Catalyst Pharmaceutical Partners, Inc.
Form 10-K
April 02, 2007

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
[Mark One]

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2006
OR

o **TRANSITION REPORT UNDER 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 or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
220 Miracle Mile Suite 234 Coral Gables, Florida	33134
(Address of principal executive offices)	(Zip Code)

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

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

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

Indicate by checkmark 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 þ No o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act (Check one):
Large Accelerated Filer o Accelerated Filer o Non-Accelerated Filer þ
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ
Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date: 12,527,564 shares of common stock, $0.001 par value per share, were outstanding as of March 23, 2007.

CATALYST PHARMACEUTICAL PARTNERS, INC.
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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 in Item 1A, Risk Factors. We, our, ours, us, or the Company when used he refers to Catalyst Pharmaceutical Partners, Inc,. a Delaware corporation.

Forward-Looking Statements

Certain statements made in this Form 10-K and the information incorporated into this Form 10-K by reference contain forward-looking statements, including statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words, believes, anticipates, proposes, plans, expects, intends, may and similar expressions are intended to 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, including but not limited to the following:

- our ability to successfully complete clinical trials required to file and obtain approval of a new drug application (NDA) to commercialize the Company s product candidate based on vigabatrin, CPP-109, and the timing of any such filing and approval;
- our ability to protect our intellectual property rights;
- market acceptance of any products as to which we may receive approval for commercialization;
- the ability of others to develop, obtain approval of, and commercialize competitive products; and
- the information contained in the Risk Factors section of this Form 10-K.

Our current plans and objectives are based on assumptions relating to the development of our business. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements made herein, which reflect our views only as of the date of this Form 10-K, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. *Business*

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of addiction. Our initial product candidate is CPP-109, which is based on the chemical compound *gamma-vinyl-GABA,* commonly referred to as vigabatrin. We intend to conduct clinical studies of CPP-109 for use in the treatment of cocaine addiction and methamphetamine addiction. We also believe that CPP-109 has the potential to treat other addictions, including addictions to nicotine, prescription pain medications, alcohol, and marijuana, as well as treatments for obsessive-compulsive disorders, such as obesity and compulsive gambling. We intend to seek to develop CPP-109 to treat other forms of addiction, such as those described above, subject to the availability of funding for that purpose.

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We will begin in the second quarter of 2007 a U.S. Phase II clinical trial evaluating the use of CPP-109 for the treatment of cocaine addiction. We also intend to commence during the third quarter of 2007 a U.S. Phase II clinical trial evaluating the use of CPP-109 for the treatment of methamphetamine addiction. Although the protocols for these clinical trials have not yet been finalized, each of these clinical trials is expected to be a randomized, double-blind, placebo-controlled study including approximately 150 patients. We expect to have the results of these clinical trials by the second or third quarter of 2008. These trials will be undertaken with CPP-109 manufactured by our contract manufacturer. We are currently conducting a study to demonstrate that CPP-109 is bioavailable and bioequivalent to a version of vigabatin known as Sabril (a registered trademark of Sanofi-Aventis), that is not currently approved in the United States, which could provide data potentially linking CPP-109 to the extensive body of published clinical literature on Sabril. We expect to have the results of our bioequivalence study in the second quarter of 2007 and do not expect that this bioequivalence study will affect the timing of our contemplated U.S. Phase II clinical trials. If the results of our upcoming clinical trials are compelling, we intend to conduct the follow-on pivotal U.S. Phase III clinical trial that we believe will be required before we can file a new drug application, or NDA, for CPP-109. However, there can be no assurance that the FDA will not require additional studies, including an additional Phase III study, or that we will ever receive an approval for any NDA that we may file in the future for CPP-109.

We have been granted an exclusive worldwide license from Brookhaven Science Associates, as operator of Brookhaven National Laboratory under contract from the U.S. Department of Energy (Brookhaven), to nine U.S. patents and four U.S. patent applications 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 2021. Additionally, we have received approval from the European Union (EU) with respect to one of our principal patents, which will allow us to seek registration for this patent in eighteen EU member states.

In December 2004, the U.S. Food & Drug Administration (FDA) accepted our Investigational New Drug application, or IND, for CPP-109 for the treatment of cocaine addiction. In addition, we have been granted Fast Track status by the FDA for CPP-109. Fast Track status means, among other things, that the FDA recognizes cocaine addiction as an unmet medical need for which no pharmacological products are currently approved for marketing, and consequently the FDA may initiate reviews of sections of the NDA before the application is completed in order to expedite review of the NDA. However, the receipt of Fast Track status does not mean that the regulatory requirements necessary to obtain an approval are any less stringent. Further, Fast Track status may be withdrawn at any time and does not guarantee that we will qualify for, or be able to take advantage of, priority review procedures following submission of an NDA. Notwithstanding, and although there can be no assurance, we believe that our receipt of Fast Track status for CPP-109 may accelerate the regulatory approval process.

On November 13, 2006, we completed an initial public offering in which we sold 3,350,000 shares of our common stock at a price of $6.00 per share. In the offering, we raised net proceeds of approximately $17.6 million, which we are using for product development and general corporate purposes.

Our Strategy

Our goal is to be a leading specialty pharmaceutical company focused on the in-licensing and development of proprietary product candidates in the field of addiction. Our near-term strategy is to focus on the regulatory approval of CPP-109 for the treatment of cocaine addiction and methamphetamine addiction. Our long-term strategy is to gain approvals for additional indications for CPP-109, seek approvals for CPP-109 internationally and to in-license other product candidates to treat addiction. Specifically, we intend to:

Focus on CPP-109 for cocaine addiction and methamphetamine addiction. Beginning in the second quarter of 2007, we intend to commence a U.S. Phase II clinical trial evaluating the use of CPP-109 as a treatment for cocaine addiction. Shortly thereafter, during the third quarter of 2007, we intend to commence a U.S. Phase II clinical trial evaluating the use of CPP-109 as a treatment for methamphetamine addiction. Treatments for cocaine addiction and methamphetamine addiction address a significant unmet medical need, and we believe that our receipt of Fast Track status for CPP-109 for cocaine addiction may facilitate the regulatory approval process.

Develop additional indications for CPP-109. The mechanism of action of CPP-109 makes it suitable as a potential treatment for addiction states that share the common element of heightened dopamine levels. Our

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research indicates that CPP-109 is a platform technology with the potential to treat other conditions involving heightened dopamine levels such as addictions to nicotine, prescription pain medications, alcohol, marijuana, and obsessive-compulsive disorders, including obesity and compulsive gambling. We hope to develop one or more of these additional applications, subject to the availability of funding.

Acquire or license additional addiction therapies. Subject to the availability of additional funding, we may seek to acquire or license one or more additional product candidates to expand our development programs. We have entered into no such agreements to date.

Develop second generation of CPP-109. Subject to the availability of additional funding, we plan to develop a new formulation of CPP-109. If we are successful, we intend to initially seek approval for this new form in Europe, where we may be able to obtain exclusive marketing rights. Subsequently, we may seek approval for this new formulation in the United States.

Leverage the services of thought leaders in addiction treatment. We believe that the members of our Scientific Advisory Board are among the most respected researchers in the field of addiction therapy. We intend to utilize their knowledge, services and relationships to guide our development process and commercialization strategy.

Disease Background and Our Market Opportunity

Historically, addicted individuals have been treated primarily through behavioral modification, which has a high rate of relapse. According to a survey conducted by the Substance and Mental Health Services Agency (SAMHSA), treatment completion rates in 2000 for outpatient treatment were only 41% for alcohol and 21% for cocaine. For the treatment of cocaine dependence, there is a one-year relapse rate of 69% after 90 days or less of outpatient treatment and 80% after 90 days or less of long-term residential treatment. We believe that a pharmacological treatment for cocaine addiction and/or methamphetamine addiction 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. We believe that currently approved drugs for addiction treatment, as well as compounds under development (other than CPP-109), 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; and

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

For example, we believe that a product candidate known as TA-CD, which is being developed as a cocaine vaccine, would be limited to treating only cocaine addiction and could be overwhelmed by increasing doses of cocaine. Similarly, we believe that baclofen, which is a type of chemical known as a GABA B agonist and which has been evaluated to treat cocaine addiction but is not approved for that indication, is receptor active and requires increasing dosing over time. Such limitations may result in the United States Drug Enforcement Agency designating Baclofen, if approved, as scheduled, subjecting it to a high level of regulatory control as to manufacturing, distribution, prescription and use. Neither of these compounds is approved for marketing as a treatment for addiction in the U.S., and we believe that these limitations will significantly limit the potential of these drugs as addiction treatments.

We believe that CPP-109 does not suffer from these limitations, and therefore has the potential to become a widely prescribed, safe and effective treatment for cocaine, methamphetamine and other addictions, if approved.

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Pharmacodynamics of Addictive Drugs

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.

Addictive drugs are used recreationally because of the transient, pleasurable effect they have on the user. These effects are the result of biochemical changes the drug causes in the brain.

Normal brain activity occurs through electrical signals which are transmitted across brain cells known as neurons. Signals are transmitted from neuron to neuron across a small gap, known as the synaptic cleft, by the release of chemical messengers known as neurotransmitters. The releasing, or pre-synaptic, neuron sends a neurotransmitter into the synaptic cleft to the receiving, or post-synaptic, neuron, which has specialized receptor molecules that pick up the neurotransmitter, triggering the post-synaptic neuron to initiate its own release. The repetition of this process from neuron to neuron, along what are known as the mesolimbic pathways, is responsible for the transport of signals in the brain. Once the neurotransmitter has stimulated the receptor, it is either broken down or reabsorbed into the pre-synaptic neuron.

Almost all drugs of abuse affect the pathway for the neurotransmitter known as dopamine. Dopamine is associated with the pleasure system of the brain, causing feelings of enjoyment in order to motivate certain behaviors, such as eating or sexual function. Dopamine is a naturally produced chemical that binds to dopamine-specific receptors on the neuron. Under normal conditions, only a portion of the brain s dopamine receptors are occupied at any one time. After dopamine is released from the receptor, the pre-synaptic neuron reuptakes dopamine using a protein that is a dopamine reuptake transporter, and the dopamine is subsequently stored or broken down by an enzyme called monamine oxidase, or MAO. Drugs that block the natural reuptake or breakdown of dopamine result in elevated levels of dopamine in the synaptic cleft, triggering feelings of pleasure and euphoria.

