Catalyst Pharmaceutical Partners, Inc.
Form 10-K
March 31, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[Mark One]

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2009

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File No. 001-33057

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**76-0837053**
(State of jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
355 Alhambra Circle, Suite 1370	
Coral Gables, Florida	**33134**
(Address of principal executive offices)	**(Zip Code)**

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

Securities Registered Pursuant to Section 12(b) of the Act.

Common Stock, par value $0.001 per share	**Nasdaq Capital Market**
(Title of each class)	**(Name of exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act.: None

Indicate by check mark if registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if registrant is not required to file reports pursuant to Rule 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to rule 405 of Regulation S-T ((§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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 (Check one):

Large accelerated filer ¨	**Accelerated filer ¨**
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	**Smaller reporting company x**

As of June 30, 2009, the last business day of the Registrant s most recently completed second quarter, the aggregate market value of all voting, and non-voting common equity held by non-affiliates was $5,630,275.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 18,043,385 shares of common stock, $0.001 par value per share, were outstanding as of March 26, 2010.

Part III incorporates certain information by reference from the registrant s definitive proxy statement for the 2010 annual meeting of stockholders. The proxy statement with respect to the 2010 annual meeting of stockholders will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2009.

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CATALYST PHARMACEUTICAL PARTNERS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2009

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PART I

You are urged to read this Annual Report on Form 10-K (Form 10-K) in its entirety. This Form 10-K contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from the projected results discussed in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those discussed below and in Item 1A, Risk Factors. We, our, ours, us, Catalyst, or the Company when used herein, refers to Catalyst Pharmaceutical Partners, Inc., a Delaware corporation.

Forward-Looking Statements

Catalyst Pharmaceutical Partners, Inc. is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of drug addiction and 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 treatment and which demonstrates the potential to address an unmet medical need. 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, another GABA aminotransferase inhibitor that we believe is more potent than vigabatrin but may have 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 and drug addiction. We believe that we control all current intellectual property for drugs that have a mechanism of action related to GABA aminotransferase.

The successful development of pharmaceutical products 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 our 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 new drug applications (NDA s) for CPP-109 and CPP-115;
- our ability to protect our intellectual property and 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 than 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 Form 10-K, 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.

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Item 1. Business

Catalyst Pharmaceutical Partners, Inc. is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of drug addiction and 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 treatment and which demonstrates the potential to address an unmet medical need. 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, another GABA aminotransferase inhibitor that we believe is more potent than vigabatrin but may have 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 and drug addiction. We believe that we control all current intellectual property for drugs that have a mechanism of action related to GABA aminotransferase.

Recent Developments

CPP-109

On February 23, 2010, we announced that we signed a non-binding Letter of Intent with the National Institute on Drug Abuse (NIDA) to conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction. It is anticipated that NIDA, under their agreement with Veteran s Administration Cooperative Studies Program, will provide substantial resources for the trial and that we will contribute approximately $2.8 million in resources as part of the estimated $10 million trial cost. It is anticipated that an approximately 200 patient double-blind, placebo-controlled trial will be initiated during the summer of 2010 and will take 18 months to complete. It will be conducted at eight leading addiction facilities across the United States. The clinical 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 to support approval of an NDA. We expect to sign a binding clinical trial agreement with NIDA with respect to this trial in the near future.

CPP-115

On February 22, 2010, we announced our initial development plans for CPP-115. Over the next year, we plan to advance the development of CPP-115 by completing a series of non-clinical studies designed to demonstrate critical safety and efficacy characteristics of CPP-115, as follows:

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

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

We will complete other safety evaluations including genotoxicity and cardiac safety.

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

Most of the safety studies described above, including results from the first assessments of the comparative retinotoxicity of CPP-115 versus vigabatrin, are expected to be completed by the end of the third quarter of 2010 . During that same period, we also expect to complete the above-described animal model efficacy screening of CPP-115 as a potential treatment for both epilepsy and drug addiction. We further expect data from the above-described non-clinical studies, including additional evaluations after 90 days of dosing of visual safety with retinal histopathology, clinical chemistry, hematology, urinalysis and any necessary organ histopathology, will be completed by the end of the first quarter of 2011. We expect to spend approximately $1.2 million to complete all the non-clinical studies described herein. There can be no assurance that CPP-115 will ultimately be proven to be safe and effective to treat epilepsy or that CPP-115 will be determined not to have the visual field defects side effect profile of vigabatrin.

Capital Resources

We believe that our existing cash resources will allow us: (i) to fund the pre-clinical studies of CPP-115, which are estimated to be approximately $1.2 million, (ii) to fund our share of the costs of the clinical trial of CPP-109 that we intend to conduct with NIDA, which are estimated to be approximately $2.8 million over a two-year period, and (iii) to meet general corporate requirements through at least the first quarter of 2011. However, we will require substantial additional funding to complete the additional clinical trials that we believe will be required to be completed before we are in a position to file NDAs for CPP-109 and CPP-115. We will also require additional working capital to support our operations in periods after the first quarter of 2011.

We expect to raise required additional funds through public or private equity offerings, corporate collaborations or other means. We also intend to seek governmental grants for a portion of the required funding for our clinical and non-clinical trials. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on our business.

NASDAQ Listing

Our common stock is currently traded on the Nasdaq Capital Market. On November 13, 2009, we were informed by the Nasdaq Stock Market 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 do 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. To date, we have not met that requirement.

If we do not regain compliance with the Rule prior to the expiration of the grace period, we may be eligible for an additional 180-day grace period if at such time we meet the initial listing standards for listing on the Nasdaq Capital Market, with the exception of the bid price requirement. At the present time, we do not meet those initial listing standards because our market capitalization held by non-affiliates is less than $15 million.

If we are not eligible for the additional 180-day grace period and we are not in compliance with the minimum bid price requirement by May 12, 2010, Nasdaq will send us a delisting determination letter. Delisting will occur nine days after the date of the letter unless we appeal to the Nasdaq Hearings Panel within seven days after the date of the letter. Any delisting is delayed until the appeal is heard and a determination is made by the Hearings Panel. Generally, a hearing is held within 4-6 weeks after a request for a hearing is made, and a determination is made 2-3 weeks after the date of the hearing. Among other things, the Hearings Panel may grant a further 180 day extension from the date of the delisting determination letter to us so we can regain compliance with Nasdaq listing rules.

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If the Nasdaq Hearings Panel denies our appeal, we can make a further appeal to the Nasdaq Listings Council. An appeal to the Listings Council does not automatically delay delisting proceedings, though the Listing Council may, in its sole and absolute discretion, decide to stay delisting proceedings while it considers an appeal. The Listings Council may grant an extension of up to 360 days from the date of the determination letter to regain compliance.

While we believe we can regain compliance before May 12, 2010 or otherwise obtain an extension of the period in which we can regain compliance with the Nasdaq rules, there can be no assurance of this fact. If we are ultimately unable to regain compliance with the Nasdaq rules (either by May 12, 2010 or during any grace period that we are granted), our common stock will be delisted from trading on the Nasdaq Capital Market.

Our Strategy

Our strategy is designed to help us become a leading biopharmaceutical company focused on the in-licensing and development of proprietary product candidates for the treatment of diseases of the central nervous system. Our near-term strategy is to focus on the regulatory approval of CPP-109 for the treatment of cocaine addiction and to initially demonstrate the safety and efficacy of CPP-115 for the treatment of epilepsy and addiction in a series of non-clinical studies. Our long-term strategy is to gain approvals for additional indications for CPP-109, including methamphetamine addiction, seek approvals for CPP-109 internationally and to initially gain approval for CPP-115 to treat epilepsy and later pursue a second indication for cocaine addiction. Specifically, we intend to:

Focus on CPP-109 for cocaine addiction. A treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status from the FDA for CPP-109 for cocaine addiction may facilitate the regulatory approval process. In the first quarter of 2010, we announced that we signed a non-binding Letter of Intent with NIDA to conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction. We expect to execute a clinical trial agreement with NIDA in the near future with respect to this trial and to commence the trial in the summer of 2010, with a goal of completing this trial by the fourth quarter of 2012. Assuming success, we expect that this trial will serve as one of the adequate and well controlled trials required to support approval of an NDA.

Establish proof of concept for CPP-115 in non-clinical studies. Over the next year, we plan to advance the development of CPP-115 by completing a series of non-clinical studies designed to demonstrate critical safety and efficacy characteristics of CPP-115 for the treatment of epilepsy and cocaine addiction. We hope to have enough data from these studies during the third quarter of 2010 to actively seek a strategic partner to help fund further development of CPP-115.

Develop additional indications for CPP-109. The mechanism of action of CPP-109 makes it suitable as a potential treatment for addiction and obsessive-compulsive disorders that share the common element of heightened dopamine levels. Research indicates that CPP-109 is a platform technology with the potential to treat other conditions involving heightened dopamine levels such as addictions to methamphetamine, nicotine, prescription pain medications, alcohol, marijuana, and obsessive-compulsive disorders, including binge eating patterns and compulsive gambling. We hope to develop CPP-109 for one or more of these additional indications, subject to the availability of funding.

Identify and initiate strategic partnering discussions for specific indications in the U.S. and Europe. We believe that there may be several potential pharmaceutical partners interested in jointly developing and marketing CPP-109 and CPP-115 in the U.S. and/or Europe. We have held preliminary discussions with several parties regarding potential transactions, but no agreements have been entered into to date.

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Our Platform Technology: GABA-aminotransferase Inhibition

Mechanism of Action

We believe that our product candidates, CPP-109 and CPP-115, will be effective treatments for addiction and CPP-115 will be an effective treatment for epilepsy because they increase GABA levels through the inhibition of GABA-aminotransferase (GABA-AT). In the case of epilepsy, increased GABA decreases the overall excitability by raising the action potential threshold of many neurons. In the case of addiction, increased GABA dampens the perception of pleasure and reward associated with increased levels of dopamine brought about by all drugs of abuse, but most notably by stimulants like cocaine and methamphetamine. Addictive drugs have been shown to block or overwhelm mechanisms involved in the removal of dopamine from synaptic clefts in the mesolimbic pathways of the brain, resulting in highly elevated levels of dopamine available to stimulate receptors and a dramatically heightened sense of pleasure or reward.

GABA, the most abundant inhibitory neurotransmitter in the brain, inhibits over-excitation of neurons. When GABA binds to a GABA receptor, it raises the action potential threshold of that neuron and inhibits the post-synaptic neuron from firing and triggering the release of neurotransmitters and sending a signal to subsequent neurons. GABA helps induce relaxation and sleep, and contributes to functions such as motor control and vision. An enzyme known as GABA-AT is responsible for the eventual breakdown of GABA and helps to balance the inhibitory effects of GABA. Disease states like epilepsy and addiction that result from excessive neuronal activity are treatable by enhancing the amount of endogenous GABA in the brain through the blockade of GABA-AT.

CPP-109 and CPP-115 are GABA analogs that inhibit GABA-AT. CPP-109 is readily absorbed and promptly available to the central nervous system, producing effects that last for many hours after a single dose. Therefore, administration of CPP-109 results in significantly elevated GABA levels. The pharmacokinetic behavior of CPP-115 has not yet been established, but due to the structural similarities between these two drugs, it is expected to be absorbed and cross the blood-brain-barrier as well. Due to the fact that CPP-109 is not a receptor active drug, its administration does not appear to affect the baseline levels of dopamine, nor those variations in dopamine levels caused by normal stimuli. CPP-115, which works by the same mechanism, is expected to exhibit similar neurochemical behavior.

History and Side Effect Profile of Vigabatrin

Vigabatrin has been marketed over the past decade in over 30 countries by Sanofi-Aventis and its predecessors under the brand names Sabril®, Sabrilex® and Sabrilan® (hereinafter referred to as Sabril®) as a secondary treatment for adult epilepsy and as a primary treatment for the management of infantile spasms, known as West Syndrome. The composition of matter patents for Sabril® in the U.S. expired more than ten years ago. On August 21, 2009, the FDA approved two NDAs for Sabril® for the treatment of infantile spasms and as an adjunctive (add-on) therapy for adult patients with refractory complex partial seizures, who have failed several treatments. The NDAs are for different formulations of Sabril®, and both NDAs are held by Lundbeck Inc. Because of the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) program and is only available through a special restricted distribution program approved by the FDA.

In chronic use for the treatment of epilepsy, vigabatrin has been generally well tolerated. The most common side effects reported have been drowsiness and fatigue. However, one clearly established adverse side effect is the development, with increasing cumulative dosage levels of vigabatrin approaching 1,500 grams, of peripheral visual field defects, or VFDs, in approximately 33% of users. These VFDs are manifest as a constriction of the peripheral field of vision.

Prior research has indicated that VFDs occur at doses far higher than the total dosage amount we anticipate will be used for addiction treatment. However, we have not completed the testing necessary to determine whether this is the case. To date, we believe that no subjects treated in the three trials conducted in Mexico, described herein, or our U.S. cocaine clinical trial or methamphetamine proof-of-concept study, have shown evidence of peripheral visual field loss. Other than the visual field defects, vigabatrin is a relatively well tolerated drug with lower than average neurological side effects compared to other approved epilepsy therapies.

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CPP-115 is structurally similar to vigabatrin. Due to these similarities, we believe that there is a high probability that these two drugs will share a number of biochemical features related to absorption, metabolism, and elimination. As such, we expect the two drugs to exhibit similar safety profiles. However, we expect significant differences related to the inactivation of GABA-AT, which we believe may lead to a substantial reduction, or possibly elimination, of VFDs. Consequently, we postulate that CPP-115 has the capability to exhibit a significant improvement to visual safety, while having other safety and efficacy characteristics similar to vigabatrin. However, there can be no assurance that this will prove to be the case.

Underlying Research

Our interest in vigabatrin was based on research undertaken at Brookhaven National Laboratory (Brookhaven) regarding the pathology and treatment of cocaine addiction and other addictions. Brookhaven scientists have shown that the dopamine pathway responds similarly to drugs of abuse. In 1997, scientists at Brookhaven, using positron emission tomography (PET) scans, became the first researchers to image the effects of addicting substances in live human subjects and animals. Through the use of PET scans, Brookhaven scientists were able to show that as the number of occupied dopamine receptors in the brain increased, so too did the high, or euphoric feeling, of the user.

Our interest in CPP-115 started with our desire to determine what other compounds had been developed and patented that had GABA-AT as their mechanism of action. In that search, we became aware of research at Northwestern University (Northwestern), on the mechanism of vigabatrin s inactivation of GABA-AT and on their subsequent research to find more specific and potent inhibitors of GABA-AT designed using their knowledge of the mechanism of inactivation of GABA-AT. In 1991, scientists at Northwestern published the biochemical mechanism of inactivation of GABA-AT by vigabatrin. That knowledge enabled them to design a number of new molecules that were systematically tested for their ability to inhibit GABA-AT. This work culminated in the discovery of a class of molecules, including CPP-115, that were very effective and specific inhibitors of GABA-AT. These molecules were patented in 2004 and are included in our license with Northwestern.

These development efforts were led by Dr. Richard B. Silverman, the John Evans Professor of Chemistry at Northwestern. Dr. Silverman, who holds 41 patents, is the inventor of pregabalin, also known as Lyrica®, which is marketed by Pfizer. His goal in inventing the compound that became CPP-115 was to seek to mimic the mechanism of action of vigabatrin, while making it both more potent and specific.

CPP-109 (Vigabatrin) To Treat Addiction

In 2004, the FDA accepted our IND for CPP-109 for the treatment of cocaine addiction. We have been granted Fast Track status for CPP-109 from the FDA for cocaine addiction. Under the Federal Food, Drug, and Cosmetic Act, or FDA Act, the FDA is directed to facilitate the development and expedite review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designation emphasizes communication between us and the FDA and affords us benefits that may help to expedite the approval process. For example, Fast Track designation affords us the potential to submit an NDA for CPP-109 on a rolling, or modular, basis, allowing the FDA to review sections of the NDA in advance of receiving our full submission. The designation also means that we may have increased communications with the FDA regarding the design of our clinical studies, which we hope will expedite the development and review of our application for the approval of CPP-109 for cocaine addiction and provide greater certainty overall in the regulatory pathway. There can be no assurance that our receipt of Fast Track status will assist us in the regulatory process for CPP-109.

Our Clinical Studies

In 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with addiction to cocaine. The trial enrolled 186 cocaine addicted patients at 11 addiction treatment clinical centers in the United States. Patients were treated for a period of 12 weeks, with an additional 12 weeks of follow-up. On May 29, 2009, we announced that the top-line data from this trial showed that CPP-109 did not demonstrate statistical significance in the primary endpoint that a significantly larger proportion of CPP-109 treated subjects than placebo-treated subjects were cocaine free during the last two weeks of the treatment period (Weeks 11 and 12).

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On September 30, 2009, we announced additional results from this clinical trial. Based on post hoc analyses for vigabatrin levels in urine samples collected during the trial, we have concluded that less than 40% of the trial subjects were medication compliant. As a result, we now believe that the study was inadequately powered to properly test the efficacy of CPP-109 for the treatment of patients with cocaine addiction. On the basis of a comprehensive review of the study data, however, we concluded that: (i) CPP-109 was safe and well tolerated; and (ii) while there were no statistically significant differences between active and placebo groups for the protocol-specified primary and secondary efficacy endpoints, there were positive and consistent data trends observed in favor of CPP-109 across measures of cocaine abstinence, reduction in cocaine use, and reduction in use days.

When corrected for poor medication compliance, the following favorable outcome trends were observed: (i) cocaine use as measured by benzoylecgonine (the major metabolite of cocaine) levels in urine collected from subjects were consistently lower in the CPP-109 treatment group during the 12 week treatment period, generally indicating a reduction of cocaine use; and (ii) in those subjects who were compliant with study medication, the differences between CPP-109 and placebo were amplified, which suggest that CPP-109 may facilitate abstinence, reduce overall cocaine use as measured by urine benzoylecgonine levels (an objective measure of daily cocaine usage), and reduce cocaine usage days (an objective measure of dependence severity).

Consistent with previous published addiction trials conducted by other parties, the protocol of our cocaine trial assessed subjects medication compliance based on self reporting and on counting the unused medication returned by subjects. The subjects self-reported a compliance level of 85%, which was inconsistent with our urine data. This low medication compliance effectively reduced the power of the study, because not all subjects in the treatment group were actually treated. However, analyses of subject responses, corrected for poor medication compliance, makes the response ratios observed in our trial more consistent with the results reported by Dr. Jonathan Brodie et al. in a double-blind, placebo-controlled, 103-patient Phase II trial evaluating vigabatrin for the treatment of cocaine addiction that was completed in Mexico in 2007 (the results of which trial were recently published in The American Journal of Psychiatry).

During June 2008, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We had planned to enroll 180 methamphetamine addicted patients at 15 addiction treatment clinical centers in the United States. However, in March 2009, in order to conserve cash, we converted our methamphetamine trial into a proof-of-concept study evaluating the results obtained from the 57 patients who had already been randomized into the trial. The patients we enrolled were treated for a period of 12 weeks and we evaluated data related to endpoints based on abstinence, reductions in methamphetamine use and craving for evidence of potential efficacy.

On September 30, 2009, we announced the top-line results of our proof-of-concept study. The results showed that there was a 2.5 times higher rate of abstinence in the last two weeks of the study in the vigabatrin group versus the placebo group. While we consider this to be an encouraging trend, the results were not statistically significant due to the low sample size. We also believe that medication compliance, similar to the cocaine trial, may have been below expectations.

On February 23, 2010, we announced that we signed a non-binding Letter of Intent with the National Institute on Drug Abuse (NIDA) to conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction. It is anticipated that NIDA, under their agreement with the Veteran s Administration Cooperative Studies Program, will provide substantial resources for the trial and that we will contribute approximately $2.8 million in resources as part of the estimated $10 million trial cost. It is anticipated that an approximately 200 patient double-blind, placebo-controlled trial will be initiated during the summer of 2010 and will take 18 months to complete. It will be conducted at eight leading addiction facilities across the United States. The clinical 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 to support approval of a NDA. We expect to sign a binding clinical trial agreement with NIDA with respect to this trial in the near future.

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Some of the studies that we expect will be required to assess the efficacy of CPP-109 for the treatment of cocaine addiction and/or methamphetamine addiction, including at least one pivotal Phase III trial, will require us to obtain additional funding. Our current intent is to seek the funding for future CPP-109 trials from future sales of our securities, and grants from NIDA (as described above) or other government agencies, and/or from potential strategic partnerships. There can be no assurance that any such funding will be available on terms that are acceptable to us, or at all. Further, there can be no assurance that future clinical trials of CPP-109 evaluating its efficacy for use in the treatment of cocaine or methamphetamine addiction will be successful or that we will ever be able to commercialize CPP-109 for the treatment of cocaine and/or methamphetamine addiction.

