including, but not limited to: Clinical Investigator Brochure data; safety data (including lists of deaths, adverse event and drop-outs); general investigational plan for the upcoming year; and formulation and pre-clinical data (including toxicology findings) shall be provided to DPMCDA as they become available.

(c) For purposes of this Agreement, it is agreed that NIDA shall monitor the clinical trial specified in Attachment B, through the use of qualified GCP monitors. Monitoring will comply with FDA, cGCP and ICH guidelines. Copies of monitoring reports will be provided to DPMCDA, Collaborator and to the Clinical Trial Sites(s) that was the subject of the monitoring report.

6. DRUG INFORMATION AND SUPPLY

Collaborator agrees to provide the Agent (and matching placebo if applicable to the clinical investigation) to DPMCDA without charge in sufficient quantity to complete the studies agreed upon with DPMCDA. The contact person for DPMCDA will be Liza Gorgon (Telephone: (301) 443-1138) and the Collaborator contact will be Douglas Winship (Telephone: (305) 529-2522, x12). Collaborator shall provide certificates of analysis to DPMCDA for each lot of the Study Agent (Vigabatrin) provided. Collaborator is responsible for the manufacture of clinical supplies for shipment to the VA Pharmacy. The VA Pharmacy will be responsible for shipping clinical supplies to the clinical sites.

7. DATA RIGHTS

Generally, data generated in trials sponsored by NIDA with funding provided through grants or Cooperative Agreements are considered the property of the Extramural Principal Investigator; data generated in trials sponsored by NIDA with funding provided through Contracts are considered the property of NIDA. Raw data owned by NIDA generated by this study shall be made fully available to Collaborator for its own analysis and for its applications to FDA, except that any information that would

identify human subjects of research or patients shall always be maintained confidentially. In accordance with the HHS Office of Human Research Protection guidelines, Collaborator access to and review of Identifiable Private Information shall be only for on-site quality auditing. Collaborator will receive Identifiable Private Information only for purposes of satisfying FDA or other health authorities' reporting requirements, and for internal research purposes, directly related to obtaining regulatory approval of Agent. Collaborator is prohibited from access, review, receipt, or use of such information for other purposes. NIDA's raw data will be released by NIDA only in accordance with applicable federal regulations and guidelines, or in accordance with the terms of Article 22. **EXPIRATION AND TERMINATION and RIGHT OF GOVERNMENT TO CONTINUE DEVELOPMENT.**

The Parties are encouraged to make publicly available the results of their research and development activities. Before either Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the Agent, the other Party shall have sixty (60) days to review the proposed publication or other disclosure to assure that Confidential Information is protected, except to the extent that such disclosure is required by applicable law or regulation. Either Party may request in writing that the proposed publication or other disclosure be delayed for up to thirty (30) additional days as necessary to file a Patent Application. Collaborator retains the right to access the Raw Data and Summary Data for legitimate business or regulatory purposes and to use the Raw Data and Summary Data for any regulatory filings Collaborator deems necessary or appropriate, except where the terms of Article 22. **EXPIRATION AND TERMINATION and RIGHT OF GOVERNMENT TO CONTINUE DEVELOPMENT** may apply.

NIDA will supply Collaborator with all information submitted in its IND, if filed, subject to the limitations set forth in this Agreement. Collaborator shall supply NIDA information from Collaborator's IND including, but not limited to, Annual Reports, Clinical Brochures, Adverse Drug Experiences, and formulation and preclinical data, including toxicology findings.

Upon completion of the Study, Collaborator shall be provided with a copy of the complete analysis data set and safety data in a machine-readable format to be determined jointly. The process of determining Collaborator's specifications for storing and transfer of data shall be mutually agreed upon. If meeting these specifications would result in additional costs to NIDA, Collaborator shall reimburse NIDA for the reasonable additional costs in a manner to be negotiated by NIDA and Collaborator after discussing the data requirements.

8. FDA MEETINGS

All meetings with FDA concerning Agent will be discussed by Collaborator and NIDA in advance and will be held on FDA determined dates. The parties agree that NIDA shall fully participate in market development plans for Agent and in discussions with FDA regarding the design and endpoints for the pivotal trials. NIDA will participate in meetings with the FDA only at the Collaborator's request. However, Collaborator shall take the initiative in arranging meetings with the FDA and will be ultimately responsible for pursuing approval of the Agent by FDA.