Over time, the feeling of euphoria fades due to the natural reduction in dopamine and through the action of GABA, or gamma-aminobutyric acid, which is an inhibitory neurotransmitter found in the brain. GABA, in turn, is broken down by a chemical called GABA transaminase, or GABA-T. Under normal conditions, dopamine effects are moderated by GABA, which in turn is moderated by GABA-T, maintaining the brain in a balanced, pre-arousal state.

Mechanism of Action of Cocaine. 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.

Mechanism of Action of Methamphetamine. Methamphetamine is chemically similar to dopamine and another neurotransmitter called norepinephrine. Due to its chemical structure, methamphetamine is carried into the pre-synaptic neuron and triggers the release of dopamine and norepinephrine into the synaptic cleft. Methamphetamine also reverses the action of the transporter molecules that normally cause dopamine or norepinephrine reuptake from the synaptic cleft back into the neuron, resulting in a flood of dopamine back into the synaptic cleft. In addition, methamphetamine blocks the enzymes that cause the breakdown of these neurotransmitters. The resulting elevated levels of dopamine trigger feelings of euphoria and pleasure, and excess norepinephrine may be responsible for the alertness and anti-fatigue effects associated with the drug.

Similar to cocaine s mechanism of addiction, methamphetamine users undergo the desensitization process, resulting in increasing usage to achieve the same effects.

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Industry Background Substance Abuse and Addiction

Addiction is a worldwide health problem that affects millions of people and has wide-ranging negative social consequences. In 2005, an estimated 19.7 million people in the United States suffered from dependence on illicit drugs, according to the National Survey on Drug Use and Health, published by SAMHSA, which we refer to as the SAMHSA survey. According to the Office of National Drug Control Policy, costs of drug abuse to society were an estimated $180 billion in 2002 in the United States.

Addiction is not only a U.S. health problem. For example, according to the United Nations Office on Drugs and Crime, in 2004 there were approximately 3.5 million users of cocaine and 2.7 million users of amphetamine-type stimulants across Europe. 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.

Cocaine Addiction. According to the SAMHSA survey, an estimated 2.4 million people had used cocaine in the month preceding the survey. Additionally, in 2005, approximately 900,000 people had used cocaine for the first time within the preceding 12 months, an average of approximately 2,400 new users per day. According to the same study, approximately 797,000 patients received treatment for cocaine abuse in 2005. According to the National Institute of Drug Abuse, or 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.

Methamphetamine Addiction. According to the SAMHSA survey, an estimated 512,000 people had used methamphetamine in the month preceding the survey. Additionally, an estimated 192,000 people had used methamphetamine for the first time within the preceding 12 months, an average of 526 new users per day. Additionally, according to the SAMHSA survey, 351,000 patients received treatment for methamphetamine and other stimulant abuse in 2005. A study conducted by the Center for Business Research at the University of Arkansas Sam W. Walton College of Business and funded by the Wal-Mart Foundation in 2004 determined that each methamphetamine-using employee costs his or her employer $47,500 per year due to lost productivity, absenteeism, higher healthcare costs and higher workers compensation costs. Similar to cocaine addiction, there are no currently approved drugs for treatment of methamphetamine addiction.

Nicotine Addiction. According to the SAMHSA survey, an estimated 71.5 million people had used tobacco products in the month preceding the survey. Further, the study reported that in 2004 the number of people who started smoking within the preceding 12 months was approximately 2.3 million. According to NIDA, in 2000 over $75 billion in annual direct healthcare costs and an estimated $82 billion in indirect costs were attributable to smoking. According to the National Institutes of Health, 70% of adult smokers in the U.S. want to quit and 40% make a serious attempt to quit each year. However, fewer than 5% succeed in any given year, according to industry data. Global sales of smoking cessation products were approximately $1.4 billion in 2004.

Other Addictions. According to the SAMHSA survey, in 2005 an estimated 6.4 million people took prescription drugs for non-medical purposes, including approximately 4.7 million who abused prescription pain relievers. Further, according to the SAMHSA survey, approximately 16 million people in the United States were classified as heavy drinkers. Additionally, according to the SAMHSA survey there are approximately 14.6 million persons who used marijuana in the month preceding the survey and approximately 1.1 million persons sought treatment in 2005. Finally, obsessive-compulsive disorders such as obesity and compulsive gambling have been shown to have similar dopamine-related mechanisms of action to drug addiction and affect millions of persons in the United States and around the world.

Our Platform Technology

Mechanism of Action of CPP-109. We believe that our product candidate, CPP-109, will be an effective addiction treatment because it eliminates the perception of pleasure and reward associated with the use of dopamine-enhancing drugs and behavior. 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.

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However, dopamine is associated with other actions beyond the mediation of those responses. Simply blocking dopamine effects at the receptor site is ineffective and associated with profound side effects, such as the extensive impairment of motor functions seen in patients with Parkinson s disease. Therefore, more sophisticated approaches to regulating the specific actions of dopamine are required.

GABA, the most abundant inhibitory neurotransmitter in the brain, balances the brain by inhibiting over-excitation. When GABA binds to a GABA receptor, it inhibits the post-synaptic neuron from triggering the release of neurotransmitters, preventing the subsequent firing of an electrical signal. GABA helps induce relaxation and sleep, and contributes to functions such as motor control and vision. An enzyme known as GABA-T is responsible for the eventual breakdown of GABA once the feeling of euphoria has faded.

Vigabatrin is a GABA analog that inhibits GABA-T. The drug is readily absorbed and promptly available to the central nervous system, producing effects that last for many hours after a single dose. Therefore, administration of vigabatrin results in significantly elevated GABA levels. This prevents the perception of pleasure and reward resulting from dramatic increases in dopamine levels caused by cocaine and/or methamphetamine use. Vigabatrin administration does not appear to affect the baseline levels of dopamine, nor those variations in dopamine levels caused by normal stimuli.

History and Side Effect Profile. Vigabatrin has been marketed over the past decade in over 30 countries by Sanofi-Aventis and its predecessors under the brand name Sabril as a secondary treatment for adult epilepsy and as a primary treatment for the management of infantile spasms, known as West Syndrome. The composition of matter patents for Sabril expired in 1993. No forms of vigabatrin, including Sabril, have been approved in the United States for any indication.

In chronic use for the treatment of epilepsy, vigabatrin has been generally well tolerated. The most common side effects reported have been drowsiness and fatigue. However, one clearly established adverse side effect is the development, with increasing cumulative dosage levels of vigabatrin approaching 1,500 grams, of peripheral visual field defects, or VFDs, in approximately 33% of users. These VFDs are manifest as a constriction of the peripheral field of vision, or the loss of visual acuity at the extreme left and right edges of the field of vision. While the exact cause of these VFDs is unknown, they are believed to be irreversible, with the resultant requirement that recipients of vigabatrin must receive regular six month visual tests while using the drug.

Prior research has indicated that VFDs occur at doses far higher than the dosage amount we anticipate will be used for addiction treatment. However, we have not completed the testing necessary to determine whether this is the case.

Brookhaven s Research. Our initial interest in vigabatrin was based on Brookhaven s research with it regarding the pathology and treatment of cocaine and other addictions. Brookhaven scientists have shown that the dopamine pathway responds similarly to drugs of abuse. In 1997, scientists at Brookhaven harnessed an emerging technology, positron emission tomography scans, or PET scans, and became the first to image the effects of addicting substances in live human and animal subjects. Through the use of PET scans, Brookhaven scientists were able to show that as the number of engaged dopamine receptors in the brain increased, so too did the high , or euphoric feeling, of the user.

Our Clinical Research

In 2004, the FDA accepted our IND for CPP-109 for the treatment of cocaine addiction. We have been granted Fast Track status for CPP-109 from the FDA. Under the Federal Food, Drug and Cosmetic Act, or FFDCA, 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 opportunity to submit an NDA for CPP-109 on a rolling, or modular, basis, allowing the FDA to review sections of the NDA in advance of receiving our full submission. The designation also means that we may have increased communications with the FDA regarding the design of our clinical studies, which we hope will expedite the development and review of our application for the approval of CPP-109 for cocaine addiction and provide greater certainty overall in the regulatory pathway. There can be no assurance that our receipt of Fast Track status will assist us in the regulatory process for CPP-109.

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We intend to commence a U.S. Phase II clinical trial in the second quarter of 2007 to evaluate CPP-109 for the treatment of cocaine addiction. While the final design of this clinical trial and the number of patients to be included has not yet been finalized, we currently anticipate that this trial will be a double-blind, randomized, placebo-controlled trial involving approximately 150 patients at multiple treatment sites in the United States. To be eligible to participate in the trial, participants must meet specific clinical standards for cocaine dependence, as specified in DSM-IV, a set of diagnosis guidelines established for clinical professionals. Additionally, trial participants cannot meet the DSM-IV criteria for dependence on other addictive substances. Further, eye safety studies will be conducted on all trial participants to determine the extent of VFDs among such participants, if any. A similar U.S. Phase II clinical trial evaluating CPP-109 for the treatment of methamphetamine addiction will also be simultaneously conducted under similar parameters to the study for cocaine addiction. The trial evaluating CPP-109 for the treatment of methamphetamine addiction is expected to commence in the third quarter of 2007.

Even if the data from our upcoming clinical trials are compelling, we expect that we will have to conduct at least one pivotal U.S. Phase III clinical trial before we will be permitted to file an NDA seeking regulatory approval for CPP-109.

Further we will need to provide evidence to the FDA that CPP-109 is safe. We believe that because vigabatrin has been on the market for many years and, except for the issue of VFDs, which has been widely reported on by the scientific community, has been well tolerated and shown no significant side effects, that significant, unknown safety concerns are unlikely. Nevertheless, we believe that the FDA will also require one or more Phase I clinical trials. While the scope of the required clinical trials is currently uncertain, it is likely that we will be required to include studies of pharmacokinetics, cardiac function, drug-drug interaction and the effect of the drug on special populations. We expect to conduct the required Phase I trial(s) during the pendency of our Phase II clinical trials or thereafter.

There can be no assurance as to if and when we will obtain an NDA to market CPP-109.

