CATALYST PHARMACEUTICAL PARTNERS, INC.
Form 10-K
March 30, 2012
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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, 2011

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	**(IRS Employer**

incorporation or organization)	**Identification No.)**

355 Alhambra Circle, Suite 1500

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 x 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, 2011, 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 $30,212,440.

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: 24,741,520 shares of common stock, $0.001 par value per share, were outstanding as of March 23, 2012.

Part III incorporates certain information by reference from the registrant s definitive proxy statement for the 2012 annual meeting of stockholders. The proxy statement with respect to the 2012 annual meeting of stockholders will be filed no later than 120 days after the close of the registrant s fiscal year ended December 31, 2011.

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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

Some of the statements in this Annual Report on Form 10-K are forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements do not relate strictly to historical or current matters. Rather, forward-looking statements are predictive in nature and may depend upon or refer to future events, activities or conditions. Although we believe that these statements are based upon reasonable assumptions, we cannot provide any assurances regarding future results. We undertake no obligation to revise or update any forward-looking statements, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the section entitled Item 1A Risk Factors and Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations Caution Concerning Forward-Looking Statements.

Item 1. Business

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in development. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 and CPP-115 have both been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 and CPP-115 are 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 other selected central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, 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 drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

The successful development of CPP-109, CPP-115, or any other product we may acquire, develop or license in the future, 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, or if any net cash inflows will actually commence, due to the numerous risks and uncertainties associated with developing such products, including the uncertainty of:

- the results of our pre-clinical studies and clinical studies and trials, and the number of clinical trials (and the scope of such trials) that will be required for us to seek and obtain approval of New Drug Applications (NDAs) for CPP-109 and CPP-115; and

- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

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We are currently involved in the following product development activities: (i) the FDA has accepted our Investigational New Drug Application (IND) for CPP-115 (ii) we have commenced an initial Phase I(a) clinical study evaluating the safety of CPP-115 in healthy volunteers; and (iii) we are jointly conducting with the National Institute on Drug Abuse (NIDA) and the Veterans Administration (VA) a U.S. Phase II(b) clinical trial of CPP-109 and, based on current information, we expect to obtain top line results from this trial early in the first quarter of 2013.

Based on an analysis of our current financial condition and forecasts of available cash, we believe that we have sufficient resources to: (i) complete the above-described Phase I(a) clinical study of CPP-115 and the Phase II(b) clinical trial of CPP-109 and (ii) support our operations through the first quarter of 2013. However, there can be no assurance that we will actually have sufficient funds for these purposes. We will require additional funding to complete any other pre-clinical studies and trials that may be required to submit NDAs for and commercialize CPP-109 and CPP-115 and to support our operations beyond the first quarter of 2013. There can be no assurance that we will obtain additional funding or ever be able to commercialize either of our product candidates. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources below.

Our Drug Candidates

The following table summarizes key information regarding our drug candidates:

Drug Candidate	Indications	Current Status
CPP-109	Addiction	Conducting a Phase II(b) clinical trial in conjunction with NIDA and the VA for cocaine addiction.
CPP-115	Addiction, Epilepsy	Conducting a Phase I(a) human safety study

Mechanism of Action

We believe that our drug candidates, CPP-109 and CPP-115, will be effective treatments for addiction and that our drug candidate, CPP-115, will be an effective treatment for both addiction and epilepsy because they increase endogenous GABA levels in the brain through the inhibition of GABA-aminotransferase (GABA-AT). GABA-AT is responsible for the eventual breakdown of GABA and helps to balance its inhibitory effects.

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 that send a signal to subsequent neurons. This is the mechanism explaining the efficacy of CPP-109 vigabatrin as a treatment for complex partial seizures. In the case of addiction, increased GABA reduces the perception of pleasure and reward by dampening levels of dopamine release 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 also helps induce relaxation and sleep, and contributes to functions such as motor control and vision.

CPP-109 and CPP-115 are GABA analogs that are readily absorbed and promptly available to the central nervous system, producing effects that last for many hours after a single dose. Due to the fact that these drugs are not receptor active , their administration does not appear to affect the baseline levels of dopamine, nor those variations in dopamine levels caused by normal stimuli. We believe that the similarities between CPP-115 and the well characterized drug, CPP-109, will simplify the development of CPP-115 because potential development risks can be predicted and managed.

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History and Side Effect Profile of Vigabatrin

Vigabatrin has been marketed for decades in over 30 countries by Sanofi-Aventis and its predecessors under the brand names Sabril®, Sabrilex® and Sabrilan® (hereinafter referred to as Sabril®) as an adjunct (add-on) treatment for adult epilepsy and as a primary treatment for the management of infantile spasms. 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 therapy for adult patients with refractory complex partial seizures who have failed treatments with several other anti-epileptic drugs. The NDAs are for different formulations of Sabril® and both NDAs are held by Lundbeck Inc. (Lundbeck). Due to 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 with lower than average neurological side effects compared to other approved epilepsy therapies. The most common side effects reported have been drowsiness and fatigue. However, one clearly established adverse side effect is the development, of peripheral visual field defects, or VFDs. VFDs occur in approximately 33% of patients when cumulative dosage levels of vigabatrin approach approximately 1,500 grams. These VFDs are manifest as a constriction of the peripheral field of vision (i.e. tunnel vision).

Based on available information as described above and our clinical trial experience to date, we believe that VFDs occur at cumulative doses far higher than the total dosage amount we anticipate will be used for addiction treatment. To date, we believe that no subjects treated in the trial conducted in Mexico, or in our previously completed U.S. Phase II(a) cocaine trial or our methamphetamine human proof-of-concept study, have shown any evidence of VFDs.

CPP-115 is structurally similar to vigabatrin. Due to these similarities, we believe that these two drugs will share a number of biochemical features related to absorption, metabolism, and elimination, and our pre-clinical studies of CPP-115 to date support our expectations. However, based upon our pre-clinical studies of CPP-115 to date, we expect that there will be a significant reduction, and possibly elimination, of VFDs from the use of CPP-115 compared to vigabatrin. However, there can be no assurance that this will ultimately prove to be the case.

CPP-109 (Vigabatrin) To Treat Addiction

In 2002, we obtained from Brookhaven National Laboratory (Brookhaven) an exclusive license for several patent and patent applications to develop vigabatrin as a treatment for cocaine and other addictions. 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 FDCA, 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. However, there can be no assurance that our receipt of Fast Track status will assist us in the regulatory process for CPP-109.

CPP-115 for the Treatment of Addiction and Epilepsy

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.

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The development efforts of CPP-115 were led by Dr. Richard B. Silverman, the John Evans Professor of Chemistry at Northwestern University (Northwestern). Dr. Silverman, who holds 44 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 mimic the mechanism of action of vigabatrin, while making it both more potent and specific.

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.

Based on testing to date, 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 dosage forms potentially administrable by other routes of administration compared with the marketed oral, immediate release formulations of vigabatrin, Sabril®. Further, based on pre-clinical testing completed to date, CPP-115 has a superior specificity to GABA aminotransferase and we believe, will have a better side effect profile (e.g. less visual field defects) compared with Sabril®.

CPP-115 has been granted Fast Track status by the FDA for the treatment of cocaine addiction and orphan drug designation for the treatment of infantile spasms. CPP-115 has also been granted orphan medicinal product designation in the EU for the treatment of West Syndrome (a form of infantile spasms).

Our Strategy

Our strategy is to become a leading specialty pharmaceutical company focused on the in-licensing and development of proprietary drug candidates for the treatment of selected 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 addiction and epilepsy. Our long-term strategy is to gain approvals for additional indications for CPP-109, including methamphetamine addiction, and to initially gain approval for CPP-115 to treat addiction and epilepsy. 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. Enrollment for our U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction we are conducting with NIDA and the VA began in the first quarter of 2011. This trial is currently ongoing and we expect to receive top-line results from this trial early in the first quarter of 2013. 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.

Develop additional indications for CPP-109. The mechanism of action of CPP-109 and pre-clinical data indicate it to be suitable as a potential treatment for addictions to methamphetamine, nicotine, prescription pain medications, alcohol and marijuana, as well as for 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.

Continue clinical and pre-clinical work on CPP-115. During the fourth quarter of 2011, we completed our IND-enabling studies, filed an IND, and began a Phase I(a) human clinical trial for CPP-115 to evaluate its safety. We expect to receive final results from this Phase I(a) human clinical trial during the second quarter of 2012. Subject to the availability of funding, we hope to begin further human clinical trials for CPP-115 during the latter part of 2012 or early 2013.

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 Potential Markets

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. 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 to substances, such as cocaine and methamphetamine. 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.

We believe that CPP-109 and CPP-115 do not suffer from these limitations and therefore, if approved, that both will have the potential to become widely prescribed, safe and effective treatments 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. 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.

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A June 2011 report of the National Center on Addiction and Substance Abuse at Columbia University titled Adolescent Substance Abuse : America s #1 Public Health Problem found that in annual federal, state and local government spending as a result of substance abuse and addiction was at least $467.7 billion almost $1,500 for every man, woman, and child in America. A 2009 report from the same group found that for every dollar federal and state governments spent on substance abuse and addiction in 2005, 95.7 cents went to shoveling up the wreckage and only 1.9 cents to prevention and treatment and 0.4 cents to research.

In 2010, an estimated 22.6 million people in the United States aged 12 or over were current users of illicit drugs (defined as usage in the past month), according to the National Survey on Drug Use and Health, published by SAMHSA, which we refer to as the SAMHSA survey. This represents 8.9% of the total population aged 12 or older. This rate was higher than the rate in 2009 (8.7%), 2008 (8.0%), 2007 (8.0%), 2005 (8.1%) and 2004 (7.9%).

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

According to the same survey, the number and percentage of past-month nonmedical users of stimulants decreased slightly from 1.3 million (0.5%) in 2009 to 1.1 million (0.4%) in 2010, based on a decrease in methamphetamine users, from 502,000 (0.2%) to 353,000 (0.1%). These numbers are similar to those seen in 2008 and represent the resumption of a trend that had seen methamphetamine use fall from 2006 to 2008, but increase in 2009.

In addition, approximately 5.1 million people in 2010, or 2.0% of the population aged 12 or over took prescription pain relievers for non-medical purposes in the month preceding the survey. This remained substantially unchanged from 2009, when 5.2 million people, or 2.1% of the population aged 12 or over, took prescription pain relievers for non-medical purposes in the month preceding the survey. Further, approximately 16.9 million people aged 12 or over in the United States were classified as heavy drinkers in 2010. Additionally, there are approximately 17.4 million persons aged 12 or over who used marijuana in the month preceding the survey and approximately 1.0 million people sought treatment in 2010. Finally, obsessive-compulsive disorders such as 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.

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.

We intend to focus our development efforts for CPP-115 on its use as a treatment for infantile spasms and adult complex partial seizures. Although vigabatrin (CPP-109) is one of the drugs in our development pipeline, we have no plans to develop CPP-109 for the treatment of epilepsy.

An infantile spasm (IS) is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood. The onset of infantile spasms is usually in the first year of life, typically between 4-8 months. The seizures primarily consist of a sudden bending forward of

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the body with stiffening of the arms and legs; some children arch their backs as they extend their arms and legs. Spasms tend to occur upon awakening or after feeding, and often occur in clusters of up to 100 spasms at a time. Infants may have dozens of clusters and several hundred spasms per day. Infantile spasms usually stop by age five, but may be replaced by other seizure types.

In complex partial seizures, consciousness is altered. 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.

According to the Epilepsy Foundation, there are about 3 million epilepsy patients in the United States, with approximately 200,000 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.

Anti-epileptic drugs work through a variety of mechanisms, including inhibition of sodium ion channels and the enhancement of GABA mechanisms. Although the different types of epilepsy vary greatly, in general, available medications can only control seizures in about two-thirds of patients. CPP-115, like vigabatrin (CPP-109), is a GABA-AT inhibitor, and we are developing it initially for infantile spasms and complex partial seizures. Based on the historic use of vigabatrin in treating epilepsy, we believe that CPP-115 may ultimately work best as an adjunct therapy to existing drugs.

Vigabatrin is used in over 30 countries for the treatment of infantile spasms and for the treatment of adult complex partial seizures in patients who have failed several treatments. On August 21, 2009, Sabril® was approved for these indications in the United States.

Our Clinical Trials

CPP-109

In 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II(a) clinical trial evaluating the use of CPP-109 in treating subjects addicted to cocaine. The trial enrolled 186 cocaine addicted patients at 11 addiction treatment research centers and clinical research centers throughout 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).

On September 30, 2009, we announced additional results from our U.S. Phase II(a) cocaine 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 trial 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 trial 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, 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 (iii) in those subjects who were compliant with study medication, the differences between CPP-109 and placebo were amplified, which suggests 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).

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Consistent with previously 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 greater than 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 published in *The American Journal of Psychiatry* in November 2009). See Clinical and Pre-Clinical Studies of Our Product Candidates Undertaken by Others below.

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 small sample size. We also believe that medication compliance, similar to our previously discussed cocaine trial, was below expectations.

Based on the results from our Phase II cocaine trial and our methamphetamine proof-of-concept study, we expect that the data from those studies will be treated as supportive of any NDA application that we file.

On April 13, 2010, we signed a Clinical Trial Agreement (CTA) with NIDA to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Phase II(b) Trial). As part of the CTA, NIDA, under their agreement with the Veterans Administration Cooperative Studies Program, agreed to provide substantial resources towards the completion of the Phase II(b) Trial. This approximately 200 subject double-blind, placebo-controlled trial is being conducted at twelve leading addiction research facilities across the United States. The Phase II(b) Trial, which is being overseen by us, NIDA and the VA, was initiated in November 2010 and began enrolling patients during the first quarter of 2011. Based on currently available information, we expect to have top-line results from this trial early in the first quarter of 2013. The Phase II(b) 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 as one of the adequate and well controlled trials required to support approval of an NDA for CPP-109.