Clinical studies of vigabatrin undertaken by others

The primary focus of our product development efforts is on our clinical trials. However, we have in the past supported and will continue in the future to support clinical studies by academic investigators of the use of vigabatrin for the treatment of addiction, including members of our Scientific Advisory Board and the academic institutions with which they are affiliated. In some cases, we may provide unrestricted sponsorship funds for such studies. In other cases, we may provide alternative assistance to the investigator. We expect to continue to support investigator studies in the future to the extent that they meet criteria acceptable to us. Such criteria include research on the use of vigabatrin to treat addiction, to assist investigators in designing their studies so that such studies are most appropriately conducted and, to the extent possible, to make sure that these investigator studies potentially complement, and do not adversely impact our activities.

A study describing the positive results obtained in an investigator-initiated, Phase II, randomized double-blind, placebo-controlled trial conducted in Mexico in 2007 was published in the November 2009 issue of The American Journal of Psychiatry, a world leading peer-reviewed medical journal. The paper, entitled Randomized, Double-Blind, Placebo-Controlled Trial of Vigabatrin for the Treatment of Cocaine Dependence in Mexican Parolees, was authored by Jonathan D. Brodie, M.D., Ph.D., Brady G. Case, M.D., Emilia Figueroa, M.D., Stephen L. Dewey, Ph.D., James A. Robinson, M.Ed., Joseph A. Wanderling, M.A. and Eugene M. Laska, Ph.D. The trial provided evidence that vigabatrin may be effective in the treatment of cocaine addiction. One hundred and three (103) community-based, non-hospitalized cocaine addicted individuals participated in this trial conducted at a single site in Mexico City, Mexico. Of the 103 participants, 50 were treated with vigabatrin and 53 received placebo. A total of 53 subjects completed the 9 week treatment period. Twice-weekly urine screening tests were obtained from each subject in order to objectively evaluate each subject s cocaine use. All subjects were also offered one group counseling session per week. The primary outcome measure of the trial was no positive urine tests for cocaine use during the last three weeks of the nine-week trial.

Eighteen subjects fulfilled the criteria for the primary outcome measure. Fourteen of the 50 subjects treated with vigabatrin (28.0%) versus four of the 53 subjects treated with placebo (7.5%) met the primary outcome measure. This result was statistically significant with a p-value of 0.009 (A P-value represents the probability that, if the test is repeated, a similar observation will be made. Generally, a P-value of less than 0.05 indicates that the different results between treatment groups was unlikely to be random). Additional findings included increased retention and self-reported abstinence from alcohol favoring vigabatrin.

We have been advised that one of our clinical collaborators has recently 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 will be 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 North Shore Long Island Jewish Health System (LIJ) and by Jonathan D. Brodie, M.D., Ph.D. from the Department of Psychiatry at New York University s School of Medicine. Opioid abuse is one of the many substance addiction indications covered under our exclusive license of Brookhaven s vigabatrin use patent portfolio. We will supply study materials (CPP-109) to facilitate this study.

We continue to have discussions with noted addiction researchers who are actively pursuing funding or conducting research on CPP-109 in areas including:

(i) Alcohol and cocaine co-addiction treatment;

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(ii) Nicotine dependence; and

(iii) Additional studies to further elucidate CPP-109 s mechanism of action for treating addiction.

CPP-115 for the Treatment of Epilepsy and Addiction

In August 2009, we licensed the exclusive worldwide rights to commercialize certain composition of matter patents relating to a new class of novel GABA aminotransferase inhibitors and derivatives of vigabatrin. We intend to develop these compounds for a broad range of central nervous system illnesses that could benefit from the inhibition of GABA aminotransferase. CPP-115 is our lead compound from this group of composition of matter patents.

CPP-115 works by the same mechanism of action as CPP-109; the inhibition of GABA aminotransferase, which leads to increased brain GABA levels that reduce epileptogenesis or dampen the addiction reinforcing dopamine surge. We believe that CPP-115 and vigabatrin are the only two GABA aminotransferase inhibitors, either under development or marketed at this time, and that our patent estates for CPP-109 and CPP-115 are the only existing, currently in force, intellectual property rights for drugs with this primary mode of action.

CPP-115 has been shown to be at least 200 times more potent than CPP-109, our version of vigabatrin, in both in-vitro and animal model studies. The increased potency could enable the development of superior or alternative dosage forms and routes of administration compared with the marketed version of vigabatrin, Sabril® (which is marketed in the U.S. by Lundbeck Inc. for infantile spasms and refractory complex partial seizures that have failed to be effectively treated by several pharmacological treatments). It may also have superior specificity to GABA aminotransferase and, possibly, a better side effect profile (e.g. less visual field defects) compared with Sabril®.

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

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

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

We will complete other safety evaluations including genotoxicity and cardiac safety.

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

By the end of the third quarter of 2010, most of the safety studies described above, including results from the first assessments of the comparative retinotoxicity of CPP-115 versus vigabatrin, are expected to be completed. Furthermore, during that same period, we expect to complete the above-described animal model efficacy screening of CPP-115 as a potential treatment for both epilepsy and drug addiction. We further expect data from the above-described non-clinical studies, including additional evaluations after 90 days of dosing of visual safety with retinal histopathology, clinical chemistry, hematology, urinalysis and any necessary organ histopathology, will be completed by the end of the first quarter of 2011. We expect to spend approximately $1.2 million to complete all the non-clinical studies described herein. There can be no assurance that CPP-115 will ultimately be proven to be safe and effective to treat epilepsy or that CPP-115 will be determined not to have the visual field defects side effect profile of vigabatrin.

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We will require substantial additional funding to develop CPP-115. Based on the results of our currently ongoing studies of CPP-115, as described above, we hope to identify a strategic partner to work with us in the development of CPP-115. We expect that development of CPP-115 to get to the point where an IND can be filed will require approximately $2.8 million (in addition to the $1.2 million referred to above) and that Phase I studies of CPP-115 would require additional funding of approximately $3.0 million. Subject to the availability of funding, we hope to complete a Phase I study of CPP-115 during the first half of 2012. There can be no assurance that we will obtain the funding for future CPP-115 trials or that any future trials of CPP-115 that we undertake will be successful.

Disease Background and Our Market Opportunity

We have identified two initial market opportunities that can be exploited by pharmacotherapies that inhibit GABA-aminotransferase (GABA-AT): epilepsy and drug addiction.

Research has established that neurochemical signals responsible for craving and addiction can be modulated through a GABA-ergic mechanism. We have been developing CPP-109 for the treatment of drug addiction and will also be evaluating CPP-115 for potential use in the treatment of drug addiction. Due to the differing stages of development for these two drugs, we expect CPP-109 to be approved as the first drug to treat cocaine addiction with CPP-115 following later for both epilepsy and then cocaine, methamphetamine and/or other forms of drug addiction.

Epilepsy is not a neurological disorder with a single underlying cause, but is instead a complex category of neurological disorders of varied neurological origin exhibiting a large spectrum of severities. As such, there are a large number of therapies spanning many pharmacological mechanisms of actions, certain medical devices, and in extreme cases, brain surgery. We will develop a new drug, CPP-115, to reduce neuronal excitability through a GABA-ergic mechanism, analogous to vigabatrin.

Drug Addiction

Historically, individuals suffering from addiction have been treated primarily through behavioral modification and therapy. These treatments have shown a high rate of relapse. According to a survey conducted by the Substance and Mental Health Services Agency (SAMHSA), treatment completion rates in 2000 for outpatient treatment were only 41% for alcohol and 21% for cocaine. For the treatment of cocaine dependence, there was a one-year relapse rate of 69% after 90 days or less of outpatient treatment and 80% after 90 days or less of long-term residential treatment. We believe that a pharmacological treatment for cocaine addiction and/or other stimulant addictions, including methamphetamine, would complement and significantly improve the effectiveness of counseling programs.

Despite the significant public health implications, there are very few therapies approved for the treatment of addiction, either in the United States or in the rest of the world. Further, there are no therapies currently approved for stimulant addiction. We believe that currently approved drugs for addiction treatment, as well as compounds under development (other than CPP-109 and CPP-115), are subject to the following limitations:

no single compound has broad applicability for treatment of multiple addictions;

many of these compounds are receptor active, which means they have drug-like effects themselves and have the potential for abuse or addiction;

increasing dosages over time may be required due to development of tolerance; and

they are often ineffective at eliminating drug cravings or responding to increasing levels of drug use.

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We believe that CPP-109 (and possibly CPP-115 as well) do not suffer from these limitations and therefore, if approved, CPP-109 and CPP-115 have the potential to become a widely prescribed, safe and effective treatment for cocaine, methamphetamine and other addictions.

Addictive drugs are used recreationally because of the transient, pleasurable effect they have on the user. Recent scientific evidence has established that drug abuse can interfere with the brain s normal balance of neurotransmitter release and reuptake, resulting in addiction. If this balance is not restored, addicted individuals, even after significant periods of abstinence, may be incapable of suppressing cravings or quitting through willpower alone, even with the assistance of professional counseling.

Cocaine binds to the dopamine reuptake transporter protein of the pre-synaptic neurons preventing the reuptake and eventual breakdown of dopamine, resulting in enhanced and prolonged stimulation of dopamine on post-synaptic receptors, causing a feeling of prolonged euphoria for the user.

Addiction to cocaine is caused by a neurological process called desensitization. Because the brain senses an unnaturally high level of dopamine, it responds by reducing the amount of dopamine released and the number of dopamine receptors created. Consequently, when the cocaine wears off, the user has a lower amount of dopamine and fewer functioning dopamine receptors, which results in a depressed mood. This desensitization process creates a lowering of mood each time the user takes more of the drug, causing the user to seek additional cocaine to restore normal feelings, and requiring the user to take an increasing amount of cocaine to achieve the same feeling of euphoria as before.

Addiction is a worldwide health problem that affects millions of people and has wide-ranging negative social consequences. In 2008, an estimated 20.1 million people in the United States aged 12 or over suffered from dependence on illicit drugs, according to the National Survey on Drug Use and Health, published by SAMHSA, which we refer to as the SAMHSA survey. According to the Office of National Drug Control Policy, costs of drug abuse to society were an estimated $180 billion in 2002 in the United States.

According to the SAMHSA survey, an estimated 1.9 million people had used cocaine in the month preceding the survey. Additionally, in 2008, approximately 722,000 people aged 12 or over had used cocaine for the first time within the preceding 12 months, an average of approximately 1,978 new users per day. In addition, approximately 663,000 patients received treatment for cocaine abuse in 2008. According to NIDA, there are no pharmacologic treatments for cocaine addiction currently approved for marketing by the FDA. We believe that other therapies being developed for the treatment of cocaine addiction, but not yet approved for marketing, suffer from the significant limitations discussed earlier which have not been exhibited to date by CPP-109 or CPP-115.

According to the SAMHSA survey, in 2008, 1.9 million people aged 12 or over took prescription pain relievers for non-medical purposes in the month preceding the survey. Further, approximately 17.3 million people aged 12 or over in the United States were classified as heavy drinkers. Additionally, there are approximately 15.2 million persons aged 12 or over who used marijuana in the month preceding the survey and approximately 947,000 persons sought treatment in 2008. Finally, obsessive-compulsive disorders such as binge eating patterns and compulsive gambling have been shown to have similar dopamine-related mechanisms of action to drug addiction and affect millions of persons in the United States and around the world.

Addiction is not only a U.S. health problem. In 2007, according to the United Nations Office on Drugs and Crime, there were between 4.3 million and 4.6 million users of cocaine and between 2.4 million and 3.1 million users of amphetamine-type stimulants between the ages of 15 and 64 across Europe who had used these drugs within the past year. We believe that the direct and indirect costs of cocaine and methamphetamine use are indicative of a significant global public health problem, representing a significant unmet medical need for which no adequate pharmaceutical therapies exist.

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Epilepsy

Epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behavior or sometimes convulsions, muscle spasms, and loss of consciousness. Epilepsy is a disorder with many possible causes. Anything that disturbs the normal pattern of neuron activity - from illness to brain damage to abnormal brain development, can lead to seizures. Epilepsy may develop because of an abnormality in brain wiring, an imbalance of nerve signaling chemicals called neurotransmitters, imbalance of sensitivity to neurotransmitters, or some combination of these factors. Having a seizure does not necessarily mean that a person has epilepsy. Only when a person has had two or more seizures is he or she considered to have epilepsy.

There have been many attempts to categorize seizures, based on both their causes and subtypes. The two main categories of seizures include partial seizures and generalized seizures. Generalized seizures are more common in children under the age of 10; afterwards more than half of all new cases of epilepsy will have partial seizures. Partial seizures are those that begin in a focal or discreet area of the brain. This type can be further subdivided into, simple partial and complex partial.

In simple partial seizures, no change in consciousness occurs. Patients may experience weakness, numbness, and unusual smells or tastes. Twitching of the muscles or limbs, turning the head to the side, paralysis, visual changes, or vertigo may occur. When motor symptoms spread slowly from one part of the body to another, this epileptic march has been termed Jacksonian epilepsy.

In complex partial seizures, consciousness is altered during the event. Patients may have some symptoms similar to those in simple partial seizures but have some change in their ability to interact with the environment. Patients may exhibit automatisms (automatic repetitive behavior) such as walking in a circle, sitting and standing, or smacking their lips together. Often accompanying these symptoms are the presence of unusual thoughts, such as the feeling of déjà vu, uncontrollable laughing, fear, visual hallucinations, and experiencing unusual unpleasant odors. These symptoms are thought to be caused by abnormal discharges in the temporal lobe.

Generalized seizures involve larger areas of the brain and from the onset often involve both hemispheres (sides). They are further divided into many subtypes. The more common include tonic-clonic (grand mal) and absence (petit mal). Grand mal is what most people associate with seizures. Specific movements of the arms and legs and/or the face may occur with loss of consciousness. A yell or cry often precedes the loss of consciousness. Prior to this, patients may have an aura (an unusual feeling that often warns the patient that they are about to have a seizure). The person will abruptly fall and begin to have jerking movements of their body and head. Drooling, biting of the tongue and incontinence of urine may occur. When the jerking movements stop, the patient may remain unconscious for a period of time. The seizure usually lasts 5 to 20 minutes. They often awaken confused and may sleep for a period of time. The patients may experience prolonged weakness after the event.

According to the Epilepsy Foundation, there are about 2.5 million epilespy patients in the United States, with approximately 180,000 new cases diagnosed in the U.S. each year. Worldwide, 50 million people are estimated to have epilepsy. The incidence of epilepsy appears to depend somewhat on the age of the individual. The risk of epilepsy from birth through age 20 is approximately 1%. Within this group, incidence is highest during the first year of life and increases somewhat at the onset of puberty. From age 20 to 55 it decreases again, but increases after age 55.

The main treatment options for people with epilepsy are anticonvulsant medications, surgery and vagus nerve stimulation (VNS). A ketogenic diet is also a treatment option for some children. Certain medical devices or surgery may be effective for some patients, but invasive treatment options carry the risk of bleeding, infection or other complications, are generally reserved for a small subset of severely ill patients and are usually used only after drug therapy has failed. Despite the variety of existing drugs, implantable medical devices and surgeries for epilepsy, approximately one-third of the epilepsy patient population remains resistant to currently available medical treatment according to *Brain*, a journal of neurology.

Many drugs are available to treat epilepsy, several of which have only recently been released. Older, classic medications used to treat epilepsy include: Dilantin, Phenobarbital, Tegretol, Mysoline, Zarontin, Depakene, Depakote, Depakote ER, Valium and tranquilizers such as Tranxene and Klonopin. Newer drugs to treat epilepsy include: Felbatol, Gabitril, Keppra, Lamictal, Lyrica®, Neurontin, Topamax, Trileptal and Zonegran.These drugs are believed to work through a variety of mechanisms, including inhibition of sodium ion channels and the enhancement of GABA.

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In general, for a given type of epilepsy there are only minor differences among appropriate drugs. The choice is most often based on other factors specific to each patient, such as which side effects can be tolerated by the patient, other illnesses they may have, and which delivery method is acceptable. Each of these drugs is associated with side effects, such as dizziness, drowsiness, fatigue, nausea and depression as well as mood, attention and sleeping disorders, which limit their utility in the treatment of many patients. Many patients require combination therapy to adequately control seizure activity. Although the different types of epilepsy vary greatly, in general, medications can only control seizures in about two-thirds of patients.

The drug with which treatment is best initiated depends on the type of seizures to be treated. The dose of the selected drug is gradually increased until seizures are controlled or side effects prevent further increases. If seizures continue despite treatment at the maximal tolerated dose, a second drug is added and the dose increased depending on tolerance; the first drug is then gradually withdrawn.

In treatment of partial and secondarily generalized tonic-clonic seizures, the success rate is higher with Tegretol, Dilantin, or Depakote than with Luminal or Mysoline. Neurontin, Topamax, Lamictal, Trileptal, Keppra, and Zonegran are newer antiepileptic drugs that are effective for partial or secondarily generalized seizures. Felbatol is also effective for such seizures but, because it may cause aplastic anemia or fulminant hepatic failure, is used only in selected patients unresponsive to other measures. Gabitril is another adjunctive agent for partial seizures. In most patients with seizures of a single type, satisfactory control can be achieved with a single anticonvulsant drug. Treatment with two drugs may further reduce seizure frequency or severity, but usually at the cost of more side effects.

Vigabatrin is used in over 30 countries for the treatment of complex partial seizures in patients who have failed several treatments, and West Syndrome. On August 21, 2009, Sabril® was approved for these indications in the United States. In general, GABA-AT inhibitors, like vigabatrin, are an effective treatment for epilepsies of the myoclonic variety. Although vigabatrin (CPP-109) is one of the drugs in our development pipeline, there are no plans to develop CPP-109 for the treatment of epilepsy and to directly compete against Sabril® for that use at this time.

CPP-115, like vigabatrin (CPP-109), is a GABA-AT inhibitor and we will be developing it for both epilepsy (specifically, complex partial seizures and West Syndrome) and drug addiction (cocaine addition).

With the exception of the visual field defects, vigabatrin is a relatively well tolerated drug. However, there can be no assurance that CPP-115 will be equally well tolerated or that it will exhibit fewer visual field defects (as we have hypothesized) than vigabatrin. The side effect profile of CPP-115 will play a very large role in the ultimate acceptance and marketing of the drug. Due to these unknowns, it would be speculative to provide estimates regarding the potential market size for CPP-115.

We are pursuing CPP-115 for the treatment of epilepsy and this drug, like vigabatrin, is a GABA-AT inhibitor. There is data regarding vigabatrin, which works by the same mechanism as CPP-115, which indicates that the inhibition of GABA-AT is an effective way to treat myoclonic seizure activity, particularly complex partial seizures and West Syndrome. However, there are other mechanisms of action shared by other successful epilepsy pharmacotherapies that include blockade or modulation of sodium, potassium, or calcium channels, GABA agonists, antagonists, and modulators, GABA transporter inhibitors and modulators, a2d ligands, and SV2a ligands, so there can be no assurance that one of the current therapies or even a new therapy that works by one, or more, of these alternate mechanism could be found to be effective for one, or more, of CPP-115 s potential market segments.

Intellectual Property Rights

Protection of our intellectual property and proprietary technology is a strategic priority for our business. We rely on a combination of patent, trademark, copyright and trade secret laws along with institutional know-how and continuing technological advancement, to develop and maintain our competitive position. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing the proprietary rights of others, and prevent others from infringing our proprietary rights, is crucial to our continued success. We will be able to protect our products and technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, trademarks or copyrights, or are effectively maintained as trade secrets, know-how or other proprietary information. See Item 1A., Risk Factors Risks Related to Our Intellectual Property.

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Brookhaven License Agreement

We have been granted an exclusive, worldwide license from Brookhaven to nine patents relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions, with expiration dates for the issued patents between 2018 and 2023. Additionally, we received approval from the European Union (EU) with respect to one of our principal patents, which has allowed us to seek registration for this patent in eighteen EU member states.

The license agreement, which is dated as of April 30, 2006 and which supersedes a previous license agreement that was entered into in 2002, grants us an exclusive worldwide license, including the right to sublicense, to make, have made, use, and/or sell licensed products and practice the licensed process with respect to the medical application in humans of vigabatrin under certain patent rights. These rights are subject to the United States government s rights to practice the licensed process for its own use. The purpose of this agreement is to permit us to commercialize products upon the receipt of government regulatory approval for the use of vigabatrin for the treatment of human drug addiction and addiction-related behavior. In exchange for such rights, we paid Brookhaven an initial fee of $50,000 and have agreed to pay a fee of $100,000 in the year of NDA approval for CPP-109, $250,000 in each of the second and third years following approval, and $500,000 per year thereafter until the last patent expires. In addition, upon the filing of an NDA for CPP-109 and the approval of an NDA for CPP-109, we will be obligated to reimburse Brookhaven for certain expenses it incurs in connection with the filing, prosecution and maintenance of all patents and patent applications included in the patent rights we have licensed.