Clinical Studies That We Support

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

The clinical trial in Mexico that we are currently supporting described below is an example of such a study. Enrollment for the Mexico trial began in January 2007; however, enrollment has not yet been completed. The principal investigators of this trial are Jonathan Brodie, Ph.D., M.D., a professor of Psychiatry at New York University and a member of our Scientific Advisory Board, and Emilia Figueroa, M.D., a physician addiction specialist who directs several addiction treatment clinics in Mexico. Dr. Brodie designed the protocol for this trial, which is a double-blind, placebo-controlled study and involves 100 patients at a single location in Mexico City. Subjects are being selected from a pool of cocaine-dependent prison parolees who meet the specific clinical standards for cocaine dependence, as specified in DSM-IV. The trial is expected to continue for one year. The primary endpoint of the trial is patient abstinence from cocaine for a period of 21 days following treatment. We are supporting this study through an unrestricted grant to the NYU School of Medicine.

Pilot Studies

Our intention to advance CPP-109 as a potential treatment for cocaine addiction and methamphetamine addiction is based on two open-label human pilot studies conducted in 2003 and 2004 in Mexico by John Brodie, M.D., Ph.D., a member of our Scientific Advisory Board. We believe these pilot studies support the therapeutic potential of vigabatrin as a treatment for cocaine addiction and methamphetamine addiction. However, both studies involved a small number of patients, a high number of patients dropped out of both studies and neither study provided enough evidence regarding safety and efficacy to support an NDA filing with the FDA. In addition, these

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studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol. For these reasons, there can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these pilot studies. These pilot studies are described below:

Cocaine Pilot Study 2003 Mexico.

The first pilot study of vigabatrin for treating cocaine addiction was conducted in Mexico in 2003. The results of this study were published in a peer-reviewed journal, in an article authored by Jonathan D. Brodie, Emilia Figueroa and Stephen L. Dewey. Dr. Dewey is also a member of our Scientific Advisory Board.

Study design. The protocol was designed as an outpatient, open-label, fixed-dose, time-limited trial in a setting with psychotherapeutic support and intervention. A total of 20 subjects, consisting of 19 men and one woman were enrolled.

Enrollment criteria. Subjects were primarily daily cocaine abusers meeting DSM-IV criteria for cocaine dependence with a minimum of three years of continuous use. Most of the subjects were polydrug abusers whose cocaine use was often supplemented with methamphetamine, marijuana, and/or alcohol. As a prerequisite for inclusion, all subjects indicated that they were interested in breaking their drug dependence and gave informed, signed consent. Exclusion criteria included intravenous drug use and subjects treated within the past year for substance abuse. At the beginning of the study, the average age of the subjects was 29, with an average 12-year history of cocaine abuse and an average daily consumption of 1.7 grams of cocaine.

Dosing. Following an admission physical examination and screening for medical exclusion criteria, all subjects were given a screening urinalysis and a craving questionnaire and were then placed on vigabatrin. Each subject was given escalating doses of vigabatrin. Vigabatrin was administered on day one at two grams, consisting of one gram twice daily. After three days, the dosage was increased to 1.5 grams twice daily and on day seven vigabatrin was administered at a continuing dose of two grams twice daily. All dosing was done under observation in the clinic. Subjects who had a negative drug screen for four successive weeks, or 28 days in total, were then tapered down by one gram of vigabatrin per day per week.

Testing. All subjects were encouraged to participate in group and individual counseling programs and were required to twice weekly provide urine samples in addition to filling out a daily questionnaire of drug use and craving. The drug screen included cocaine, heroin, methamphetamine, tetrahydrocannabinol, or THC, and phencyclidine, or PCP.

Results. Of the 20 subjects enrolled in the study:

Eight remained in the program and were drug-free for periods ranging from 46 to 58 days at the end of the study. Only two subjects had a single slip or relapse into cocaine use once the craving stopped. A slip restarted the consecutive days clean or drug-free value.

Of the 12 subjects who failed to complete the program, eight requested termination within 10 days, stating that they did not wish to stop their cocaine use. The other four subjects stayed in the protocol for periods of 25 to 43 days but continued to use cocaine, although in reduced amounts: two out of the four had an 80% reduction, one out of the four had a 50% reduction, and the other did not reduce at all, according to self-reports by the subjects, despite their claim that the drug did not engender the usual high.

Most trial completers reported that their craving was not eliminated until an average of 17.9 days following vigabatrin administration. Craving was never eliminated in the four subjects who continued to use cocaine in addition to vigabatrin for three weeks, nor in the eight early non-completers.

The trial completers did not differ significantly from the non-completers in age, duration of cocaine abuse, or average daily use. The consecutive days clean for the completers averaged

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48.5 days, compared to an average of 1.9 days for non-completers, with a P-value, which is a measure of statistical significance, of less than 0.0001. There was also a clear distinction between the two groups on the basis of weight gained during the trial: an average of 18.2 pounds for the completers, compared to an average of 0.2 pounds for non-completers, with a P-value of less than 0.0001. A P-value of less than 0.05 indicates that the different results between treatment groups was not random. No subject who continued cocaine use during their participation in the study reported increased appetite or experienced weight gain. In order for the study s outcomes to be convincing in light of concerns about vigabatrin s safety and efficacy, an outcome measure of 28 consecutive days clean, in which the subject tested negative for cocaine, was utilized. We believe this measure was particularly stringent for an outpatient setting and in the field of addiction therapy where statistical significance often exceeds therapeutic reality.

A comparison of statistical information regarding trial completers and non-completers is set forth below:

	Completers (n = 8)	**Non-Completers (n = 12)**	
Age	28.8 ± 5.7	29.3 ± 6.2	P=0.73 (ns)*
Abuse History (Years)	9.5 ± 4.9	11.5 ± 6.7	P=0.74 (ns)*
Mean Cocaine Use(g/day)	1.8 ± 1.5	1.6 ± 0.8	P=0.62 (ns)*
Consecutive Clean Days	48.5 ± 5.7	1.9 ± 3.3	P < 0.0001
Weight Increase (lbs)	18.2 ± 10.7	0.2 ± 0.6	P < 0.0001

* Not statistically significant.

Subjects in this study were all cocaine users who consumed cocaine five to seven days per week and had been doing so for three to 15 years. Nevertheless, 40% of those who entered the study completed it without relapse. Once cocaine use ceased, six of the eight completers were entirely drug free for the duration of the study, or seven weeks. The others had a single slip and were again clean for greater than four weeks. On the other hand, the mean time to relapse of all 12 non-completers was less than two days. Significantly, all of the trial completers gained weight, while none of the non-completers gained any. Weight gain precisely paralleled cessation of cocaine use by self-report as well as by the twice weekly drug screen and daily observation. We believe that this is not surprising in view of the well-known appetite-suppressing effects of cocaine.

Notwithstanding, because of the small size of the studies and the number of patients who dropped out, the results of these studies and the P-values derived from these studies may not be reliable or repeatable, and may not be duplicated in future larger studies. Further, the P-values derived from the results of this pilot study have no relevance in determining whether CPP-109 compared to placebo can be distinguished in a randomized placebo-controlled clinical study.

We believe that trial completers manifested clear behavioral changes. They showed gains in self-esteem, reestablished healthy family relationships, and went to work or actively sought work. There were no relapses over an extended period despite completers remaining in the same neighborhood environment in which cocaine was readily available and with all of the cues and social pressures that had previously supported their addiction. We believe that without psychosocial intervention it is likely that the fraction of subjects who complete a program would be lower than observed in this study. For example, in this study most subjects who continued using cocaine reported an altered and diminished response or reward but persisted in their use, albeit at reduced amounts. If the outcome measure was a greater than 80% reduction in cocaine consumption, then that criterion was met by 10 of the 12 subjects who stayed on vigabatrin for more than 10 days. In addition, all eight subjects who completed the program noted a cessation of

craving which persisted during the exit, or vigabatrin taper, phase. We believe this suggests that elimination of craving might be the single most important factor in achieving successful therapeutic remission.

Side Effects Observed. Overall, vigabatrin was well tolerated. No subjects reported visual disturbances of any kind throughout their exposure to vigabatrin or admitted to vision changes of any kind upon questioning. The

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major side effects were transient somnolence, or drowsiness, in the first 10 days, observed in 17 of the 20 subjects, and an intermittent low-grade headache, observed in 9 of the 20 subjects, that occasionally persisted for several weeks, although never severe enough for the subject to request termination on that basis.

Cocaine and Methamphetamine Pilot Study 2004

The second pilot study was conducted in Mexico between November 2003 and January 2004 under Dr. Brodie s supervision and with our financial support. The results of this study were published in a peer-reviewed journal, in an article authored by Jonathan D. Brodie, Emilia Figueroa, Eugene M. Laska and Stephen L. Dewey. Drs. Brodie, Laska and Dewey are members of our Scientific Advisory Board. This was an open-label, nine-week study involving 30 subjects dependent on methamphetamine and/or cocaine. The study evaluated the efficacy of vigabatrin for treatment of cocaine and methamphetamine abuse and examined whether short-term usage of vigabatrin caused VFDs.

Study design. All subjects, consisting of 29 men and one woman, met DSM-IV criteria for drug dependence. The protocol for this study was reviewed and approved by the Government of Mexico according to the standards of the Helsinki Convention as currently modified.

Enrollment criteria. Subjects abused methamphetamine, cocaine, or both on a daily basis, but were otherwise in good health. The average duration of drug dependence for all subjects was 12.8 years. All 30 subjects enrolled met DSM-IV criteria for substance abuse, three met the criteria for dependence on cocaine alone, 10 met the criteria for methamphetamine dependence alone, and 17 met the criteria for dependence on both cocaine and methamphetamine. Complete preadmission histories and physical examinations for all subjects were obtained.

Ophthalmologic Measurement. The baseline ophthalmologic examination consisted of funduscopy, in which a doctor examines the back of the eye with an ophthalmoscope in order to assess any damage to the blood vessels that supply the retina. In addition, visual acuity was determined by conventional ophthalmic techniques, and measurements of the subject s visual field were performed utilizing a measurement technique known as an automated Humphreys VF60-4 protocol. These tests were repeated in the middle and end of treatment and again at one to two months following treatment cessation. Ophthalmic measurements were performed at the Codet Eye Institute, Tijuana, B.C. Mexico. In addition, these data were independently evaluated by a Board Certified Ophthalmologist, Robert D. Fechtner, M.D., at the University of Medicine and Dentistry, Newark, New Jersey, who had no knowledge of each subject s identity. Dr. Fechtner is a member of our Scientific Advisory Board.