Pursuant to the CTA, we have provided the study drug (and matching placebo) to the VA Clinical Pharmacy to be packaged suitably for use in the Phase II(b) Trial. In conjunction with NIDA and the VA, we have developed the Phase II(b) Trial protocol and informed consent and have submitted such documents to the FDA for review. We are also responsible for, among other duties, funding patient recruitment activities and advertising for the Phase II(b) Trial, establishing and funding a contract with a vendor capable of decrypting and converting the visual field data obtained from study subjects into a format analyzable by the VA statisticians who will interpret the study data. We have also agreed to fund the treatment costs for up to 25 study subjects. Further, pursuant to the CTA, NIDA has provided input on the protocol and informed consent and, under their agreement with the VA, is funding qualified study sites and investigators. NIDA has also presently contracted to treat more than 200 study subjects. Finally, NIDA, through its agreement with the VA, is providing clinical monitoring of all sites, pursuant to the CTA.

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

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The protocol for the Phase II(b) Trial has been designed to attempt to mitigate compliance issues that were observed in our previous U.S. Phase II(a) cocaine clinical trial and our methamphetamine proof-of-concept study. In the Phase II(b) Trial, subjects are being observed taking their medication on the days that they are at the trial sites for tests and therapy. Urine samples collected from subjects are also being monitored to determine whether trial subjects are taking their medication (CPP-109 or placebo). Further, the subjects are also undergoing therapy once per week and will receive substantially lower compensation for participation than in our previous trials. Finally, the trial is being conducted at 12 addiction treatment oriented centers, and the patient recruitment firm that is working with us on this trial has been directed to target trial subjects more likely to be genuinely interested in seeking treatment to overcome their addiction to cocaine. Although there can be no assurance, we believe that with these modifications we should avoid the medication compliance issues observed in our prior clinical studies.

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, there is a possibility that if the data from the Phase II(b) Trial is sufficiently compelling, that the FDA will allow us to file an NDA for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat addiction. However, it is more likely that the FDA will require at least one Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will allow us to file an NDA for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA permits us to file an NDA based on the results of our current Phase II(b) trial, it is unlikely that we will be in a position to submit an NDA for CPP-109 before sometime in the second half of 2013. Finally, if the FDA requires more than one Phase III clinical trial, our NDA submission would be delayed even further. There can be no assurance that the data from our ongoing Phase II(b) Trial will be sufficiently compelling or that even if such data are sufficiently compelling, that the FDA will allow us to file an NDA for CPP-109 based on the results of that trial.

Lundbeck s exclusivity for Sabril® tablets to treat refractory complex partial seizures in adults will expire on August 20, 2014. We currently expect to submit a 505(b)(2) application in submitting an NDA for CPP-109. A 505(b)(2) application is one that relies, at least partially upon, data that a company does not own or have right of reference to, including published literature. A 505(b)(2) application can also rely upon the FDA s previous rulings on safety and efficacy for previously approved products. Data on manufacturing, bioequivalence, and bioavailability must be submitted, along with information to support any change relative to the previously approved product, as well as information on the patent status of the product previously approved and the product for which an NDA has been submitted. See Regulatory Matters The Hatch Waxman Act below. There can be no assurance whether, or to what extent, the FDA will accept 505(b)(2) data for any NDA that we may file for CPP-109.

CPP-115

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

In visual safety studies of rats exposed for 90 days to either CPP-115, vigabatrin or placebo, CPP-115 caused substantially less retinal damage than vigabatrin at well above the expected therapeutic doses.

The oral pharmokinetic behavior of CPP-115 in rats supports further development as an orally delivered pharmacotherapy.

CPP-115 was found to not inhibit or induce metabolic enzymes and is not itself metabolized. As a result, drug-drug interactions or other metabolism-related side effects are unlikely. Additionally, non-metabolized drugs are advantageous for treating drug addicts, a population that often has impaired liver function.

With the exception of its biochemical target, GABA-aminotransferase, CPP-115 did not show any clinically significant binding to 111 of the most prominent receptors, proteins and transporters.

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Additionally, CPP-115 showed no binding to other GABA-related targets (GABA receptors and transporters). Therefore, CPP-115 is very specific and not likely to induce drug-drug interactions or unintended side effects.

CPP-115 did not show any interference with the hERG channel and is therefore not likely to induce heart arrhythmias.

CPP-115 did not show any abnormalities in an in-vitro battery of genotoxicity studies and thus is not likely to be carcinogenic.

CPP-115 did not show any inhibition of ALT and AST at doses far above the expected therapeutic dosage. This is in contrast to vigabatrin s known inhibition at therapeutic doses of these key liver transaminase enzymes.

CPP-115, like vigabatrin, was found to significantly reduce seizures in accepted animal models of epilepsy, as evaluated by the National Institutes of Health s Anticonvulsant Screening Program (ASP) at lower doses than vigabatrin.

CPP-115 was found to eliminate cocaine-conditioned place preference and significantly reduced cocaine-induced dopamine surge, key tests needed to demonstrate a drug s effectiveness as a potential treatment for stimulant addiction. These effects were observed at doses more than 200 times lower than that needed by vigabatrin to achieve the same effect.

During the third quarter of 2011, we completed our IND-enabling studies for CPP-115 and filed an IND for CPP-115 in November 2011. Following the acceptance of our IND, we began enrollment for our Phase I(a) human clinical trial evaluating the safety of CPP-115, and expect to have results from this trial during the second quarter of 2012. Subject to the results of this trial and the availability of funding, we hope to begin other human clinical trials for CPP-115 in late 2012 or early 2013.

Clinical and Pre-Clinical Studies of our Product Candidates Undertaken by Others

The primary focus of our product development efforts is on our clinical trials and pre-clinical studies. However, we have in the past supported and will continue in the future to support pre-clinical studies and clinical trials by academic investigators of the use of vigabatrin for the treatment of addiction and various forms of epilepsy and other central nervous system disorders, 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, most typically providing CPP-109 or CPP-115 drug substance or dosage form as well as matching placebo. We expect to continue supporting investigator studies in the future to the extent that they meet criteria acceptable to us. Such criteria include research on the use of vigabatrin and/or CPP-115 to treat addiction, various forms of epilepsy and/or other central nervous system disorders, 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. Drs. Dewey, Brodie and Laska are members of our Scientific Advisory Board. 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

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counseling session per week. The primary outcome measure of the trial was no self-reported cocaine use or 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. In addition, 12 of the abstinent subjects on vigabatrin versus 2 of the abstinent placebo subjects remained abstinent for 4 additional weeks (p=0.002). Generally, a p-value of less than 0.05 indicates that the different results between treatment groups were unlikely to be random). Additional findings included increased retention and self-reported abstinence from alcohol favoring vigabatrin.

Two of our collaborators have received a $1.2 million grant from the U. S. Department of Defense to conduct an animal study of the use of vigabatrin in combination with opiates to effectively manage pain while reducing the potential for opiate addiction. This research is being conducted by a research team led by Wynne K. Schiffer, Ph.D. and Stephen L. Dewey, Ph.D. of The Feinstein Institute for Medical Research at 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 are supplying study materials (CPP-109) to facilitate this study.

A team of researchers led by Kyle M. Kampman, M.D., Associate Professor of Psychiatry at the Veteran s Administration Medical Center Department: Psychiatry affiliated with the University of Pennsylvania School of Medicine s Treatment Research Center have initiated a randomized, double-blind placebo-controlled study in 60 cocaine and alcohol co-dependent subjects. Subjects are receiving either CPP-109 (vigabatrin) or matching placebo, in addition to weekly counseling for eight weeks. The primary outcome measures are cocaine abstinence confirmed by twice weekly urine drug screens and alcohol abstinence measured by self-report. Recruitment is targeted to be completed in 12 months. NIDA is providing the majority of funding for this study as part of a pilot trial program included in a P50 center grant. The goal of this pilot project is to rapidly screen medications for the treatment of comorbid alcohol and cocaine dependence in small clinical trials. The program also utilizes state of the art techniques to ensure excellent medication adherence and treatment retention so that reliable results can be obtained rapidly to inform future larger trials. We have provided CPP-109 and matching placebo and financial support to conduct eye-safety examinations to facilitate the study.

An animal study reporting positive pre-clinical efficacy in a rat multiple hit model in which the use of CPP-115 was evaluated for the treatment of infantile spasms was reported on at the American Epilepsy Society s 65th Annual Meeting held in December 2011. The study was authored by Stephen W. Briggs, Tomonori Ono, MD, PhD, Solomon L. Moshe, MD and Aristea S. Galanopoulou, MD, PhD of the Saul R. Korey Department of Neurology, Dominick P. Purpura Department of Neuroscience, Laboratory of Developmental Epilepsy, The Comprehensive Epilepsy Center (CEC) at Montefiore Medical Center / Albert Einstein College of Medicine of Yeshiva University, Bronx, New York. The study concluded that (i) CPP-115 suppresses spasms in the multiple-hit model of IS, with onset of effect as early as the day after the first dose; (ii) the therapeutic doses of CPP-115 were well tolerated in developing rat pups; and (iii) CPP-115 showed efficacy for a longer duration at lower doses that were better tolerated than the previously tested therapeutic vigabatrin doses.

CPP-115 is being evaluated by the Anticonvulsant Screening Program (ASP) of the National Institute of Neurological Disorders and Stroke (NINDS), one of the institutes within the National Institutes of Health (NIH). To date, CPP-115 has been tested in about 20 animals models of epilepsy, including maximal electric shock (MES) in both rats and mice, corneal kindling in mice, minimal clonic seizure (6 Hz) model in mice, and subcutaneous picrotoxin (scPIC). CPP-115 was also evaluated for potential efficacy in neuroprotection and neuropathic pain models. CPP-115 has shown significant potential in a variety of epilepsy models and NIH is continuing the evaluation of CPP-115 in other models of epilepsy. An evaluation of CPP-115 in additional models for neuropathic pain is also ongoing.

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We recently agreed to provide study materials (CPP-109) and financial support for a small proof-of-concept study to be undertaken at an academic institution in the United States to evaluate the use of CPP-109 in treating Tourette Syndrome. This proof-of-concept study is expected to take approximately one year to complete.

Competitive Landscape

Disease Background and Our Market Opportunity

We are focusing primarily on two market opportunities that can be exploited by pharmacotherapies that inhibit GABA-aminotransferase (GABA-AT); drug addiction and epilepsy.

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 as well. 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. Epilepsy is not a neurological disorder with a single underlying cause, but is instead a complex spectrum of neurological disorders with many neurological origins exhibiting a large variation of severities. As such, there are a large number of therapies spanning many pharmacological mechanisms of actions, several medical devices, and in extreme cases, neurosurgical procedures including up to removal of half of the brain. We will develop a new drug, CPP-115, that reduces neuronal excitability through a GABA-ergic mechanism.

CPP-109

While there are no currently approved therapies for cocaine addiction, we are aware of certain other therapies that are under development. These can be broadly classified into six 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 prevent a cocaine induced dopamine surge by limiting the release of dopamine (drugs that act on GABA receptors, for example) or drugs that block the effects of a cocaine induced dopamine surge (dopamine receptor antagonists, for example). All of the known drugs in this class, with the exception of the GABA-AT inhibitors (CPP-109 and CPP-115) are receptor active and could 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.

Analeptics. These compounds stimulate the central nervous system. None of these compounds are presently approved for marketing to treat addiction, although we believe that one such product is currently undergoing Phase II clinical trials.

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 may 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 of the abuse

drug. To date, reported data from clinical trials have not shown that the vaccines are capable of facilitating the attainment and maintenance of abstinence, a key therapeutic goal.

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D3 Antagonists. These compounds block the dopamine signal at the subclass of dopamine receptor (D3) thought to be responsible for the reward signals stimulated by drugs of abuse. Glaxo Smith Kline (GSK) developed a D3 antagonist (GSK598809) through Phase I for cocaine addiction, but has halted development of all CNS drugs and announced that it is exiting the CNS drug market segment. GSK is seeking to divest this asset. Abbott Laboratories is currently in Phase II development of ABT-925, another D3 antagonist, for the treatment of schizophrenia. Independent academic investigators are evaluating ABT-925 for the treatment of cocaine addiction and smoking cessation. Other D3 antagonists may also be under development.

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. Because of the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated REMS program.

We are not aware of any on-going or planned studies by Lundbeck intended to evaluate Sabril® for any addiction indication, and we believe that any attempted commercialization by Lundbeck of Sabril® for the treatment of cocaine and/or other addictions 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.

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 refractory to treatment with any currently available 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 neuropathic pain, migraine, dementia, and bipolar disorders.

Intellectual Property Rights

Licensing and Patents

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.

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, with the principal patents expiring in 2018. 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.

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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 also have the right to enter into sub-license agreements, and if we do a royalty of 20% of any sub-license fees will be payable to Brookhaven.

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.

During July 2010, we announced that the European Patent Office has granted to Brookhaven a European patent for the use of vigabatrin for the prevention of addiction to opioids (e.g. oxycodone, hydrocodone) used in pain management. By dampening dopamine release and thus, the euphoria associated with opioids, the opioid/vigabatrin combination may lower or prevent addictive liability without adversely affecting pain relief. Further, we announced in December 2010 that the Canadian Intellectual Property Office has granted to Brookhaven a patent for the use of vigabatrin for the prevention of addiction in pain management. The patent is broad and includes the use of vigabatrin/CPP-109 in combination with opioids (e.g., oxycodone, hydrocodone) for pain management. We license these patents from Brookhaven.