We have also agreed to consult with Brookhaven on at least a quarterly basis with respect to drug development steps taken and progress made toward the objective of gaining marketing approval from the FDA for any licensed product from the beginning of our agreement through the date the FDA grants us its approval to sell any licensed product. We have also agreed to have in effect and maintain a liability insurance policy in an amount of at least $1,000,000 to cover claims arising out of the manufacture and use of licensed products and such policy shall designate Brookhaven as an additional insured. We have agreed to increase and maintain, throughout the life of the agreement and for five years after its termination, liability insurance coverage in the amount of at least $5,000,000 upon acceptance by the FDA of our application to commence Phase III clinical trials involving licensed products. Our agreement with Brookhaven expires simultaneously with the expiration of the last to expire patent it has licensed to us.

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses as of December 31, 2009 was approximately $1.2 million. We believe that we are only contingently liable to Brookhaven for approximately $166,000, and we have advised Brookhaven that we are disputing their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until we submit an NDA for CPP-109.

Northwestern University License Agreement

On August 27, 2009, we entered into a license agreement with Northwestern University under which we acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered and patented by Northwestern University. Under the terms of the license agreement, Northwestern University granted us an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. We have designated the lead compound to be developed under this license as CPP-115.

We believe that the newly licensed compounds are the only known GABA aminotransferase inhibitors in existence or in development other than vigabatrin. We also believe that the newly licensed compounds may be significantly more potent than vigabatrin, and due to subtle differences in the biochemistry of the inactivation of GABA-AT, they may also exhibit less visual side effects than vigabatrin. We plan to seek to develop these compounds for the treatment of several indications, including epilepsy and drug addiction. However, these compounds are at a very early stage of development and there can be no assurance as to whether these new compounds will ever be determined to be safe and effective.

Under our license agreement with Northwestern, we will be responsible for continued research and development of any resulting product candidates. We have the right to terminate the agreement in whole or in part after August 27, 2012, upon written notice. As of December 31, 2009, we have paid Northwestern University upfront payments aggregating $35,000 and we are obligated to pay certain additional fees, $32,871 in expenses, and milestone payments in future years relating to our clinical development activities under this license or payable upon passage of time. The first milestone payment of $50,000 is due on or before August 27, 2012. We are also obligated to pay Northwestern royalties on any products resulting from the license agreement.

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Manufacturing and Marketing

CPP-109

Since the composition of matter patent for vigabatrin has previously expired, we will not, to our knowledge, violate any patents if we commercialize CPP-109. We have entered into a new agreement to formulate and manufacture CPP-109 for use in our future clinical trials. We also intend in the future to manufacture commercial quantities of CPP-109 on a contract basis, if the FDA approves an NDA for CPP-109.

Our supplier has agreed to manufacture CPP-109 for us in quantities that we believe will be sufficient to conduct our future U.S. Phase II clinical trials evaluating CPP-109 for the treatment of cocaine addiction along with a matching placebo. Our contract contains no renewal provisions. Pursuant to our agreement, we have agreed to indemnify our supplier against: (i) costs relating to any potential injury suffered by persons who take CPP-109 that our supplier manufactures; (ii) any losses arising from our negligence in labeling, handling or storing CPP-109; (iii) any specifications which we give them that are incorrect or do not meet FDA-approved standards; (iv) any misrepresentation or breach by us of the agreement; and (v) any patent infringement claims that may result from the use of CPP-109.

Further, our supplier has agreed to indemnify us against any losses related to its negligence or willful misconduct in the manufacture of CPP-109; any misrepresentation by our supplier in the agreement; and any claims by third parties that our supplier infringed or misappropriated any intellectual property in its manufacture of CPP-109.

Any NDA that we file for CPP-109 will require a manufacturing plan. If the manufacturing plan and data are insufficient, the NDA will not be approved. Further, even if we receive approval of an NDA for CPP-109, if our manufacturer does not follow good manufacturing practices, or cGMP, in the manufacture of our products, it may delay product launches or shipments or adversely affect our business.

Since we intend to contract with a third party to manufacture our products, if the FDA approves an NDA for CPP-109, our contract manufacturer will be required to comply with all applicable environmental laws and regulations that affect the manufacturing process. As a result, we do not believe that we will have any significant exposure to environmental issues.

CPP-115

We have entered into a contract to manufacture the active pharmaceutical ingredient (API) sufficient to meet the needs of our initial non-clinical program described above. We have taken steps to insure that the amount of API ordered in this contract is sufficient for our initial needs, but there is no absolute assurance of this.

We have no plans at this time to build or acquire the manufacturing capability needed to prepare either the CPP-115 API or CPP-115 product on a commercial scale. We expect at this time that these materials will be prepared by a contractor with suitable capabilities for these tasks and that we will enter into appropriate supply agreements with these contractors at appropriate times in the development and commercialization of this product. There are no plans at this time to enter into such agreements. Further, the contractors selected would have to be inspected by the FDA and found in substantial compliance with federal regulations in order for an NDA for CPP-115 to be approved and there can be no assurance that the contractors we select in the future would pass such an inspection.

Marketing

We do not have any in-house marketing, distribution, or production capabilities. In order to generate sales of CPP-109, CPP-115 or any other product candidates we may develop, we must either acquire or develop an internal marketing force with technical expertise and with supporting documentation capabilities, or make arrangements with third parties to perform these services for us. The acquisition and development of a marketing and distribution infrastructure will require substantial resources, which may divert the attention of our management and key personnel away from our product development efforts. To the extent that we enter into marketing and distribution arrangements with third parties, our revenues will depend on the efforts of others. If we fail to enter into such agreements, or if we fail to develop our own marketing and distribution channels, we would experience delays in product sales and incur increased costs.

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Competition

The biotechnology and pharmaceutical industries are highly competitive. In particular, competition for the development and marketing of therapies to treat epilepsy and addictive substances such as cocaine and methamphetamine is intense and expected to increase. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approval of products, and manufacturing and marketing products. We compete against pharmaceutical companies that are developing or currently marketing therapies for addictive substances. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of substance abuse treatments, technologies and processes that are, or in the future may be, the basis for competitive commercial products. While we believe that our product candidates will offer advantages over many of the currently available competing therapies, our business could be negatively impacted if our competitors present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payers.

CPP-109

While there are no currently approved therapies for cocaine or methamphetamine addiction, we are aware of certain other therapies that are under development. These can be broadly classified into four groups:

Cocaine-mimetics. The mechanism of action of these drugs is similar to cocaine. None of these approaches have, to our knowledge, shown any efficacy.

Cocaine-antagonists. These compounds are intended to selectively target GABA, moderating dopamine levels in the brain. We believe that many of these compounds are receptor active and require increasing dosing over time. None of these compounds are presently approved for marketing to treat addiction.

Dopamine ß-hydroxylase inhibitors. These compounds block the enzyme that converts dopamine to norepinephrine, which raises dopamine levels in the central nervous system (CNS). We believe that this strategy is designed to address withdrawal, rather than craving and euphoria. This approach, to our knowledge, has yet to show any efficacy.

Addiction Vaccines. These vaccines are designed to block cocaine or methamphetamine transport into the brain. They are not broadly immunogenic in humans to date and require several injections. They also do not address issues relating to craving or other behaviors associated with cocaine or methamphetamine addiction. We also believe that they can be overwhelmed by increasing dosages.

On August 21, 2009, the FDA approved two NDAs for Sabril® for the treatment of infantile spasms and as an adjunctive (add-on) therapy for adult patients with refractory complex partial seizures, who have failed several treatments. The NDAs are for different formulations of Sabril®, and both NDAs are held by Lundbeck Inc. (Lundbeck). Because of the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) program and is only available through a special restricted distribution program approved by the FDA.

We believe that any attempted commercialization by Lundbeck of Sabril® for the treatment of cocaine and/or methamphetamine addiction would violate our licensed patents, and we have advised Lundbeck of our belief in that regard. We would vigorously assert our intellectual property rights if Lundbeck sought to market Sabril® for the treatment of any addictive or obsessive compulsive conditions covered by our patents. There can be no assurance we would be successful in that regard.

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CPP-115 For Epilepsy

Epilepsy represents a large and growing market opportunity. Sales of drugs currently marketed for the treatment of epilepsy totaled approximately $8.9 billion in the United States during 2006, according to IMS Health. These sales included prescriptions of these drugs for both epilepsy and other indications, including neuropathic pain.

The market for epilepsy treatments is highly competitive. Large pharmaceutical companies, including Pfizer (Neurontin®, Lyrica®, Dilantin®, Zarontin®), J&J (Topamax®), UCB (Keppra®), Abbott (Depakote®), GSK (Lamictal®), Roche (Klonopin®), and Novartis (Trileptal®) sell, or are developing, epilepsy therapies. However, as stated earlier, approximately one-third of all epilepsy patients are not readily helped by any current known epilepsy treatments.

It is difficult to determine sales of products specifically for epilepsy as many of these products are used in other indications such as neuropathy, pain, migraine, dementia, and bipolar disorders. However, according to IMS Health, in 2004, 80% of epilepsy cases were treated by Tegretol®, Depakote®, Dilantin® or Emeside/Zarontin, either as monotherapy or in combination (i.e. adjunctive treatment). Sales information for epilepsy drugs (including all uses of each drug) is included in the following table:

Drug	Manufacturer	Most Recent Sales Year Data	Annual Sales	Comments
Tegretol XR®	Novartis	2008	$451 million worldwide	Increased by 9% over 2007
Depakote®	Abbott	2008	$130 million worldwide	Patent expired in 2008, so generic competition began in the middle of the year
Lamictal®	GSK	2008	$1.34 billion worldwide	U.S. patent expired in 2008 and sales decreased 22% from 2007, however an extended release version is in development and in 2008, Lamictal® was approved in Japan as an anti-epileptic drug.
Trileptal®	Novartis	2008	$332 million	Decreased by 52%

			worldwide	since 2007
Keppra®	UCB Pharma	2008	$1.79 billion worldwide	Increased from $1.45 billion in 2007, but lost U.S. exclusivity in 2008; however, an extended release version is in the pipeline, and UCB has filed for additional pediatric indications
Sabril®	Sanofi-Aventis	2007	$32 million worldwide, ex U.S.	Approved in U.S. for infantile spasms and refractory and complex partial seizures in 2009.

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Government Regulation

The FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically begins with pre-clinical laboratory and animal tests and the submission to the FDA of a notice of claimed investigational exemption or an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the pre-clinical tests must comply with federal regulations and requirements including good laboratory practices. The results of pre-clinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long term pre-clinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials must be conducted in compliance with federal regulations, good clinical practices or GCP, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

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Clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence on effectiveness. Phase II usually involves trials in a limited patient population, to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all pre-clinical, clinical and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it often follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provides substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues an approvable letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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The Hatch-Waxman Act

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a full or stand-alone NDA, is governed by Section 505(b)(1) of the FDC Act. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of pre-clinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. We intend to submit a Section 505(b)(1) application for CPP-109 for cocaine addiction.

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of a 505(b)(2) application or an abbreviated new drug application, or ANDA.

An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. These applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a Paragraph 4 certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph 4 certification to the FDA, the applicant must also send notice of the Paragraph 4 certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph 4 certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph 4 certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years of marketing exclusivity following approval of a drug containing no previously approved active ingredients (or salts and esters thereof), during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph 4 challenge to a listed patent, in which case the submission may be made four years following the original product approval.

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A 505(b)(2) NDA enables the applicant to rely, in part, on the safety and efficacy data of an existing product, or published literature, in support of its application. 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon certain pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph 4 certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

In August 2009, the FDA approved Lundbeck s NDAs for Sabril® (vigabatrin) tablets for the treatment of refractory complex partial seizures in patients who have failed several treatments and for sachets for the treatment of infantile spasms (West s Syndrome). The NDAs were granted the five year exclusivity described above and therefore that exclusivity will not be available to CPP-109 upon approval at a later date.

Federal law provides for the extension of a patent s expiration date for up to five years if that patent is listed in the FDA s Orange Book, was not previously extended for any other approved product, and if that patent covers a product containing an active ingredient that was not previously approved in any other product. Since the FDA approved both of Lundbeck s NDAs (described previously), any patents listed in the Orange Book for CPP-109 would not be eligible for a patent term extension due to the fact that vigabatrin will have been previously approved in Lundbeck s NDAs. For the purposes of implementing this federal law, a separate enantiomer of a previously approved chemical entity is considered a new chemical entity. Therefore, should Catalyst pursue the development of a next generation product containing *S*-vigabatrin and list a patent in the Orange Book, that patent would be eligible for up to five years of patent term extension. Furthermore, CPP-115 is a new chemical entity and the patents we have licensed would be eligible for extension under this law.

Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug for the same new dosage form, route of administration or combination, or new use. Non-patent exclusivity under the Hatch-Waxman Act does not prevent a competitor from submitting, or the FDA from approving, a full 501(b)(1) NDA. Furthermore, this three year period of exclusivity does not prevent an applicant from filing an ANDA or 505(b)(2) application prior to the expiration of the exclusivity, and in which the applicant is requesting approval after the expiration of this three year period of exclusivity. CPP-109 is expected to be eligible for three year s exclusivity.

Federal law provides for a period of seven years of exclusivity as an orphan drug for the first drug containing a particular active ingredient approved for a particular orphan indication . An orphan indication is an indication for a disease observed in less than 200,000 people in the United States. Sabril® was granted orphan drug exclusivity for the treatment of West Syndrome and it is expected that CPP-115 would be granted orphan drug designation for the treatment of the same condition when the FDA and/or international regulatory agencies have been satisfied that we have produced a sufficient quantity of information to demonstrate that CPP-115 may be effective for treating this indication.

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Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. The FDA may also require as a condition of approval for drugs with significant safety issues, implementation of a Risk Evaluation and Mitigation Strategy (REMS). Such strategy may include Black Box warnings, limitations on promotion and distribution, and periodic testing of patients on the drug to monitor whether administration of the drug continues to be safe and effective for the patient.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase IV testing, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Fast Track Designation

Under the fast track program, the sponsor of a new drug candidate intended for the treatment of a serious or life-threatening condition and which demonstrates the potential to address unmet medical needs for the condition may request the FDA to designate the drug candidate as a fast track drug concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor s request. Once the FDA designates a drug as a fast track product, it is required to facilitate the development and expedite the review of that drug.

In addition to other benefits such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track drug s NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is submitted, if the drug candidate is intended for the treatment, diagnosis or prevention of a serious or life-threatening condition, demonstrates the potential to address an unmet medical need, or provides a significant improvement compared to marketed drugs.

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Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

Health Care Reform

In March 2010, Congress passed legislation to reform the health-care system, including the cost, delivery and availability of pharmaceutical products to patients. This legislation was later signed into law by President Obama. It is unknown what effect, if any, this legislation will have on our business. Prior stimulus legislation passed by Congress and President Obama in an attempt to help the economy included funding for research projects through the National Institute of Health, and there are ongoing efforts to pass further stimulus legislation. There can be no assurance, any further efforts to pass additional stimulus legislation may help companies like us or our competitors obtain the funding for some of our studies.

Foreign regulations

Any marketing of CPP-109 or CPP-115 outside of the United States will be contingent on the receipt of approval from various regulatory authorities. Foreign regulatory systems, which vary from country to country, generally include risks similar to those associated with FDA regulation in the U.S. Under the European Union regulatory system, applications for drug approval may be submitted either in a centralized or decentralized manner. Under the centralized procedure, a single application to the European Medicines Agency leads to an approval granted by the European Commission which permits marketing of the product throughout the European Union. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not comply with requirements for the centralized procedure. Under the decentralized procedure, the holders of national marketing authorization in one of the countries within the European Union may submit further applications to other countries within the European Union, who will be requested to recognize the original authorization based on an assessment report provided by the country in which marketing authorization is held.

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As with FDA approval, we may not be able to secure regulatory approvals in certain European countries in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements would apply to any products that are approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

Outside of the European Union, we are subject to widely varying foreign obligations, which may be quite different from those of the FDA, governing clinical studies, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been received, we must obtain separate approval for products by the comparable regulatory authorities of foreign countries prior to the commencement of marketing CPP-109 in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are significant restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

Our Employees

As of March 26, 2010, we had six employees. We also utilize the services of consultants including a member of our Board of Directors, our Chief Medical Officer and several members of our Scientific Advisory Board. None of our employees are covered by a collective bargaining agreement. We believe our relationship with our employees and consultants is good.

Our Scientific Advisory Board

We rely on prominent scientists and physicians to advise us on our pipeline of drug candidates and the clinical development of CPP-109 and CPP-115. All of our advisors are employed by organizations other than ours and may have commitments to or consulting or advisory agreements with other entities that may limit their availability to us. Our Scientific Advisory Board currently consists of the following members:

Stephen L. Dewey, Ph.D. serves as Chairman of our Scientific Advisory Board. Dr. Dewey, a former Senior Scientist at Brookhaven National Laboratory, is now the Head of the Center for Behavioral and Molecular Imaging at the Feinstein Institute for Medical Research at the North Shore-LIJ Health System. Dr. Dewey is a recognized authority in positron emission tomography, which uses certain compounds to visualize and quantify biochemical processes as well as the distribution and movement of drugs in the living human and animal body. Dr. Dewey was with Brookhaven since 1986, serving as Assistant Scientist, Associate Scientist, Scientist, Tenured Scientist and Senior Scientist. Dr. Dewey recently moved his entire research program to the Feinstein Institute for Medical Research. Dr. Dewey is a Professor of Molecular Medicine at the Hofstra University School of Medicine as well as a Research Professor of Psychiatry at the New York University School of Medicine and an Adjunct Professor of Neurobiology and Behavior and Cellular and Molecular Pharmacology at Stony Brook University. Dr. Dewey has been developing a novel approach to treating addiction and is devoted to research within this area. Dr. Dewey is a co-inventor of Brookhaven s patents for substance addiction, including Brookhaven s patents covering the use of vigabatrin to treat addiction.

Jonathan Brodie, Ph.D., M.D. is the Marvin Stern Professor of Psychiatry at New York University School of Medicine. Dr. Brodie completed his B.S. in Chemistry as a Ford Foundation Scholar and his Ph.D. in Physiological Chemistry (Organic Chemistry minor) at the University of Wisconsin-Madison. He was a National Institute of Health, or NIH, postdoctoral Fellow in Biochemistry at Scripps Clinic and Research Foundation and a tenured Associate Professor of Biochemistry at the School of Medicine at SUNY at Buffalo. He then received his M.D. at New York University School of Medicine and joined the faculty after completing his residency in psychiatry at NYU/ Bellevue Medical Center. He was a member of the Promotions and Tenure Committee of the School of Medicine as well as a member of the Executive Advisory Committee of the General Clinical Research Center and the Protocol Review Committee of the Center for Advanced Brain Imaging (CABI) of Nathan Kline Institute. For 15 years, he was the NYU Director of the Brookhaven National Laboratory/ NYUSOM collaboration investigating the use of positron emitters and PET in neuroscience and psychiatry. He also served as Interim Chairman of the Department of Psychiatry at the NYU School of Medicine. Additionally, Dr. Brodie serves as a psychopharmacology preceptor to psychiatry residents. As a clinician, he treats patients in general issues of adult psychiatry including anxiety and depression. Dr. Brodie is a co-inventor of Brookhaven s patents for substance addiction, including Brookhaven s patents covering the use of vigabatrin to treat addiction.

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Donald R. Jasinski, M.D. is Chief of the Center for Chemical Dependence at Johns Hopkins Bayview Medical Center in Baltimore, Maryland and Professor of Medicine John Hopkins University School of Medicine. Dr. Jasinski received his medical degree from the University of Illinois School of Medicine. After receiving his degree, Dr. Jasinski worked at the U.S. Public Health Service at the Addiction Research Center in Kentucky, which was the first national laboratory set up to deal with narcotics and their effects. Dr. Jasinski has pioneered the use of buprenorphine to treat opioid dependence. Buprenorphine, which was developed as a pain reliever for cancer patients, is now seen by many in the medical community as the best drug on the market to treat patients who are addicted to heroin.

Robert D. Fechtner, M.D. is Professor of Ophthalmology and Director, Glaucoma Division at the Institute of Ophthalmology and Visual Science and chair of the Institutional Review Board UMDNJ New Jersey Medical School, Newark, New Jersey. Dr. Fechtner received his B.S. in Biomedical Science and his medical degree from the University of Michigan School of Medicine. He completed his residency at Albert Einstein College of Medicine in New York. This was followed by a fellowship in glaucoma at the University of California, San Diego under a National Research Service Award from the National Institutes of Health. After several years on the faculty at University of Louisville, he joined the faculty at New Jersey Medical School. Dr. Fechtner has published over 100 scientific articles, abstracts and chapters.

Eugene Laska, Ph.D. is Professor of Psychiatry at the Department of Psychiatry at New York University Medical Center. Dr. Laska received a Ph.D. in Mathematics at New York University, and then completed a PHS Postdoctoral Fellowship at the Department of Statistics at Stanford University. Dr. Laska is the Director of the Statistical Sciences and Epidemiology Division of the Nathan Kline Institute for Psychiatric Research. Dr. Laska is also the Director of the WHO Collaborating Center for Research and Training in Mental Health Program Management, and has served as a consultant to large and small pharmaceutical companies in the areas of biostatistics and clinical trial design.