9. PROPRIETARY DATA

For a period of five (5) years from the date of disclosure, NIDA shall treat as confidential any preclinical or formulation data and information that Collaborator has provided NIDA in writing, and which Collaborator has designated as being proprietary and confidential, except where the terms of 22. **EXPIRATION AND TERMINATION and RIGHT OF GOVERNMENT TO CONTINUE DEVELOPMENT** may apply. If

Collaborator informs NIDA that this information or data is still secret and confidential, and NIDA concurs, this obligation of confidentiality shall be extended for an additional two (2) years. During this period, NIDA shall take all necessary and reasonable precautions to prevent such confidential information from being disclosed or provided to any unauthorized person, firm, company or organization. NIDA agrees that any information or data provided by Collaborator and designated by Collaborator as confidential shall not be used, reproduced, or disclosed other than for the purpose of carrying out this Agreement and the activities contemplated by the Protocol(s), and shall be disclosed only to NIDA employees, grantees and/or contractors who are directly concerned with the use and evaluation of the confidential information and who are bound to the same obligations as NIDA under this Agreement, unless otherwise agreed to in writing by Collaborator or required under court order or the Freedom of Information Act (5 U.S.C. § 552). Collaborator hereby designates the Clinical Brochure as confidential information. Collaborator shall place a notice (e.g., "CONFIDENTIAL" or similar notation) on all other written information it delivers under this Agreement that it asserts is confidential information. With respect to oral information that Collaborator asserts is confidential information, Collaborator shall reduce to writing, within 30 days after such oral disclosure, the primary substance of the information contained in the oral disclosure that Collaborator considers confidential information.

10. ACCESS, REVIEW, and RECEIPT of IDENTIFIABLE PRIVATE INFORMATION

Collaborator access to and review of Identifiable Private Information shall be only for on-site quality auditing. Collaborator will receive Identifiable Private Information only if necessary for purposes of satisfying FDA or other health authorities' reporting requirements, and for internal research purposes directly related to obtaining regulatory approval of Study Agent. Collaborator is prohibited from access, review, receipt, or use of such information for other purposes. All IRB approved protocols and informed consent documents related to this research project shall clearly describe this practice. If the Collaborator will have access to Identifiable Private Information, the protocol and the informed consent must clearly state (i) the existence of the Collaborator; (ii) the Collaborator's access to Identifiable Private Information, if any; and (iii) the extent to which confidentiality shall be maintained. For clinical protocol(s) involving a third party, the other party's access, review, receipt, or use of Identifiable Private Information shall be subject to the same limitations as described in this Article. Furthermore, all IRBs charged with reviewing clinical studies undertaken under this agreement shall apprise research subjects, as documented in approved informed consent documents, of the role of Collaborator (Catalyst Pharmaceutical Partners) in the studies, including the ability of Collaborator (Catalyst Pharmaceutical Partners) or its designees to access records as described above. Each IRB shall be provided with the checklist provided as Attachment A, whose content shall be approved by Collaborator and NIDA prior to being provided to each IRB.

11. DATA EXCHANGE

Collaborator shall provide DPMCDAs with all information submitted with its IND related to Vigabatrin including, but not limited to, Annual Reports, Clinical Investigator Brochures, safety data and formulation and pre-clinical data, including toxicology findings. Collaborator is the sponsor for the Vigabatrin IND under which this Study shall be performed and by Letter of Authorization (LOA) or right of reference may authorize Collaborator to cross-reference an existing IND, NDA, Drug Master File or data held by NIDA.

12. MONITORING

NIDA shall permit Collaborator and/or Collaborator's designee(s) reasonable access to Study site(s) with advance notice to monitor the conduct of the Study to audit records, case report forms, source

documents, and other data relating to the Study, in order to verify NIDA 's compliance with its obligations herein. Any information that would identify human subjects of research or patients shall always be maintained confidentially. The restrictions of Article 7 of this agreement specifying access to identifying patient information in compliance with the HHS Office of Human Research Protection guidelines, shall also apply to any monitoring of the study by Collaborator.