Dosing. Vigabatrin administration was initiated at 500 milligrams twice daily for three days, then 1.5 grams per day for the next four days and two grams per day for the next week. On day 15, subjects were placed on three grams per day, maintained at that dose for the next 28 days, and then tapered to zero over the next three weeks. Completers received a cumulative dose of vigabatrin of 137 grams, which is less than 10% of the 1,500 gram lifetime exposure that we believe is associated with an increase in the incidence of visual field defects.

Testing. Twice-weekly urine samples were obtained under direct observation and tested for cocaine, methamphetamine, marijuana, heroin, and alcohol. Daily vital signs were monitored, and all subjects were encouraged to participate in weekly group therapy.

Results. Of the 30 volunteers enrolled:

11 subjects dropped out before completing 4 weeks,

One subject completed 8 weeks; and

18 subjects completed all nine weeks, consisting of all three cocaine-only users, 6 of the 10 methamphetamine-only users, and 9 of the 17 users of both methamphetamine and cocaine.
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Completers did not differ significantly from non-completers in either the pre-study daily usage or years of dependence. Further administration of vigabatrin did not have an effect on vital signs, even with continued use of cocaine and methamphetamine. Further, there were no VFDs or other changes in visual acuity detected in any subject, regardless of whether the subject completed the study or not.

Completers reported increased appetite and showed a significant weight gain over non-completers, gaining an average of 11.4 pounds, compared to an average of 4.4 pounds for non-completers, with a P- value of 0.004. However, because of the small size of the study and the number of patients who dropped out of the studies, these results may not be reliable or repeatable, and may not be duplicated in future trials. Fifteen completers were methamphetamine-free and/or cocaine-free for four consecutive weeks, with no slips, while two were never drug-free although use was markedly reduced according to self-reports by the users. The average drug-free interval was 40.1 consecutive days, with an average use of 0.03 grams of cocaine or methamphetamine over the last three weeks of the study.

Patents and Intellectual Property Rights

Brookhaven license agreement

We have been granted an exclusive, worldwide license from Brookhaven to nine patents and four patent applications 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 occurring between 2018 and 2021. Additionally, we recently received approval from the European Union with respect to one of our principal patents, which will allow us to seek registration for this patent in eighteen EU member states.

The license agreement, which is dated as of April 30, 2006 and which supercedes 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, we have agreed to reimburse Brookhaven for all reasonable and customary expenses it incurs from the beginning of our agreement in connection with the filing, prosecution and maintenance of all patents and patent applications included in the patent rights we have licensed. We were obligated to reimburse Brookhaven for such expenses upon our filing of an NDA.

We have also agreed to consult with Brookhaven not less frequently than quarterly 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.

General

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

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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.

Manufacturing, Marketing and Reimbursement

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 acquired a sufficient quantity of the active pharmaceutical ingredient used in vigabatrin to supply our current U.S. Phase II, bioequivalence and pre-clinical trial requirements. We also have an agreement with a contract manufacturer, Pharmaceutics International, Inc. (PII), to formulate and manufacture CPP-109 for use in our upcoming clinical trials. We also intend in the future to contract with PII and/or another contract manufacturer to manufacture commercial quantities of CPP-109 if the FDA approves an NDA for CPP-109.

Under our current agreement with PII, they have agreed to manufacture for us CPP-109 in quantities that we believe will be sufficient to conduct our currently ongoing bioequivalence study and our contemplated U.S. Phase II clinical trials for the treatment of cocaine addiction and methamphetamine addiction, along with a matching placebo. Such materials have been manufactured and we anticipate having sufficient quantities of trial materials and matching placebos to start our contemplated U.S. Phase II clinical trials on a timely basis.

Our contract with PII contains no renewal provisions. Pursuant to the agreement, we will make payments to PII, aggregating $513,200, based on achievement of milestones related to the schedule of work PII has agreed to perform for us. Approximately $207,000 of this amount had been paid through December 31, 2006. Under our contract with PII, we have agreed to indemnify PII against:

- costs relating to any potential injury suffered by persons who take CPP-109 that PII manufactures;
- any losses arising from our negligence in labeling, handling or storing CPP-109;
- any specifications which we give them that are incorrect or do not meet FDA-approved standards;
- any misrepresentation or breach by us of the agreement; and
- any patent infringement claims that may result from the use of CPP-109.

PII has agreed to indemnify us against:

- any losses related to its negligence or willful misconduct in the manufacture of CPP-109;
- any misrepresentation by PII in the agreement; and
- any claims by third parties that PII infringed or misappropriated any intellectual property in its manufacture of CPP-109.

The contract with PII can be terminated by us at any time with thirty days written notice. However, if we choose to terminate the agreement, we will be responsible for paying all costs PII incurs relating to its manufacture of CPP-109 up to the date of such termination. PII may terminate the contract only if we are in breach of our material obligations, after giving thirty days notice and an opportunity to cure; such time period being reduced to ten days if the breach relates to a breach of our monetary obligations.

Because CPP-109 is not presently approved in the United States for any indication, we must file an NDA as if vigabatrin were a new chemical entity. Such NDA will include our manufacturing plan for CPP-109. If the manufacturing plan and data are insufficient, the NDA will not be approved. Further, even if we receive approval of an NDA for CPP-109, if our manufacturer does not follow good manufacturing practices, or cGMP, in the manufacture of our products, it may delay product launches or shipments or adversely affect our business.

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Since we intend to contract with a third party to manufacture our products, our contract manufacturer will be obligated 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.

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

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 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 payors.

While there are no currently approved therapies for cocaine or methamphetamine addiction, we are aware of other therapies under development. These can be broadly classified into three 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. These compounds include:

methylphenidate, which is marketed as Ritalin by Novartis, and

GBR-12909, which is known as vanoxerine and is currently in Phase II clinical trials sponsored by the National Institute of Drug Abuse, or NIDA.

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

baclofen, marketed as Lioresal by Novartis;

topiramate, marketed as Topamax by Ortho-McNeil Neurologics;

tiagabine, marketed as Gabitril by Cephalon;

gabapentin, marketed as Neurontin by Pfizer; and

progabide, marketed as Gabrene by Sanofi-Aventis.

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Addiction Vaccines. These vaccines are designed to block cocaine transport into the brain. They do not address issues relating to craving or other behaviors associated with cocaine addiction. We also believe that they can be overwhelmed by increasing dosages of cocaine. These compounds include TA-CD, which is a cocaine vaccine currently in Phase II clinical trials sponsored by Celtic Pharma Development U.K. Plc.

In addition to these therapies, we are aware that InterveXion Therapeutics LLC is developing two monoclonal antibody based compounds for treatment of methamphetamine and phencyclidine, or PCP, addictions.

Finally, Ovation Pharmaceuticals, Inc., which holds the North American rights to Sabril as an adjunctive therapy for the treatment of epilepsy and as a primary treatment for West Syndrome, has indicated its intent to undertake studies with respect to the use of Sabril in treating cocaine addiction and methamphetamine addiction. Ovation has recently entered into a cooperative research and development agreement, or CRADA, with NIDA to study the use of Sabril in the treatment of cocaine addiction and methamphetamine addiction. The CRADA contemplates in-kind contributions by NIDA with respect to Ovation s clinical studies and is a three to five-year program through Phase II clinical trials. We believe, although there can be no assurance, that our development plan for CPP-109 will allow us to move our product development efforts more quickly than can generally be completed under a CRADA. Further, we believe that any commercialization by Ovation of Sabril for the treatment of cocaine addiction and/or methamphetamine addiction would violate our licensed patents, and we have advised Ovation of our belief in that regard. We would vigorously assert our intellectual property rights if Ovation sought to market Sabril for the treatment of cocaine addiction. There can be no assurance we would be successful in that regard.

Our Competitive Strengths

We believe that the key strengths that distinguish us from our competitors include:

CPP-109, if approved, will offer potentially significant advantages over current treatments for drug addiction. As set forth above, relapse rates for traditional counseling treatments are very high, while clinical studies of vigabatrin to date have shown low relapse rates among the 26 patients who completed treatment. There can be no assurance, however, that the relapse rates over wider studies or in general use will remain as low.

If approved, we believe that the use of CPP-109 in conjunction with counseling will potentially offer a more efficacious and cost-effective addiction treatment than is currently available.

Unlike other compounds, we believe that CPP-109 has no abuse liability; that is, we believe that CPP-109 does not substitute addiction to one drug for addiction to another drug. As a result, we believe it will be easier for patients to cease using CPP-109 after treatment without withdrawal effects.

CPP-109 s mechanism of action potentially allows it to be used to treat most types of substance addiction and abuse.

We have been granted Fast Track status for CPP-109 by the FDA, which allows us an expedited review process with the FDA of any NDA we may file for CPP-109 relating to its use in treating cocaine addiction.

Government Regulation

The FDA Approval Process

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

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

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

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

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

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

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

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

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also

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refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues an approval letter, an approvable letter or a not-approvable letter. Both approvable and not-approvable letters generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

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

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 FFDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of pre-clinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. We intend to submit a Section 505(b)(1) application for CPP-109.

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

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

If the ANDA applicant has provided a Paragraph 4 certification to the FDA, the applicant must also send notice of the Paragraph 4 certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of

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the Paragraph 4 certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph 4 certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph 4 challenge to a listed patent, in which case the submission may be made four years following the original product approval. 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 FDA cannot grant effective approval of an ANDA based on that listed drug for the same new dosage form, route of administration or combination, or new use. Non-patent exclusivity under the Hatch-Waxman Act does not prevent a competitor from submitting, or the FDA from approving, a full NDA.

Other Regulatory Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

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

Fast Track Designation

Under the fast track program, the sponsor of a new drug candidate intended for the treatment of a serious or life-threatening condition for which there is no effective treatment 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 FDA, FDA may initiate review of sections of a fast track drug s NDA before the application is complete. This

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rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under FDA policies, a drug candidate is eligible for priority review, or review within a six-month time frame from the time a complete NDA is accepted for filing, if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track designated drug candidate would ordinarily meet the FDA s criteria for priority review.