Thomas Kosten, M.D., is Waggoner Professor of Psychiatry and Neuroscience at Baylor College of Medicine and a former Professor and Chief of Psychiatry at Yale University and at the Veterans Administration (VA) Hospital in Connecticut. Dr. Kosten is also Research Director of the VA National Substance Use Disorders Quality Enhancement Research Initiative (QUERI) based at the Houston VA and the founder of the Division of Substance Abuse at Baylor, where he directs their NIH Medications Development Center for Substance Abuse. Dr. Kosten has been supported by a Research Scientist Award from the NIH since 1987 and has served on national and international review groups for medications development in substance abuse. Dr. Kosten is the founding Vice Chair for Added Qualifications in Addiction Psychiatry of the American Board of Psychiatry and Neurology. He is a Distinguished Fellow in the American Psychiatric Association and fellow of the American College of Neuropsychopharmocology, Past President of the American Academy of Addiction Psychiatry, and President of the College on Problems of Drug Dependence. He has several major awards for clinical research, and is editor of two major journals in substance abuse and has been on the American Journal of Psychiatry board. His recent work includes serving on the National Academy of Sciences Institute of Medicine committee on vaccines for substance abuse. From his studies in substance dependence, post-traumatic stress disorder, and neuroimaging, he has published over 500 papers, books, and reviews. His neuroimaging research includes detecting and treating cocaine-induced cerebral perfusion defects, and using functional MRI to predict pharmacotherapy outcome. He has been involved in clinical trials involving such products as a vaccine to treat cocaine addiction, immunotherapy for hallucinogens, buprenorphine for opioid dependence, disulfiram for cocaine dependence, vasodilators for cocaine-induced cerebral perfusion defects, and combing medications with contingency management for opioid and cocaine dependence.

Richard A. Rawson, Ph.D. is a member of the University of California, Los Angeles Department of Psychology and is currently a Professor-in-Residence. He also serves as the Associate Director of the UCLA Integrated Substance Abuse Programs in the UCLA School of Medicine, where he oversees a portfolio of addiction research ranging from brain imaging studies to numerous clinical trials on pharmacological and psychosocial addiction treatments to the study of how new treatments are applied in the treatment system. During the past decade, Dr. Rawson has worked with the U.S. State Department on large substance abuse research and treatment projects, exporting U.S. technology and addiction science to Mexico, Thailand, Israel, Egypt, South Africa and the Palestinian Authority. He also directs the capacity building and training component of the United Nations International Network of Drug Treatment and Rehabilitation Resource Centers, and is currently principal investigator of the Pacific Southwest Addiction Technology Center and the NIDA Methamphetamine Clinical Trials Group. Dr. Rawson has published two books, 20 book chapters and over 175 professional papers. He also conducts more than 50 workshops annually, as well as paper presentations and training sessions. Dr. Rawson earned his Ph.D. in experimental psychology from the University of Vermont.

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Available Information

We make available free of charge on or through our internet website our Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (SEC). Our internet address is www.catalystpharma.com. The content on our website is not, nor should it be deemed to be, incorporated by reference into this Form 10-K.

Item 1A. Risk Factors

Our business involves a high degree of risk. You should carefully consider the risks and uncertainties described below, and all of the other information contained in this Form 10-K in assessing the risks relating to ownership of our common stock. The risks described below could cause our business, results of operations, financial condition and prospects to materially suffer and the market price of our stock to decline.

Risks Related to Our Business

We are a development stage company. Our limited operating history makes it difficult to evaluate our future performance.

We are a development stage company. We are the successor by merger to a company that began operations in 2002. As such, we have a limited operating history upon which you can evaluate our current business and our prospects. The likelihood of our future success must be viewed in light of the problems, expenses, difficulties, delays and complications often encountered in the operation of a new business, especially in the pharmaceutical industry, where failures of new companies are common. We are subject to the risks inherent in the ownership and operation of a development stage company, including regulatory setbacks and delays, fluctuations in expenses, competition and government regulation. If we fail to address these risks and uncertainties our business, results of operations, financial condition and prospects would be adversely affected.

We have no products currently available and we have never had any products available for commercial sale.

We have had no revenues from operations to date, currently have no products available for commercial sale, and have never had any products available for commercial sale. We expect to incur losses at least until we can commercialize CPP-109. Our net loss was $7,241,928 for the year ended December 31, 2009, and as of December 31, 2009 we had a deficit accumulated during the development stage of $27,705,232. We may never obtain approval of an NDA for CPP-109 or CPP-115 and may never achieve profitability.

Our business will require additional capital.

Our business goals include developing CPP-109 for use in treating various addictions and CPP-115 for various addictions and additional central nervous system diseases commencing with epilepsy. Our primary focus is on seeking approval of an NDA that will allow us to market CPP-109 for the treatment of cocaine addiction and generate significant non-clinical safety and efficacy data for CPP-115 in the areas of epilepsy and addiction. At the present time, we will require additional funding to complete the Phase III clinical trial that we believe we will be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction. We will also require additional funding to complete the non-clinical trials of CPP-109 that will be required before we can file an NDA for CPP-109 for cocaine addiction. Further, we will require additional working capital to support our operations during periods after the first quarter of 2011. Finally, we hope to develop clinical trials to seek commercialization of CPP-109 to treat methamphetamine addiction and to commercialize CPP-109 for sale in Europe. We do not presently have the funds needed to complete all the necessary trials to gain such U.S. and foreign approvals. Other than the U.S. Phase II(b) cocaine trial described herein, these other trials have not yet been developed, we cannot estimate the ultimate costs of these trials, and we will need additional funding to pay such costs.

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We expect to raise any required additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations, governmental research grants or cost sharing arrangements with NIDA, the National Institute of Neurological Disorders and Stroke (NINDS) or other appropriate agencies that operate under the NIH umbrella, or other means. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

There is currently limited clinical evidence supporting the use of vigabatrin to treat addiction.

There is limited clinical evidence currently indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, one double-blind, placebo controlled trial and two open-label clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine addiction and methamphetamine addiction. Only 76 persons receiving vigabatrin completed these trials in the aggregate. Further, these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol. In the U.S. one double-blind, placebo controlled trial and one proof-of concept study have been completed. Only 121 persons received CPP-109/vigabatrin in these trials in the aggregate. There can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these studies, and particularly the results of the double-blind, placebo-controlled trial that was completed in Mexico. None of these studies, individually, or in the aggregate, provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA.

Our product development efforts may fail.

Development of our pharmaceutical product candidates is subject to risks of failure. For example:

- CPP-109 or CPP-115 may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;
- CPP-109 or CPP-115 may not be economical to market or take substantially longer to obtain necessary regulatory approvals than anticipated;
- Initial non-clinical studies for CPP-115 may not show sufficient safety or efficacy in animals; or
- Competitors may market equivalent or superior products.

As a result, our product development activities may not result in any safe, effective and commercially viable products, and we may not be able to commercialize our products successfully. Our failure to develop safe, effective, and/or commercially viable products would have a material adverse effect on our business, prospects, results of operations and financial condition.

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Failure can occur at any stage of our product development efforts.

We will only obtain regulatory approval to commercialize CPP-109 or CPP-115 if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well-controlled clinical studies that the drug is safe and effective for its intended use and that it otherwise meets approval requirements. A failure of one or more pre-clinical or clinical studies can occur at any stage of product development. We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for or commercializing our product candidates, including but not limited to:

- regulators or institutional review boards, which are commonly called IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions may be imposed upon us by the FDA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for reinspection due to changes in the regulatory environment;
- the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and
- the costs of our pre-clinical and/or clinical trials may be greater than we anticipate.

Vigabatrin has known side effects that may hinder our ability to produce safe and commercially viable products.

When used long-term as a treatment for epilepsy, a formulation of vigabatrin known as Sabril® has been found to cause the development of peripheral visual field defects, known as VFDs, which increase progressively with continuing drug treatment. We intend to include a standardized evaluation of each patient s visual fields as part of our clinical studies and trials. We do not yet know whether our ultimate formulation for and dosing of vigabatrin will cause VFDs or how the potential for this known side effect will affect our ability to obtain marketing approval for CPP-109.

In addition to VFDs, a wide variety of other adverse effects, including depression and other psychiatric reactions, have been noted in patients treated with Sabril®. As patients with seizures often require treatment with multiple drugs, the relationship of such adverse effects to Sabril®, including the VFDs described above, has not always been clear; however, such other side effects tended to disappear when treatment with Sabril® was stopped.

These known side effects, as well as other side effects that may be discovered during our clinical trials, may cause the FDA or other governmental agencies to halt clinical trials prior to their completion, prevent the initiation of further clinical trials, or deny the approval of CPP-109 as a treatment for addiction. These known side effects will most likely cause the FDA to require as a condition of approval, implementation of a Risk Evaluation and Mitigation Strategy (REMS), as was required for the recent approvals of Sabril® for infantile spasms and refractory complex partial seizures. Such strategy may include Black Box warnings, limitations on promotion and distribution, and/or testing of patients on drug to monitor whether the administration of the drug continues to be safe and effective for the patient. Should CPP-115 prove to have VFDs, the above risks will apply to it as well.

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We rely on third parties to conduct our non-clinical and clinical trials, and if they do not perform their obligations to us we may not be able to obtain approval for CPP-109 or CPP-115.

We do not have the ability to conduct our non-clinical and clinical trials independently. We rely on academic institutions, governmental agencies such as NIDA and other third-party research organizations to assist us in designing, managing, monitoring and otherwise carrying out our trials. Accordingly, we do not have control over the timing or other aspects of our trials. If these third parties do not successfully carry out their duties, both our trials and our business may be materially adversely affected. While we believe that there are numerous third parties that can assist us with our trials, if the third parties with which we contract do not perform, our product development efforts would likely be delayed by any such change, and our efforts would likely be more expensive.

If we conduct studies with other parties, such as NIDA, we may not have control over all decisions associated with that trial. To the extent that we disagree with the other party on such issues as study design, study timing and the like, it could adversely affect our product development plans.

Although we intend to rely on third parties to manage the data from these trials, we are responsible for confirming that each of our trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies will require us to comply with applicable regulations and standards, commonly referred to as good laboratory practice and good clinical practice, for conducting, recording and reporting the results of trials to assure that the data and the results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for our product candidates if these requirements are not met.

If we are unable to apply for approval for additional indications for CPP-109 through supplemental NDAs, or if we are required to generate safety and efficacy data beyond what we have planned in order to obtain such approval for additional indications, we may suffer material harm to our future financial performance.

Our current plans for the development of CPP-109 include efforts to minimize the data we will need to generate in order to obtain marketing approval of CPP-109 for methamphetamine addiction and other additional indications. If we are successful in obtaining approval of an NDA for CPP-109 as a treatment for cocaine addiction, of which there can be no assurance, we plan to subsequently submit supplemental NDAs for additional indications. Depending on the data we rely upon, approval for additional indications for CPP-109 may be delayed. In addition, even if we receive supplemental NDA approval, the FDA has broad discretion to require us to generate additional data related to safety and efficacy to supplement the data used in the supplemental NDA. We could be required, before obtaining marketing approval for CPP-109 for additional indications, to conduct substantial new research and development activities, which could be more costly and time-consuming than we currently anticipate. The FDA may not agree that we can market CPP-109 for additional indications. If we are required to generate substantial additional data beyond what we have planned to support approval, our product development and commercialization efforts will be delayed and we may suffer significant harm to our future financial performance. In addition, submission of supplemental NDAs for additional indications, conducting new research and development and generating additional data to support FDA approval will require that we obtain additional financing, and we can provide no assurance that we will be able to obtain such financing on acceptable terms, or at all.

The initial non-clinical studies for CPP-115 may not show safety or efficacy in animals.

There can be no assurance that CPP-115 will prove to be safe and/or effective in our upcoming non-clinical animal studies.

We will need to develop marketing, distribution and production capabilities or relationships to be successful.

We do not currently have any marketing, distribution or production capabilities. In order to generate sales of CPP-109, CPP-115 or any other products we may develop, we must either acquire or develop an internal marketing force with technical expertise and with supporting documentation capabilities, or make arrangements with third parties to perform these services for us. The acquisition and development of a marketing and distribution infrastructure will require substantial resources and compete for available resources with our product development efforts. To the extent that we enter into marketing and distribution arrangements with third parties, our revenues will depend on the efforts of others. If we fail to enter into such agreements, or if we fail to develop our own marketing and distribution channels, we would experience delays in product sales and incur increased costs.

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Similarly, we have no manufacturing capacity for production of our products. We have entered into an agreement for the manufacture of CPP-109 for use in our U.S. Phase II clinical trials. We also intend in the future to enter into an agreement with a contract manufacturer to manufacture CPP-109 for us if we are successful in obtaining FDA approval to commercialize this product. Any third party we contract with may not meet our manufacturing requirements, and may not pass FDA inspection. Moreover, if any third party fails to perform on a timely basis we may not be able to find a suitable replacement. If we cannot obtain sufficient amounts of CPP-109, CPP-115 or any related final product, it would have a material adverse effect on our ability to successfully market CPP-109 or CPP-115.

Our business is subject to substantial competition.

The biotechnology and pharmaceutical industries are highly competitive. In particular, competition for the development and marketing of therapies to treat epilepsy and addictive substances such as cocaine and methamphetamine is intense and expected to increase. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approval of products and manufacturing and marketing products. We compete against pharmaceutical companies that are developing or currently marketing therapies for epilepsy and addictive substances. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of epilepsy and substance abuse treatments, technologies and processes that are, or in the future may be, the basis for competitive commercial products. While we believe that our product candidates will offer advantages over many of the currently available competing therapies, our business could be negatively impacted if our competitors present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payers.

Lundbeck Inc., f/k/a Ovation Pharmaceuticals, Inc. (Lundbeck), holds the North American rights to Sabril®. On August 21, 2009, the FDA approved two NDAs for Sabril® for the treatment of infantile spasms and as an adjunctive (add-on) therapy for adult patients with refractory complex partial seizures, who have failed several treatments. The NDAs are for different formulations of Sabril®, and both NDAs are held by Lundbeck, Inc. Because of the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) program and is only available through a special restricted distribution program approved by the FDA. Although Sabril® is approved for the treatment of certain types of epilepsy, no law prohibits doctors from using Sabril® for other indications, including addiction. However, physicians seeking to treat patients off label still need to comply with all the conditions of the above-described restrictions placed by the FDA on the marketing or distribution of the drug, which could discourage the off-label use of Sabril®.

Lundbeck had previously announced that they had been granted Fast Track status by the FDA with respect to Sabril® for the treatment of cocaine and methamphetamine addiction. However, we have no evidence that Lundbeck is pursuing clinical trials intended to support approval for either of these indications. We believe that any commercialization by Lundbeck of Sabril® for the treatment of addiction would violate our licensed patents, and we have advised Lundbeck of our belief in that regard. We would vigorously assert our intellectual property rights if Lundbeck sought to market Sabril® for the treatment of cocaine addiction and methamphetamine addiction. There can be no assurance we would be successful in that regard.

Many of our competitors, including Lundbeck, have substantially greater financial, technical, and human resources than we do. In addition, many of our competitors have significantly greater experience than we do in conducting clinical studies and obtaining regulatory approvals of prescription drugs. Accordingly, our competitors may succeed in obtaining FDA approval for products more rapidly than we can. Furthermore, if we are permitted to commence commercial sales of our product candidates, we may also compete with respect to manufacturing efficiency and marketing capabilities. For all of these reasons, we may not be able to compete successfully.

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Lundbeck will likely not be required to submit the same quantity of information to the FDA for approval for treatment of addiction that we will be required to submit.

The FDA approval of Sabril® for the treatment of epilepsy will indicate that sufficient pre-clinical studies, and Phase I studies such as pharmacokinetics, cardiac function, drug-drug interaction and/or the effect of the drug in special populations were contained in those NDAs. Lundbeck would likely seek to rely on those same studies for approval of Sabril® for the treatment of addiction. However, we would be required to conduct those pre-clinical and clinical studies at our own expense and will not be permitted to rely on the studies of Sabril® contained in Lundbeck s NDA. The FDA s approval of Sabril® for the treatment of epilepsy indicates that Lundbeck has satisfied FDA GMP requirements for that product. We would have to provide independent evidence that our product meets GMP requirements.

We may encounter difficulties in managing our growth, which would adversely affect our results of operations.

If we are successful in obtaining approval to commercialize CPP-109 or CPP-115, we will need to significantly expand our operations, which could put significant strain on our management and our operational and financial resources. We currently have six employees and conduct much of our operations through outsourcing arrangements. To manage future growth, we will need to hire, train, and manage additional employees. Concurrent with expanding our operational and marketing capabilities, we will also need to increase our product development activities. We may not be able to support, financially or otherwise, future growth, or hire, train, motivate, and manage the required personnel. Our failure to manage growth effectively could limit our ability to achieve our goals.

Our success in managing our growth will depend in part on the ability of our executive officers to continue to implement and improve our operational, management, information and financial control systems and to expand, train and manage our employee base, and particularly to expand, train and manage a specially-trained sales force to market our products. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Our inability to manage growth effectively could cause our operating costs to grow at a faster pace than we currently anticipate, and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We face a risk of product liability claims and may not be able to obtain adequate insurance.

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and/or sale of CPP-109 or CPP-115. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and result in large judgments against us. We currently carry liability insurance with an aggregate annual coverage limit of $5,000,000 per claim and $5,000,000 in the aggregate, with a deductible of $10,000 per occurrence. Our insurance may not reimburse us, for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of CPP-109, CPP-115 or any of our other future products used in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

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Our commercial success depends on reimbursement from third-party and governmental insurers.

Sales of pharmaceutical products in the United States depend largely on reimbursement of patients costs by private insurers, government health care programs including Medicare and Medicaid, and other organizations. These third-party payers control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. In particular, the rising costs of pharmaceutical products are a subject of considerable attention and debate. Third-party payers are increasingly altering reimbursement levels and challenging the price and cost-effectiveness of pharmaceutical products. The reimbursement status of newly approved pharmaceutical products in particular is generally uncertain. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for CPP-109, CPP-115 and other products we may develop could affect the extent to which we are able to commercialize our products successfully.

The obligations incident to being a public company place significant demands on our management.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of Sarbanes-Oxley, the SEC adopted rules requiring public companies to include a report of management on a company s internal control over financial reporting in their Annual Report on Form 10-K. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Based on current rules, we are required to report under Section 404(a) of Sarbanes-Oxley as to management s report under of the effectiveness of our internal control over financial reporting. If we are unable to conclude that we have effective internal control over our financial reporting as required by Section 404(a), investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock. Further, commencing with the 2010 fiscal year, our independent registered public accounting firm will be required, under Section 404(b) of Sarbanes-Oxley, to report on our internal control over financial reporting.

Risks Related to Our Intellectual Property

We are dependent on our relationship and license agreements with Brookhaven and Northwestern, and we rely upon the patents granted to us for vigabatrin and CPP-115 pursuant to the license agreements.

All of our patent rights for CPP-109 are derived from our license agreement with Brookhaven. Pursuant to this license agreement, we have licensed rights under nine patents in the United States, and 21 patents and 48 pending patent applications outside of the United States that were filed and obtained by Brookhaven relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions. The nine issued patents expire between 2018 and 2023. We also have the right to future patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. See Business Intellectual Property Rights for more information about our license with Brookhaven and our licensed patents and patent applications. These rights are subject to the right of the U.S. government, under limited circumstances, to practice the covered inventions for or on its own behalf. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations to Brookhaven. If we violate or fail to perform any term or covenant of the license agreement, Brookhaven may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Brookhaven, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-109, and our business, results of operations, financial condition and prospects would be materially adversely affected.

If we obtain approval to market CPP-109, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by Brookhaven, to exclude others from competing with us. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims sufficiently broad to prevent others from practicing our technologies or marketing competing products. Third parties may intentionally design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others.

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All of our patent rights for CPP-115 are derived from our license agreement with Northwestern University. Pursuant to this license agreement, we have exclusive worldwide rights to two patents in the United States. These were filed and obtained by Northwestern University relating to compositions of matter for a class of molecules, including CPP-115. Both patents expire in 2023. Additionally, we have licensed rights from Northwestern to a pending patent for derivatives of vigabatrin that are unrelated to CPP-115. See Business Intellectual Property Rights for more information about our license with Northwestern and our licensed patents and patent applications. These rights are subject to the right of Northwestern, under limited circumstances, to practice the covered inventions for or on its own behalf for research. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations, including milestone payments, to Northwestern. If we violate or fail to perform any term or covenant of the license agreement, Northwestern may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Northwestern, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-115, and our business, results of operations, financial condition and prospects would be materially adversely affected.

If we obtain approval to market CPP-115, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by Northwestern, to exclude others from competing with us. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Third parties may intentionally attempt to design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others.

As a result of the foregoing factors, we cannot be certain how much protection from competition patent rights will provide us.