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses as of December 31, 2011 was approximately $1.3 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 under which we acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered and patented by Northwestern. Under the terms of the license agreement, Northwestern 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, based on our pre-clinical testing to date of CPP-115, that the newly licensed compounds are significantly more potent than vigabatrin with less visual side effects than vigabatrin. We plan to seek to develop these compounds for the treatment of several indications, including epilepsy (specifically, complex partial seizures and infantile spasms) and drug

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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, 2011, we have paid Northwestern upfront payments and milestone fees aggregating $85,000 and maintenance and patent fees aggregating $42,872, and we are obligated to pay certain additional fees and milestone payments in future years relating to our clinical development activities under this license or payable upon passage of time. The next milestone payment of $100,000 is due on the earlier of successful completion of the Phase I(a) clinical trial for CPP-115 or August 27, 2013. We are also obligated to pay Northwestern royalties on any products resulting from the license agreement. We also have the right to enter into sub-license agreements, and if we do, a royalty on any sub-license fees will be payable to Northwestern.

We have recently filed an application under the Patent Cooperation Treaty (PCT) seeking to protect CPP-115 in all anticipated non-US markets around the world. Prosecution of this patent is ongoing. There can be no assurance that the claims of this patent will be allowed, or if allowed, that such claims will provide adequate patent protection for CPP-115.

Provisional patent application for the use of GABA aminotransferase inhibitors to treat Tourette Syndrome and related license agreement

We, as a co-inventor, with scientists at New York University and the Feinstein Institute for Medical Research, recently filed a provisional patent application with the U.S. Patent and Trademark Office for the use of GABA aminotransferase inhibitors, including CPP-109 and CPP-115, in the treatment of Tourette Syndrome. We also recently entered into a license agreement with NYU and the Feinstein Institute granting us worldwide rights with respect to such patent. Further, we recently agreed to support an investigator-led proof-of-concept study at an academic institute in the U.S. evaluating the use of CPP-109 for the treatment of Tourette Syndrome. We intend to pursue the development of CPP-109 and/or CPP-115 for this indication and the provisional patent application if the results of this investigator-led proof-of-concept study show potential efficacy.

Manufacturing and Supply

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 and matching placebo for us in quantities that we believe will be sufficient to conduct our current clinical trial evaluating CPP-109 for the treatment of cocaine addiction. 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 (cGMP), in the manufacture of our products, it may delay product launches or our ability to manufacture or ship product, adversely affecting our business.

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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 ongoing pre-clinical studies and Phase I(a) human safety study of CPP-115. While we have taken steps to insure that the amount of API ordered under this contract is sufficient for our needs, 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.

Competition

The biotechnology and pharmaceutical industries are highly competitive. In particular, competition for the development and marketing of therapies to treat addictive substances such as cocaine and methamphetamine and epilepsy 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.

Regulatory Matters

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, record-keeping, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our drugs must be approved by the FDA through the new drug application, or NDA, process before they may be legally marketed in the United States.

In the United States, drugs are subject to rigorous regulation by the FDA under the Federal Food, Drug and Cosmetic Act, or FDCA, and implementing regulations, as well as other federal and state statutes. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA s refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution,

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injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to the FDA s Good Laboratory Practice regulations;
- submission of an investigational new drug application (IND), which must become effective before human clinical trials may begin and which must include approval by an institutional review board (IRB) at each clinical site before the trials are initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA s Good Clinical Practice regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to, and acceptance by, the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and
- FDA review and approval of the NDA.

United States Drug Development Process

Once a pharmaceutical candidate is identified for development it enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Prior to beginning human clinical trials, an IND sponsor must submit an IND to the FDA. The IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some pre-clinical testing may continue even after the IND is submitted. In addition to including the results of the pre-clinical studies, the IND will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, raises concerns or questions about the conduct of the trial. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may, at any time, impose a clinical hold on ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the investigation new drug to healthy volunteers or patients under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations.

Clinical trials must be conducted under protocols detailing the objectives of the trial and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, an Institutional Review Board (IRB) at each institution participating in the clinical trial must review and approve each protocol before any clinical trial commences at that institution. All research subjects must provide informed consent, and informed consent information must be submitted to the IRB for approval prior to initiation of the trial. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if adverse events or other certain types of other changes occur.

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Human clinical trials are typically conducted in three phases. These phases may be sequential, or may overlap or be combined:

In Phase I, the drug is introduced into healthy human subjects or patients with the disease and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening illnesses, especially where the drug may be too toxic or have other side effects where it would not be deemed safe to give to healthy volunteers, the initial human testing may be conducted in patients.

Phase II involves studies in a limited patient population to identify potential adverse effects and safety risks, to evaluate, on a preliminary basis, the efficacy of the product, and to determine optimal dosage and dosage tolerance.

In Phase III, dosage is further evaluated along with safety and efficacy in an expanded patient population. These studies establish the overall risk-benefit ratio of the product and provide, if appropriate, an adequate basis for product labeling.

While Phase I, Phase II, and Phase III tests are generally required for approval of an NDA, certain drugs may not require one or more steps in the process depending on other testing and the situation involved. Additionally, the FDA, an IRB, or the sponsor may stop testing at any time if results show patients being exposed to unnecessary health risks or overly dangerous side effects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other requirements, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

United States Review and Approval Process

FDA approval of an NDA is required before marketing of the product may begin in the United States. The NDA must include the results of product development, pre-clinical studies and clinical studies, together with other detailed information, including information on the chemistry, manufacture and composition of the product. The FDA has 60 days from its receipt of the NDA to review the application to ensure that it is sufficiently complete for substantive review before accepting it for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The submission of an NDA is also subject to the payment of user fees; although a waiver of such fees may be obtained under certain limited circumstances. Further, the sponsor of an approved NDA is subject to annual product and establishment user fees. The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. 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. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured to determine whether its manufacturing is cGMP compliant to assure and preserve the product s identity, strength, quality, purity and stability.

If the FDA s evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a complete response letter. The complete response letter outlines the deficiencies in the submission and often requires additional testing or information in order for the FDA to reconsider the application.

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Even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. With limited exceptions, the FDA may withhold approval of a NDA regardless of prior advice it may have provided or commitments it may have made to the sponsor.

Post-Approval Requirements and Consideration

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 REMS strategy. 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 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.

Foreign Regulation

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.

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., similar post-approval regulatory requirements would likely 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 or CPP-115 in those countries. The approval process varies from country to country, and the

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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.

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.

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 (ANDA).

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA, but a third alternative is a special type of NDA, commonly referred to as a 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA s findings of safety and efficacy of an approved product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternative path to FDA approval for new or improved formulations or new uses of previously approved products. A 505(b)(2) application allows the applicant to file an application 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 the FDA s findings with respect to particular pre-clinical studies or clinical trials conducted for an approved product, although the FDA may also require companies to perform additional studies or measurements to support the change from the approved product.

Relative to normal regulatory requirements for a 505(b)(1) NDA, regulation may permit a 505(b)(2) applicant to forego costly and time-consuming drug development studies by relying upon the FDA s finding of safety and efficacy for a previously approved drug product. Under some circumstances, the extent of this reliance approaches that permitted under the generic drug approval provisions. This approach is intended to encourage innovation in drug development without requiring duplicative studies to demonstrate what is already known about a drug, while protecting the patent and exclusivity rights for the approved drug.

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 or 505(b)(2) 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 or 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) 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

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patent infringement lawsuit within 45 days of the receipt of a Paragraph 4 certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application 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 or 505(b)(2) applicant.

The ANDA or 505(b)(2) 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 and 505(b)(2) applications 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.

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 composition of matter patent for Sabril® expired more than ten years ago, this type of extension will not affect our efforts to obtain approval for CPP-109 (vigabatrin). Further, this extension of patent expiration date will not be available to us if we are successful in obtaining approval of CPP-109 because vigabatrin has previously been approved in another product (Sabril®). However, we expect that this extension will be available to us for CPP-115.

Federal law also provides for a five-year extension of marketing exclusivity (often called new chemical entity exclusivity) where a product is approved for an active ingredient that was not previously approved in any other product. 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. These NDAs were granted the five year exclusivity described above (which will expire in August 2014) and therefore that exclusivity will not be available to CPP-109 upon approval at a later date and will prevent the marketing of CPP-109 until after August 20, 2014 unless we file an application for CPP-109 under Section 505(b)(1).

Additionally, 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 or a 505(b)(2) NDA 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 505(b)(1) NDA. Further, 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 where the applicant is requesting approval after the expiration of this three year period of exclusivity. We expect that CPP-109, if approved, will be eligible for this three year period of exclusivity.

Fast-Track Designation

We have been granted Fast Track status for both CPP-109 and CPP-115 for the treatment of cocaine addiction. 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.

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Orphan Drug Designation

On September 15, 2010, CPP-115 was granted orphan drug designation by the FDA for the treatment of infantile spasms. Under the Orphan Drug Act of 1983 (ODA), the FDA incentivizes companies which develop drugs for diseases that affect fewer than 200,000 people in the United States. Among other benefits, upon approval by the FDA of a product intended to treat an orphan disease, the holder of the NDA is granted seven years of marketing exclusivity.

On February 9, 2012, CPP-115 was granted orphan medicinal product designation for the treatment of West Syndrome by the European Commission through the European Medicines Agency s Committee for Orphan Medicinal Products. To qualify as an orphan drug in the EU, a medication must be intended for the treatment of a life-threatening or chronically debilitating condition affecting no more than five in ten thousand people in the EU. There must also either be no satisfactory method to treat the disease or condition, or the new treatment must provide a significant benefit over the method of treatment currently available to those affected by the condition. Orphan drug designation in the EU allows us to obtain reductions in fees, assistance with development protocols, access to a centralized authorization procedure for all markets within the EU, as well as ten years of marketing exclusivity.

Sabril® was previously granted orphan drug designation by the FDA for the treatment of infantile spasms. Upon approval of its NDA for Sabril® as a treatment of infantile spasms, Lundbeck was granted seven years of marketing exclusivity for Sabril® for the treatment for infantile spasms. Since we do not plan on seeking approval for CPP-109 for the treatment of infantile spasms, the marketing exclusivity granted to Lundbeck for Sabril will not affect our product development efforts.

Priority Review

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

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

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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.

Our Employees

As of March 23, 2012, we had six employees. We also utilize the services of consultants, including 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 the development of our drug candidates. 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 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 an 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 is a former 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. Additionally, Dr. Brodie serves as a psychopharmacology mentor 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. He is actively engaged in addiction and pain research as well as other aspects of neuropharmacology.

Robert D. Fechtner, M.D. is Professor of Ophthalmology and Director, Glaucoma Division at the Institute of Ophthalmology and Visual Science 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 and his family returned home to New Jersey where he joined the faculty at New Jersey Medical School. Dr. Fechtner has published over 70 articles and chapters and is on the editorial boards of American Journal of Ophthalmology and Journal of Glaucoma.

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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 Division of the Nathan Kline Institute for Psychiatric Research. Dr. Laska has also served as a consultant to large and small pharmaceutical companies in the areas of biostatistics and clinical trial design.

Thomas R. Kosten, M.D., is the JH Waggoner Professor of Psychiatry, Pharmacology and Neuroscience, vice-Chair for Psychiatry and Co-director of the Institute for Clinical and Translational Research at Baylor College of Medicine. His other key appointments are Distinguished Professor of Psychiatry at Peking University Medical School and Professor of Epidemiology and of Behavioral Health at MD Anderson Cancer Prevention Center. He is a former Professor at Yale University School of Medicine, the founding Vice Chair for Addiction Psychiatry of the American Board of Psychiatry and Neurology, and Past President of both the American Academy of Addiction Psychiatry and the College on Problems of Drug Dependence. He is a Distinguished Fellow in the American Psychiatric Association and a Fellow of the American College of Neuropsychopharmacology. He has served as a Congressional Fellow in the US House of Representatives and is a long-standing member of various substance abuse commissions for the National Academy of Sciences. Since 2001, he has retained the ongoing distinction as a Top Doc in the field of addictions; an annual ranking by U.S. News and World Report. He is on the board of several notable journals in substance abuse. He has also published over 550 papers, books, and reviews describing his medication contributions including vaccines for cocaine, opiates and methamphetamine, and disulfiram as a pharmacogenetic treatment for 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 US State Department on large substance abuse research and treatment projects, exporting US 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.

Richard B. Silverman, Ph.D. is the John Evans Professor of Chemistry at Northwestern University. He is the inventor of Pfizer s $3.7 billion/year Lyrica® (pregabalin), marketed worldwide for the treatment of epilepsy, neuropathic pain, fibromyalgia, and (in Europe) for generalized anxiety disorder. He has received numerous awards, most recently the 2011 E.B. Hershberg Award for Important Discoveries in Medicinally Active Substances from the American Chemical Society, the 2009 Perkin Medal, from the Society of Chemical Industry, and, in 2009, he was inducted into the American Chemical Society Medicinal Chemistry Hall of Fame; in 2011 he also was named a Fellow of the American Chemical Society. Dr. Silverman holds 44 patents, has published over 290 peer-reviewed articles and has written four books over his 35-year career in academia.

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.

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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 availability of capital, 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 product sales 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 $6,391,062 for the year ended December 31, 2011, and as of December 31, 2011 we had a deficit accumulated during the development stage of $38,102,617. 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 will require additional capital to meet our product development objectives. We presently have funds that will allow us to complete: (i) the Phase I(a) clinical trial of CPP-115 evaluating the safety of CPP-115 in humans, and (ii) the U.S. Phase II(b) clinical trial of CPP-109 that we are jointly conducting with NIDA and the VA. We currently expect to receive the results from the U.S. Phase I(a) trial of CPP-115 in the second quarter of 2012 and the Phase II(b) trial of CPP-109 early in the first quarter of 2013. Based on currently available information, we estimate that we have sufficient working capital to support our operations through the end of the first quarter of 2013. The expectations described above are based on current information available to us. If the cost of these studies is greater than we expect, or it takes longer to complete and obtain the results of these studies, our assumptions may not prove to be accurate.