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

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

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

Physician Drug Samples

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

Foreign regulations

Any marketing of CPP-109 outside of the United States will be contingent on receiving approval from the various regulatory authorities. Foreign regulatory systems, although they vary from country to country, 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

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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., post-approval regulatory requirements would apply to any products that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

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

Employees

As of March 23, 2007 we had five employees. We also utilize the services of consultants, including one of our officers, a member of our Board of Directors and several members of our Scientific Advisory Board. None of our employees are covered by a collective bargaining agreement. We believe our relationship with our employees and consultants is good.

Our Scientific Advisory Board

We rely on prominent scientists and physicians to advise us on our pipeline of drug candidates and the clinical development of CPP-109. All of our advisors are employed by organizations other than us 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 is a Senior Chemist at Brookhaven National Laboratory. Dr. Dewey is a recognized authority in positron emission tomography, which uses certain compounds to visualize and quantitative biochemical processes as well as the distribution and movement of drugs in the living human and animal body. Dr. Dewey has been with Brookhaven since 1986, serving as Assistant Chemist, Associate Chemist, Chemist, Tenured Scientist and Senior Chemist. Dr. Dewey is also a Research Professor of Psychiatry at the New York University School of Medicine and an Adjunct Professor of Neurobiology and Behavior at SUNY at Stony Brook. Dr. Dewey has been developing a novel approach to treating addiction within Brookhaven s PET program and is devoted to research within this area. Dr. Dewey is a co-inventor of Brookhaven s patents for substance addiction, including Brookhaven s patents covering the use of vigabatrin to treat addiction.

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

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

Robert D. Fechtner, M.D. is Professor of Ophthalmology and Director, Glaucoma Division at the Institute of Ophthalmology and Visual Science 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.

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

Thomas Kosten, M.D., is Waggoner Professor of Psychiatry and Neuroscience at Baylor College of Medicine and a former Professor and Chief of Psychiatry at Yale University and at the Veterans Administration (VA) Hospital in Connecticut. Dr. Kosten is also Research Director of the VA National Substance Use Disorders Quality Enhancement Research Initiative (QUERI) based at the Houston VA and the founder of the Division of Substance Abuse at Baylor, where he directs their NIH Medications Development Center for Substance Abuse. Dr. Kosten has been supported by a Research Scientist Award from the NIH since 1987 and has served on national and international review groups for medications development in substance abuse. Dr. Kosten is the founding Vice Chair for Added Qualifications in Addiction Psychiatry of the American Board of Psychiatry and Neurology. He is a Distinguished Fellow in the American Psychiatric Association and fellow of the American College of Neuropsychopharmocology, Past President of the American Academy of Addiction Psychiatry, and President of the College on Problems of Drug Dependence. He has several major awards for clinical research, and is Editor of two major Journals in substance abuse and has been on the American Journal of Psychiatry board. His recent work includes serving on the National Academy of Sciences Institute of Medicine committee on vaccines for substance abuse. From his studies in substance dependence, post-traumatic stress disorder, and neuroimaging, he has published over 450 papers, books, and reviews. His neuroimaging research includes detecting and treating cocaine-induced cerebral perfusion defects, and using functional MRI to predict pharmacotherapy outcome. He has been involved in clinical trials involving such products as a vaccine to treat cocaine addiction, immunotherapy for hallucinogens, buprenorphine for opioid dependence, disulfiram for cocaine dependence, vasodilators for cocaine-induced cerebral perfusion defects, and combing medications with contingency management for opioid and cocaine dependence.

Richard A. Rawson, Ph.D. is a member of the University of California, Los Angeles Department of Psychology and is currently a Professor-in-Residence. He also serves as the Associate Director of the UCLA Integrated Substance Abuse Programs in the UCLA School of Medicine, where he oversees a portfolio of addiction research ranging from brain imaging studies to numerous clinical trials on pharmacological and psychosocial addiction treatments to the study of how new treatments are applied in the treatment system. During the past decade, Dr. Rawson has worked with the 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

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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.

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. Our Internet address is www.catalystpharma.com.

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

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

We have had no revenues from operations to date, currently have no products available for commercial sale, and have never had any products available for commercial sale. We expect to incur losses at least until we can commercialize CPP-109. Our net loss was $2,729,454 for the year ended December 31, 2006, and as of December 31, 2006 we had a deficit accumulated during the development stage of $5,759,214. We may not obtain approval of an NDA for CPP-109 and may never achieve profitability.

Our business will require additional capital.

Our business goals include developing CPP-109 for use in treating various addictions, including cocaine addiction and methamphetamine addiction. While we expect that the proceeds from our recently completed initial public offering and July 2006 private placement should allow us to complete all of the clinical and pre-clinical trials required to seek approval of an NDA for CPP-109 to treat cocaine addiction, our expectation, which is based on information available to us at the date of this report, may not be correct. For example, most of the expenses for completing the development of CPP-109 to treat cocaine addiction will be in the form of fees and expenses, and we will be required to pay a contract research organization to conduct this work for us. We have not yet selected or contracted with any third party for this purpose, and our estimate of the fees and expenses we will have to pay is based on the experiences of our management team, Board members and scientific advisors in dealing with these types of organizations rather than firm quotes. The actual cost to us could be significantly greater than we expect. In addition, the FDA could require us to alter or delay our clinical trials at any stage, which may significantly increase the costs of our trials. Further, we intend to develop

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clinical studies to seek commercialization of CPP-109 to treat methamphetamine addiction and to commercialize CPP-109 for sale in Europe. We do not presently have the funds needed to complete all the necessary studies to gain such U.S. and foreign approvals. Other than the U.S. Phase II cocaine and methamphetamine trials described herein, these other studies have not yet been developed, we do not know the ultimate costs of these studies, and we will need additional funding to pay such costs. Required funds may not be available, or even if they are available, they may not be available on terms acceptable to us. Further, to the extent that we raise such funds through collaborative arrangements, it may be necessary to relinquish some of the rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to raise required funds, our business and prospects would be adversely affected.

There is currently little scientific evidence supporting the use of vigabatrin to treat addiction.

There is currently little scientific evidence indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, two open-label pilot clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine addiction and methamphetamine addiction. Only 26 persons in the aggregate completed these trials. Additionally, some of the study results described in this Form 10-K, such as evidence regarding beneficial weight gain, employment or other behavioral changes, have little scientific correlation to the safety or efficacy of CPP-109 as a treatment for addiction, and therefore are not reliable as evidence of safety or efficacy. Further, these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol. For these reasons, there can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these pilot studies. The results of these pilot studies are not necessarily predictive of results that will be obtained in later stages of clinical testing in the United States or ensure success in later stage clinical trials and neither study provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA.

Our product development efforts may fail.

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

- CPP-109 may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;
- CPP-109, even if found to be safe and effective, could prove difficult or impossible to manufacture on a large scale or on a cost-effective basis;
- CPP-109 may be uneconomical 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 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 if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well-controlled clinical studies that the drug is safe and effective for its intended use and that it otherwise meets approval requirements. A failure of one or more pre-clinical or clinical studies can occur at any stage of product development. We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for or commercializing CPP-109, including but not limited to:

- regulators or institutional review boards, which are commonly called IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

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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;

we may be unable to reach agreements on acceptable terms with prospective clinical research organizations and/or principal investigators who will conduct our clinical trials;

the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;

we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;

our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;

our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and

the costs of our pre-clinical or clinical trials may be greater than we anticipate.

We are dependent on a single chemical compound, vigabatrin.

To date, we have invested, and will in the foreseeable future continue to invest, most or all of our time and resources to develop products using a single chemical compound, vigabatrin, for the treatment of addictions. Because all of our potential products are based on this chemical compound, if we cannot successfully develop and market products using it, and if we are not successful in commercializing such products, it would have an adverse effect on our business, financial condition, results of operations and prospects.

Vigabatrin, the single chemical compound on which we depend, 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, that increase progressively with continuing drug treatment. We intend to include a standardized evaluation of each patient s visual fields before, during and after completion 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 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 may also cause the FDA to impose marketing restrictions on CPP-109. For example, the FDA may require specialized training for, or otherwise limit the ability of, physicians to prescribe CPP-109 and of pharmacists to fill prescriptions for CPP-109, may restrict our ability to advertise CPP-109, and may require us to keep a registry of patients who are prescribed CPP-109 to prevent such patients from using CPP-109 over an extended period of time.

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

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

Although we intend to rely on third parties to manage the data from these clinical trials, we are responsible for confirming that each of our clinical 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 regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and the results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for CPP-109 if these requirements are not met.

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

Our current plans for development of CPP-109 include efforts to minimize the data we will need to generate in order to obtain marketing approval of CPP-109 for methamphetamine addiction and other additional indications. If we are successful in obtaining approval of an NDA for CPP-109 as a treatment for cocaine addiction, of which there can be no assurance, in the future we plan to submit supplemental NDAs for additional indications. Depending on the data we rely upon, approval for additional indications for CPP-109 may be delayed. In addition, even if we receive supplemental NDA approval, the FDA has broad discretion to require us to generate additional data related to safety and efficacy to supplement the data used in the supplemental NDA. We could be required, before obtaining marketing approval for CPP-109 for additional indications, to conduct substantial new research and development activities, which could be more costly and time-consuming than we currently anticipate. We may not be able to obtain shortened review of our applications, and the FDA may not agree that we can market CPP-109 for additional indications. If we are required to generate substantial additional data 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.

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

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

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sufficient amounts of CPP-109 or any related final product, it would have a material adverse effect on our ability to successfully market
CPP-109.

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 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 payors.

Ovation Pharmaceuticals, Inc., which holds the North American rights to Sabril as an adjunctive therapy for the treatment of epilepsy and as a primary treatment for West Syndrome, has indicated its intent to undertake studies with respect to the use of Sabril in treating cocaine and methampetamine addiction. Ovation has recently entered into a CRADA with NIDA to study the use of Sabril in the treatment of cocaine addiction and methamphetamine addiction. The CRADA contemplates in-kind contributions by NIDA with respect to Ovation s clinical studies and is a three to five-year program through Phase II clinical trials. We believe, although there can be no assurance, that our development plan for CPP-109 will allow us to move our product development efforts more quickly than can generally be completed under a CRADA. Further, we believe that any commercialization by Ovation of Sabril for this use would violate our licensed patents, and we have advised Ovation of our belief in that regard. We would vigorously assert our intellectual property rights if Ovation sought to market Sabril for the treatment of cocaine addiction and methamphetamine addiction. There can be no assurance we would be successful in that regard.