Our success will depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

While we are not currently aware of any third-party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our products or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we are aware that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the U.S., patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

If a third party claims that we infringe its patents, any of the following may occur:

- we may be required to pay substantial financial damages if a court decides that our technologies infringe a competitor s patent, which can be tripled if the infringement is deemed willful, or be required to discontinue or significantly delay development, marketing, selling and licensing of the affected products and intellectual property rights;

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a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

we may have to redesign our product so that it does not infringe others patent rights, which may not be possible or could require substantial funds or time and require additional studies.

In addition, employees, consultants, contractors and others may use the proprietary information of others in their work for us or disclose our proprietary information to others. As an example, we do not have written agreements regarding confidentiality or any other matters with several principal members of our Scientific Advisory Board. If our employees, consultants, contractors or others disclose our data to others or use data belonging to others in connection with our business, it could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties.

The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

There is substantial history of litigation and other proceedings regarding patent and intellectual property rights in the pharmaceutical industry. We may be forced to defend claims of infringement brought by our competitors and others, and we may institute litigation against others who we believe are infringing our intellectual property rights. The outcome of intellectual property litigation is subject to substantial uncertainties and may, for example, turn on the interpretation of claim language by the court, which may not be to our advantage, or on the testimony of experts as to technical facts upon which experts may reasonably disagree.

Under our license agreement with Brookhaven, we have the right to bring legal action against any alleged infringers of the patents we license. However, we are responsible for all costs relating to such potential litigation. We have the right to any proceeds received as a result of such litigation, but, even if we are successful in such litigation, there is no assurance we would be awarded any monetary damages.

Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. For example, Lundbeck, which holds rights in North America to Sabril® for the treatment of epilepsy, has in the past indicated its intent to develop Sabril® for the treatment of cocaine addiction and methamphetamine addiction. However, we have no evidence that Lundbeck is pursuing clinical trials intended to support approval for either of these indications. We believe that Lundbeck would infringe our patent rights if they seek to commercialize Sabril® to treat cocaine addiction and/or methamphetamine addiction, and we have advised Lundbeck of our belief in that regard. We intend to vigorously pursue infringement claims against Lundbeck if it seeks to commercialize Sabril® for these indications. However, we, unlike Lundbeck and many of our other competitors, are a relatively small company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management s attention and quickly consume our financial resources.

In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings with the U.S. Patent Office or in other proceedings outside the U.S., including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted from product development or other more productive matters.

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Risks Related to Government Regulation

We have not received regulatory approval in the United States or any foreign jurisdiction for the commercial sale of any of our product candidates. The regulatory approval process is lengthy, and we may not be able to obtain all of the regulatory approvals required to manufacture and commercialize our product candidates.

We do not have any products that have been approved for commercialization. We will not be able to commercialize our products until we have obtained the requisite regulatory approvals from applicable governmental authorities. To obtain regulatory approval of a product candidate, we must demonstrate to the satisfaction of the applicable regulatory agency that such product candidate is safe and effective for its intended uses. The type and magnitude of the testing required for regulatory approval varies depending on the product candidate and the disease or condition for which it is being developed. In addition, in the U.S. we must show that the facilities used to produce the product candidate are in compliance with cGMP. We will also have to meet similar regulations in any foreign country where we may seek to commercialize CPP-109 or CPP-115. In general, these requirements mandate that manufacturers follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. The process of obtaining regulatory approvals typically takes several years and requires the expenditure of substantial capital and other resources. Despite the time, expense and resources invested by us in the approval process, we may not be able to demonstrate that our product candidates are safe and effective, in which event we would not receive the regulatory approvals required to market them.

The FDA and other regulatory authorities generally approve products for particular indications. While our current focus for CPP-109 is on its development as a treatment of cocaine addiction and methamphetamine addiction, we also intend to pursue CPP-109 as a treatment for addictions to other substances involving heightened dopamine levels, such as nicotine, prescription pain medications, alcohol and marijuana, and related addictive disorders such as obesity and compulsive gambling. CPP-109 may not be approved for any or all of the indications that we request, which would limit the indications for which we can promote it and adversely impact our ability to generate revenues. We may be required to conduct costly, post-marketing follow-up studies if FDA requests additional information.

Our receipt of Fast Track status does not mean that our product development efforts will be accelerated.

The FDA has granted Fast Track designation to CPP-109 for the treatment of cocaine addiction. Fast Track designation means that the FDA recognizes cocaine addiction as a serious or life threatening condition for which there is an unmet medical need and consequently may initiate review of sections of an NDA before the application is complete. However, Fast Track designation does not accelerate the time needed to conduct clinical trials, nor does it mean that the regulatory requirements necessary to obtain an approval are less stringent. Our Fast Track designation does not guarantee that we will qualify for, or be able to take advantage of, priority review procedures following a submission of an NDA. Additionally, our Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data from our clinical development program, or if a competitor s product is approved for the indication we are seeking.

If our pre-clinical or clinical trials are unsuccessful or significantly delayed, our ability to commercialize our products will be impaired.

Before we can obtain regulatory approval for the sale of our product candidates, we will have to conduct, at our own expense, pre-clinical tests in animals in order to support the safety of CPP-109 and CPP-115. Pre-clinical testing is expensive, difficult to design and implement, can take several years to complete and is uncertain as to outcome. Our pre-clinical tests may produce negative or inconclusive results, and on the basis of such results, we may decide, or regulators may require us, to halt ongoing clinical trials or conduct additional pre-clinical testing.

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We will also need to conduct additional clinical trials demonstrating the efficacy and safety of CPP-109 in humans. In the United States, we commenced a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction in July 2007 and commenced a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for methamphetamine addiction in the second quarter of 2008, which in 2009 we converted into a proof-of-concept study. Neither of these completed trials provided efficacy data which would support approval of CPP-109 in the U.S. We will also be required to conduct one or more Phase I clinical trials for CPP-109. While the scope of the required Phase I clinical trials are currently uncertain, it is likely that we will be required to perform studies of pharmacokinetics, cardiac function, drug-drug interaction and/or the effect of the drug on special populations. We will also implement additional trials (including at least one U.S. Phase III clinical trial) in order to seek approval to commercialize CPP-109 for the treatment of cocaine addiction. The results of the trials for cocaine and methamphetamine were inconclusive for purposes of determining whether CPP-109 can be a successful method for treating cocaine and methamphetamine addiction. As a result, we will have to perform additional Phase II trials. However, even if the results of our clinical trials are promising, CPP-109 may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Future clinical trials for CPP-109 may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, an inability to recruit clinical trial participants at the expected rate, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays. The risks described above also apply to CPP-115.

Our contemplated U.S. Phase II clinical trial with NIDA, or any other clinical trials we might develop and implement, may not be completed in a timely manner or at all. CPP-109 may not be found to be safe and effective, and may not be approved by regulatory authorities for the proposed indication, especially in light of known side effects associated with the drug. Further, regulatory authorities and IRBs that must approve and monitor the safety of each clinical study may suspend a clinical study at any time if the patients participating in such study are deemed to be exposed to any unacceptable health risk. We may also choose to suspend clinical trials and studies if we become aware of any such risks. We might encounter problems in our U.S. Phase II clinical trials or in other future studies we may conduct, including problems associated with VFDs or other side effects that will cause us, regulatory authorities or IRBs to delay or suspend such trial or study.

In other countries where CPP-109 or any other product we develop may be marketed, we will also be subject to regulatory requirements governing human clinical studies and marketing approval for drugs. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement varies widely from country to country.

Due to the nature of patients addicted to drugs, we may face significant delays in our clinical trials due to an inability to recruit patients for our clinical trials or to retain patients in the clinical trials we may perform.

We may encounter difficulties in our future clinical trials recruiting patients due to the nature of the addiction mechanism and our resulting target patient population. Because addicts are typically addicted to multiple substances, we may not be able to recruit a sufficient number of eligible participants within our anticipated timeframe or at all. In addition, due to the neurological and physiological mechanisms and implications of substance addiction, it is likely that many of our clinical trial participants will either not comply with trial protocols, or not complete the trial. An unusually low rate of compliance or completion will present challenges, such as determining the statistical significance of trial results. Additionally, we compete for trial subjects with others conducting clinical trials testing other treatments for addictions. Finally, unrelated third parties, including Lundbeck and investigators in the academic community, have expressed interest in testing vigabatrin for the treatment of drug abuse. If these third-party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected.

We have not conducted any pre-clinical testing for CPP-109 and we are not certain at this time which pre-clinical tests the FDA will require with respect to any NDA that we may file.

The FDA will require us to submit data from pre-clinical testing for CPP-109 before approving our product. Some testing, such as carcinogenicity studies, which seek to identify the potential of a drug to cause tumors in animals and to assess the relevant risk in humans, will take, if required, several years to complete. We do not yet know what pre-clinical tests will be required or whether any pre-clinical tests will begin as planned, will need to be restructured or will be completed on schedule, if at all. We do not know whether the pre-clinical tests that we undertake, if conducted, will be acceptable to the FDA. We have initiated discussions with the FDA to obtain agreement on the preclinical testing program they will require from us to support an NDA for CPP-109. However, no agreements have been reached in that regard.

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Our development of CPP-109 may require more than one U.S. Phase III clinical trial.

Generally, the process of seeking approval of an NDA requires multiple clinical trials, including two pivotal U.S. Phase III clinical trials. In our case, because CPP-109 is intended to treat a serious condition for which there is no approved therapy, it is possible that the FDA will permit us to file an NDA for CPP-109 on the basis of one U.S. Phase III trial supported by the safety and efficacy data obtained from our Phase II clinical trials, to the extent that such data are compelling. Even if the FDA permits us to file an NDA with only one pivotal U.S. Phase III trial, it is unlikely that we will submit an NDA for CPP-109 for several years. Further, if the FDA requires more than one Phase III clinical trial, our NDA submission would be delayed even further.

The development of CPP-115 is at a very early stage.

Our development of CPP-115 is at a very early stage and it is likely going to be many years before we are in a position to file an NDA for CPP-115. Further, our ability to develop CPP-115 will be dependent on our having the resources to conduct the trials that would be required. There can be no assurance that we will ever file and NDA for CPP-115.

If our third-party suppliers or contract manufacturers do not maintain appropriate standards of manufacturing in accordance with cGMP and other manufacturing regulations, our development and commercialization activities could suffer significant interruptions or delays.

We rely, and intend to continue to rely, on third-party suppliers and contract manufacturers to provide us with materials for our clinical trials and commercial-scale production of our products. These suppliers and manufacturers must continuously adhere to cGMP as well as any applicable corresponding manufacturing regulations outside of the U.S. In complying with these regulations, we and our third-party suppliers and contract manufacturers must expend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that our products meet applicable specifications and other regulatory requirements. Failure to comply with these requirements could result in an enforcement action against us, including warning letters, the seizure of products, suspension or withdrawal of approvals, shutting down of production and criminal prosecution. Any of these third-party suppliers or contract manufacturers will also be subject to audits by the FDA and other regulatory agencies. If any of our third-party suppliers or contract manufacturers fail to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our products could suffer significant interruptions and delays.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- reliance on the continued financial viability of the third parties;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;
- impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet the demands of our customers;
- the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

If any of our contract manufacturers fail to achieve and maintain appropriate manufacturing standards, patients using our product candidates could be injured or die, resulting in product liability claims. Even absent patient injury, we may be subject to product recalls, product seizures or

withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

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Post-approval marketing of our products will be subject to substantial government regulation. Failure to comply with these regulations could result in fines and withdrawal of approvals.

Even if our products receive regulatory approvals, we will be subject to extensive ongoing government regulation. The FDA or other regulatory authorities may impose strict limitations on the distribution, marketing, and use for a product, impose a risk evaluation and mitigation strategy, or REMS, that could include further restrictions on distribution and use, subsequently withdraw approval or take other actions against us or our products for many reasons, including subsequent discoveries of previously unknown problems or safety issues with the product. Also, based on subsequent events or other circumstances that may come to our attention, we may voluntarily take action to limit the marketing or use of one or more of our products. We may also be required to conduct additional post-approval pre-clinical or clinical studies.

We are subject to inspection and market surveillance by regulatory authorities for compliance with regulations that prohibit the promotion of a medical product for a purpose or indication other than those for which approval has been granted. While a medical product manufacturer may not promote a product for such off-label use, doctors are allowed, in the exercise of their professional judgment in the practice of medicine, to use a product in ways not approved by regulatory authorities. Regulatory authorities have broad enforcement power, and any failure by us to comply with manufacturing or marketing regulations could result in penalties, including warning letters, fines, partial or total suspension of production, product recalls or seizures, withdrawals of previously approved marketing approvals or applications, and criminal prosecutions.

Substantial and changing healthcare regulations by state and federal authorities in the U.S. could reduce or eliminate our commercial opportunity in the addiction treatment industry.

Healthcare organizations, both public and private, continue to change the manner in which they operate and pay for services. These organizations have had to adapt to extensive and complex laws and regulations and judicial decisions governing activities including drug manufacturing and marketing. Additionally, the healthcare industry in recent years has been subject to increasing levels of government regulation of reimbursement rates and capital expenditures. We believe that the industry will continue to be subject to increasing regulation, as well as political and legal action, as additional proposals to reform the healthcare system continue to be discussed by Congress and state legislatures. This is particularly so in light of the legislative reform recently approved by Congress. Any new legislative initiatives, if enacted, may further increase government regulation of or other involvement in healthcare, lower reimbursement rates and otherwise change the operating environment for healthcare companies. We cannot predict the likelihood of all future changes in the healthcare industry in general, or the addiction treatment industry in particular, or what impact they may have on our results of operations, financial condition or business. Government regulations applicable to our proposed products or the interpretation thereof might change and thereby prevent us from marketing some or all of our products and services for a period of time or indefinitely.

Risks Related to Our Common Stock

We are highly dependent on our small number of key personnel and advisors.

We are highly dependent on our officers, on our Board of Directors and on our scientific advisors. The loss of the services of any of these individuals could significantly impede the achievement of our scientific and business objectives. Other than an employment agreement with Patrick J. McEnany, our Chairman, President and Chief Executive Officer with respect to his services, and the consulting agreements we have with one of our officers, one of our board members and several of our scientific advisors, we have no employment or retention agreements with our officers, directors or scientific advisors. If we lose the services of any of our existing officers, directors or scientific advisors, or if we were unable to recruit qualified replacements on a timely basis for persons who leave our employ, our efforts to develop CPP-109, CPP-115 or other products might be significantly delayed. We do not carry key-man insurance on any of our personnel.

We have relationships with our scientific advisers and collaborators at academic and other institutions. Such individuals are employed by entities other than us and may have commitments to, or consulting advisory contracts with, such entities that may limit their availability to us. Although each scientific advisor and collaborator has agreed not to perform services for another person or entity that would create an appearance of a conflict of interest, the Chairman of our Scientific Advisory Board, Stephen L. Dewey, Ph.D., is actively involved in the investigation of neurological mechanisms involved in the addiction process. His research might result in pharmaceutical products that are competitive with, or superior to, vigabatrin. Similarly, other similar conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

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The trading price of the shares of our common stock could be highly volatile.

The trading price of the shares could be highly volatile in response to various factors, many of which are beyond our control, including:

- the potential delisting of our common stock from the Nasdaq Capital Market (as more fully described below);
- developments concerning our clinical studies and trials;
- announcements of product development successes and failures by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in reimbursement levels;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses (particularly our license from Brookhaven), research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- intellectual property, product liability or other litigation against us;
- changes in the market valuations of similar companies;
- changes in pharmaceutical company regulations or reimbursements as a result of healthcare reform or other legislation;
- changes in economic conditions; and
- sales of shares of our common stock, particularly sales by our officers, directors and significant stockholders, or the perception that such sales may occur.

In addition, equity markets in general, and the market for emerging pharmaceutical and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the United States, Europe or globally could impact our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or financial results. These broad market and industry factors may materially affect the market price of our shares, regardless of our own development and operating performance.

In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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Our common stock may be delisted from the Nasdaq Capital Market

Our common stock currently trades on the Nasdaq Capital Market. On November 13, 2009, we were informed by 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, our common stock would be delisted from the Nasdaq Capital Market if, by May 12, 2010, we do not regain compliance with the requirement by our common stock trading at a bid price of at least $1.00 for a period of at least ten consecutive trading days. To date, we have not met that requirement.

Information about the status of our Nasdaq listing is set forth below in Item 5, Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. There can be no assurance that our common stock will remain listed on the Nasdaq Capital Market. If our common stock is delisted from the Nasdaq Capital Market, the price of our common stock may be adversely affected, and you may face liquidity issues if you attempt to sell our common stock.

Delaware law and our certificate of incorporation and by-laws contain provisions that could delay and discourage takeover attempts that stockholders may consider favorable.

Certain provisions of our certificate of incorporation and by-laws, and applicable provisions of Delaware corporate law, may make it more difficult for or prevent a third party from acquiring control of us or changing our Board of Directors and management. These provisions include:

- the ability of our Board of Directors to issue preferred stock with voting or other rights or preferences;
- limitations on the ability of stockholders to amend our charter documents, including stockholder supermajority voting requirements;
- the inability of stockholders to act by written consent or to call special meetings;
- requirements that special meetings of our stockholders may only be called by the Board of Directors; and
- advance notice procedures our stockholders must comply with in order to nominate candidates for election to our Board of Directors or to place stockholders proposals on the agenda for consideration at meetings of stockholders.

In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in a business combination with any person who owns 15% or more of our common stock for a period of three years from the date such person acquired such common stock, unless board or stockholder approval is obtained. These provisions could make it difficult for a third party to acquire us, or for members of our Board of Directors to be replaced, even if doing so would be beneficial to our stockholders.

Any delay or prevention of a change of control transaction or changes in our Board of Directors or management could deter potential acquirors or prevent the completion of a transaction in which our stockholders could receive a substantial premium over the then current market price for their shares.

Future sales of our common stock may cause our stock price to decline.

As of March 26, 2010 we had 18,043,385 shares of our common stock outstanding, of which 5,559,423 shares were held by affiliates. We have also registered for future sale: (i) 2,188,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and (ii) 2,352,254 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. Sales of restricted shares or shares underlying stock options, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock or other securities, and we currently do not anticipate paying any cash dividends in the foreseeable future. Accordingly, investors should not invest in our common stock if they require dividend income. Our stockholders will not realize a return on their investment unless the trading price of our common stock appreciates, which is uncertain and unpredictable.

Item 2. Properties

We currently operate our business in leased office space in Coral Gables, Florida and Upper Saddle River, New Jersey. We pay annual rent on our office space of approximately $77,000.

Item 3. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 4. Removed and Reserved

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Market Information

Our common stock trades on the Nasdaq Capital Market under the symbol CPRX. Previously, from November 8, 2006 through 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.

	High	Low
Year Ended December 31, 2009		
First Quarter	**$ 2.75**	**$ 1.25**
Second Quarter	**$ 2.25**	**$ 0.61**
Third Quarter	**$ 1.39**	**$ 0.41**
Fourth Quarter	**$ 1.17**	**$ 0.60**
Year Ended December 31, 2008		
First Quarter	**$ 3.87**	**$ 2.94**
Second Quarter	**$ 3.74**	**$ 3.20**
Third Quarter	**$ 4.44**	**$ 2.63**
Fourth Quarter	**$ 2.94**	**$ 1.34**

The closing sale price for the common stock on March 26, 2010 was $0.74. As of March 26, 2010, there were approximately 65 holders of record of our common stock, which includes custodians who hold our securities for the benefit of others.

Dividend Policy

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.

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NASDAQ Listing

Our common stock is currently traded on the NASDAQ Capital Market. On November 13, 2009, we were informed by the Nasdaq Stock Market 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, our common stock would be delisted from the Nasdaq Capital Market if, by May 12, 2010, we do not regain compliance with the requirement by our common stock trading at a bid price of at least $1.00 for a period of at least ten consecutive trading days. To date, we have not met that requirement.

If we do not regain compliance with the Rule prior to the expiration of the grace period, we may be eligible for an additional 180-day grace period if at such time we meet the initial listing standards for listing on the Nasdaq Capital Market, with the exception of the bid price requirement. At the present time we do not meet those initial listing standards because our market capitalization held by non-affiliates is less than $15 million.

If we are not eligible for the additional 180-day grace period and we are not in compliance with the minimum bid price requirement by May 12, 2010, Nasdaq will send us a delisting determination letter. Delisting will occur nine days after the date of the letter unless we appeal to the Nasdaq Hearings Panel within seven days after the date of the letter. Any delisting is delayed until the appeal is heard and a determination is made by the Hearings Panel. Generally, a hearing is held within 4-6 weeks after a request for a hearing is made, and a determination is made 2-3 weeks after the date of the hearing. Among other things, the Hearings Panel may grant a further 180 day extension from the date of the delisting determination letter to us so we can regain compliance with Nasdaq listing rules.

If the Nasdaq Hearings Panel denies our appeal, we can make a further appeal to the Nasdaq Listings Council. An appeal to the Listings Council does not automatically delay delisting proceedings, though the Listing Council may, in its sole and absolute discretion, decide to stay delisting proceedings while it considers an appeal. The Listings Council may grant an extension of up to 360 days from the date of the determination letter to regain compliance.