At the present time, we will require additional funding to complete studies or trials other than those described above, including any Phase III clinical trial that we may be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction and any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and epilepsy. Since these studies and trials have not yet been developed, we cannot estimate what our funding requirements will be with respect to such additional studies and trials. We will also require additional working capital to support our operations beyond the first quarter of 2013. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

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, and/or other means. However, there is no assurance that any such grants will be made available, and if available, that we will qualify to receive any such grants. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations.

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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.

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 addictive substances such as cocaine and methamphetamine and epilepsy 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 substance abuse treatments and epilepsy, 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.

Many of our competitors 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.

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 may result in large judgments against us. We currently carry liability insurance with an aggregate annual coverage limit of $15,000,000 per claim and $15,000,000 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 potential future products we may acquire and use 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.

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. Based on current rules, we are required to annually report under Section 404(a) of Sarbanes-Oxley regarding our management s assessment as to 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, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

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Risks Related to the Development of Our Drug Candidates

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 double- blind, placebo controlled proof-of concept study have been completed. Only 121 persons in the aggregate received CPP-109 (vigabatrin) in these trials. None of these studies, individually, or in the aggregate, provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA. Further, less than 200 persons have received vigabatrin in clinical trials assessing its efficacy to treat addiction, which is a limited number of subjects.

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; 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.

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 and trials 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 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;

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- our third-party contractors, clinical investigators or contractual collaborators 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 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 REMS strategy, as was required for the recent approvals of Sabril® for refractory complex partial seizures and infantile spasms. 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 (even at levels lower than CPP-109), the above risks will apply to it as well.

We rely on third parties to conduct our pre-clinical studies and clinical studies and 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 pre-clinical studies and clinical studies and trials independently. We rely on academic institutions, governmental agencies, such as NIDA and the VA, and third-party research organizations to assist us in designing, managing, monitoring and otherwise carrying out our studies and trials. Accordingly, we do not have control over the timing or other aspects of our studies and trials. If these third parties do not successfully carry out their duties, our studies, trials and our business may be materially adversely affected. While we believe that there are numerous third parties that can assist us with our studies and 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 drug development plans.

Although we intend to rely on third parties to manage the data from these studies and trials, we are responsible for confirming that each of our studies and 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 such studies and trials to assure that the data and the results are credible and accurate and that the human study and 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.

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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 other additional indications including, but not limited to, methamphetamine addiction. 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 conduct trials in support of, and 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 included 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.

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

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 drug 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.

We have no in-house manufacturing capacity and, to the extent we are successful in completing the development of our product candidates, we will be obliged to rely on contract manufacturers. We cannot assure you that we will successfully manufacture any product we may develop, either independently or under manufacturing arrangements, if any, with third party manufacturers. Moreover, if any manufacturer should cease doing business with us or experience delays, shortages of supply or excessive demands on their capacity, we may not be able to obtain adequate quantities of product in a timely manner, or at all. Manufacturers, and in certain situations their suppliers, are required to comply with current NDA commitments and good manufacturing practices requirement enforced by the FDA, and similar requirements of other countries. The failure by a manufacturer to comply with these requirements could affect its ability to provide us with product.

Any manufacturing problem, natural disaster affecting manufacturing facilities, or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we will be reliant on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to future contract manufacture caused by problems at suppliers could delay shipment of products, increase our cost of goods sold and result in lost sales. If our suppliers were to be unable to supply us with adequate supply of our product candidates, it could have a material adverse effect on our ability to commercialize CPP-109 or CPP-115.

In the past and currently, we purchase all supplies of our product candidates from single suppliers. While we have contractual freedom to source this ingredient elsewhere, there is no guarantee we will either be successful in identifying alternative supplier(s) or

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that these manufacturers will be qualified to manufacture the product to our specifications or that such future supplier(s) will have the manufacturing capacity to meet future requirements. All such suppliers are subject to regulatory approval. We cannot assure you that any alternative supplier will have the necessary capacity to meet our requirements or that we can contract with any such manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our 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.

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.

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 currently 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 manufacture our 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.

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The FDA and other regulatory authorities generally approve products for particular indications. Our current focus for CPP-109 and CPP-115 is to develop treatments for addiction and, with respect to CPP-115, to also develop treatments for epilepsy. CPP-109 and/or CPP-115 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 and to CPP-115 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 studies or our clinical studies and 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 any of our product candidates, we may 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.

We may also need to conduct additional clinical studies and trials demonstrating the efficacy and/or safety of CPP-109 in humans. In the United States, in 2009 we completed both a Phase II(a) clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction and a clinical proof-of-concept study to assess its efficacy as a treatment for methamphetamine addiction. Neither of these completed studies/trials provided efficacy data which would allow us to obtain approval to commercialize CPP-109 in the U.S. We may also have to conduct additional human trials (in addition to the current Phase II(b) human clinical trial) in order to seek approval to commercialize CPP-109 for the treatment of cocaine addiction. 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 our development of CPP-115.

Any clinical trials we might develop and implement, may not be completed in a timely manner or at all. Our product candidates may not be found to be safe and effective, and may not be approved by regulatory authorities for the proposed indication. 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 human clinical studies and trials if we become aware of any such risks. We might encounter problems in our clinical trials, 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, CPP-115 or any other product we develop may be marketed, we will also be subject to regulatory requirements governing human clinical studies, trials and marketing approval for drugs. The requirements governing the conduct of clinical studies, trials, product licensing, pricing and reimbursement varies widely from country to country.

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

We may encounter difficulties in our future clinical studies and 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 study and trial participants will either not comply with trial protocols, or not complete the study or trial. An unusually low rate of compliance or completion will present challenges, such as determining the statistical significance of study or trial results. Additionally, we compete for study and trial subjects with others conducting clinical trials testing other treatments for addictions. Finally, unrelated third parties 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.

Our development of CPP-109 may require at least one, or 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, there is a possibility that if the data from the Phase II(b) Trial are sufficiently compelling, that the FDA will allow us to file an NDA for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat addiction. However, the FDA could require a Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will allow us to file an NDA for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA permits us to file an NDA based on our current Phase II(b) trial, it is unlikely that we will submit an NDA for CPP-109 until not earlier than the middle of 2013. Finally, if the FDA requires one or more Phase III clinical trials, our NDA submission would be delayed even further. There can be no assurance that the data will be compelling from our currently ongoing Phase II(b) clinical trial or that even if such data are compelling, that the FDA will allow us to file an NDA based on the results of that trial.

The development of CPP-115 is at an early stage.

Our development of CPP-115 is at an early stage, and it is likely going to be several 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 studies and trials that would be required. There can be no assurance that we will ever file an 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.

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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 drug 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.

If we rely on a sole source of supply to manufacture our products we could be impacted by the fortunes of our supplier.

We intend to attempt to source our products from more than one supplier. We also intend to enter into contracts with any supplier of our products to contractually obligate them to meet our requirements. However, if we are reliant on a single supplier and that supplier cannot or will not meet our requirements (for whatever reason), our business could be adversely impacted.

Even if we obtain regulatory approvals, our drug candidates, CPP-109 and CPP-115, will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals, and our business would be severely harmed.

Even if we receive regulatory approval of any drugs we are developing or may develop, we will be subject to continuing regulatory review, including the review of clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during preapproval clinical studies and trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA. The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions.

Our product promotion and advertising is also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA-approved labeling. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety related information, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue an untitled letter or warning letter,

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which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

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 healthcare reform 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 Dependence on Third Parties

We are dependent on our relationship and license agreements with Brookhaven and Northwestern, and we rely upon the patent rights 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 have broad foreign filings in major international markets, 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, with the principal patents expiring in 2018. We also have the right to future patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. See Item 1. Business Licensing and Patents 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.

All of our patent rights for CPP-115 are derived from our license agreement with Northwestern. Pursuant to this license agreement, we have exclusive worldwide rights to two patents in the United States. These were filed and obtained by Northwestern 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 Licensing and Patents 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

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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.

A patent to protect CPP-115 in all anticipated non-U.S. markets throughout the world was filed in March 2011 under the Patent Cooperation Treaty (PCT). Prosecution of this patent is ongoing, but it cannot be assured that the claims of this patent will be allowed, or, even if allowed, whether such claims will be allowed in a form that will provide adequate protection for CPP-115 outside the United States.

If we obtain approval to market CPP-109 or CPP-115, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by Brookhaven and Northwestern, respectively, 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. 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.

We rely on third parties to conduct our pre-clinical studies and our clinical studies and trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We do not currently have the ability to independently conduct pre-clinical studies or clinical studies and trials for our drug candidates, and we rely on third parties such as governmental agencies (including NIDA and the VA), and third-party contract research organizations, medical institutions and clinical investigators, to conduct such studies and trials. Our reliance on third parties for development activities reduces our control over these activities. These third parties may not complete activities on schedule, or may not conduct our pre-clinical studies and our clinical studies and trials in accordance with regulatory requirements or our study design. To date, the parties with which we are working have performed well, and we have no reason to believe they will not continue to do such work in the future. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe there are a number of other parties with which we could engage to continue these activities, it may cause a delay in the affected study or trial and/or increase the cost of such study or trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

Risks Related to Our Intellectual Property

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

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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;

- 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 currently 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 agreements, 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, Ovation Pharmaceuticals, which held the rights in North America to Sabril® for the treatment of epilepsy (prior to the acquisition of Ovation by Lundbeck), had, in the past indicated its intent to develop Sabril® for the treatment of cocaine addiction and methamphetamine addiction. However, we have no current evidence that Lundbeck, which now owns Ovation, 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

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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.

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 our medical director and with 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, CPP-109 or CPP-115. Similarly, other similar conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

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

The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. Market prices for early-stage pharmaceutical companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- developments concerning our clinical studies and trials and our pre-clinical studies;
- announcements of product development successes and failures by us or our competitors;
- new products introduced or announced by us or our competitors;
- adverse changes in the abilities of our third-party manufacturers to provide drug or product in a timely manner or to meet FDA requirements;
- changes in reimbursement levels;

changes in financial estimates by securities analysts;

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- actual or anticipated variations in operating results;
- expiration or termination of licenses (particularly our licenses from Brookhaven and Northwestern), 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.

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.

On September 20, 2011, the Board of Directors approved the adoption of a stockholder rights plan. The rights plan was implemented through our entry into a rights agreement with Continental Stock Transfer & Trust Company, as rights agent, and the declaration of a non-taxable dividend distribution of one preferred stock purchase right (each, a Right) for each outstanding share of our common stock. The dividend was paid on October 7, 2011 to holders of record as of that date. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if a person acquires beneficial ownership of 17.5% or

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more of our common stock (or, in the case of a person who beneficially owned 17.5% or more of our common stock on the date the rights plan was adopted, such person acquires beneficial ownership of any additional shares of our common stock) or after the date of the Rights Agreement, commences a tender offer that, if consummated, would result in beneficial ownership by a person of 17.5% or more of our common stock. The rights will expire on September 20, 2016, unless the rights are earlier redeemed or exchanged.

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 23, 2012 we had 24,741,520 shares of our common stock outstanding, of which 5,594,233 shares were held by affiliates. We also had outstanding an aggregate of 3,479,108 options to purchase shares of common stock, of which 3,059,108 shares were exercisable, and common stock purchase warrants to purchase 1,523,370 shares of common stock. We have registered for future sale: (i) 2,688,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and (ii) 1,459,216 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. The outstanding options make a part of the shares registered both under and outside of our 2006 Stock Incentive Plan. 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.

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. We pay annual rent on our office space of approximately $72,000.

Item 3. Legal Proceedings

We are not currently a party to any legal proceedings.

Item 4. Mine Safety Disclosures

Not Applicable.

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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. 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 Capital Market for the period indicated.

	High	Low
Year Ended December 31, 2010		
First Quarter	$ 0.87	$ 0.56
Second Quarter	$ 2.00	$ 0.71
Third Quarter	$ 1.32	$ 0.90
Fourth Quarter	$ 1.19	$ 0.91
Year Ended December 31, 2011		
First Quarter	$ 1.38	$ 1.05
Second Quarter	$ 1.93	$ 1.10
Third Quarter	$ 1.82	$ 1.07
Fourth Quarter	$ 1.46	$ 0.96
Year ended December 31, 2012		
First Quarter (through March 23, 2012)	$ 1.34	$ 1.05

The closing sale price for the common stock on March 23, 2012 was $1.07. As of March 23, 2012, there were 54 holders of record of our common stock, which includes custodians who hold our securities for the benefit of others. We estimate that there are approximately 2,650 beneficial holders of our common stock.