13. DATA and SAFETY MONITORING BOARD

A duly constituted Data and Safety Monitoring Board (hereinafter DSMB) has the authority and responsibility to review accumulating data from clinical investigations conducted at NIDA. The clinical investigation that is the subject of this Agreement shall be reviewed by the DSMB. The DSMB will meet on a regular basis and will review safety and efficacy data. The Principal Investigators must report all adverse drug experiences regardless of severity and must present a brief progress statement on the Study to each regularly scheduled meeting of the DSMB. The progress statement should contain an assurance that there is no evidence of safety or toxicity issues that should be addressed by the DSMB. The DSMB shall report early evidence of pre-specified or unanticipated benefit or harm to participants in the trial that may be attributable to the Agent or the treatments under evaluation in the clinical investigation. The DSMB shall conduct an independent, objective review of all accumulated data in such a manner as to maximize the benefits to the trial participants and to the research effort. The DSMB shall consider whether or not a Protocol modification is indicated based on this review, and the DSMB shall advise NIDA on the appropriateness of continuing the Study as designed.

It is understood and agreed that NIDA and Collaborator shall provide clinical trial data to the DSMB, in the format specified by the DSMB, three (3) weeks prior to the meeting dates established and specified by the DSMB. It is further understood and agreed that NIDA will format the data for submission to the DSMB through the statistical center contracted by NIDA, as supplied by participating clinical trial sites on a schedule to be specified by the statistical center.

It is further understood and agreed that both Collaborator and NIDA will have key trial personnel available to meet with the DSMB and provide information, if so requested, and agree to abide by final decisions of the DSMB.

14. PUBLICATIONS AND COMMERCIALIZATION

NIDA and clinical site investigators engaged in the clinical trial(s) retain the full right to present and publish the data at such time and place as they see fit. Collaborator shall receive copies of any abstract or manuscript relating to the Study prior to their submission for publication with sufficient time for advisory review and comment. Such abstracts and manuscripts shall be submitted to Collaborator at least sixty (60) days prior to publication, except as otherwise mutually agreed. Upon written request by Collaborator, such publication shall be delayed an additional thirty (30) days to allow Collaborator to seek patent or other proprietary protection relating to the Agent, where appropriate.

Recognizing that both NIDA and Collaborator scientists may play an important role in the design, analysis, and interpretation of the findings of the Study, consideration shall be given by NIDA to include appropriate individuals from Collaborator in the authorship of publications based on the Study.

It is understood and agreed that DPMCDCA will pay for the data processing associated with publishing the main study findings, but will not pay for subsequent data processing costs for other publications, sub analyses, or other purposes not specifically required by the FDA in support of the IND/NDA.

15. USE OF NAME

Collaborator may use, refer to and disseminate reprints of scientific, medical and other published articles that disclose the name of NIDA, NIH, PHS, or DHHS, consistent with U.S. copyright laws, provided such use does not constitute an endorsement of any commercial product or service by NIDA, NIH, PHS, or DHHS. Collaborator shall take every step possible to ensure that references to the articles are accurate, and shall explicitly state that any such reference does not claim, infer or imply an endorsement or recommendation of the product by the Investigator, NIDA, NIH, PHS, or DHHS. Collaborator shall not use the name of any of the foregoing in any advertising, packaging, or promotional material in connection with Agent except with the written permission of NIDA, or as may be required by law. Collaborator-issued press releases that reference or rely on the work of NIDA under this Agreement shall be made available to NIDA at least seven days prior to publication for review and comment.

16. INTELLECTUAL PROPERTY

Generally, the rights of ownership of inventions, discovered or made solely in connection with work covered by this Agreement, are retained by the organization that is the employer of the inventor. Both Collaborator and NIDA recognize that these rights shall be determined under patent law. NIDA shall notify Collaborator upon filing a patent application on any invention NIDA employees make while using the Agent furnished to NIDA under this Agreement. Collaborator may apply for a nonexclusive, partially exclusive, or exclusive royalty-bearing license to make, use, and/or sell products embodying the invention as claimed in the filed patent application, subject to the terms of 35 USC §§ 207, 208, and 209, and under 37 CFR § 404, to any NIDA inventions arising during this study when a U.S. Government employee is the sole inventor.