Many of our competitors, including Ovation, 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 CPP-109, 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 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, 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 five employees and five consultants and conduct most 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

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at a faster pace than we currently anticipate, and could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and sale of CPP-109. 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. Liability claims may be expensive to defend and result in large judgments against us. We currently carry liability insurance with an aggregate annual coverage limit of $5,000,000 per claim and $5,000,000 in the aggregate, with a deductible of $10,000 per occurrence and $50,000 in the aggregate. Our insurance may not reimburse us, 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 or any of our other future products 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.

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 payors 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 payors 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 and other products we may develop could affect the extent to which we are able to commercialize our products successfully.

We have limited experience as a public company, and the obligations incident to being a public company will place significant demands on our management.

From our inception until November 2006, we operated as a private company, not subject to the requirements applicable to public companies.

Following completion of their audit of our financial statements for 2005, 2004 and 2003, our independent auditors, Grant Thornton, LLP, advised our Board of Directors and management that during the course of their audit, they noted an internal control deficiency constituting a significant deficiency and a material weakness as defined in professional standards. The deficiency noted related to our knowledge of accounting for equity instruments. Our auditors identified that we had not recorded compensation expense related to the issuance of non-employee stock options and had not reported sufficient compensation expense relating to stock that we issued to our consultants and scientific advisors for services. The required adjustments aggregated approximately $1.7 million. Management believes that it has corrected this weakness by hiring a Corporate Controller/Chief Accounting Officer in January 2007 with experience in preparing financial statements in accordance with generally accepted accounting principles.

As a public reporting company, we will need to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of Sarbanes-Oxley, the SEC adopted rules requiring public companies to include a report of management on a company s internal control over financial reporting in their Annual Report on Form 10-K. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management s assessment of the effectiveness of our internal control over financial reporting. Based on current rules, we will be required to come into compliance with Section 404 of Sarbanes-Oxley over the next few years. If at such time as we become obligated to comply with Section 404 of Sarbanes-Oxley we are unable to conclude that we have effective internal control over our financial reporting as required by Section 404 , 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 Our Intellectual Property

We are dependent on our relationship and license agreement with Brookhaven, and we rely upon the patents granted to us pursuant to the license agreement.

All of our patent rights are derived from our license agreement with Brookhaven. Pursuant to this license agreement, we have licensed rights under nine patents and four patent applications in the United States, and 79 corresponding patents and patent applications outside of the United States, that were filed and obtained by Brookhaven relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions. The nine issued patents expire between 2018 and 2021. We also have the right to future patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. See Business Patents and Intellectual Property Rights for more information about our license with Brookhaven and our licensed patents and patent applications. These rights are subject to the right of the U.S. government, under limited circumstances, to practice the covered inventions for or on its own behalf. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations to Brookhaven. If we violate or fail to perform any term or covenant of the license agreement, Brookhaven may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Brookhaven, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-109, and our business, results of operations, financial condition and prospects would be materially adversely affected.

The license agreement also grants us rights to four pending U.S. patent applications. These applications may not result in issued patents. If patents are issued, any such patents might not provide any commercial benefit to us.

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

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

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

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

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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.

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

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

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

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

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

Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. For example, Ovation, which holds rights in North America to Sabril for the treatment of epilepsy, has indicated its intent to seek to develop Sabril for the treatment of cocaine addiction and methamphetamine addiction. We believe that Ovation would infringe our patent rights if they seek to commercialize vigabatrin to treat cocaine addiction and/or methamphetamine addiction, and we have advised Ovation of our belief in that regard. We intend to vigorously pursue infringement claims against Ovation if it seeks to commercialize Sabril for these indications. However, we, unlike Ovation 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

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attention of our management and scientific personnel will be diverted from product development or other more productive matters.

Risks Related to Government Regulation

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

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

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

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

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

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

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

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Additionally, we will need to conduct clinical trials demonstrating the safety of CPP-109 in humans. In the United States, where vigabatrin is not currently approved for use, we intend to commence during the second quarter of 2007 a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction and shortly thereafter, to commence a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for methamphetamine addiction. We will also be required to conduct one or more Phase I clinical trials for CPP-109. While the scope of the required Phase I clinical trials are currently uncertain, it is likely that we will be required to perform studies of pharmacokinetics, cardiac function, drug-drug interaction and the effect of the drug on special populations. We may also develop and implement additional studies (including at least one U.S. Phase III clinical trial) in order to seek approval to commercialize CPP-109 for the treatment of cocaine addiction and methamphetamine addiction. However, even if the results of our upcoming clinical trials are promising, a drug 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.

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

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

If we cannot demonstrate that CPP-109 is bioavailable and bioequivalent to Sabril, our product development efforts may be substantially delayed.

We have entered into an agreement with PII to formulate and manufacture CPP-109 for use in our U.S. Phase II clinical trials. We have recently commenced a trial to demonstrate that CPP-109 is bioequivalent to Sabril in order to seek to take advantage of the extensive body of literature that has previously been published regarding vigabatrin. If we cannot demonstrate that CPP-109 is bioavailable and bioequivalent to Sabril, the FDA may require us to repeat or conduct additional clinical trials using CPP-109. This would likely result in significant delays in our product development activities, which would have a material adverse effect on our business.

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

We may encounter difficulties in our clinical trials due to the nature of the addiction mechanism and our resulting target patient population. We do not know how long it will take to recruit patients for our Phase II clinical trials. Trial participants will be required to meet specific clinical standards for cocaine dependence and methamphetamine dependence, as specified in DSM-IV, a set of diagnosis guidelines established for clinical professionals. Further, participants must meet DSM-IV criteria only with respect to cocaine dependence or methamphetamine dependence, and will not be eligible to participate in our study if they meet the DSM-IV criteria for dependence with respect to other addictive substances (except nicotine). 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, and as evidenced by the pilot studies of vigabatrin, it is likely that many of our clinical trial participants will not complete the trial. An unusually low rate of completion will present challenges, such as determining the statistical significance of trial

results. Additionally, we compete for trial subjects with others conducting clinical trials testing other treatments for addictions. Finally, unrelated third parties, including Ovation and investigators in the academic community, have expressed interest in testing vigabatrin for the treatment of drug

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abuse. If these third-party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected.

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

The FDA will require us to submit the data from our pre-clinical testing for CPP-109 before approving our product. Some testing, such as carcinogenicity studies, which seek to identify the potential of a drug to cause tumors in animals and to assess the relevant risk in humans, will take, if required, several years to conduct. Some pre-clinical testing has previously been performed with respect to Sabril, and some of the data from such testing is publicly available. However, we do not yet know whether the FDA will consider such public data in reviewing any NDA we may file, what pre-clinical tests will be required or whether any pre-clinical tests will begin as planned, will need to be restructured or will be completed on schedule, if at all. We do not know whether the pre-clinical tests that we undertake, if conducted, will be acceptable to the FDA.

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

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- 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 high manufacturing standards, patients using our product candidates could be injured or die, resulting in product liability claims, product recalls, product

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

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

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

We are subject to inspection and market surveillance by regulatory authorities for compliance with regulations that prohibit the promotion of a medical product for a purpose or indication other than those for which approval has been granted. While a medical product manufacturer may not promote a product for such off-label use, doctors are allowed, in the exercise of their professional judgment in the practice of medicine, to use a product in ways not approved by regulatory authorities. A pattern of widespread off-label use could cause regulatory authorities to scrutinize our marketing activities.

Regulatory authorities have broad enforcement power, and any failure by us to comply with manufacturing or marketing regulations could result in penalties, including warning letters, fines, partial or total suspension of production, product recalls or seizures, withdrawals of previously approved marketing approvals or applications, and criminal prosecutions.

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

Healthcare organizations, 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 future proposals to reform the healthcare system are considered by Congress and state legislatures. 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 earnings, financial condition or business. Government regulations applicable to our proposed products or the interpretation thereof might change and thereby prevent us from marketing some or all of our products and services for a period of time or indefinitely.

Risks Related to Our Common Stock

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

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

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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 a member of the Brookhaven staff and is actively involved in Brookhaven s investigation of the neurological mechanisms involved in the addiction process. His research might result in pharmaceutical products that are competitive with, or superior to, vigabatrin. Similarly, other similar conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

We are effectively controlled by our Chairman and Chief Executive Officer, who is able to significantly influence or exert control over the outcome of most stockholder actions, including the election of all directors. This control could lead to entrenchment of our directors and management.

Our Chairman and Chief Executive Officer, Patrick J. McEnany, beneficially owns approximately 30% of our outstanding common stock. As a result, Mr. McEnany is in a position to significantly influence or exert control over the outcome of most stockholder actions, including the election of all directors. As a result, Mr. McEnany could take actions that might not be considered by other stockholders to be in their best interest.

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

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

- developments concerning our clinical studies and trials;
- announcements of product development failures and successes by us or our competitors;
- new products introduced or announced by us or our competitors;
- changes in reimbursement levels;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses (particularly our license from Brookhaven), research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- intellectual property, product liability or other litigation against us;
- changes in the market valuations of similar companies; 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

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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.

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, 2007 we had 12,527,564 shares of our common stock outstanding, of which 9,177,564 shares are restricted securities. The holders of 100% of our restricted shares have entered into lock-up agreements with the underwriters under which they have agreed not to sell their shares of common stock for 180 days from the date our initial public offering without the prior written consent of First Albany Capital Inc. We also intend to register for future sale the 2,188,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and the 2,374,149 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. Sales of restricted shares or shares underlying stock options, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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.

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Item 2. ***Properties***

We currently operate our business in leased office space in Coral Gables, Florida and Upper Saddle River, New Jersey. We pay annual rent on our office space of approximately $31,500. In anticipation of the expansion of our operations, we have recently obtained additional leased space.