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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Performance Graph

The following graph compares the cumulative total shareholder return on our common stock since December 31, 2006 to three indices: the Russell Microcap Index, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on December 31, 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, 2011, 2010, 2009 and for the cumulative period from inception (January 4, 2002) through December 31, 2011, and the balance sheet data as of December 31, 2011 and 2010, have been derived from our audited financial statements included elsewhere in this Form 10-K. The selected statement of operations data for the years ended December 31, 2008 and 2007 and the selected balance sheet data at December 31, 2009, 2008 and 2007 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,
	2011	2010	2009	2008	2007	2011
Statement of Operations Data:						
Revenues government grant	$	$ 488,958	$	$	$	$ 488,958
Operating costs and expenses:						
Research and development	3,383,965	2,306,781	5,097,440	8,710,441	3,040,659	25,643,708
General and administrative	2,698,174	2,206,358	2,177,954	2,183,504	1,986,470	14,105,748
Total operating cost and expenses	6,082,139	4,513,139	7,275,394	10,893,945	5,027,129	39,749,456
Loss from operations	(6,082,139)	(4,024,181)	(7,275,394)	(10,893,945)	(5,027,129)	(39,260,498)
Interest income	10,985	17,858	33,466	329,348	887,636	1,477,789
Change in fair value of warrants liability	(319,908)					(319,908)
Loss before income taxes	(6,391,062)	(4,006,323)	(7,241,928)	(10,564,597)	(4,139,493)	(38,102,617)
Provision for income taxes						
Net loss	$ (6,391,062)	$ (4,006,323)	$ (7,241,928)	$ (10,564,597)	$ (4,139,493)	$ (38,102,617)
Net loss per share basic and diluted	$ (0.29)	$ (0.22)	$ (0.48)	$ (0.81)	$ (0.33)	
Weighted average shares outstanding basic and diluted	21,728,292	18,580,223	15,066,799	13,013,041	12,525,405	

	As of December 31,				
	2011	2010	2009	2008	2007
Balance Sheet Data:					
Cash and cash equivalents	$ 6,029,067	$ 5,475,158	$ 7,779,277	$ 11,766,629	$ 15,943,896
Working capital	5,394,382	5,476,443	7,593,272	10,485,039	16,228,401
Total assets	6,249,257	5,831,488	7,966,382	12,032,968	16,679,922
Warrants liability	1,645,240				
Total liabilities	2,488,559	313,709	348,522	1,472,753	357,165
Stockholders equity	3,760,698	5,517,779	7,617,860	10,560,215	16,322,757

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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.

Introduction

Management s Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to provide an understanding of our financial condition, changes in financial condition and results of operations. The discussion and analysis is organized as follows:

Overview. This section provides a general description of our business, trends in our industry, as well as significant occurrences which we believe are important in understanding our financial condition and results of operations.

Recent Accounting Pronouncements. This section provides an analysis of relevant recent accounting pronouncements issued by the Financial Accounting Standards Board (FASB) and /or other standard-setting bodies and the effect of those pronouncements.

Results of Operations. This section provides an analysis of our results of operations for all three fiscal years presented in the accompanying statements of operations.

Liquidity and Capital Resources. This section provides an analysis of our cash flows, capital resources, off-balance sheet arrangements and our outstanding commitments, if any.

Critical Accounting Policies and Estimates. This section discusses those accounting policies that are both considered important to our financial condition and results of operations, and require significant judgment and estimates on the part of management in their application. All of our significant accounting policies, including the critical accounting policies, are also summarized in the notes to the accompanying financial statements.

Caution Concerning Forward-Looking Statements. This section discusses how certain forward-looking statements made throughout this MD&A and in other sections of this report are based on management s present expectations about future events and are inherently susceptible to uncertainty and changes in circumstance.

Overview

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in development. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the 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 other selected central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, 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 drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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The successful development of CPP-109, CPP-115 or any other product we may acquire, develop or license is highly uncertain. We cannot reasonably estimate or know the nature, timing, or estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence, or if any net cash inflows will actually 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 pre-clinical studies and trials, and other product development activities;
- the results of our pre-clinical studies and clinical studies and 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, and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We are currently involved in the following product development activities: (i) the FDA has accepted our Investigational New Drug Application (IND) for CPP-115 (ii) we have to commenced an initial Phase I clinical study evaluating the safety of CPP-115 in healthy volunteers; and (iii) we are jointly conducting with NIDA and the VA a U.S. Phase II(b) clinical trial of CPP-109 (and, based on current information, we expect to obtain top line results from this trial early in the first quarter of 2013).

Based on an analysis of our current financial condition and forecasts of available cash, we believe that we have sufficient resources to: (i) complete the above-described Phase I(a) clinical trial of CPP-115 and Phase II(b) clinical trial of CPP-109 and (ii) support our operations through the first quarter of 2013. However, there can be no assurance that we will actually have sufficient funds for these purposes. We will also require additional funding to complete any other pre-clinical and clinical studies and trials that may be required for us to submit NDAs for and commercialize CPP-109 and CPP-115 and to support our operations beyond the first quarter of 2013. There can be no assurance that we will obtain additional funding or ever be able to commercialize either of our product candidates. See Liquidity and Capital Resources below.

Basis of presentation

Revenues government grant

We are a development stage company and have no revenues from product sales to date. We will not have revenues from product sales until such time as we receive approval of 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.

During 2010, we were notified that we had been certified to receive a cash grant aggregating $488,958 under the Qualifying Therapeutic Discovery Projects Program (section 48D of the Internal Revenue Code), $354,933 of which was received in 2010, and the remaining amount of $134,025 was received in 2011. The grant related to two qualifying therapeutic projects, CPP-109 for the treatment of stimulant dependence and CPP-115 for the treatment of epilepsy and stimulant dependence. We have recorded such as government grant revenue in the accompanying statements of operations.

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 pre-clinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, 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

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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 studies and trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study and trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical study and 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 or milestones, the successful enrollment of patients, the allocation of responsibilities among the parties to the agreement, and the completion of portions of the clinical study or 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 pre-clinical and clinical studies or trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies or trials at a given point in time, we could be required to record significant additional research and development expenses in future periods. Pre-clinical and clinical study and trial activities require significant up front expenditures. We anticipate paying significant portions of a study or trial s cost before such begins, and incurring additional expenditures as the study or 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 and 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 the awards.

Warrants Liability

We issued warrants to purchase shares of our common stock as part of the equity financing completed in October 2011. In accordance with U.S. generally accepted accounting principles, we have recorded the fair value of the warrants as a liability in the accompanying balance sheet at December 31, 2011 using a Black-Scholes option-pricing model. We will remeasure the fair value of the warrants liability at each reporting date until the warrants are exercised or have expired. Changes in the fair value of the warrants liability are reported in the statements of operations as income or expense. The fair value of the warrants liability is subject to significant fluctuation based on changes in the inputs to the Black-Scholes option-pricing model, including our common stock price, expected volatility, expected life, the risk-free interest rate and dividend yield. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of the warrants.

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Income taxes

We have incurred operating losses since inception. As of December 31, 2011 and 2010, we had net operating loss carryforwards of approximately $19,980,000 and $17,439,000, respectively. Our net deferred tax asset has a 100% valuation allowance as of December 31, 2011 and 2010, 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 through 2031. If an ownership change, as defined under Internal Revenue Code 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 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.

Recent Accounting Pronouncements

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present components of other comprehensive income as part of the statement of changes in stockholders equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. These changes become effective for fiscal years beginning after December 15, 2011, except for the reclassification adjustments out of accumulated other comprehensive income that become effective for fiscal years ending after December 15, 2012. The adoption of these changes will not have a material effect on our financial statements as we do not currently report any components of comprehensive income (loss) other than our net loss.

Results of Operations

Years Ended December 31, 2011 and 2010

Revenues

We had no revenues for the year ended December 31, 2011. We had a $488,958 government grant awarded to us in 2010, which was our only revenue in 2010. The government grant was a Section 48D tax grant that we received in the fourth quarter of 2010 and the first quarter of 2011.

Research and Development Expenses

Year	Amount	Change from Prior Year	Percentage of Total Operating Costs and Expenses
2011	$ 3,383,965	46.7%	55.6%
2010	$ 2,306,781	(54.7%)	51.1%

Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2011 increased compared to amounts expended in the same period in 2010. During 2011, we continued our Phase II(b) trial studying CPP-109 for the treatment of cocaine addiction that was initiated in the fourth quarter of 2010, performed pre-clinical testing for CPP-115, and began our Phase I(a) trial for CPP-115. We expect that research and development expenses will continue to be substantial in 2012 as we continue the research and development activities described under the overview section of this Item 7.

In our research and development activities for 2011 and 2010, we recorded stock-based compensation relating to the value of stock options granted to certain employees and non-employees. The amount of stock-based compensation recorded in 2011 and 2010 relating to our research and development activities was $111,283 and $179,737, respectively. The weighted-average grant-date fair value of the stock options granted in 2011 and 2010 was $0.79 and $0.75, respectively.

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Selling and Marketing Expenses

We had no selling and marketing expenses during 2011 and 2010. 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

Year	Amount	Change from Prior Year	Percentage of Total Operating Costs and Expenses
2011	$ 2,698,174	22.3%	44.4%
2010	$ 2,206,358	1.3%	48.9%

Included in general and administrative expenses in the years 2011 and 2010 was stock-based compensation expense of $305,452 and $270,352, respectively. General and administrative expenses include, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our administrative employees, consultants and members of our Board. The increase in general and administrative expenses for the year ended December 31, 2011 when compared to the same period in 2010 is primarily due to increases in payroll expense, as we accrued severance related to a separation during 2011, director compensation, travel expenses and stock-based compensation expense offset by decreases in professional fees. We expect general and administrative cost to remain relatively stable in future periods as we continue the monitoring and oversight of our clinical trials evaluating CPP-109 and CPP-115.

Stock-Based Compensation

We issued stock options to several of our employees, directors, and consultants in 2011 and 2010. Total stock-based compensation expense for the years ended December 31, 2011 and 2010 was $416,735 and $450,089, respectively.

Change in fair value of warrants liability

In connection with the October 2011 equity offering, we issued warrants to purchase an aggregate of 1,523,370 shares of common stock. The fair value of the warrants is recorded in the liability section of the balance sheet and was estimated at $1.6 million and $1.3 million at December 31, 2011 and at the closing date of the October 2011 offering, respectively. The fair value of the warrants liability is determined at the end of each reporting period with the resulting gains or losses recorded as the change in fair value of warrants liability in the statements of operations. For the year ended December 31, 2011, we recognized a loss of $319,908 due to the change in the fair value of the warrants liability. The loss during 2011 was principally a result of the increase of our stock price between the closing date of the equity offering and December 31, 2011. Future changes in the fair value of the warrants liability will be due primarily to fluctuations in the value of our common stock.

Interest Income

We reported interest income in all periods relating to our investment of funds received from our registered direct offerings. The decrease in interest income for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was due to lower interest rates and lower average investment balances as the proceeds from our registered direct offerings were used to fund our product-development activities and our operations. Substantially all such funds were invested in short-term interest bearing obligations.

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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.

Net Loss

Net loss was $6,391,062 in the year ended December 31, 2011 ($0.29 per basic and diluted share), as compared to $4,006,323 in the year ended December 31, 2010 ($0.22 per basic and diluted share).

Years Ended December 31, 2010 and 2009

Revenues

We had $488,958 of revenues for the year ended December 31, 2010, all of which were derived from the Section 48D tax grants awarded to us in 2010 that we received in the fourth quarter of 2010 and the first quarter of 2011. We had no revenues for the year ended December 31, 2009.

Research and Development Expenses

Year	Amount	Change from Prior Year	Percentage of Total Operating Costs and Expenses
2010	$ 2,306,781	(54.7%)	51.1%
2009	$ 5,097,440	(41.5%)	70.0%

Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2010 decreased significantly compared to amounts expended in the same period in 2009. During 2009, we completed our U.S. 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 our research and development activities for 2010 and 2009, we recorded stock-based compensation relating to the value of stock options and restricted shares granted to certain employees and non-employees. The amount of stock-based compensation recorded in 2010 and 2009 relating to our research and development activities was $179,737 and $272,184, respectively. The weighted-average grant-date fair value of the stock options granted in 2010 and 2009 was $0.75 and $0.55, respectively.

Selling and Marketing Expenses

We had no selling and marketing expenses during 2010 and 2009. 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

Year	Amount	Change from Prior Year	Percentage of Total Operating Costs and Expenses
2010	$ 2,206,358	1.3%	48.9%
2009	$ 2,177,954	(0.3%)	30.0%

Included in general and administrative expenses in the years 2010 and 2009 was stock-based compensation expense of $270,352 and $329,254, respectively. General and administrative expenses include, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our administrative employees, consultants and members of our Board. The increase in general

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and administrative expenses for the year ended December 31, 2010 when compared to the same period in 2009 is primarily due to increases in consulting and travel expenses, offset by decreases in stock-based compensation expense and professional fees.

Stock-Based Compensation

We issued stock options to several of our employees, directors, and consultants in 2010 and 2009. Total stock-based compensation expense for the years ended December 31, 2010 and 2009 was $450,089 and $601,438, respectively.

Interest Income

We reported interest income in all periods relating to our investment of funds received from our registered direct offerings. The decrease in interest income for the year ended December 31, 2010 as compared to the year ended December 31, 2009 was due to lower interest rates and lower average investment balances as the proceeds from our registered direct offerings were used to fund our product-development activities and our operations. Substantially all such funds were invested in short-term interest bearing obligations.

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.

Net Loss

Net loss was $4,006,323 in the year ended December 31, 2010 ($0.22 per basic and diluted share), as compared to $7,241,928 in the year ended December 31, 2009 ($0.48 per basic and diluted share).

Liquidity and Capital Resources

Our historical capital resource requirements have been the funding of working capital and pre-clinical and clinical testing of our drug candidates, CPP-109 and CPP-115. We have historically funded all of our operating requirements from equity issuances.

Since our inception, we have financed our operations primarily through the net proceeds of our private placements, an initial public offering (IPO) and from registered direct offerings under our shelf registration statements. At December 31, 2011, we had cash and cash equivalents of $6,029,067 and working capital of $5,394,382, as compared to cash and cash equivalents of $5,475,158 and working capital of $5,476,443 at December 31, 2010. At December 31, 2011 substantially all of our cash and cash equivalents were deposited with one financial institution. Throughout 2011, we periodically had cash balances at certain financial institutions in excess of federally insured limits.