Nothing herein shall be construed as granting to NIDA any license or right under Collaborator patents and know-how on the Agent except the right to conduct the Study using samples of the Agent supplied under this Agreement. Neither party shall be obligated to enter into any further arrangement regarding the Agent or its development, except where the terms of Article 22. **EXPIRATION AND TERMINATION and RIGHT OF GOVERNMENT TO CONTINUE DEVELOPMENT** may apply. Collaborator may proceed with the development of the Agent as a pharmaceutical product at its own discretion and cost, even in parallel with the Study.

17. OTHER INTERACTIONS

In order to foster development of Agent, the participation of NIDA staff will likely be required at selected scientific or development meetings. As part of this Agreement, it is agreed that Collaborator may agree to provide for the transportation and lodging costs for attendance of NIDA staff in such activities. Selection of participating NIDA staff must be based on choices mutually acceptable to both Collaborator and NIDA. Both parties must agree that the activities would be appropriate under this Agreement, and acceptance of Collaborator's support of NIDA's participation in these activities will be contingent upon appropriate NIDA approval. Other interactions that materially assist the development of potentially important new therapies will also be possible. Again, mutual agreement and appropriate NIDA approval will be necessary, according to the terms of this Agreement. However, notwithstanding anything to the contrary, this Agreement does not represent a Cooperative Research And Development Agreement ("CRADA" under the Federal Technology Transfer Act, 15 U.S.C. § 3701 et seq.). Travel costs are limited by the Federal Travel Rules and Regulations for all government staff whether paid for by government funds or private Collaborators.

18. LIABILITY

Each of the Parties shall be liable for any loss, claim, damage or liability incurred by that Party as a result of its activities under this Agreement, provided that DPMCDAs, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). Nothing herein shall be construed as requiring either Party to indemnify the other for any loss, claim, damage or liability under this Agreement.

19. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the federal law of the United States as interpreted by the Federal Courts of the District of Columbia. Further, NIDA and Collaborator shall comply with all applicable DHHS regulations relating to Human Subject use, and all applicable PHS policies, in connection with this study.

Collaborator will obtain a DHHS Certificate of Confidentiality (see 42 CFR Part 2a) on behalf of all Clinical Trial Sites prior to initiation of the Protocol. Collaborator will provide each Clinical Trial Site with a copy of the Certificate and relevant information concerning its scope and duration.

20. SEVERABILITY, INTEGRATION and SURVIVABILITY

The terms of this Agreement are severable. Titles and headings of the articles of this Agreement are for convenient reference only, do not form a part of this Agreement, and shall in no way affect its interpretation. If any item or provision of this Agreement shall to any extent be invalid or unenforceable, the remainder of this Agreement shall not be affected, and each remaining item and provision of this Agreement shall be valid and shall be enforceable to the fullest extent permitted by law. This Agreement constitutes the entire agreement between the Parties concerning the subject matter of this Agreement, and supersedes any prior understanding or written or oral agreement.

The provisions of Articles 7, 9, 10-11, 13-16, 18-22 shall survive the termination of this Agreement.

21. AMENDMENTS

Upon mutual agreement of both parties, this Agreement may be amended as necessary to ensure the Agreement accurately reflects the terms and scope of the collaborative effort. All amendments must be in writing and signed by authorized representatives of both parties.

22. EXPIRATION AND TERMINATION and RIGHT OF GOVERNMENT TO CONTINUE DEVELOPMENT

A. This Agreement expires on the earlier to occur of the completion of the Study or five (5) years after the date of full execution of this Agreement. If the Study has not been completed within five (5) years of the date of full execution of this Agreement, this Agreement may be renewed for successive two (2) year renewal terms by simple letter agreement until completion of this Study, unless earlier terminated as provided below. Said expiration date may be changed by mutual agreement and written amendment of this Agreement.