While we believe we can regain compliance before May 12, 2010 or otherwise obtain an extension of the period in which we can regain compliance with the Nasdaq rules, there can be no assurance of this fact. If we are ultimately unable to regain compliance with the Nasdaq rules (either by May 12, 2010 or during any grace period that we are granted), our common stock might be delisted from trading on the Nasdaq Capital Market. If our common stock is delisted from the Nasdaq Capital Market, the price and trading liquidity of our common stock may be adversely affected.

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Performance Graph

The following graph compares the cumulative total shareholder return on our common stock since November 8, 2006, which is the date that our common stock first began trading on the NASDAQ Global Market, to two indices, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on November 8, 2006. The comparisons in this graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock.

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Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2009, 2008, 2007 and for the cumulative period from inception (January 4, 2002) through December 31, 2009, and the balance sheet data as of December 31, 2009 and 2008, have been derived from our audited financial statements included elsewhere in this Form 10-K. The income statement data for 2006 and 2005 and the balance sheet data as of December 31, 2006 and 2005 have been derived from financial statements that are not included in this Form 10-K. Historical results are not necessarily indicative of future results. This selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this Form 10-K.

	Year Ended December 31,					Cumulative period from inception (January 4, 2002) through December 31, 2009
	2009	2008	2007	2006	2005	
Statement of Operations Data:						
Revenues	$	$	$	$	$	$
Operating costs and expenses:						
Research and development	5,097,440	8,710,441	3,040,659	1,087,144	1,330,515	19,952,962
General and administrative	2,177,954	2,183,504	1,986,470	1,815,183	491,653	9,201,216
Total operating cost and expenses	7,275,394	10,893,945	5,027,129	2,902,327	1,822,168	29,154,178
(Loss) from operations	(7,275,394)	(10,893,945)	(5,027,129)	(2,902,327)	(1,822,168)	(29,154,178)
Interest income	33,466	329,348	887,636	172,873	16,788	1,448,946
Loss before income taxes	(7,241,928)	(10,564,597)	(4,139,493)	(2,729,454)	(1,805,380)	(27,705,232)
Provision for income taxes						
Net loss	$ (7,241,928)	$ (10,564,597)	$ (4,139,493)	$ (2,729,454)	$ (1,805,380)	$ (27,705,232)
Net loss per share basic and diluted	$ (0.48)	$ (0.81)	$ (0.33)	$ (0.36)	$ (0.29)	
Weighted average shares outstanding basic and diluted	15,066,799	13,013,041	12,525,405	7,687,630	6,204,918	

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	As of December 31,				
	2009	2008	2007	2006	2005
Balance Sheet Data:					
Cash and cash equivalents	**$ 7,779,277**	**$ 11,766,629**	**$ 15,943,896**	**$ 20,434,702**	**$ 771,127**
Working capital	**7,593,272**	**10,485,039**	**16,228,401**	**19,814,976**	**428,579**
Total assets	**7,966,382**	**12,032,968**	**16,679,922**	**20,619,479**	**789,450**
Total liabilities	**348,522**	**1,472,753**	**357,165**	**772,846**	**342,988**
Stockholders equity	**7,617,860**	**10,560,215**	**16,322,757**	**19,846,633**	**446,462**

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with Selected Financial Data and our financial statements and related notes appearing elsewhere in this Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under the caption Risk Factors in Item 1A of this Form 10-K.

Overview

Catalyst Pharmaceutical Partners, Inc. is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of drug addiction and 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 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, another GABA aminotransferase inhibitor that we believe is more potent than vigabatrin but may have 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 and drug addiction. We believe that we control all current intellectual property for drugs that have a mechanism of action related to GABA aminotransferase.

The successful development of CPP-109, CPP-115 or any other product we may develop, acquire, 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 clinical trials and our other product development activities;
- the results of our 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 NDA s for CPP-109 and CPP-115; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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Based on an analysis of our current financial condition and forecasts of available cash, we believe we will need additional capital to fund many of the future clinical and non-clinical trials of CPP-109 and CPP-115 that will be required before we are permitted to file an NDA for CPP-105 or CPP-115. There can be no assurance that we will ever be able to commercialize CPP-109 and/or CPP-115. See Liquidity and Capital Resources below.

Basis of presentation

Revenues

We are a development stage company and have had no revenues to date. We will not have revenues until such time as we seek and obtain approval of NDA s for CPP-109 or CPP-115, successfully commercialize our products or enter into a licensing agreement which may include up-front licensing fees, of which there can be no assurance.

Research and development expenses

Our research and development expenses consist of costs incurred for company-sponsored research and development activities. The major components of research and development costs include non-clinical study costs, clinical manufacturing costs, clinical trial expenses, consulting, scientific advisors and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials and allocations of various overhead costs related to our product development efforts. To date, all of our research and development resources have been devoted to the development of CPP-109 and CPP-115, and we expect this to continue for the foreseeable future. Costs incurred in connection with research and development activities are expensed as incurred.

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies at a given point in time, we could be required to record significant additional research and development expenses in future periods. Clinical trial activities require significant up front expenditures. We anticipate paying significant portions of a trial s cost before such trial begins, and incurring additional expenditures as the trial progresses and reaches certain milestones.

Selling and marketing expenses

We do not currently have any selling or marketing expenses, as we have not yet received approval for the commercialization of CPP-109 or CPP-115. We expect we will begin to incur such costs upon our filing of an NDA, so that we can have a sales force in place to commence our selling efforts immediately upon receiving approval of such NDA, of which there can be no assurance.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries, personnel expenses for accounting, corporate and administrative functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal, information technology, accounting and consulting services.

Stock-based compensation

We recognize expense for the fair value of all stock-based awards to employees, directors, scientific advisors and consultants in accordance with U.S. generally accepted accounting principles. For stock options we use the Black-Scholes option valuation model in calculating the fair value of these awards, and recognize stock-based compensation expense ratably over the vesting period.

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Income taxes

We have incurred operating losses since inception. As of December 31, 2009 and 2008, we had United States federal and state net operating loss carryforwards of approximately $15,820,000 and $11,016,000, respectively. Our net deferred tax asset has a 100% valuation allowance as of December 31, 2009 and 2008, as we believe it is more likely than not that the deferred tax asset will not be realized. The net operating loss carry-forwards will expire at various dates beginning 2023 and ending in 2029. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitations.

As required by ASC 740, *Income Taxes*, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following the audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which are included elsewhere in this filing, and have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors we believe are reasonable based on the circumstances, the results of which form our management s basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The list below is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, or GAAP. There are also areas in which our management s judgment in selecting any available alternative would not produce a materially different result. Our financial statements and the notes thereto included elsewhere in this report contain accounting policies and other disclosures as required by GAAP.

Pre-clinical study and clinical trial expenses

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are based on actual and estimated costs of the services received and efforts expended pursuant to contracts with multiple research institutions and any contract research organization (CRO) that conducts and manages our clinical trials. The financial terms of these agreements are subject to negotiation and will vary from contract to contract and may result in uneven payment flows. Generally, these agreements will set forth the scope of the work to be performed at a fixed fee or unit price. Payments under these contracts will depend on factors such as the successful enrollment of patients or the completion of clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would be required to modify our estimates accordingly on a prospective basis.

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Stock-based compensation

We recognize stock-based compensation for the fair value of all share-based payments, including grants of stock options and restricted stock units. For stock options we use the Black-Scholes option valuation model to determine the fair value of stock options on the date of grant. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield. Our expected volatility is based on the historical volatility of other publicly traded development stage companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated expected life of our stock option awards. For the years ended December 31, 2009, 2008 and 2007, the assumptions used were an estimated annual volatility of 90%, 80% and 100%, average expected holding periods of four to five, three to five years and four to five years, and risk-free interest rates of 1.26% to 2.60%, 1.55% to 3.23% and 3.50% to 4.90%, respectively.

Results of Operations

Years Ended December 31, 2009 and 2008

Revenues. We had no revenues for the years ended December 31, 2009 and 2008.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2009 and 2008 were $5,097,440 and $8,710,441, respectively. Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2009 decreased significantly compared to amounts expended in the same period in 2008, as we completed our Phase II clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and our proof-of-concept study evaluating CPP-109 for use in the treatment of methamphetamine addiction. In addition, payroll expenses and benefits decreased for the year ended December 31, 2009 as compared to the same period in 2008, as we reduced our workforce upon completion of our clinical trial and proof-of-concept study. We expect that research and development expenses will continue to be substantial in 2010 as we continue our research and development activities.

In our research and development activities for 2009 and 2008, we recorded stock-based compensation relating to the value of stock options and restricted shares granted to employees and non-employees. The amount of stock-based compensation recorded in 2009 and 2008 relating to our research and development activities was $272,184 and $458,289, respectively. The weighted average fair value of the stock options granted in 2009 and 2008 was $0.55 and $1.67, respectively.

Selling and Marketing Expenses. We had no selling and marketing expenses during the 2009 and 2008 fiscal years. We anticipate that we will begin to incur sales and marketing expenses when we file NDA s for CPP-109 or CPP-115, in order to develop a sales organization to market products we may develop upon the receipt of required approvals.

General and Administrative Expenses. General and administrative expenses were $2,177,954 and, $2,183,504, respectively, for the years ended December 31, 2009 and 2008. Included in general and administrative expenses in each of these years was stock-based compensation expense of $329,254 and $259,279, respectively. General and administrative expenses includes, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our administrative employees, consultants and members of our Scientific Advisory Board. The decrease in general and administrative expenses for the year ended December 31, 2009 when compared to the same period in 2008 is primarily due to decreases in consulting and travel expenses, offset by increases in professional fees and stock-based compensation expense. We expect general and administrative costs to remain relatively stable in future periods as we continue the development of our business as described here-in.

Stock-Based Compensation. We issued stock options and restricted stock to several of our employees, consultants and scientific advisors in 2009 and 2008. See Research and Development above. Total stock-based compensation expense for the years ended December 31, 2009 and 2008 was $601,438 and $717,568, respectively. The decrease in stock-based compensation expense from the prior year is primarily related to non recurring 2008 employee year-end option bonus awards and restricted share unit grants to scientific advisors. This decrease was partly offset by the stock-based compensation related to the 2009 fourth quarter grants.

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Interest Income. We reported interest income in all periods relating to our investment of funds received from our private placements, our IPO and our registered direct offerings. The decrease in interest income for the year ended December 31, 2009 as compared to the year ended December 31, 2008 was due to lower interest rates and lower investment amounts as the proceeds from the IPO and registered direct offerings were used to fund our clinical trial and proof-of-concept study expenses and our operations. Substantially all such funds were invested in short-term interest bearing obligations, certificates of deposit and direct or guaranteed obligations of the United States government.

Income taxes. We have incurred net operating losses since inception. Consequently, we have applied a 100% valuation allowance against our deferred tax asset as we believe that it is more likely than not that the deferred tax asset will not be realized.

Years Ended December 31, 2008 and 2007

Revenues. We had no revenues for the years ended December 31, 2008 and 2007.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2008, and 2007 were $8,710,441 and $3,040,659, respectively. Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2008 grew significantly compared to amounts expended in the same period in 2007, as we incurred expenses for services related to the initiation of our Phase II clinical trials evaluating CPP-109 for use in the treatment of cocaine addiction and methamphetamine addiction and incurred expenses for raw materials and finished products for use in the clinical trial and proof-of-concept study. In addition, payroll expenses and benefits increased for the year ended December 31, 2008 as compared to the same period in 2007, as we expanded our research and development staff.

Included in research and development costs were $458,289 and $365,107 for the years ended December 31, 2008 and 2007, respectively, for stock-based compensation relating to shares of our common stock issued to several of our consultants and scientific advisors for services rendered and the value of stock options granted to employees and non-employees. The weighted average fair value of stock options granted in 2008 and 2007 was $1.67 and $2.65, respectively.

Selling and Marketing Expenses. We had no selling and marketing expenses during the 2008 and 2007 fiscal years. We anticipate that we will begin to incur sales and marketing expenses when we file NDA s for CPP-109 or CPP-115, in order to develop a sales organization to market products we may develop upon the receipt of required approvals.

General and Administrative Expenses. General and administrative expenses were $2,183,504 and $1,986,470, respectively, for the years ended December 31, 2008 and 2007. Included in general and administrative expenses in each of these years was stock-based compensation expense of $259,279 and $191,236, respectively. General and administrative expenses includes, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our administrative employees, consultants and members of our Scientific Advisory Board. The increase in general and administrative expenses for the year 2008 as compared to the year 2007 is primarily due to increases in payroll expenses and benefits, depreciation and professional fees.

Stock-Based Compensation. We issued stock options and restricted stock to several of our scientific advisors, consultants and employees in 2008 and 2007. See Research and Development above. Total stock-based compensation expense for the years ended December 31, 2008 and 2007 was $717,568 and $556,343, respectively. This increase in stock-based compensation expense from the prior year is mainly due to employee year-end option bonus awards and restricted share unit grants to scientific advisors.

Interest Income. We reported interest income in all periods relating to our investment of funds received from our private placements, our IPO and our registered direct offering. The decrease in interest income for the year ended December 31, 2008 as compared to the year ended December 31, 2007 was due to lower interest rates and lower investment amounts as the proceeds from the IPO and registered direct offering were used to fund our clinical trial expenses and our operations. Substantially all such funds were invested in short-term interest bearing obligations, certificates of deposit and direct or guaranteed obligations of the United States government.

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Income taxes. We have incurred net operating losses since inception. Consequently, we have applied a 100% valuation allowance against our deferred tax asset as we believe that it is more likely than not that the deferred tax asset will not be realized.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the net proceeds of our private placements, the IPO and two registered direct offerings under a shelf registration statement. At December 31, 2009, we had cash and cash equivalents of $7,779,277 and working capital of $7,593,272. At December 31, 2009 substantially all of our cash and cash equivalents were deposited with one financial institution. Throughout 2009, we periodically had cash balances at certain financial institutions in excess of federally insured limits.

Operating Capital and Capital Expenditure Requirements

We have to date incurred operating losses, and we expect these losses to increase substantially in the future as we expand our product development programs and prepare for the commercialization of CPP-109 and CPP-115. We anticipate using current cash on hand to finance these activities. It may take several years to obtain the necessary regulatory approvals to commercialize CPP-109 or CPP-115 in the United States.

We believe that our existing cash resources will allow us: (i) to fund the pre-clinical studies of CPP-115, which are estimated to be approximately $1.2 million, (ii) to fund our share of the costs of the clinical trial of CPP-109 that we intend to conduct with NIDA, which are estimated to be approximately $2.8 million over a two-year period, and (iii) to meet general corporate requirements through at least the first quarter of 2011.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other product development activities;
- future clinical trial results;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the effect of competition and market developments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in other products.

At the present time, we estimate that we will require additional funding to complete: (i) the additional clinical trials that we believe we will be required to complete before we are in a position to file an NDA for CPP-109 and CPP-115; and (ii) the non-clinical testing of CPP-109 and

CPP-115 that we believe we will be required to complete before we can file an NDA for CPP-109 or CPP-115. We will also require additional working capital to support our operations in periods after the first quarter of 2011.

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We expect to raise any required additional funds through public or private equity offerings, corporate collaborations or other means. We also intend to seek governmental grants for a portion of the required funding for our clinical trials and non-clinical trials. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

On June 2, 2008, we filed a shelf registration statement with the SEC to sell up to $30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. The number of shares we can sell and the amount of proceeds we can raise from the sale of such shares are limited to 20% of outstanding common stock and 33% of our public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules.

To date, we have completed two registered direct public offerings to institutional investors under our shelf registration statement:

- On September 12, 2008, we raised net proceeds of approximately $4.1 million on the sale of 1,488,332 shares of our common stock: and
- On October 2, 2009, we raised net proceeds of approximately $3.7 million on the sale of 3,973,000 shares of our common stock.

As of December 31, 2009, we had approximately $21.5 million of authorized but unissued common stock available for future offerings under our shelf registration. However, there can be no assurance that we will be able to sell additional shares under our shelf registration statement.

If we are delisted from the Nasdaq Capital Market, we expect that we will be able to continue to use our shelf registration statement until it expires.

Cash Flows

Net cash used in operating expenses was $7,683,189 and $8,260,412, respectively, for the years ended December 31, 2009, and 2008. During the year ended December 31, 2009, net cash used in operating activities was primarily attributable to our net loss of $7,241,928 and decreases of $83,072 in accounts payable and $1,041,159 in accrued expenses and other liabilities, offset by decreases of $39,152 in prepaid expenses and deposits and $12,153 in interest receivable. The loss was further offset by $631,665 of non-cash expenses. Non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities was $2,298 and $1,345, respectively, for 2009 and 2008. Such funds were used for purchases of computer equipment.

Net cash provided by financing activities was $3,698,135 and $4,084,490, for 2009 and 2008. During 2009, net cash from financing activities consisted of the net proceeds from the sale of shares of common stock pursuant to the shelf registration and prospectus supplement. During 2008, net cash from financing activities was comprised of the net proceeds from the sale of shares of common stock pursuant to the shelf registration and prospectus supplement of $4,087,900, offset by $3,410 for the payment of employee withholding tax related to the vesting of restricted stock units. Funds from these sales of common stock have been used to fund our research and development costs and our general and administrative costs in 2009 and 2008.

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Contractual Obligations

As of December 31, 2009, we had contractual obligations as follows:

Contractual Obligations (1)	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Operating lease obligations	**$ 194,276**	**$ 65,213**	**$ 129,063**	**$**	**$**
License obligations	**97,871**	**21,435**	**76,436**		
Total	**$ 292,147**	**$ 86,648**	**$ 205,499**	**$**	**$**

(1) We have not included milestone or royalty payments obligations in the table above that we are not able to determine when or if the related milestones will be achieved, or when or if the events triggering payment of the obligations will occur.

We have entered into the following contractual arrangements:

Payments to Brookhaven under our license agreement. We have agreed to pay Brookhaven a fee of $100,000 in the year of NDA approval for CPP-109, $250,000 in each of the second and third years following approval, and $500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed products for certain of their patent-related expenses. We believe that such potential obligation is approximately $166,000 at December 31, 2009 and 2008. See Dispute with Brookhaven below.

Payments to Northwestern under our license agreement. We have agreed to pay Northwestern an upfront fee of $35,000, expense reimbursements of approximately $33,000, and certain milestone payments in future years relating to clinical development activities with respect to CPP-115 or payable upon passage of time, and royalties on any products resulting from the license agreement. The first milestone payment of $50,000 is due on or before August 27, 2012. At December 31, 2009, we had paid the $35,000 upfront fee, and had accrued license fees of $43,706 in the accompanying balance sheet.

Payments to our contract manufacturers. We estimate that we will pay our contract manufacturers approximately $1,225,000, with payments to be based on the achievement of milestones relating to the schedule of work that they have agreed to perform for us. At December 31, 2009, we had paid approximately $1,090,000 of this amount.

Employment agreements. We have entered into an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately $341,000 per annum.

Leases for office space. We have entered into lease agreements for our office space that require payments of approximately $6,000 per month.

Dispute with Brookhaven

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses as of December 31, 2009 was approximately $1.2 million. We believe that we are only liable to Brookhaven for approximately $166,000, and we have advised Brookhaven that we dispute their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by us of an NDA

for CPP-109.

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Off-Balance Sheet Arrangements

We currently have no debt. Capital lease obligations as of December 31, 2009 and 2008 were not material. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued FASB Accounting Standards Codification (ASC) Topic 105, *Generally Accepted Accounting Principles* (ASC 105) (the Codification). ASC 105 supersedes all existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. Going forward, the FASB will not issue new standards in the form of Statements, FASB Staff Positions or Emerging Issues Task Force Abstracts. Instead, it will issue Accounting Standards Updates (ASU), which will serve to update the Codification, provide background information about the guidance, and provide the basis for conclusions on the changes to the Codification. The Codification was effective for financial statements issued for fiscal years and interim periods beginning after September 15, 2009. As a result of the adoption, we have included references to the Codification, as appropriate, in these financial statements, referred to previously under the former FASB references.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of changes in the value of market risk-sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Our exposure to interest rate risk is currently confined to our cash that is invested in highly liquid money market funds. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasized liquidity and preservation of principal over other portfolio considerations.

Item 8. Financial Statements and Supplementary Data

See the list of financial statements filed with this report under Item 15 below.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. The term disclosure controls and procedures , as defined in Rules 13a-15(e) and 15(d)-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

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Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2009, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Securities Exchange Act of 1934, as amended, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management s Annual Assessment of Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements prepared for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our principal executive officer and our principal financial officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2009 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and in accordance with the interpretive guidance issued by the SEC in Release No. 34-55929. Based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2009.

There have been no changes in our internal control or in other factors that could have a material affect, or are reasonably likely to have a material affect to the internal control subsequent to the date of the evaluation in connection with the preparation of this Form 10-K.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. The Company s internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management s report in this Form 10-K.

Item 9B. Other Information

Not applicable.

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PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the SEC in connection with our 2009 Annual Meeting of Stockholders. Our Proxy Statement for the 2010 Annual Meeting of Stockholders is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2009 and is incorporated into this report by this reference.