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 will likely take several years to obtain the necessary regulatory approvals to commercialize CPP-109 or CPP-115 in the United States.

We currently believe that we have the cash resources to complete our currently ongoing clinical trials and studies and to continue our operations through the first quarter of 2013. These expectations are based on current information available to us. If the cost of these studies is greater than we expect, or if such studies take longer to complete, our assumptions may not prove to be accurate.

At the present time, we will require additional funding to complete studies or trials other than those described above, including any Phase III clinical trial that we may be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction and any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and epilepsy.

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Since these additional studies or trials have not yet been developed, we cannot estimate what our funding requirements will be with respect to such studies or trials. We will also require additional working capital to support our operations beyond the first quarter of 2013. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

In that regard, 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 and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in other products.

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 pre-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 December 3, 2010, we filed a shelf registration statement with the SEC to sell up to $30 million of common stock and warrants to purchase common stock. This shelf registration statement was declared effective by the SEC on December 15, 2010. 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 our outstanding common stock and 33% of our public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules. There can be no assurance we will be able to successfully sell any more shares under our 2010 shelf registration statement.

To date we have completed two underwritten public offerings under our 2010 shelf registration statement:

On March 11, 2011, we raised net proceeds of approximately $2.2 million from the sale of 2,259,943 shares of our common stock.

On October 28, 2011, we raised net proceeds of approximately $3.2 million from the sale of 3,046,740 shares of our common stock and five-year warrants to purchase 1,523,370 shares of our common stock at an exercise price of $1.30 per share.

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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. We completed three registered direct public offerings to institutional investors under our 2008 shelf registration statement:

On September 12, 2009 we raised net proceeds of approximately $4.1 million from the sale of 1,488,332 shares of our common stock;

On October 6, 2009, we raised net proceeds of approximately $3.7 million from the sale of 3,973,000 shares of our common stock; and

On August 8, 2010, we raised net proceeds of approximately $1.5 million from the sale of 1,351,352 shares of our common stock.

Our 2008 shelf registration statement expired on June 26, 2011 and we can no longer sell any shares under this shelf registration statement.

Cash Flows

Net cash used in operations was $4,985,049 and $3,757,405, respectively, for the years ended December 31, 2011, and 2010. During the year ended December 31, 2011, net cash used in operating activities was primarily attributable to our net loss of $6,391,062 and an increase of $31,272 in prepaid expenses and deposits, partially offset by a decrease in government grant receivable of $134,025 and increases of $158,001 in accounts payable and of $365,781 in accrued expenses and other liabilities. The loss was further offset by $779,478 of non-cash expenses. Non-cash expenses include depreciation, stock-based compensation expense and the change in fair value of the warrants liability.

Net cash used in investing activities was $3,620 and $2,867, respectively, for 2011 and 2010. Such funds were used primarily for purchases of computer equipment.

Net cash provided by financing activities was $5,542,578 and $1,456,153, respectively, for 2011 and 2010. During 2011 and 2010, net cash from financing activities consisted of the net proceeds from the sale of shares of common stock and warrants to purchase common stock in registered direct public offerings under our shelf registration statements. Such funds have been used to fund our research and development costs and our general and administrative costs.

Contractual Obligations (1)

As of December 31, 2011, we had contractual obligations as follows:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Operating lease obligations	$ 398,069	$ 53,666	$ 134,282	$ 142,294	$ 67,827
License obligations	105,000	105,000			
Total	$ 503,069	$ 158,666	$ 134,282	$ 142,294	$ 67,827

(1) We have not included in the table above milestone or royalty payment obligations where 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, 2011. See Dispute with Brookhaven below.

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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 was made during December 2011 after the filing of an IND for CPP-115. At December 31, 2011, we had paid $127,812 in connection with this agreement, and had accrued license fees of $102,500 in the accompanying balance sheet.

Payments under our agreement with NIDA. We have agreed to supply the study drug (and matching placebo) as well as fund certain expenses for the U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction that we are jointly conducting with NIDA and the VA. We currently estimate that we will pay approximately $1.4 million in connection with this agreement. As of December 31, 2011 we had paid approximately $1.0 million of this amount and had accounts payable of approximately $55,000 and accrued liabilities of approximately $75,000 in the accompanying balance sheet in connection with these agreements.

Payments for drug development, pre-clinical and clinical studies and trials. We estimate that we will pay various consultants, drug manufacturers and other vendors approximately $1.0 million in connection with our drug development work, including pre-clinical and clinical studies and trials, consulting and data analysis. At December 31, 2011, we had paid approximately $502,000 of this amount and had accounts payable of approximately $57,000 and accrued liabilities of approximately $20,000 in the accompanying balance sheet in connection with these agreements.

Employment agreement. We have entered an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately $387,000 per annum in 2012.

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, 2011 was approximately $1.3 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 the Company of an NDA for CPP-109.

Off-Balance Sheet Arrangements

We currently have no debt. Capital lease obligations as of December 31, 2011 and 2010 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.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which 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.

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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 pre-clinical and 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 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 estimates accordingly on a prospective basis.

Warrants Liability

We have issued warrants to purchase our common stock that may require us to purchase unexercised warrants for a cash amount equal to their fair value following the announcement of specified events defined as Fundamental Transactions (Fundamental Transactions) involving the Company, which is deemed to occur if we are acquired in an all cash transaction or by a company that is not listed on a national securities exchange, or when the common stock is no longer listed on a national securities exchange. The cash settlement provisions require use of the Black-Scholes model in calculating the cash payment value in the event of a Fundamental Transaction. As a consequence of these provisions, the warrants are classified as a liability on our balance sheets. The cash settlement value at the time of any future Fundamental Transaction will depend upon the value of the following inputs at that time: the price per share of our common stock, the volatility of our common stock, the expected term of the warrant, the risk-free interest rate based on U.S. Treasury security yields, and the Company s dividend yield. The fair value of the warrants is determined using a Black-Scholes model. The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of our common stock, the historical volatility of our stock price, risk-free rates based on U.S. Treasury security yields, the expected term of the warrants and the Company s dividend yield. Changes in these assumptions can materially affect the fair value estimate. We could ultimately incur amounts to settle the warrant at a cash settlement value that is significantly different than the carrying value of the liability on our financial statements. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability. Changes in the fair value of the common stock warrants liability are recognized as a component of other income (expense) in the statement of operations.

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. For 2011, expected volatility is based on reviews of historical volatility of our common stock. For 2010 and prior, our expected volatility was based on the historical volatility of other publicly traded development stage companies in the same industry, due to our short history as a public company. 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. During 2011, we estimated the expected option life for options granted to employees and directors based upon the simplified method. Under this method, the expected option life is presumed to be the mid-point between the vesting date and the end of the contractual term. We will continue to use the simplified method until we have sufficient historical exercise data to estimate the expected life of the options. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the

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estimated expected life of our stock options awards. For the years ended December 31, 2011, 2010 and 2009, the assumptions used were an estimated annual volatility of 130%, 100% and 90%, average expected holding periods of three to five years, four to five years and four to five years, and risk-free interest rates of 0.29% to 1.55%, 0.81% to 2.44% and 1.26% to 2.60%, respectively.

Caution Concerning Forward-Looking Statements

Some of the statements in this Form 10-K are forward-looking statements , as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes , anticipates , proposes , plans , expects , intends , may , and other similar expressions intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements made in this Form 10-K are based on current expectations that involve numerous risks and uncertainties.

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

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

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

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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 from time to time 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 emphasizes 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 Securities Exchange Act of 1934 (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.

Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2011, 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.

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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, 2011 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, 2011.

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 on the internal control subsequent to the date of the evaluation in connection with the preparation of this Form 10-K.

This Form 10-K does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting since our internal control over financial reporting is not subject to attestation by our independent registered public accounting firm under the Exchange Act.

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 2012 Annual Meeting of Stockholders. Our Proxy Statement for the 2012 Annual Meeting of Stockholders is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2011 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, 2011 and 2010

Statements of Operations for the years ended December 31, 2011, 2010 and 2009 and the period from inception (January 4, 2002) through December 31, 2011

Statement of Stockholders Equity for the period from inception (January 4, 2002) through December 31, 2011

Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009 and the period from inception (January 4, 2002) through December 31, 2011

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.

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
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)
4.2	Rights Agreement between the Company and Continental Stock Transfer and Trust Company(10)

4.3	Form of Warrant to Purchase Common Stock(11)
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(3)
10.3 +	Amendment to Employment Agreement between the Company and Patrick J. McEnany(5)
10.4 +	Amendment to Employment Agreement between the Company and Patrick J. McEnany(9)

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Exhibit No.	Description of Exhibit
10.5 +	Stock Option Agreement between the Company and Patrick J. McEnany(1)
10.6 +	Stock Option Agreement between the Company and Hubert Huckel(1)
10.7+	Agreement between the Company and Charles Gorodetzky(1)
10.8+	2006 Stock Incentive Plan(1)
10.9+	Amendment No. 1 to 2006 Stock Incentive Plan (7)
10.10	License Agreement, as amended, between the Company and Brookhaven National Laboratories(1)
10.11	License Agreement between the Company and Northwestern University(4)
10.12	Agreement between the Company and the Division of Pharmacotherapies and Medical Consequences of Drug Abuse, National Institute on Drug Abuse(6)
10.13	Lease Agreement between the Company and 355 Alhambra Plaza, Ltd.(2)
10.14	First Amendment to Lease Agreement between the Company and 355 Alhambra Plaza, Ltd. (8)
10.15	License Agreement among the Company, New York University, and The Feinstein Institute for Medical Research*
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*
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase

(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 Current Report on Form 8-K dated December 23, 2008
(4) Filed by reference to the Company s Current Report on Form 8-K dated September 2, 2009
(5) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2009
(6) Filed by reference to the Company s Registration Statement on Form S-3 (File No. 333-170945)

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(7) Filed by reference to the Company s 2011 Annual Meeting Proxy Statement on Schedule 14A dated April 11, 2011
(8) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended June 30, 2011
(9) Filed by reference to the Company s Current Report on Form 8-K dated September 14, 2011
(10) Filed by reference to the Company s Current Report on Form 8-K dated September 20, 2011
(11) Filed by reference to the Company s Current Report on Form 8-K dated October 28, 2011
* Filed herewith
** Pursuant to Rule 406 of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.
+ 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 30th day of March, 2012.

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 Patrick J. McEnany	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	March 30, 2012
/s/ Alicia Grande Alicia Grande	Vice President, Treasurer, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2012
/s/ Hubert E. Huckel, M.D. Hubert E. Huckel, M.D.	Director	March 30, 2012
/s/ Charles B. O Keeffe Charles B. O Keeffe	Director	March 30, 2012
/s/ Philip H. Coelho Philip H. Coelho	Director	March 30, 2012
/s/ David S. Tierney, M.D. David S. Tierney, M.D.	Director	March 30, 2012
/s/ Milton J. Wallace Milton J. Wallace	Director	March 30, 2012

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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, 2011 and 2010, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2011 and the period from January 4, 2002 (date of inception) through December 31, 2011. 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, 2011 and 2010, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2011 and the period from January 4, 2002 (date of inception) through December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP
GRANT THORNTON LLP

Miami, Florida
March 30, 2012

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CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

BALANCE SHEETS

	December 31, 2011	December 31, 2010
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 6,029,067	$ 5,475,158
Government grant receivable		134,025
Prepaid expenses	199,116	166,221
Total current assets	6,228,183	5,775,404
Property and equipment, net	12,186	45,573
Deposits	8,888	10,511
Total assets	$ 6,249,257	$ 5,831,488
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 263,934	$ 105,933
Accrued expenses and other liabilities	569,867	193,028
Total current liabilities	833,801	298,961
Accrued expenses and other liabilities, non-current	9,518	14,748
Warrants liability, at fair value	1,645,240	
Total liabilities	2,488,559	313,709
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized: none issued and outstanding at December 31, 2011 and 2010		
Common stock, $0.001 par value, 100,000,000 shares authorized; 24,701,420 shares and 19,394,737 shares issued and outstanding at December 31, 2011 and 2010, respectively	24,701	19,395
Additional paid-in capital	41,838,614	37,209,939
Deficit accumulated during the development stage	(38,102,617)	(31,711,555)
Total stockholders equity	3,760,698	5,517,779
Total liabilities and stockholders equity	$ 6,249,257	$ 5,831,488

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, 2011
	2011	2010	2009	
Revenues government grant	$	$ 488,958	$	$ 488,958
Operating costs and expenses:				
Research and development	3,383,965	2,306,781	5,097,440	25,643,708
General and administrative	2,698,174	2,206,358	2,177,954	14,105,748
Total operating costs and expenses	6,082,139	4,513,139	7,275,394	39,749,456
Loss from operations	(6,082,139)	(4,024,181)	(7,275,394)	(39,260,498)
Interest income	10,985	17,858	33,466	1,477,789
Change in fair value of warrants liability	(319,908)			(319,908)
Loss before income taxes	(6,391,062)	(4,006,323)	(7,241,928)	(38,102,617)
Provision for income taxes				
Net loss	$ (6,391,062)	$ (4,006,323)	$ (7,241,928)	$ (38,102,617)
Net loss per share basic and diluted	$ (0.29)	$ (0.22)	$ (0.48)	
Weighted average shares outstanding basic and diluted	21,728,292	18,580,223	15,066,799	

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, 2011

	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, net			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, net	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, net			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 common stock, net			1,488	4,086,412		4,087,900

Issuance of stock options for services		583,836		583,836
Issuance of restricted stock units for services, net	44	130,275		130,319
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 common stock, net	3,973	3,694,162		3,698,135
Issuance of stock options for services		581,286		581,286
Issuance of restricted stock units for services, net	5	20,147		20,152
Net loss			(7,241,928)	(7,241,928)
Balance at December 31, 2009 (carried forward)	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)