B. This Agreement may be terminated at any time by mutual written consent of the Parties.

C. Either Party may unilaterally terminate this Agreement at any time without cause by giving written notice to the other Party at least sixty (60) days prior to the desired termination date. If Collaborator unilaterally terminates this Agreement for any reason other than the safety of the Study subjects, Collaborator agrees to supply enough Study Agent to complete the Protocols as are then ongoing, pursuant to Article 6. In the event of any termination hereunder, all Parties shall continue their obligations until that time when all currently enrolled Human Subjects have either completed the Study, voluntarily withdrawn for the Study or otherwise reached termination points specified in the Protocol. Collaborator shall also continue to support the IND for Study Agent for the duration of the Study.

D. Either Party may unilaterally terminate this Agreement at any time for cause by giving written notice to the other Party, if the other Party has breached a material obligation under this Agreement and failed to remedy such breach within thirty (30) days of receipt of written notice of breach.

E. The provisions of this Agreement as they relate to confidentiality and drug supply shall survive the expiration or earlier termination of this Agreement.

F. If Collaborator elects to terminate this Agreement (other than as a result of a breach of this Agreement by DPMCDA), but DPMCDA wishes to continue development of the Agent, NIH by virtue of this Agreement shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced throughout the world for or on behalf of the United States Government any invention Collaborator has regarding the Study Agent, its manufacture or use for medical research purposes, including those related to or connected with therapy for drug dependence. In addition, Collaborator shall provide DPMCDA with the Agent (and matching placebo, if required), at Collaborator's cost, for future preclinical studies and clinical trials by:

- 1) allowing DPMCDA to purchase the Study Agent (and matching placebo, if required) from Collaborator's inventory;
- 2) arranging for an independent contractor to manufacture and provide DPMCDA with the Study Agent (and matching placebo, if required); or
- 3) providing all information necessary to allow DPMCDA to contract for the manufacture of the Study Agent (and matching placebo, if required) independently of Collaborator.

This obligation shall remain in effect until the earlier of the date on which DPMCDA can obtain an alternate source of materials acceptable to DPMCDA or two years from the date of notification by Collaborator that it has elected to terminate this Agreement under the provisions of this Paragraph.

G. For purposes of this Agreement:

- 1) "safety" shall be defined by an independent Data Safety Monitoring Board (DSMB) utilized to review each study conducted. "Efficacy" shall be defined as statistically significant effects attributed to the compound. The quantitative and qualitative judgments of "safety" and "efficacy" shall be determined by an independent Data Safety Monitoring Board (DSMB) utilized to review the protocol. The decision of the DSMB shall be binding as to the issues of "safety" and "efficacy" concerning the protocol undertaken by the Parties under this Agreement.

In the event that the DSMB determines, after review of data submitted by NIDA and the Collaborator that the compound is not safe or not efficacious, as administered under the individual protocol undertaken under this agreement, neither NIDA nor the Collaborator shall be

required to perform further research and development with the compound beyond any continuing obligations to research subjects and the requirements of the FDA concerning IND maintenance and records retention. In the event development is terminated for reasons of safety or efficacy, no commercialization license based on failure of Collaborator to continue development shall be granted to the Government. NIDA and Collaborator may voluntarily agree to negotiate in good faith as to whether further research and development utilizing different methods, dosage levels, or dosage forms is feasible and desirable. In the event that the Parties mutually agree to further attempts at development, a new agreement reflecting the terms and conditions for further research and development shall be executed.

2) In the event Collaborator fails to manufacture or otherwise provide to the Government the subject compound (and matching placebo where relevant) in sufficient quantity and quality (e.g. GMP when required by the FDA) to allow evaluation of the compound for IND and/or NDA filing as contemplated in this agreement, Collaborator authorizes the Government to independently pursue the development of Study Agent. In the event that Collaborator is no longer willing or able to supply Study Agent, Collaborator agrees to supply NIDA with manufacturing methods, and authorization for NIDA to use all the nonclinical and clinical data necessary for the Government to continue research and development of Study Agent.

3) If the Government pursues an indication for Study Agent as a treatment for cocaine dependence in accordance with the provisions of this Agreement, the Collaborator shall authorize the Government to refer to the data in the Drug Master File, Investigational New Drug Application(s) (INDs) and New Drug Application(s) (NDAs) for the compound in connection with FDA's or other (international or non-U.S.) regulatory body's consideration of any filing made by the Government to obtain an approved NDA for the cocaine dependence indication. The Collaborator shall execute such documents as may be reasonably required to effect such authorization. The Collaborator shall be reasonably available to respond to inquiries from the FDA regarding information or data contained in the Drug Master File, IND(s), NDA(s) or other information and data provided to the Government by the Collaborator; provided, however, that nothing herein shall require the Collaborator to under-take additional studies of any kind or to prepare and submit any additional data to the FDA.