We have adopted a code of ethics that applies to our chief executive officer, chief financial officer, and to all of our other officers, directors, employees and agents. The code of ethics is available on our website at www.catalystpharma.com. We intend to disclose future amendments to, or waivers from, certain provisions of our code of ethics on the above website within five business days following the date of such amendment or waiver.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by this reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by this reference.

Item 13. Certain Relationships and Related Transactions

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by this reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated into this report by this reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

1. The following financial statements of Catalyst Pharmaceutical Partners, Inc. and Report of Grant Thornton LLP, independent registered public accounting firm, are included in this report:

Report of Grant Thornton LLP, Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2009 and 2008

Statements of Operations for the years ended December 31, 2009, 2008 and 2007 and the period from inception (January 4, 2002) through December 31, 2009

Statement of Stockholders Equity for the period from inception (January 4, 2002) through December 31, 2009

Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007 and the period from inception (January 4, 2002) through December 31, 2009.

Notes to Financial Statements

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

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Exhibit No.	Description of Exhibit
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)
10.1 +	Employment Agreement between the Company and Patrick J. McEnany(2)
10.2 +	Amendment to Employment Agreement between the Company and Patrick J. McEnany(5)
10.3	License Agreement, as amended, between the Company and Brookhaven National Laboratories(1)
10.4 +	Stock Option Agreement between the Company and Patrick J. McEnany(1)
10.5 +	Stock Option Agreement between the Company and Hubert Huckel(1)
10.6 +	Reserved
10.7 +	Reserved
10.8 +	Reserved
10.9 +	2006 Stock Incentive Plan(1)
10.10	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
10.11 +	Consulting Agreement between the Company and Charles O Keeffe(1)
10.12 +	Consulting Agreement between the Company and Donald R. Jasinski(1)
10.13 +	Agreement between the Company and Charles Gorodetzky(1)
10.14	Agreement between the Company and Pharmaceutics International, Inc.(1)
10.15 +	Reserved
10.16 +	Amendment No. 1 to Consulting Agreement between Charles O Keeffe and the Company(2)
10.17	Lease Agreement between the Company and 355 Alhambra Plaza, Ltd.(2)
10.18 +	Letter Agreement between the Company and Jack Weinstein(4)

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Exhibit No.	Description of Exhibit
10.19	License Agreement between the Company and Northwestern University(5)
10.20 +	Amendment to Employment Agreement between the Company and Patrick J. McEnany(6)
23.1	Consent of Independent Registered Public Accounting Firm*
31.1	Section 302 CEO Certification*
31.2	Section 302 CFO Certification*
32.1	Section 906 CEO Certification*
32.2	Section 906 CFO Certification*

(1) Filed by reference to the Company s Registration Statement on Form S-1 (File No. 333-136039)
(2) Filed by reference to the Company s Current Report on Form 8-K dated January 3, 2007
(3) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended March 31, 2007
(4) Filed by reference to the Company s Current Report on Form 8-K dated December 23, 2008.
(5) Filed by reference to the Company s Current Report on Form 8-K dated September 2, 2009
(6) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2009
* Filed herewith
+ Management contract or compensatory plan

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has caused this Annual Report on Form 10-K to be signed by the undersigned, thereunto duly authorized, this 31st day of March, 2010.

CATALYST PHARMACEUTICAL PARTNERS, INC.

By: /s/ Patrick J. McEnany
Patrick J. McEnany, Chairman,

President and CEO

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons, in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Patrick J. McEnany	Chairman of the Board of Directors,	March 31, 2010
Patrick J. McEnany	President and Chief Executive	
	Officer (Principal Executive Officer)	
/s/ Jack Weinstein	Vice President, Treasurer and Chief	March 31, 2010
Jack Weinstein	Financial Officer (Principal	
	Financial Officer)	
/s/ Alicia Grande	Corporate Controller/Chief	March 31, 2010
Alicia Grande	Accounting Officer	
/s/ Hubert E. Huckel, M.D.	Director	March 31, 2010
Hubert E. Huckel, M.D.		
/s/ Charles B. O Keeffe	Director	March 31, 2010
Charles B. O Keeffe		
/s/ Philip H. Coelho	Director	March 31, 2010
Philip H. Coelho		
/s/ David S. Tierney, M.D.	Director	March 31, 2010
David S. Tierney, M.D.		

/s/ Milton J. Wallace	Director	March 31, 2010
Milton J. Wallace		

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Years ended December 31, 2009, 2008, and 2007

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REPORT OF INDEPENDENT REGISTERED

PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Catalyst Pharmaceutical Partners, Inc.

We have audited the accompanying balance sheets of Catalyst Pharmaceutical Partners, Inc. (a Development Stage Company) (the Company) as of December 31, 2009 and 2008, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009 and the period from January 4, 2002 (date of inception) through December 31, 2009. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Catalyst Pharmaceutical Partners, Inc. (a Development Stage Company) as of December 31, 2009 and 2008, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2009 and the period from January 4, 2002 (date of inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company adopted new accounting guidance on January 1, 2007 related to the accounting for uncertainty in income tax reporting. In addition, as discussed in Note 2 to the financial statements, the Company adopted new accounting guidance on January 1, 2006 related to accounting for share-based payments.

/s/ Grant Thornton LLP
GRANT THORNTON LLP
Miami, Florida

March 31, 2010

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

BALANCE SHEETS

	December 31, 2009	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,779,277	$ 11,766,629
Interest receivable		12,153
Prepaid expenses	108,147	136,374
Total current assets	7,887,424	11,915,156
Property and equipment, net	68,447	96,376
Deposits	10,511	21,436
Total assets	$ 7,966,382	$ 12,032,968
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 249,635	$ 332,707
Accrued expenses and other liabilities	44,517	1,097,410
Total current liabilities	294,152	1,430,117
Accrued expenses and other liabilities, non-current	54,370	42,636
Total liabilities	348,522	1,472,753
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: no shares issued and outstanding, at December 31, 2009 and 2008		
Common stock, $0.001 par value, 100,000,000 shares authorized 18,038,385 shares and 14,060,385 shares issued and outstanding at December 31, 2009 and 2008, respectively	18,038	14,060
Additional paid-in capital	35,305,054	31,009,459
Deficit accumulated during the development stage	(27,705,232)	(20,463,304)
Total stockholders equity	7,617,860	10,560,215
Total liabilities and stockholders equity	$ 7,966,382	$ 12,032,968

The accompanying notes are an integral part of these financial statements.

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

STATEMENTS OF OPERATIONS

	Year Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through December 31, 2009
	2009	2008	2007	
Revenues	$	$	$	$
Operating costs and expenses:				
Research and development	5,097,440	8,710,441	3,040,659	19,952,962
General and administrative	2,177,954	2,183,504	1,986,470	9,201,216
Total operating costs and expenses	7,275,394	10,893,945	5,027,129	29,154,178
Loss from operations	(7,275,394)	(10,893,945)	(5,027,129)	(29,154,178)
Interest income	33,466	329,348	887,636	1,448,946
Loss before income taxes	(7,241,928)	(10,564,597)	(4,139,493)	(27,705,232)
Provision for income taxes				
Net loss	$ (7,241,928)	$ (10,564,597)	$ (4,139,493)	$ (27,705,232)
Net loss per share basic and diluted	$ (0.48)	$ (0.81)	$ (0.33)	
Weighted average shares outstanding basic and diluted	15,066,799	13,013,041	12,525,405	

The accompanying notes are an integral part of these financial statements.

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

STATEMENT OF STOCKHOLDERS EQUITY

for the period from January 4, 2002 (date of inception) through December 31, 2009

	Preferred Stock Series A	Preferred Stock Series B	Common Stock	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total
Balance at January 4, 2002 (date of inception)	$	$	$ 21,888	$ 78,112	$	$ 100,000
Issuance of common stock			7,296	117,704		125,000
Issuance of stock options for services				75,833		75,833
Net loss					(255,945)	(255,945)
Balance at December 31, 2002			29,184	271,649	(255,945)	44,888
Issuance of preferred stock	700			669,757		670,457
Issuance of stock options for services				75,833		75,833
Net loss					(428,615)	(428,615)
Balance at December 31, 2003	700		29,184	1,017,239	(684,560)	362,563
Issuance of stock options for services				294,833		294,833
Net loss					(539,820)	(539,820)
Balance at December 31, 2004	700		29,184	1,312,072	(1,224,380)	117,576
Issuance of common stock			39,545	1,006,971		1,046,516
Issuance of common stock and stock options for services			146	1,087,604		1,087,750
Net loss					(1,805,380)	(1,805,380)
Balance at December 31, 2005	700		68,875	3,406,647	(3,029,760)	446,462
Change in par value	(630)		(61,988)	62,618		
Issuance of preferred stock Series B , net		8		3,225,132		3,225,140
Issuance of common stock (IPO), net			3,350	17,634,670		17,638,020
Conversion of preferred stock Series A into common stock, upon closing of IPO	(70)		1,022	(952)		
Conversion of preferred stock Series B into common stock, upon closing of IPO		(8)	1,116	(1,108)		
Issuance of common stock and stock options for services			142	1,266,323		1,266,465
Net loss					(2,729,454)	(2,729,454)
Balance at December 31, 2006			12,517	25,593,330	(5,759,214)	19,846,633
Issuance of common stock and stock options for services			11	579,676		579,687
Amortization of restricted stock for services				35,930		35,930
Net loss					(4,139,493)	(4,139,493)
Balance at December 31, 2007			12,528	26,208,936	(9,898,707)	16,322,757
Issuance of stock options for services				583,836		583,836
Issuance of restricted stock units for services, net			44	130,275		130,319

Issuance of common stock, net			1,488	4,086,412		4,087,900
Net loss					(10,564,597)	(10,564,597)
Balance at December 31, 2008			14,060	31,009,459	(20,463,304)	10,560,215
Issuance of stock options for services				581,286		581,286
Issuance of restricted stock units for services			5	20,147		20,152
Issuance of common stock, net			3,973	3,694,162		3,698,135
Net loss					(7,241,928)	(7,241,928)
Balance at December 31, 2009	$	$	$ 18,038	$ 35,305,054	$ (27,705,232)	$ 7,617,860

The accompanying notes are an integral part of these financial statements.

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through December 31, 2009
	2009	2008	2007	
Operating Activities:				
Net loss	$ (7,241,928)	$ (10,564,597)	$ (4,139,493)	$ (27,705,232)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation and amortization	30,227	32,757	15,761	85,413
Stock-based compensation	601,438	717,568	556,343	4,755,337
Decrease in interest receivable	12,153	51,556	22,078	
Decrease (increase) in other prepaid expenses and deposits	39,152	386,719	(465,696)	(118,658)
(Decrease) increase in accounts payable	(83,072)	112,841	(228,206)	249,634
(Decrease) increase in accrued expenses and other liabilities	(1,041,159)	1,002,744	(185,721)	41,364
Net cash used in operating activities	(7,683,189)	(8,260,412)	(4,424,934)	(22,692,142)
Investing Activities:				
Capital expenditures	(2,298)	(1,345)	(65,872)	(96,339)
Net cash used in investing activities	(2,298)	(1,345)	(65,872)	(96,339)
Financing Activities:				
Proceeds from issuance of common stock, net	3,698,135	4,087,900		26,575,571
Proceeds from issuance of preferred stock, net				3,895,597
Payment of employee withholding tax related to restricted stock units		(3,410)		(3,410)
Net cash provided by financing activities	3,698,135	4,084,490		30,467,758
Net (decrease) increase in cash and cash equivalents	(3,987,352)	(4,177,267)	(4,490,806)	7,679,277
Cash and cash equivalents beginning of period	11,766,629	15,943,896	20,434,702	100,000
Cash and cash equivalents end of period	$ 7,779,277	$ 11,766,629	$ 15,943,896	$ 7,779,277
Non-cash Investing and Financing activities:				
Non-cash incentive received from lessor	$	$	$ 52,320	$ 52,320

The accompanying notes are an integral part of these financial statements.

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of Business

Catalyst Pharmaceutical Partners, Inc. (the Company) is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of addiction and epilepsy. The Company was incorporated in Delaware in July 2006. It is the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation (CPP-Florida), which commenced operations in January 2002.

The Company has incurred operating losses in each period from inception through December 31, 2009. The Company has been able to fund its cash needs to date through an initial funding from its founders, four private placements, an initial public offering (IPO), and two registered direct offerings via a shelf registration to institutional investors; one in 2008 and one in 2009. See Note 10.

Merger

On September 7, 2006, the Company completed a merger with Catalyst CPP-Florida in which CPP-Florida was merged with and into the Company and all of CPP-Florida s assets, liabilities and attributes were transferred to the Company by operation of law. Prior to the merger, the Company was a wholly-owned subsidiary of CPP-Florida. The merger was effected to reincorporate the Company in Delaware.

After the merger, holders of CPP-Florida common stock held an equal number of shares of the Company s common stock, holders of CPP-Florida Series A preferred stock held an equal number of shares of the Company s Series A Preferred Stock and holders of CPP-Florida Series B Preferred Stock held an equal number of shares of the Company s Series B Preferred Stock.

Shares of CPP-Florida common and preferred stock had a par value of $0.01 per share. Shares of the Company s common and preferred stock have a par value of $0.001 per share. An adjustment was made to capital stock and additional paid-in capital during 2006 to reflect this change. Upon closing of the IPO, all the outstanding shares of preferred stock were converted into common stock.

Capital Resources

In June 2008, the Company filed a registration statement on Form S-3 in order to be able to sell up to $30,000,000 of its authorized but unissued common stock through future offerings. During September 2008, the Company sold 1,488,332 shares of its common stock under such registration statement at a price of $3.00 per share and received gross proceeds of approximately $4.5 million before commissions and incurred expenses of approximately $377,000. During October 2009, the Company sold 3,973,000 shares of its common stock under the same registration statement at a price of $1.00 per share and received gross proceeds of approximately $4.0 million before commissions and incurred expenses of approximately $275,000. The Company has approximately $21.5 million of authorized but unissued common stock available for future offerings under its shelf registration statement. See Note 10.

The Company will require additional capital to fund many of the clinical and non-clinical studies of CPP-109 and CPP-115 required to file New Drug Applications (NDA) with the U.S. Food and Drug Administration (FDA). The Company will also require additional working capital to support its operations in periods after the first quarter of 2011.

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1. Organization and Description of Business (continued)

In addition to the filing of the above described shelf registration statement, the Company may raise the additional funds required through public or private equity offerings, debt financings, corporate collaborations, governmental research grants or other means. The Company may also seek to raise new capital to fund additional product development efforts, even if it has sufficient funds for its planned operations. Any sale by the Company of additional equity or convertible debt securities could result in dilution to the Company s current stockholders. There can be no assurance that any such required additional funding will be available to the Company at all or available on terms acceptable to the Company. Further, to the extent that the Company raises additional funds through collaborative arrangements, it may be necessary to relinquish some rights to the Company s technologies or grant sublicenses on terms that are not favorable to the Company. If the Company is not able to secure additional funding when needed, the Company may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on the Company s business.

2. Basis of Presentation and Significant Accounting Policies

a. **DEVELOPMENT STAGE COMPANY.** Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage and the Company s financial statements are presented in accordance with U.S. generally accepted accounting principles. The Company s primary focus is on the development and commercialization of its product candidates CPP-109 and CPP-115.

b. **USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

c. **CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments, purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist mainly of U.S. Treasury bills and money market funds. The Company has substantially all of its cash and cash equivalents deposited with one financial institution.

d. **PREPAID EXPENSES.** Prepaid expenses consist primarily of prepaid insurance and advances under research and development contracts, including advances to the Contract Research Organization (CRO) that oversaw the Company s U.S. Phase II cocaine clinical trial and methamphetamine proof-of-concept study. Such advances are recorded as expense as the related goods are received or the related services are performed.

e. **PROPERTY AND EQUIPMENT.** Property and equipment are recorded at cost. Depreciation is calculated to amortize the depreciable assets over their useful lives using the straight-line method and commences when the asset is placed in service. Leasehold improvements are amortized on a straight-line basis over the term of the lease or the estimated life of the improvement, whichever is shorter. Useful lives generally range from three years for computer equipment to five to seven years for furniture and equipment and leasehold improvements. Expenditures for repairs and maintenance are charged to expenses as incurred.

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2. Basis of Presentation and Significant Accounting Policies (continued)

f. OPERATING LEASES. The Company recognizes lease expense on a straight-line basis over the initial lease term. For leases that contain rent holidays, escalation clauses or tenant improvement allowances, the Company recognizes rent expense on a straight-line basis and records the difference between the rent expense and rental amount payable as deferred rent. As of December 31, 2009 and 2008, we had $42,637 and $52,602, respectively, of deferred rent and lease incentives in accrued expenses and other liabilities.

g. FAIR VALUE OF FINANCIAL INSTRUMENTS. The Company s financial instruments consist of cash and cash equivalents, interest receivable, accounts payables and accrued expenses and other liabilities. At December 31, 2009 the fair value of these instruments approximated their carrying value.

h. RESEARCH AND DEVELOPMENT. Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research for the Company.

i. STOCK BASED COMPENSATION. The Company recognizes expense in the statement of operations for the fair value of all share-based payments to employees, directors, consultants and scientific advisors, including grants of stock options and other share based awards. For stock options, the Company uses the Black-Scholes option valuation model and the single-option award approach and straight-line attribution method. Using this approach, compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally three to five years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

For the years ended December 31, 2009, 2008, and 2007, the Company recorded stock compensation expense as follows:

	2009	2008	2007
Research and development	$ 272,184	$ 458,289	$ 365,107
General and administrative	329,254	259,279	191,236
Total stock-based compensation	$ 601,438	$ 717,568	$ 556,343

Prior to January 1, 2006, the Company recognized share-based compensation using the intrinsic value method.

j. CONCENTRATION OF CREDIT RISK. The financial instruments that potentially subject the Company to concentration of credit risk are cash equivalents (i.e. money market funds). The Company places its cash equivalents with high-credit quality financial institutions. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts.

k. INCOME TAXES. The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Prior to January 1, 2007, the Company accounted for tax contingencies in accordance with FASB ASC 450, *Contingencies*.

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2. Basis of Presentation and Significant Accounting Policies (continued)

The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for years before 2003. If the Company were to subsequently record an unrecognized tax benefit, associated penalties and tax related interest expense would be reported as a component of income tax expense.

l. COMPREHENSIVE INCOME (LOSS). U.S. generally accepted accounting principles require that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly into stockholders equity. The Company has reported comprehensive income (loss) in the statement of stockholders equity as net income (loss).

m. NET INCOME (LOSS) PER SHARE. Basic income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common stock equivalents, such as convertible preferred stock, stock options and restricted stock units. For all periods presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive. Potentially dilutive common stock equivalents as of December 31, 2009 are (i) stock options to purchase up to 2,962,461 shares of common stock at exercise prices ranging from $0.62 to $6.00 and (ii) 5,000 shares of restricted common stock that will vest in the first quarter of 2010. Potentially dilutive common stock equivalents as of December 31, 2008 were (i) stock options to purchase up to 2,772,149 shares of common stock at exercise prices ranging from $0.69 to $6.00 and (ii) 10,000 shares of restricted common stock. Potentially dilutive common stock equivalents as of December 31, 2007 were (i) stock options to purchase up to 2,568,149 shares of common stock at exercise prices ranging from $0.69 to $6.00 and (ii) 25,484 shares of restricted common stock.

n. SEGMENT INFORMATION. Management has determined that the Company operates in one reportable segment which is the development and commercialization of pharmaceutical products.

o. RECENT ACCOUNTING PRONOUNCEMENTS.

In June 2009, the Financial Accounting Standards Board (FASB) issued FASB Accounting Standards Codification (ASC) Topic 105, *Generally Accepted Accounting Principles* (ASC 105) (the Codification). ASC 105 supersedes all existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. Going forward, the FASB will not issue new standards in the form of Statements, FASB Staff Positions or Emerging Issues Task Force Abstracts. Instead, it will issue Accounting Standards Updates (ASU), which will serve to update the Codification, provide background information about the guidance, and provide the basis for conclusions on the changes to the Codification. The Codification was effective for financial statements issued for fiscal years and interim periods beginning after September 15, 2009. As a result of the adoption, the Company has included references to the Codification, as appropriate, in these financial statements, referred to previously under the former FASB references.

p. RECLASSIFICATIONS. Certain prior year amounts in the financial statements have been reclassified to conform to the current year presentation.

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3. Prepaid Expenses

Prepaid expenses consist of the following as of December 31:

	2009	2008
Prepaid insurance	$ 82,145	$ 85,750
Prepaid clinical research fees	7,283	35,489
Prepaid rent	8,035	5,701
Other	10,684	9,434
Total prepaid expenses	$ 108,147	$ 136,374

4. Property and Equipment

Property and equipment, net consists of the following as of December 31:

	2009	2008
Computer equipment	$ 29,509	$ 27,211
Furniture and equipment	44,175	44,175
Leasehold improvements	80,176	80,176
	153,860	151,562
Less: Accumulated depreciation	(85,413)	(55,186)
Total property and equipment, net	$ 68,447	$ 96,376

Depreciation and amortization expense was $30,227, $32,757 and $15,761, respectively, for the years ended December 31, 2009, 2008 and 2007. During the year ended December 31, 2007, approximately $52,000 of tenant build-out costs were paid by the landlord, directly through lease incentives, and therefore, were excluded from the cash flow statement as a non-cash investing and financing activity.

5. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following as of December 31:

	2009	2008
Accrued clinical trial expenses	$ 273	$ 1,064,539
Deferred rent and lease incentive	13,037	9,966
Accrued license fees	18,936	
Accrued professional fees	10,000	15,275
Other	2,271	7,630
Current accrued expense and other liabilities	44,517	1,097,410
Accrued license fees- non-current	24,770	
Deferred rent and lease incentive, non-current	29,600	42,636
Non-current accrued expense and other liabilities	54,370	42,636

Total accrued expenses and other liabilities	$ 98,887	$ 1,140,046

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6. Commitments

The Company has contracted with drug manufacturers and other vendors, including the CRO that oversaw the two clinical trials completed in 2009, to assist in the execution of the Company s pre-clinical and clinical trials, proof-of-concept study, analysis, and the preparation of material necessary for the future filings of NDA s with the FDA. The contracts are cancelable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

The Company has executed noncancellable operating lease agreements for its corporate offices. Certain of these leases have free and escalating rent payment provisions. The Company recognizes rent expense under such leases on a straight-line basis over the term of the lease. As of December 31, 2009, future minimum lease payments under the noncancellable operating lease agreements are as follows:

2010	$ 65,213
2011	66,627
2012	62,436
	$ 194,276

During the quarter ended March 31, 2007, the Company entered into a new lease for its corporate offices in Coral Gables, Florida. The lease provides for fixed increases in minimum annual rent payments, as well as rent free periods. The total amount of rental payments due over the lease term is being charged to rent expense on the straight-line method over the term of the lease. The differences between rent expense recorded and the amount paid is credited or charged to accrued expenses in the accompanying balance sheet. Rent expense was $69,030, $66,028 and $44,169, respectively, for the years ended December 31, 2009, 2008 and 2007. The Company s leases expire on various dates through November 2012.

Obligations under capital leases are not significant.

For commitments related to the Company s license agreements with Brookhaven, (defined below), and Northwestern (defined below) see Note 7.

7. Agreements

a. **LICENSE AGREEMENT WITH BROOKHAVEN.** The Company has entered into a license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven), whereby the Company has obtained an exclusive license for several patents and patent applications in the U.S. and outside the U.S. relating to the use of vigabatrin as a treatment for cocaine and other addictions and obsessive-compulsive disorders. This license agreement runs concurrently with the term of the last to expire of the licensed patents, the last of which currently expires in 2023. The Company paid a fee to obtain the license in the amount of $50,000. Under the license agreement, the Company has agreed to pay Brookhaven a fee of $100,000 in the year of NDA approval of CPP-109, $250,000 in each of the second and third years following approval and $500,000 per year thereafter until the license agreement expires. The Company is also obligated to reimburse Brookhaven for certain of their patent related expenses. The Company believes that as of December 31, 2009, it had a contingent liability of approximately $166,000, related to this obligation. Of these costs approximately $69,000 will become payable in six equal monthly installments at the time the Company submits an NDA to the U.S. Food and Drug Administration (FDA), and the remaining $97,000 will be due commencing within 60 days of obtaining FDA regulatory approval to sell any product. The Company also has the right to enter into sub-license agreements, and if it does, a royalty of 20% of any sub-license fees will be payable to Brookhaven.

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7. Agreements (continued)

Brookhaven has formally advised the Company that they believe that the amount potentially due from the Company to Brookhaven for reimbursement of patent related expenses as of December 31, 2009 was approximately $1.2 million. The Company believes that it is only liable to Brookhaven for the approximately $166,000 described above, and it has advised Brookhaven that it disputes their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by the Company of an NDA for CPP-109. As the Company has not yet filed an NDA for CPP-109, no amounts relating to this matter are accrued in the accompanying December 31, 2009 and 2008 balance sheets.

b. **LICENSE AGREEMENT WITH NORTHWESTERN UNIVERSITY** On August 27, 2009, the Company entered into a license agreement with Northwestern University (Northwestern), under which it acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered by Northwestern. Under the terms of the license agreement, Northwestern granted the Company an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. The Company has identified and designated the lead compound under this license as CPP-115.

Under the license agreement with Northwestern, we will be responsible for continued research and development of any resulting product candidates. As of December 31, 2009 the Company has paid Northwestern upfront payments aggregating $35,000 and has accrued license fees of $43,706 in the accompanying December 31, 2009 balance sheet for expenses, maintenance fees and milestones. In addition, the Company is obligated to pay certain milestone payments in future years relating to clinical development activities with respect to CPP-115, and royalties on any products resulting from the license agreement. The first milestone payment of $50,000 is due on or before August 27, 2012.

c. **AGREEMENT WITH CONTRACT MANUFACTURER.** The Company has entered into an agreement with a contract manufacturer under which such manufacturer has developed for the Company its version of vigabatrin, CPP-109, for use by the Company in its clinical trials and studies. The contract manufacturer is progress billing the Company under this agreement pursuant to a schedule of payments running concurrently with the work they are performing. The payments are due 30 days from the time of invoicing of the scheduled procedure. During the years ended December 31, 2009, 2008 and 2007, the Company paid approximately $116,000, $249,000 and $467,000, respectively, of costs due under this agreement, which were recorded as research and development expenses in the accompanying statements of operations.

The Company has entered into an agreement with a contract manufacturer under which such manufacturer has developed for the Company CPP-115 for use by the Company in its non-clinical studies. The contract manufacturer is progress billing the Company under this agreement pursuant to a schedule of payments running concurrently with the work they are performing. During the year ended December 31, 2009, the Company paid approximately $51,000 of costs due under this agreement, which were recorded as research and development expenses in the accompanying statement of operations.

d. **AGREEMENT WITH CONTRACT RESEARCH ORGANIZATION.** The Company entered into agreements with the CRO that oversaw the Company s recently completed U.S. Phase II cocaine clinical trial and methamphetamine proof-of-concept study. The agreement required certain advances as well as payments based on the achievement of milestones. During the years ended December 31, 2009, 2008 and 2007, respectively, the Company paid approximately $4,190,000, $4,029,000 and $1,083,000 of costs due under this agreement. At December 31, 2009, the Company has approximately $131,000 recorded in accounts payable pertaining to these contracts.

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7. Agreements (continued)

e. AGREEMENTS FOR LABORATORIES AND OTHER RELATED TRIAL TESTS. The Company has entered into various agreements for laboratories and other testing related to the trial and studies. The agreements require certain advances as well as payments based on the achievement of milestones. During the years ended December 31, 2009, 2008 and 2007 the Company paid approximately $370,000, $270,000 and $188,000, respectively, in connection with laboratories and other tests related to its U.S. Phase II cocaine clinical trial. In addition, during the years ended December 31, 2009 and 2008, the Company paid approximately $101,000 and $311,000, respectively, in connection with laboratories related to its methamphetamine proof-of-concept study. At December 31, 2009 and 2008, approximately $7,000 and $35,000 of these amounts had been advanced upon signing of the contracts and as such have been included in prepaid expenses in the accompanying balance sheets.

8. Related Party Transactions

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers and members of the Company s Scientific Advisory Board, a portion of which were with related parties under common ownership and control. During the years ended December 31, 2009, 2008 and 2007, the Company paid approximately $57,000, $155,000 and $56,000, respectively, in consulting fees to related parties.

The Company has an employment agreement with Patrick J. McEnany, its principal stockholder, Chairman, President and Chief Executive Officer. Under this agreement, Mr. McEnany will receive an annual base salary of approximately $358,000 in 2010, and may earn bonus compensation based on performance. This agreement expires in November 2011.

9. Income Taxes

As of December 31, 2009 and 2008, the Company had deferred tax assets of approximately $9,918,000 and $7,176,000, respectively, of which approximately $8,742,000 and $6,228,000 represent United States federal and state net operating loss carryforwards and start-up costs. The remaining temporary differences represent nondeductible stock option and equity expense. The related deferred tax asset has a 100% valuation allowance as of December 31, 2009 and 2008, as the Company believes it is more likely than not that the deferred tax asset will not be realized. The change in valuation allowance was approximately $2,742,000, $4,036,000 and $1,591,000 in 2009, 2008 and 2007, respectively. There are no other significant temporary differences. The net operating loss carry-forwards of approximately $15,820,000 as of December 31, 2009 will expire at various dates beginning in 2023 and ending in 2029. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitation. The effective tax rate of 0% in all periods presented differs from the statutory rate of 35% due to the valuation allowance and because the Company had no taxable income.

10. Stockholders Equity

Stock split

On October 3, 2006, the Company s board of directors approved an approximate 1.4592-to-one stock split (effected in the form of a stock dividend). All stock value, common shares outstanding and per share amounts set forth in these financial statements were adjusted retroactively to reflect this split.

Private Placements

In November 2002, the Company completed a private placement in which it raised gross proceeds of $125,000 through the sale of 729,609 shares of its common stock.

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10. Stockholders Equity (continued)

In April 2003, the Company completed a private placement in which it raised net proceeds of $670,457 through the sale of 70,000 shares of its Series A Preferred Stock.

In March 2005, the Company completed a private placement in which it raised net proceeds of $1,046,516 through the sale of 3,954,483 shares of its common stock.

On July 24, 2006, the Company completed a private placement in which it raised net proceeds of $3,225,140 through the sale of 7,644 shares of its Series B Preferred Stock.

Common Stock

The Company has 100,000,000 shares of authorized common stock with a par value of $0.001 per share. At December 31, 2009 and 2008, 18,035,385 and 14,060,385 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

On November 13, 2006, the Company closed its IPO. In the IPO, the Company sold 3,350,000 shares of its common stock at an initial public offering price of $6.00 per share. The Company received net proceeds from the offering of approximately $17,638,000 (gross proceeds of $20,100,000 less a 7% underwriting discount aggregating $1,407,000 and offering expenses of approximately $1,055,000). At the closing of the IPO, all of the Company s then outstanding Series A Preferred Stock and Series B Preferred Stock automatically converted into an aggregate of 2,136,860 shares of the Company s common stock. Costs related to the IPO were charged to paid-in-capital at the successful completion of the IPO.

On June 2, 2008, the Company filed a shelf registration statement with the SEC to sell up to $30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. Under this registration statement the Company may sell common stock periodically pursuant to a Prospectus Supplement to provide additional funds for its operations. The number of shares that the Company can sell and the amount of the gross proceeds that the Company can raise are limited to 20% of the number of shares of outstanding common stock and 33% of the Company s public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules. On September 12, 2008, the Company filed a prospectus supplement and offered for sale to institutional investors 1,488,332 shares of its common stock at $3.00 per share pursuant to the registration statement. The Company received gross proceeds of approximately $4.5 million before commissions and expenses of approximately $377,000. On October 2, 2009, the Company filed a prospectus supplement and offered for sale to institutional investors 3,973,000 shares of its common stock at $1.00 per share pursuant to the registration statement. The Company received gross proceeds of approximately $4.0 million before commissions and expenses of approximately $275,000.

In addition, on June 2, 2008 the Company filed two registration statements on Form S-8 to register: (i) shares of restricted common stock and shares of common stock underlying stock options issued under its 2006 Stock Incentive Plan, and (ii) shares of common stock underlying the stock options granted by the Company prior to its IPO.

Nasdaq Listing

On May 19, 2009, the Company received a staff deficiency letter from The Nasdaq Stock Market notifying the Company that, based on the Company s stockholders equity as reported in the Company s Quarterly Report on Form 10-Q for the period ended March 31, 2009, the Company was not in compliance with the minimum stockholders equity requirement of $10 million for continued listing on the NASDAQ Global Market as set forth in NASDAQ Listing Rule 5450(b)(1)(A). During August 2009, the Company requested a transfer of its listing from the NASDAQ Global Market to the NASDAQ Capital Market. On September 1, 2009, the Company received an approval for the transfer, effective September 3, 2009.

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10. Stockholders Equity (continued)

On November 13, 2009, the Company received a staff deficiency letter from The Nasdaq Stock Market notifying the Company that it is not in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. The Nasdaq Listing Rules (the Rules) require listed securities to maintain a minimum bid price of $1.00 per share and, based on the closing bid prices for the last 30 consecutive business days, the Company no longer meets that requirement. This notification has no immediate effect on the Company s listing on the NASDAQ Capital Market or on the trading of the Company s common stock.

Under the Rules, the Company has a grace period of 180 days to regain compliance. If at any time within the grace period the Company s common stock closes at or above $1.00 per share for a minimum of ten consecutive business days, the Nasdaq Stock Market will provide the Company with a written confirmation of compliance and the matter will be closed. In the event the Company does not regain compliance with the Rule prior to the expiration of the grace period, the Company may be eligible for an additional 180-day grace period if at such time it meets the initial listing standards for listing on the Nasdaq Capital Market, with the exception of the bid price requirement.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share at December 31, 2009 and 2008. No shares of preferred stock were outstanding at December 31, 2009 and 2008.

11. Stock Compensation Plans

The Company issues options, restricted stock, stock appreciation rights and restricted stock units (collectively, the Awards) to employees, directors, consultants and scientific advisors of the Company under the 2006 Stock Incentive Plan (the Plan) (see Note 2). Prior to July 2006, the Company granted options pursuant to written agreements to purchase an aggregate of 2,352,254 shares of common stock. Under the Plan, 2,188,828 shares of the Company s common stock were reserved for issuance. At December 31, 2009, 809,270 of these shares remained available for future issuance under the Plan.

Stock Options

The Company has granted stock options to employees, officers, directors and scientific advisors generally at exercise prices equal to the market price of the common stock at grant date. Share awards generally vest over a period of 3 to 4 years of continuous service and have contractual terms from 5 to 10 years. Certain awards provide for accelerated vesting if there is a change in control, as described in the Plan. The Company issues new shares as shares are required to be delivered upon exercise of outstanding stock options. No stock options have been exercised to date.

During the years ended December 31, 2009, 2008 and 2007 the Company recorded non-cash stock-based compensation expense related to stock options totaling $581,286, $583,836 and $520,413, respectively.

During 2009 the Company granted five-year options to purchase an aggregate of 755,000 shares of the Company s common stock to certain of the Company s officers, employees and consultants. In connection with such grants, certain officers, employees and consultants agreed to the cancellation of 743,688 previously held options, substantially all of which were fully vested on the cancellation date. Additionally, on the same date, the Company granted five-year options to purchase an aggregate of 180,000 shares to the Company s directors and corporate secretary.

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11. Stock Compensation Plans (continued)

Stock option activity under the Company s written stock option agreements and the Plan for the years ended December 31, 2009, 2008 and 2007 is summarized as follows:

	2009		2008		2007	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,772,149	$ 1.53	2,568,149	$ 1.42	2,374,149	$ 1.19
Granted	999,000	0.95	204,000	2.92	194,000	4.20
Exercised						
Forfeited or cancelled	(808,688)	2.67				
Outstanding at end of year	2,962,461	$ 1.02	2,772,149	$ 1.53	2,568,149	$ 1.42
Exercisable at end of year	2,444,128	$ 1.05	2,571,890	$ 1.35	2,320,781	$ 1.15

The aggregate intrinsic value of outstanding options and exercisable options at December 31, 2009 was $300 and $150, respectively. The weighted-average grant-date fair value of stock options granted during 2009, 2008 and 2007 was $0.55, $1.67 and $2.65, respectively. The total fair value of vested stock options during 2009, 2008 and 2007 was $634,807, $633,346 and $433,736, respectively.

The following table summarizes information about the Company s options outstanding at December 31, 2009:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price
$0.62 - $0.89	1,489,220	3.85	$ 0.68	1,474,220	3.84	$ 0.68
$0.90	935,000	4.80	$ 0.90	431,667	4.80	$ 0.90
$1.37 - $2.98	433,353	1.28	$ 1.70	433,353	1.28	$ 1.70
$2.99 - $6.00	104,888	2.93	$ 4.08	104,888	2.93	$ 4.08
	2,962,461	3.74	$ 1.02	2,444,128	3.52	$ 1.05

As of December 31, 2009, there was approximately $324,000 of unrecognized compensation expense related to non-vested stock option awards granted under the Plan. That cost is expected to be recognized over a weighted average period of approximately 1.41 years.

The Company utilizes the Black-Scholes option-pricing model to determine the fair value of stock options on the date of grant. This model derives the fair value of stock options based on certain assumptions related to the expected stock price volatility, expected option life, risk-free interest rate and dividend yield. Due to the Company s short history as a public entity, the Company s expected volatility is based on the historical volatility of other publicly traded companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated life of the stock options awards. The expected dividend rate is zero. Stock based compensation expense also includes an estimate, which the Company makes at grant date, of the number of awards that are expected to be forfeited. The Company revises this estimate in subsequent periods if actual forfeitures differ from those estimates.

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11. Stock Compensation Plans (continued)

Assumptions used during the years were as follows:

	Year ended December 31,		
	2009	2008	2007
Risk free interest rate	1.26% to 2.60%	1.55 to 3.23%	3.50 to 4.90%
Expected term	4 to 5 years	3 to 5 years	4 to 5 years
Expected volatility	90%	80%	100%
Expected dividend yield	%	%	%
Expected forfeiture rate	%	%	%

Restricted Stock Units

Under the Plan, participants may be granted restricted stock units, each of which represents a conditional right to receive shares of common stock in the future. The restricted stock units granted under this plan generally vest ratably over a three to four-year period. Upon vesting, the restricted stock units will convert into an equivalent number of shares of common stock. The amount of expense relating to the restricted stock units is based on the closing market price of the Company s common stock on the date of grant and is amortized on a straight-line basis over the requisite service period. Restricted stock unit activity during 2009, 2008 and 2007 was as follows:

	2009		2008		2007	
	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested balance at beginning of year	10,000	$ 4.03	25,484	$ 3.61		$
Granted			30,000	3.26	25,484	3.61
Vested	(5,000)	4.03	(45,484)	3.29		
Forfeited						
Nonvested balance at end of year	5,000	$ 4.03	10,000	$ 4.03	25,484	$ 3.61

During the years ended December 31, 2009, 2008 and 2007, the Company recorded non-cash stock-based compensation related to restricted stock units totaling $20,152, $133,732 and $35,930, respectively. There was no additional restricted stock unit compensation expense related to non-vested awards yet to be recognized as of December 31, 2009.

12. Benefit Plan

During 2007, the Company established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. Subject to certain dollar limits, all eligible employees may contribute up to 15% of their pre-tax annual compensation to the plan. Commencing in 2008, the Company has elected to make discretionary matching contributions of employee contributions up to 4% of an employee s gross salary. For the years ended December 31, 2009 and 2008 the Company s matching contributions were approximately $34,000 and $30,000, respectively.

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13. Quarterly Financial Information (unaudited)

The following table presents unaudited supplemental quarterly financial information for the years ended December 31, 2009 and 2008:

	Quarter Ended			
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
Revenues	$	$	$	$
Loss from operations	(3,044,543)	(1,768,812)	(1,292,314)	(1,169,725)
Net loss	(3,031,201)	(1,761,887)	(1,286,720)	(1,162,120)
Loss per share basic and diluted	$ (0.22)	$ (0.13)	$ (0.09)	$ (0.06)

	Quarter Ended			
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
Revenues	$	$	$	$
Loss from operations	(1,724,032)	(2,463,677)	(2,914,778)	(3,791,458)
Net loss	(1,584,047)	(2,377,440)	(2,855,360)	(3,747,750)
Loss per share basic and diluted	$ (0.13)	$ (0.19)	$ (0.22)	$ (0.27)

Quarterly basic and diluted net loss per common share were computed independently for each quarter and do not necessarily total to the full year basic and diluted net loss per common share.

14. Subsequent Event

On February 22, 2010, the Company executed a non-binding letter of intent with the National Institute on Drug Abuse (NIDA) to conduct a U.S. Phase II(b) clinical trial evaluating CPP-109, the Company s formulation of vigabatrin, for the treatment of cocaine addiction. It is anticipated that NIDA, under their agreement with the Veteran s Administration Cooperative Studies Program, will provide substantial resources for the trial and that the Company will contribute approximately $2.8 million in resources as part of the estimated $10 million trial cost (including study medication, patient recruitment costs and certain trial expenses). The Company expects to execute a binding clinical trial agreement with NIDA regarding this trial in the near future.

It is anticipated that this double-blind, placebo-controlled clinical trial will enroll approximately 200 patients and will be conducted at eight leading addiction facilities across the United States. The trial will seek to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and is scheduled to commence in the early summer of 2010.

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Exhibit Index

Exhibit No.	Description
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Section 302 CEO Certification
31.2	Section 302 CFO Certification
32.1	Section 906 CEO Certification
32.2	Section 906 CFO Certification