STATEMENT OF STOCKHOLDERS EQUITY

for the period from January 4, 2002 (date of inception) through December 31, 2011

	Preferred Stock Series A	Preferred Stock Series B	Common Stock	Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total
Balance at December 31, 2009 (brought forward)	$	$	$ 18,038	$ 35,305,054	$ (27,705,232)	$ 7,617,860
Issuance of common stock, net			1,352	1,454,801		1,456,153
Issuance of stock options for services				450,089		450,089
Issuance of restricted stock units for services, net			5	(5)		
Net loss					(4,006,323)	(4,006,323)
Balance at December 31, 2010			19,395	37,209,939	(31,711,555)	5,517,779
Issuance of stock options for services				416,735		416,735
Issuance of common stock and warrants, net			5,306	4,211,940		4,217,246
Net loss					(6,391,062)	(6,391,062)
Balance at December 31, 2011	$	$	$ 24,701	$ 41,838,614	$ (38,102,617)	$ 3,760,698

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, 2011
	2011	2010	2009	
Operating Activities:				
Net loss	$ (6,391,062)	$ (4,006,323)	$ (7,241,928)	$ (38,102,617)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation and amortization	42,835	25,741	30,227	153,989
Stock-based compensation	416,735	450,089	601,438	5,622,161
Change in fair value of warrants liability	319,908			319,908
(Increase) decrease in:				
Interest receivable			12,153	
Government grant receivable	134,025	(134,025)		
Prepaid expenses and deposits	(31,272)	(58,074)	39,152	(208,004)
Increase (decrease) in:				
Accounts payable	158,001	(143,702)	(83,072)	263,934
Accrued expenses and other liabilities	365,781	108,889	(1,041,159)	516,033
Net cash used in operating activities	(4,985,049)	(3,757,405)	(7,683,189)	(31,434,596)
Investing Activities:				
Capital expenditures	(3,620)	(2,867)	(2,298)	(102,826)
Net cash used in investing activities	(3,620)	(2,867)	(2,298)	(102,826)
Financing Activities:				
Proceeds from issuance of common stock and warrants, net	5,542,578	1,456,153	3,698,135	33,574,302
Proceeds from issuance of preferred stock, net				3,895,597
Payment of employee withholding tax related to restricted stock units				(3,410)
Net cash provided by financing activities	5,542,578	1,456,153	3,698,135	37,466,489
Net increase (decrease) in cash and cash equivalents	553,909	(2,304,119)	(3,987,352)	5,929,067
Cash and cash equivalents beginning of period	5,475,158	7,779,277	11,766,629	100,000
Cash and cash equivalents end of period	$ 6,029,067	$ 5,475,158	$ 7,779,277	$ 6,029,067
Non-cash investing and financing activities:				
Non-cash incentive received from lessor	$	$	$	$ 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 specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders 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, 2011. 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), a government grant and five registered direct offerings via shelf registration statements to institutional investors. See Note 11.

Merger

On September 7, 2006, the Company completed a merger with 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 shares of common stock.

Capital Resources

In June 2008, the Company filed a registration statement on Form S-3 (the 2008 Shelf Registration Statement) 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 the 2008 Shelf 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 2008 Shelf Registration Statement at a price of $1.00 per share and received gross proceeds of approximately $4.0 million before underwriting commissions and incurred expenses of approximately $275,000. During August 2010, the Company sold 1,351,352 shares of its common stock under the 2008 Shelf Registration Statement at a price of $1.11 per share and received gross proceeds of approximately $1.5 million before incurred expenses of approximately $44,000. The 2008 Shelf Registration Statement expired on June 26, 2011, and the Company can no longer sell any shares under this shelf registration statement.

In December 2010, the Company filed a registration statement on Form S-3 (the 2010 Shelf Registration Statement) in order to be able to sell up to $30,000,000 of its authorized but unissued common stock and warrants to purchase common stock through future offerings. During March 2011, the Company sold 2,259,943 shares of its common stock under the 2010 Shelf Registration Statement at a price of $1.12 per share and received gross proceeds of approximately $2.5 million before underwriting commissions and incurred expenses of approximately $300,000. During October 2011, the Company sold 3,046,740 shares of the Company s common stock together with common stock purchase warrants to purchase 1,523,370 shares of the Company s common stock at a price of $1.15 per share and corresponding warrant and received gross proceeds of approximately $3.5 million before underwriting commissions and other expenses totaling approximately $305,000. The Company has approximately $21.3 million of authorized but unissued common stock and common stock purchase warrants available for future offerings under the 2010 Shelf Registration Statement. See Note 11.

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1. Organization and Description of Business (continued)

In November 2010, the Company was notified that it had been certified to receive a cash grant aggregating $488,958 under the Qualifying Therapeutic Discovery Projects Program (section 48D of the Internal Revenue Code). The grant related to two qualifying therapeutic projects, CPP-109 for the treatment of stimulant dependence and CPP-115 for the treatment of epilepsy and stimulant dependence. Of these funds, $354,933 were received in November 2010 and $134,025 were received in February 2011.

While there can be no assurance, the Company currently believes that it has sufficient resources to complete its currently ongoing clinical studies and trials and to support its operations through the first quarter of 2013. The Company will require additional capital to fund additional clinical and pre-clinical studies of CPP-109 and CPP-115 that may be required to file New Drug Applications (NDA) with the U.S. Food and Drug Administration (FDA) and to support the Company s operations in periods after the first quarter of 2013.

In addition to the filing of the above described shelf registration statements, 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 that manner 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. **GOVERNMENT GRANT RECEIVABLE.** The government grant receivable consists of a grant receivable from the U.S. government for a portion of the cash grants awarded to the Company under the Qualifying Therapeutic Discovery Project Program during November 2010. Such funds were received in February 2011. The Company recognizes U.S. government cash grants in the period in which the Company is notified of such awards.

e. **PREPAID EXPENSES.** Prepaid expenses consist primarily of prepaid insurance, prepaid offering costs, prepaid subscription fees and prepaid research fees. Prepaid research fees consist of advances for our product development activities, including drug manufacturing, contracts for pre-clinical studies, clinical trials, regulatory affairs and consulting. Such advances are recorded as expense as the related goods are received or the related services are performed.

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

f. 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 three to six years for furniture and equipment and leasehold improvements. Expenditures for repairs and maintenance are charged to expenses as incurred.

g. 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, 2011 and 2010, the Company had $9,518 and $29,601, respectively, of deferred rent and lease incentive in accrued expenses and other liabilities.

h. FAIR VALUE OF FINANCIAL INSTRUMENTS. The Company s financial instruments consist of cash and cash equivalents, accounts payable and accrued expenses and other liabilities. At December 31, 2011, the fair value of these instruments approximated their carrying value.

i. FAIR VALUE MEASUREMENTS. Current Financial Accounting Standards Board (FASB) fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity s own assumptions that market participants assumptions would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which are typically based on an entity s own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment and considers factors specific to the asset or liability.

j. 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-related services for the Company.

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

k. 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, the single-option award approach, and the 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, 2011, 2010 and 2009, the Company recorded stock-based compensation expense as follows:

	2011	2010	2009
Research and development	**$ 111,283**	**$ 179,737**	**$ 272,184**
General and administrative	**305,452**	**270,352**	**329,254**
Total stock-based compensation	**$ 416,735**	**$ 450,089**	**$ 601,438**

l. 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 a high-credit quality financial institution. These amounts at times may exceed federally insured limits. The Company has not experienced any credit losses in these accounts.

m. 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.

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 2009. 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.

n. 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. For all periods presented, the Company s net loss equals comprehensive loss, since the Company has no items which are considered other comprehensive income (loss).

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

o. 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, common stock equivalents were excluded because their inclusion would have been anti-dilutive. The potential shares, which are excluded from the determination of basic and diluted net loss per share as their effect is anti-dilutive, are as follows:

	2011	2010	2009
Options to purchase common stock	**3,723,108**	**3,135,619**	**2,962,461**
Warrants to purchase common stock	**1,523,370**		
Unvested shares of restricted common stock			**5,000**
Potential equivalent common stock excluded	**5,246,478**	**3,135,619**	**2,967,461**

Potentially dilutive options to purchase common stock as of December 31, 2011, 2010 and 2009 have exercise prices ranging from $0.62 to $6.00. Potentially dilutive warrants to purchase common stock as of December 31, 2011 have an exercise price of $1.30.

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

q. RECENT ACCOUNTING PRONOUNCEMENTS. In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present components of other comprehensive income as part of the statement of changes in stockholders equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. These changes become effective for fiscal years beginning after December 15, 2011, except for the reclassification adjustments out of accumulated other comprehensive income that become effective for fiscal years ending after December 15, 2012. The adoption of these changes will not have a material effect on the Company s financial statements.

r. WARRANTS LIABILITY. In October 2011, the Company issued warrants to purchase shares of the Company s common stock in connection with a registered direct offering under a shelf registration statement. The Company accounted for these warrants as a liability measured at fair value due to a provision included in the warrant agreement that provides the warrant holders with an option to require the Company (or its successor) to purchase their warrants for cash in an amount equal to their Black-Scholes Option Pricing Model (the Black-Scholes Model) value, in the event that certain fundamental transactions, as defined, occur. The fair value of the warrant liability is estimated using the Black-Scholes Model which requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized each reporting period in the Change in fair value of warrants liability line in the statement of operations.

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

3. Fair Value Measurements

The Company s financial assets and liabilities measured at fair value are classified within the fair value hierarchy which is defined as follows:

Level 1 Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
Level 2 Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.
Level 3 Inputs that are unobservable for the asset or liability.

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3. Fair Value Measurements (continued)

Warrants

The Company allocated approximately $1.3 million of proceeds from its October 2011 registered direct offering to the fair value of common stock purchase warrants issued in connection with the offering that are classified as a liability. The valuation of the warrants is determined using the Black-Scholes Model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the warrants liability should be classified within Level 3 of the fair value hierarchy by evaluating each input for the Black-Scholes Model against the fair value hierarchy criteria and using the lowest level of input as the basis for the fair value classification. There are six inputs: closing price of the Company s common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of the Company s common stock; annual rate of dividends; and the risk free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrants agreement. The annual rate of dividends is based on the Company s historical practice of not granting dividends. The closing price of the Company s common stock would fall under Level 1 of the fair value hierarchy as it is a quoted price in an active market. The risk free rate of return is a Level 2 input, while the historical volatility is a Level 3 input in accordance with the fair value accounting guidance. Since the lowest level input is a Level 3, the Company determined the warrants liability is most appropriately classified within Level 3 of the fair value hierarchy. This liability is subject to fair value mark-to-market adjustment each period. The assumptions used for the October 2011 warrants liability valuation were an expected life of 5.5 years, expected annual volatility of 121% and a risk free rate of 1.28%. The assumptions used for the December 31, 2011 warrants liability valuation were an expected life of 5.34 years, expected annual volatility of 119% and a risk free rate of 0.92%. As a result, the Company recognized the change in the fair value of the warrants liability as a non-operating expense of approximately $320,000 for the year ended December 31, 2011. The resulting fair value of the warrants liability at December 31, 2011 was approximately $1.6 million.

4. Prepaid Expenses

Prepaid expenses consist of the following as of December 31:

	2011	2010
Prepaid insurance	**$ 178,536**	**$ 71,215**
Prepaid offering costs		**42,369**
Prepaid research fees		**38,719**
Prepaid subscriptions fees	**9,942**	**3,756**
Prepaid rent	**2,267**	**3,251**
Other	**8,371**	**6,911**
Total prepaid expenses	**$ 199,116**	**$ 166,221**

5. Property and Equipment

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

	2011	2010
Computer equipment	**$ 26,791**	**$ 32,376**
Furniture and equipment	**44,469**	**44,175**
Leasehold improvements		**80,176**
	71,260	**156,727**
Less: Accumulated depreciation	**(59,074)**	**(111,154)**

Total property and equipment, net	**$ 12,186**	**$ 45,573**

Depreciation expense was $42,835, $25,741 and $30,227, respectively, for the years ended December 31, 2011, 2010 and 2009. During June 2011, in connection with the renewal of the corporate office lease, the Company entered into the first amendment to the lease. The amendment extends the original lease term for five years and relocates the Company into another space within the same building. Upon relocation of the corporate office, in November 2011 the Company wrote-off the asset value and related accumulated depreciation of leasehold improvements pertaining to the previous space, substantially all of which were fully depreciated at that time.

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6. Accrued Expenses and Other Liabilities

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

	2011	2010
Accrued compensation and benefits	$ 239,442	$
Accrued professional fees	111,920	87,212
Accrued pre-clinical and clinical trial expenses	101,568	35,678
Accrued license fees	102,500	50,186
Deferred rent and lease incentive		14,853
Other	14,437	5,099
Current accrued expenses and other liabilities	569,867	193,028
Deferred rent and lease incentive- non-current	9,518	14,748
Non-current accrued expenses and other liabilities	9,518	14,748
Total accrued expenses and other liabilities	$ 579,385	$ 207,776

During December 2011, in connection with the separation agreement with one of the Company s officers, the Company accrued severance to be paid over the next year to such officer. As of December 31, 2011, approximately $233,000 of such amount was included in accrued compensation and benefits in the table above.

7. Commitments

The Company has entered into agreements with contract manufacturers for the manufacture of drug and study placebo for the Company s trials and studies, with contract research organizations (CRO) to conduct and monitor the Company s trials and studies and with various entities for laboratories and other testing related to the Company s trials and studies. The contractual terms of the agreements vary, but most require certain advances as well as payments based on the achievement of milestones. Further, these agreements are cancellable 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 committed to pay severance benefits to certain executive employees if they are terminated without cause or upon a change of control.