Item 3. ***Legal Proceedings***

We are not a party to any legal proceedings.

Item 4. ***Submission of Matters to a Vote of Securities Holders***

No matters were submitted to a vote of stockholders during the fourth quarter of 2006.

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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 has been traded on the Nasdaq Global Market since November 8, 2006 under the symbol CPRX. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low closing sales prices per share of our common stock as reported on the Nasdaq Global Market for the period indicated.

	High	Low
Year Ended December 31, 2006		
Fourth Quarter	$ 6.15	$ 4.25
Year Ended December 31, 2007		
First Quarter (to March 28, 2007)	$ 6.83	$ 3.80

The closing sale price for the common stock on March 30, 2007 was $4.00. As of March 23, 2007, there were approximately 96 holders of record 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.

Recent Sales of Unregistered Securities

In July 2006, we issued 7,644 shares of our Series B Preferred Stock to certain existing and new investors at a per share price of $435, for an aggregate consideration of $3,325,140. Upon the closing of our initial public offering, these shares of Series B Preferred Stock automatically converted into 1,115,416 shares of our common stock.

During the year ended December 31, 2006, we issued 142,274 shares to consultants and members of our scientific advisory board for services. We also owed at December 31, 2006 10,944 shares of our common stock to one of our consultants (who is also a member of our Board of Directors) for services. These shares were formally issued in March 2007.

Use of Proceeds

Our initial public offering (IPO) of common stock was effected through a Registration Statement on Form S-1 (File No. 333-136039) that was declared effective by the Securities and Exchange Commission on November 7, 2006. In the IPO, we issued 3,350,000 shares of common stock at an offering price of $6.00 per share. The offering was underwritten by First Albany Capital Inc. and Stifel, Nicolaus & Company, Incorporated.

We raised gross proceeds in the IPO of $20.1 million. We paid to the underwriters discounts and commissions of approximately $1.4 million, and we incurred offering expenses of approximately $1.1 million in connection with the offering. We are using the net proceeds of the IPO, aggregating approximately $17.6 million, for product development and general corporate purposes. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of the date of this Form 10-K, we have invested the net proceeds of the IPO in an institutional money market fund that invests primarily in commercial paper with strong credit ratings and United States government agency notes with maturities under one year.

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Item 6. ***Selected Financial Data***

The selected statement of operations data for the years ended December 31, 2006, 2005 and 2004 and the period from January 4, 2002 (inception) through December 31, 2006, and the balance sheet data as of December 31, 2006 and 2005, have been derived from our audited financial statements included elsewhere in this Form 10-K. The income statement data for 2003 and 2002 and the balance sheet data as of December 31, 2004, 2003 and 2002 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,				Period from January 4, 2002 (date of inception) through December 31, 2002	Cumulative period from January 4, 2002 (date of inception) through December 31, 2006
	2006	2005	2004	2003		
Statement of Operations Data:						
Revenues	$	$	$	$	$	$
Operating costs and expenses:						
Research and development	989,144	1,330,515	378,254	268,829	137,680	3,104,422
General and administrative	1,913,183	491,653	164,704	165,483	118,265	2,853,288
Total operating expenses	2,902,327	1,822,168	542,958	434,312	255,945	5,957,710
Loss from operations	(2,902,327)	(1,822,168)	(542,958)	(434,312)	(255,945)	(5,957,710)
Interest income	172,873	16,788	3,138	5,697		198,496
Loss before income taxes	(2,729,454)	(1,805,380)	(539,820)	(428,615)	(255,945)	(5,759,214)
Provision for income taxes						
Net loss	$ (2,729,454)	$ (1,805,380)	$ (539,820)	$ (428,615)	$ (255,945)	$ (5,759,214)
Basic and diluted net loss per share	$ (0.36)	$ (0.29)	$ (0.18)	$ (0.15)	$ (0.11)	

Weighted average shares outstanding basic and diluted	7,687,630	6,204,918	2,918,438	2,918,438	2,358,737

	As of December 31,				
	2006	**2005**	**2004**	**2003**	**2002**
Balance Sheet Data:					
Cash and cash equivalents	$ 20,434,702	$ 771,127	$ 183,911	$ 416,262	$ 107,089
Working capital (deficiency)	19,814,976	428,579	116,111	362,563	40,388
Total assets	20,619,479	789,450	185,376	416,262	111,589
Total liabilities	772,846	342,988	67,800	53,699	66,701
Stockholders equity (deficit)	19,846,633	446,462	117,576	362,563	44,888

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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.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of drug addiction. Our initial product candidate is CPP-109, which is based on the chemical compound *gamma-vinyl-GABA,* commonly referred to as vigabatrin.

We have a small management team and very few employees. This has resulted in low general and administrative expenses and overhead relative to other companies of a similar size at a similar stage of development. We have brought together a group of consultants and a scientific advisory board whose members we believe are among the most respected researchers in the field of addiction therapy. We have also benefited from the extensive early-stage research by Brookhaven studying the use of vigabatrin to treat addiction. This has allowed us to move our product development efforts forward to the point we are at today without having to build a large infrastructure or to expend significant financial resources for basic research.

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

- the scope, rate of progress and expense of our clinical trials and our other product development activities;
- the results of future clinical trials, and the number of clinical trials (and the scope of such trials) that will be required to seek and obtain approvals to commercialize CPP-109; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Research and development expenses, in the aggregate, represented approximately 34%, 73%, and 70% of our total operating expenses for the years ended December 31, 2006, 2005 and 2004, respectively. Research and development expenses consist primarily of costs incurred for and development costs related to CPP-109, personnel and related costs related to our product development activities, and outside professional fees related to clinical development and regulatory matters. We expect that our research and development expenses will substantially increase as a percentage of our total expenses due to the estimated expense of our two planned U.S. Phase II clinical trials, our financial support of an anticipated clinical trial to be conducted in Mexico by one of our scientific advisors, an anticipated U.S. Phase III clinical trial, and any required Phase I studies of CPP-109 that we determine are necessary. We estimate, based on the information available to us at the date of this report, that we will incur approximately $15.7 million in expenses, in addition to costs previously incurred, for our further clinical trials and development costs for CPP-109 to treat cocaine addiction. These estimates assume that only one U.S. Phase III clinical trial will be required by the FDA before we are able to obtain approval of an NDA for CPP-109. The net proceeds of our recently completed IPO and our July 2006 private placement will be used to fund these expenses. We do not expect that we will be able to commercialize CPP-109 for at least two to three years, and there can be no assurance that we will ever receive an approval for CPP-109 that allows us to commercialize this product.

Costs of pre-clinical and clinical trials

The above costs include assumptions about facts and events that are outside of our control. For example, most of the expenses for completing the development of CPP-109 to treat cocaine addiction will be in the form of fees and expenses we will be required to pay a contract research organization to conduct this work for us. We have

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not yet selected or contracted with any third party for this purpose, and our estimate of the fees and expenses we will have to pay is based on the experiences of our employees, consultants and scientific advisors in dealing with organizations of this type rather than firm quotes. The actual costs to us could be significantly greater than we expect. In addition, the FDA could require us to alter or delay our clinical trials at any stage, which may significantly increase the costs of that trial, as well as delay our commercialization of CPP-109 and our future revenue.

Basis of Presentation

Revenues

We are a development stage company and have had no revenues to date. We will not have revenues until such time as we receive approval of CPP-109 and successfully commercialize our product, of which there can be no assurance.

Research and development expenses

Our research and development expenses consist of costs incurred for company-sponsored research and development activities. These expenses consist primarily of direct and research-related allocated overhead expenses, material supply costs, and medical costs for VFD testing. It also includes both cash and stock-based compensation paid to our scientific advisors and consultants related to our product development efforts. To date, all of our research and development resources have been devoted to the development of CPP-109. We expect this to continue for the foreseeable future. Costs incurred in connection with research and development activities are expensed as incurred.

Clinical trial activities require significant expenditures up front. We anticipate paying significant portions of a trial s cost before any clinical trial begins, and incurring additional expenditures as the trial progresses and reaches certain milestones.

Selling and marketing expenses

We do not currently have any selling or marketing expenses, as we have not yet received approval for the commercialization of CPP-109. 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, consulting fees for one of our officers and one of our directors and consulting fees payable to members of our Scientific Advisory Board, information technology, and corporate administration functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal and accounting services.

Stock-based compensation

We recognize costs related to the issuance of common stock to employees and consultants by using the estimated fair value of the stock at the date of grant, in accordance with Statement of Financial Accounting Standards (SFAS) No. 123(R), Accounting for Stock-Based Compensation (SFAS 123(R)).

Income taxes

We have incurred operating losses since inception. As of December 31, 2006 and 2005, we had net operating loss carryforwards of approximately $2,947,000 and $1,516,000, respectively. Our net deferred tax asset has a 100% valuation allowance as of December 31, 2006 and 2005, 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 in 2022 through 2026. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitation.

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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.

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 audited financial statements and the notes thereto included elsewhere in this report contain accounting policies and other disclosures required by GAAP.

Pre-clinical study and clinical trial expenses

Research and development expenditures are charged to operations as incurred. Our expenses related to clinical trials are expected to be based on actual and estimated costs of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. 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, it is anticipated that these agreements will set forth the scope of the work to be performed at a fixed fee or unit price. Payments under the 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 expected to be accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would be required to modify our estimates accordingly on a prospective basis.

Stock-based compensation

In December 2004, the FASB issued Statement 123(R), Accounting for Share-Based Payment, which addresses the accounting for share-based payment transactions (for example, stock options and awards of restricted stock) in which an employer receives employee-services in exchange for equity securities of the company or liabilities. Statement 123(R) requires that compensation cost be measured based on the fair value of the company s equity securities. This proposal eliminates use of APB Opinion No. 25, Accounting for Stock Issued to Employees, and requires such transactions to be accounted for using a fair value-based method and recording compensation expense rather than optional pro forma disclosure. The new standard substantially amends SFAS 123. Statement 123(R) requires us to recognize an expense for the fair value of our unvested outstanding stock options beginning with our financial statements for the year ended December 31, 2006**.** The Company had no unvested stock options to employees as of January 1, 2006.