23. FORCE MAJEURE EVENT.

Neither Party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such Party, which causes such Party to be unable to perform its obligations under this Agreement, and which it has been unable to overcome by the exercise of due diligence. In the event of the occurrence of such a *force majeure* event, the Party unable to perform shall promptly notify the other Party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

SIGNATURES

This Agreement and any amendments thereto provide the basis for co-development of the Agent as a treatment for drug dependence.

By executing this Agreement each of the undersigned represents and confirms that he/she is fully authorized to bind the identified entity to its terms.

AGREED AND ACCEPTED:

FOR NIDA

/s/ Timothy P. Condon

Timothy P. Condon, Ph.D.
Deputy Director, NIDA

April 13, 2010

Date:

National Institute on Drug Abuse
Neuroscience Center, Room 4123
6001 Executive Boulevard, MSC 9551
Bethesda, Maryland 20892-9551

FOR COLLABORATOR:

The undersigned expressly certifies or affirms that the contents of any statement made or reflected in this Agreement are truthful and accurate.

/s/ Patrick J. McEnany

Patrick J. McEnany
Chairman, CEO

April 7, 2010

Date:

Catalyst Pharmaceutical Partners
355 Alhambra Circle
Suite 1370
Coral Gables, Florida 33134
305-529-2522
f. 305-529-0933
pmcenany@catalystpharma.com

Attachment A: Checklist
Attachment B: Clinical Trial Synopsis
Attachment C: Scope of Work

Consent of Independent Registered Public Accounting Firm

We have issued our report dated March 31, 2010 with respect to the financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2009 of Catalyst Pharmaceutical Partners, Inc., which are incorporated by reference in this Registration Statement. We consent to the incorporation by reference in the Registration Statement of the aforementioned report, and to the use of our name as it appears under the caption "Experts."

/s/ GRANT THORNTON LLP

Miami, Florida
December 15, 2010

December 15, 2010

Securities and Exchange Commission
Division of Corporation Finance
100 F. Street, N.E.
Washington, DC 20549
Attn: Jeffrey Riedler, Assistant Director

**Re: Catalyst Pharmaceutical Partners, Inc.
Registration Statement on Form S-3
Filed December 3, 2010
File No. 333-170945**

Dear Mr. Riedler:

We are responding to the comments contained in your letter to Patrick J. McEnany, Chief Executive Officer of Catalyst Pharmaceutical Partners, Inc. (the "Company"), dated December 14, 2010. The comments should be read in connection with the enclosed copy of Amendment No. 1, filed on the date hereof, which has been marked to show changes to the Company's Registration Statement on Form S-3 dated December 3, 2010.

1. **Please revise your disclosure to incorporate by reference the company's 8-Ks filed 2/17/2010, 2/23/2010, and 4/10/2010**

Company's Response

The 8-Ks referenced above have been added to the list of filings incorporated by reference into the Form S-3. The Company notes that the final 8-K referenced in the Staff's comment letter was filed on April 1, 2010.

2. The Registration Statement has also been updated to include an expanded discussion regarding the Company's clinical trial agreement ("CTA") with the National Institute on Drug Abuse and to file a copy of the CTA as an exhibit to the Registration Statement.

* * *

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BOCA RATON DALLAS DENVER FORT LAUDERDALE JACKSONVILLE LAS VEGAS LOS ANGELES MADISON MIAMI
NEW YORK ORLANDO PALM BEACH TALLAHASSEE TAMPA TYSONS CORNER WASHINGTON, D.C. WEST PALM BEACH

The Company acknowledges that:

- the Company is responsible for the adequacy and accuracy of the disclosure in its filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing;
and
- the Company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

We look forward to hearing back from you regarding this response. If you have any questions, please feel free to give me a call.

Sincerely,

/s/ Philip B. Schwartz

Philip B. Schwartz