The Company has executed noncancellable operating lease agreements for its office. 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, 2011, future minimum lease payments under the operating lease agreements are as follows:

2012	$ 53,666
2013	66,228
2014	68,054
2015	70,096
2016	72,198
Thereafter	67,827
	$ 398,069

During June 2011, in connection with the renewal of the corporate office lease, the Company entered into the first amendment to the lease. The amendment extends the original lease term for five years and relocates the Company into another space within the same building. The corporate office lease is cancellable upon the payment of an early termination penalty during 2015. The relocation occurred in November 2011. 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 and other liabilities in the accompanying balance sheets. Rent expense was $61,653, $65,781 and $69,030, respectively, for the years ended December 31, 2011, 2010 and 2009. The Company s leases expire on various dates through November 2017.

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 8.

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8. 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, 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, 2011 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 become payable 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.

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, 2011 was approximately $1.3 million. The Company 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, 2011 and 2010 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 that 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, the Company will be responsible for continued research and development of any resulting product candidates. As of December 31, 2011, the Company has paid Northwestern $127,872 in connection with the license, and has accrued license fees of $102,500 in the accompanying December 31, 2011 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 next milestone payment of $100,000 is due on the earlier of successful completion of the first Phase I clinical trial for CPP-115 or August 27, 2013.

c. **LICENSE AGREEMENT WITH NEW YORK UNIVERSITY AND THE FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH.** On December 13, 2011, the Company entered into a license agreement with New York University (NYU) and the Feinstein Institute for Medical Research (FIMR) under which it acquired worldwide rights to commercialize GABA aminotransferase inhibitors in the treatment for Tourette s Syndrome. The Company is obligated to pay certain milestone payments in future years relating to clinical development activities and royalties on any products resulting from the license agreement.

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8. Agreements (continued)

d. AGREEMENT WITH NIDA. On April 13, 2010, the Company signed a definitive Clinical Trial Agreement (CTA) with the National Institute on Drug Abuse (NIDA) to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Phase II(b) Trial). As part of the CTA, NIDA, under their agreement with the Veteran s Administration Cooperative Studies Program (VA), has agreed to provide substantial resources towards the completion of the Phase II(b) Trial. This approximately 200 subject double-blind, placebo-controlled trial is being conducted at twelve leading addiction research facilities across the United States. The Phase II(b) Trial, which is being overseen by the VA, was initiated in November 2010, and the Company expects to have top-line data from the Phase II(b) Trial early in the first quarter of 2013. The Phase II(b) Trial is designed to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and if successful, the Company believes that it will qualify to be one of the adequate and well controlled trials required to support approval of an NDA for CPP-109.

Pursuant to the CTA, the Company has provided the study drug (and matching placebo) for the Phase II(b) Trial and materials required to package them suitably for use in the Phase II(b) Trial. In conjunction with NIDA, the Company has developed the Phase II(b) Trial protocol and informed consent and has submitted such documents to the FDA for review. The Company is also responsible for, among other duties, funding patient recruitment activities and advertising for the Phase II(b) Trial, establishing and funding a contract with a vendor capable of decrypting and converting the visual field data obtained from study subjects into a format analyzable by the VA statisticians who will interpret the study data, and, if requested, funding the treatment costs of up to 25 study subjects. Further, pursuant to the CTA, NIDA has provided input on the protocol and informed consent and, under their agreement with the VA, is funding qualified study sites and investigators. NIDA has also presently contracted to treat more than 200 study subjects. Finally, NIDA, through its agreement with the VA, is providing clinical monitoring for all sites.

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

As of December 31, 2011, the Company estimates that it will pay approximately $1.4 million of direct costs in connection with contracts related to the Phase II(b) Trial. As of December 31, 2011, the Company had paid approximately $1.0 million of this amount and had accounts payable of approximately $55,000 and accrued expenses of approximately $75,000 in the accompanying December 31, 2011 balance sheet related to these contracts. These amounts exclude internal costs, such as salaries, benefits and other costs of the Company s personnel working on the Phase II(b) Trial.

9. Related Party Transactions

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers, directors 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, 2011, 2010 and 2009, the Company paid approximately $93,000, $79,000 and $64,000, 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 $387,000 in 2012, and may earn bonus compensation based on performance. This agreement expires in November 2013.

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10. Income Taxes

As of December 31, 2011 and 2010, the Company had deferred tax assets of approximately $13,440,000 and $11,428,000, respectively, of which approximately $11,934,000 and $10,080,000 represent United States federal and state net operating loss carryforwards and start-up costs. The remaining temporary differences represent non-deductible stock option and equity expense. The related deferred tax asset has a 100% valuation allowance as of December 31, 2011 and 2010, 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 $2,012,000, $1,510,000 and $2,742,000 in 2011, 2010 and 2009, respectively. There are no other significant temporary differences. The net operating loss carry-forwards of approximately $19,980,000 as of December 31, 2011 will expire at various dates beginning in 2023 and ending in 2031. 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.

11. 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 for periods prior to this date, 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.

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, 2011 and 2010, 24,701,420 and 19,394,737 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote for 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 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.

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11. Stockholders Equity (continued)

In addition, on June 2, 2008 the Company filed a shelf registration statement on Form S-3 (the 2008 Shelf Registration Statement) with the SEC to sell up to $30 million of common stock. This shelf registration (file no. 333-151368) was declared effective by the SEC on June 26, 2008. On September 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 under the 2008 Registration Statement and received gross proceeds of approximately $4.5 million before underwriting commissions and expenses of approximately $377,000. On October 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 under the 2008 Registration Statement and received gross proceeds of approximately $4.0 million before underwriting commissions and expenses of approximately $275,000. On August 2010, the Company filed a prospectus supplement and sold an additional 1,351,352 shares of its common stock at $1.11 per share to an institutional investor under the 2008 Shelf Registration Statement and received gross proceeds of approximately $1.5 million before expenses of approximately $44,000. The 2008 Shelf Registration Statement expired on June 26, 2011 and the Company can no longer sell shares under the 2008 Shelf Registration Statement.

Further, on December 3, 2010, the Company filed a second shelf registration statement on Form S-3 (the 2010 Shelf Registration Statement) with the SEC to sell up to $30 million of common stock and common stock purchase warrants. This shelf registration statement (file No. 333-170945) was declared effective by the SEC on December 15, 2010. On March 2011 the Company filed a prospectus supplement and offered to sell to institutional investors 2,259,943 shares of its common stock under the 2010 Shelf Registration Statement at a price of $1.12 per share and received gross proceeds of approximately $2.5 million before underwriting commissions and incurred expenses of approximately $300,000. During October 2011, the Company filed a prospectus supplement and offered to sell to institutional investors 3,046,740 shares of its common stock together with common stock purchase warrants to purchase 1,523,370 shares of the Company s common stock under the 2010 Shelf Registration Statement at a price of $1.15 per share and corresponding warrant and received gross proceeds of approximately $3.5 million before underwriting commissions and other expenses totaling approximately $305,000. See Note 1.

The number of shares that the Company can sell and the amount of the gross proceeds that the Company can raise (in the aggregate) under its currently outstanding shelf registration statements is 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.

Nasdaq Listing

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

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share at December 31, 2011 and 2010. No shares of preferred stock were outstanding at December 31, 2011 and 2010.

Stockholder Rights Plan

On September 20, 2011, the Board of Directors approved the Company s adoption of a Stockholder Rights Plan. Under the Plan, a dividend of one preferred share purchase right (a Right) was declared for each share of common stock of the Company that was outstanding on October 7, 2011. Each Right entitles the holder to purchase from the Company one one-hundredth of a share of Series A Junior Preferred Stock at a purchase price of $7.80, subject to adjustment.

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11. Stockholders Equity (continued)

The Rights will trade automatically with the common stock and will not be exercisable until a person or group has become an acquiring person by acquiring 17.5% or more of the Company s outstanding common stock, or a person or group commences, or publicly announces a tender offer that will result in such a person or group owning 17.5% or more of the Company s outstanding common stock. Upon announcement that any person or group has become an acquiring person, each Right will entitle all rightholders (other than the acquiring person) to purchase, for the exercise price of $7.80, a number of shares of the Company s common stock having a market value equal to twice the exercise price. Rightholders would also be entitled to purchase common stock of the acquiring person having a value of twice the exercise price if, after a person had become an acquiring person, the Company were to enter into certain mergers or other transactions. If any person becomes an acquiring person, the Board of Directors may, at its option and subject to certain limitations, exchange one share of common stock for each Right.

The Rights have certain anti-takeover effects, in that they would cause substantial dilution to a person or group that attempts to acquire a significant interest in the Company on terms not approved by the Board of Directors. In the event that the Board of Directors determines a transaction to be in the best interests of the Company and its stockholders, the Board of Directors may redeem the Rights for $0.001 per share at any time prior to a person or group becoming an acquiring person. The Rights will expire on September 20, 2016, unless earlier redeemed or exchanged.

12. 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, 2,688,828 shares of the Company s common stock are reserved for issuance. At December 31, 2011, 239,270 of these shares remained available for future issuance under the Plan.

Stock Options

The Company has granted stock options to employees, officers, directors, scientific advisors and consultants generally at exercise prices equal to the quoted market price of the common stock at grant date. Share awards generally vest over a period of 2 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. The Company issues new shares as shares are required to be delivered upon exercise of outstanding stock options. No stock options have been exercised through December 31, 2011.

During the years ended December 31, 2011, 2010 and 2009, the Company recorded non-cash stock-based compensation expense related to stock options totaling $416,735, $450,089 and $581,286, respectively.

During the years ended December 31, 2011 and 2010, the Company granted five-year options to purchase an aggregate of 625,000 shares and 465,000 shares, respectively, of the Company s common stock to certain of the Company s officers, employees, directors and consultants.

Stock option activity under the Company s written stock option agreements and the Plan for the year ended December 31, 2011 is summarized as follows:

	Number of Options	Weighted Average Exercise Price
Outstanding at beginning of year	**3,135,619**	**$ 1.00**
Granted	**625,000**	**1.06**
Exercised		
Forfeited, expired or cancelled	**(37,511)**	**1.22**
Outstanding at end of year	**3,723,108**	**$ 1.01**

Exercisable at end of year	**3,303,108**	**$**	**1.00**

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12. Stock Compensation Plans (continued)

The aggregate intrinsic value of outstanding options and exercisable options at December 31, 2011 was $1.5 million and $1.4 million, respectively. The weighted-average grant-date fair value of stock options granted during 2011, 2010 and 2009 was $0.79, $0.75 and $0.55, respectively. The total fair value of vested stock options during 2011, 2010 and 2009 was $438,139, $346,270 and $634,807, respectively.

The following table summarizes information about the Company s stock options outstanding at December 31, 2011:

	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-$0.69	1,489,220	1.85	$ 0.68	1,489,220	1.85	$ 0.68
$0.90	935,000	2.80	$ 0.90	935,000	2.80	$ 0.90
$1.01-$1.09	1,070,000	4.49	$ 1.07	650,000	4.34	$ 1.08
$2.49-$2.55	124,000	1.92	$ 2.51	124,000	1.92	$ 2.51
$3.15-$6.00	104,888	0.93	$ 4.08	104,888	0.93	$ 4.08
	3,723,108	2.83	$ 1.01	3,303,108	2.58	$ 1.00

As of December 31, 2011, there was approximately $312,000 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 2.00 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. The 2011 expected volatility is based on reviews of historical volatility of the Company s common stock. For 2010 and prior, the Company s expected volatility was based on the historical volatility of other publicly traded companies in the same industry, due to the Company s short history as a public entity. 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. During 2011, the Company estimated the expected option life for options granted to employees and directors based upon the simplified method. Under this method, the expected life is presumed to be the mid-point between the vesting date and the end of the contractual term. The Company will continue to use the simplified method until it has sufficient historical exercise data to estimate the expected life of the options. 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.

Assumptions used were as follows:

	Year ended December 31,		
	2011	2010	2009
Risk free interest rate	0.29% to 1.55%	0.81% to 2.44%	1.26% to 2.60%
Expected term	3 to 5 years	4 to 5 years	4 to 5 years
Expected volatility	130%	100%	90%
Expected dividend yield	%	%	%
Expected forfeiture rate	%	%	%

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12. Stock Compensation Plans (continued)

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. There was no restricted stock unit activity during 2011.

During the years ended December 31, 2011, 2010 and 2009, the Company recorded non-cash stock-based compensation expense related to restricted stock units totaling $0, $0 and $20,152, respectively.

13. 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, 2011, 2010 and 2009 the Company s matching contributions were approximately $34,000, $33,000 and $34,000, respectively.

14. Quarterly Financial Information (unaudited)

The following table presents unaudited supplemental quarterly financial information for the years ended December 31, 2011 and December 31, 2010:

	Quarter Ended			
	March 31, 2011	June 30, 2011	September 30, 2011	December 31, 2011
Revenues	$	$	$	$
Loss from operations	(1,519,250)	(1,397,463)	(1,131,010)	(2,034,416)
Net loss	(1,517,136)	(1,394,151)	(1,127,841)	(2,351,934)
Loss per share basic and diluted	$ (0.08)	$ (0.06)	$ (0.05)	$ (0.10)

	Quarter Ended			
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
Revenues government grant	$	$	$	$ 488,958
Loss from operations	(1,050,412)	(1,333,132)	(908,465)	(732,172)
Net loss	(1,045,043)	(1,328,541)	(903,985)	(728,754)
Loss per share basic and diluted	$ (0.06)	$ (0.07)	$ (0.05)	$ (0.04)

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.