Results of Operations

Revenues. We had no revenues for the years ended December 31, 2006, 2005, and 2004.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2006, 2005, and 2004 were $989,144, $1,330,515 and $378,254, respectively. Expenses to date include costs associated with the filing of our IND, payments with respect to clinical studies that we support, and payments to consultants and members of our Scientific Advisory Board and other service providers who have assisted us with respect to these matters.

In our research and development activities for 2006, 2005 and 2004, we recorded stock-based compensation relating to shares of our common stock issued to several of our consultants and scientific advisors for

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services rendered and the value of stock options granted to employee and non-employees. The amount of stock-based compensation recorded in 2006, 2005 and 2004 relating to our research and development activities was $344,649, $881,000 and $75,833, respectively. Further, the weighted average fair value of the stock options granted in 2006, 2005 and 2004 was $5.05, $1.14 and $1.00, respectively.

We expect that our research and development expenses will increase substantially as we plan for and commence our contemplated clinical trials and expand our product development activities generally. We believe that we have been able to accomplish a significant number of things in the development of CPP-109 despite the low level of our research and development costs over the last few years. This is due to the fact that much of the early stage development costs associated with the development of vigabatrin to treat addiction were incurred by Brookhaven in connection with their ongoing animal studies into the use of vigabatrin to treat addiction, and we benefit from their research by reason of our license. We have also benefited from the pilot studies that were undertaken by one of our scientific advisors team during this period. While we were a sponsor of one of these pilot studies, the bulk of the expenses relating to these studies were paid by the institutions involved and by governmental bodies with an interest in the research.

Selling and Marketing Expenses. We had no selling and marketing expenses during the 2006, 2005 and 2004 fiscal years, as we have had no revenues since inception. We anticipate that we will begin to incur sales and marketing expenses when we file an NDA for CPP-109, in order to develop a sales organization to market CPP-109 and other products we may develop upon the receipt of required approvals.

General and Administrative Expenses. General and administrative expenses were $1,913,183, $491,653, and $164,704, respectively, for the years ended December 31, 2006, 2005 and 2004. Included in general and administrative expenses in each of these years was stock-based compensation expense of $876,090, $291,750 and $219,000, respectively. General and administrative expenses includes, among other expenses, office expenses, legal and accounting fees and travel expenses for our employees, consultants and members of our Scientific Advisory Board. Our general and administrative expenses grew significantly in 2006 compared to 2005 and 2004 as we expanded our staff in preparation for our product development efforts and prepared for our IPO. We expect general and administrative expenses to further increase in future periods as we incur general non-research expenses relating to the monitoring and oversight of our clinical trials, add additional staff to support our product development efforts, expand our infrastructure to support the requirements of being a public company and otherwise expend funds to continue to develop our business as described in this Form 10-K.

Stock-Based Compensation. We issued (i) stock options to non-employee consultants in late 2004 and early 2005, (ii) stock options to our Chief Executive Officer in early 2005, (iii) shares of our common stock and stock options to several of our scientific advisors and consultants in 2006 and 2005, and (iv) stock options to an employee in 2006. See *Research and Development* above. The measurement date for all these equity instruments issued prior to 2006, other than options granted to our Chief Executive Officer, is based on the guidance of EITF 96-18, and accordingly the options are marked to their fair value at the end of each period until the performance measurement is met. The options granted to our Chief Executive Officer were accounted for using the intrinsic value method in accordance with APB No. 25, Accounting for Stock Issued to Employees, and accordingly have no compensation expense related to them because the fair value of our common stock at the grant date was equal to the exercise price of the options. For accounting purposes, we calculated stock-based compensation based on a fair value of $1.37 per common share as of December 31, 2005, $2.98 per share at June 30, 2006, $6.00 per share at September 30, 2006 and $4.83 per share at December 31, 2006 (the market value of our common stock on that date).

Our belief as to the fair value of our securities in 2005 and 2006 was determined as follows:

- our belief as to the fair value of our securities issued in fiscal 2005 was based on our analysis of the fair value of similar entities, our perception of the investment community s then view regarding companies seeking to develop pharmacologic treatments for substance abuse and the then stage of our product development efforts;

- our belief as to the fair value of our securities issued in the first half of 2006 was based on the common-equivalent per share price paid by unrelated investors who purchased securities in our private placement that closed in July 2006;

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our belief as to the fair value of our securities issued in the third quarter of 2006 was based on the proposed IPO offering price; and

our belief as to the fair value of our securities issued in the fourth quarter of fiscal 2006 was based on the market price of our common stock as quoted on the NASDAQ Global Market.

Interest Income. We reported interest income in all periods relating to our investment of funds received from our private placements and our IPO. All such funds were invested in short-term interest bearing obligations, certificates of deposit and direct or guaranteed obligations of the United States government.

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

In July 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109 (FIN No. 48). This interpretation, which clarifies SFAS No. 109, Accounting for Income Taxes, establishes the criterion that an individual tax position has to meet for some or all of the benefits of that position to be recognized in a company s financial statements. On initial application, FIN No. 48 will be applied to all tax position for which the state of limitations remains open. Only tax positions that meet the more-likely-than-not recognition threshold at the adoption date will be recognized or continued to be recognized. The cumulative effect of applying FIN No. 48 will be reported as an adjustment to retained earnings at the beginning of the period in which it is adopted. FIN No. 48 is effective for fiscal years beginning after December 15, 2006 and will be adopted by us on January 1, 2007. We have not yet estimated the effect that the adoption of FIN No. 48 will have on our financial position and results of operations.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through the net proceeds of private placements of our equity securities and through our IPO. At December 31, 2006, we had cash and cash equivalents of $20.4 million and working capital of $19.8 million.

Operating Capital and Capital Expenditure Requirements

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

We believe that our existing cash, cash equivalents and short-term investments, will be sufficient to meet our projected operating requirements for the next 24 months, including our requirements relating to obtaining necessary regulatory approvals of CPP-109 for use in treating cocaine addiction.

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;

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the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

the extent to which we acquire or invest in other products.

If we are unable to generate a sufficient amount of revenue to finance our future operations, product development and regulatory plans, we may seek to raise additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations or other means. We may seek to raise additional capital due to favorable market conditions or strategic considerations even if we have sufficient funds for planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders.

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. We do not know whether additional funding will be available on acceptable terms, or at all. 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 or sales and marketing initiatives.

Cash Flows

Net cash used in operations was $1,178,532, $455,360, and $230,520, respectively for 2006, 2005 and 2004. Net cash used in each of these periods primarily consists of net loss for these periods not attributed to stock-based compensation.

Net cash used in investing activities was $21,053, $3,940, and $1,831, respectively, for 2006, 2005 and 2004. Such funds were used primarily to purchase computer equipment.

Net cash provided by financing activities was $20,863,160, $1,046,516, and $0 in 2006, 2005 and 2004, respectively. Net cash from financing activities is comprised of the net proceeds of our IPO and the private placements that were completed in March 2005 and July 2006.

Contractual Obligations

As of December 31, 2006, we had contractual obligations as follows:

		Payments Due by Period			
	Total	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Debt	$	$	$	$	$
Capital leases					
Operating leases	38,126	31,547	6,579		
Total	$ 38,126	$ 31,547	$ 6,579	$	$

We are also obligated to make the following payments:

Payment 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.

Payments to our contract manufacturer. We are obligated to pay our contract manufacturer approximately $513,200, with payments to be based on the achievement of milestones relating to the schedule of work that it has agreed to perform for us. At December 31, 2006, we had paid approximately $207,000 of this amount.

Employment agreements. We have entered into employment agreements with two of our executive officers, which require aggregate base salary payments of $515,000 per year.

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Clinical trial costs. We will commence in the near future two U.S. Phase II clinical trials evaluating the use of CPP-109 in treating cocaine addiction and methamphetamine addiction. We expect to spend between $6 million and $7 million on these clinical trials over the next two years. We are also currently conducting a study to demonstrate that CPP-109 is bioequivalent to Sabril, and we expect to spend approximately $200,000 on this study in 2007.

Off-Balance Sheet Arrangements

We currently have no debt and no capital leases. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Recent Accounting Pronouncements

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN No. 48). This interpretation which clarifies SFAS No. 109, *Accounting for Income Taxes* , establishes the criterion that an individual tax position has to meet for some or all of the benefits of that position to be recognized in our financial statements. Upon initial application, FIN No. 48 will be applied to all tax positions for which the statute of limitations remains open. Only tax positions that meet the more-likely-than-not recognition threshold at the adoption date will be recognized or continue to be recognized. The cumulative effect of applying FIN No. 48 will be reported as an adjustment to retained earnings at the beginning of the period in which it is adopted. FIN No. 48 is effective for fiscal years beginning after December 15, 2006 and will be adopted by us on January 1, 2007. We have not yet completed our evaluation of the impact of adopting FIN No. 48 and as a result, we are not presently able to estimate the effect the adoption will have on our financial position and results of operations.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations and pronouncements that require or permit measurement similar to fair value but are not intended to measure fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. We are evaluating the impact of SFAS No. 157, but do not expect the adoption of SFAS No. 157 to have a material impact on our financial position, results of operations, or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. SAB No. 108 addresses how the effects of prior year uncorrected misstatements should be considered when quantifying misstatements in current year financial statements. SAB No. 108 requires companies to quantify misstatements using a balance sheet and income statement approach and to evaluate whether either approach results in quantifying an error that is material in light of relevant quantitative and qualitative factors. SAB No. 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the dual approach had always been used or (ii) recording the cumulative effect of initially applying the dual approach as adjustments to the carrying value of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings. Use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB No. 108 did not have a material impact on our financial statements.

Item 7A. ***Quantitative and Qualitative Disclosures About Market Risk***

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

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

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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***

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. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2006, except as set forth in the next paragraph, 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 with 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.

As stated in this Form 10-K, following completion of their audits of our financial statements for the three years ended December 31, 2005, our independent auditors, Grant Thornton, LLP, advised our Board of Directors and management that during the course of their audit, they noted an internal control deficiency constituting a significant deficiency and a material weakness as defined in professional standards. The deficiency noted related to our knowledge of accounting for equity instruments. Our auditors identified that we had not recorded compensation expense related to the issuance of non-employee stock options and had not reported sufficient compensation expense relating to stock that we issued to our consultants and scientific advisors for services. In January 2007 we corrected this weakness by hiring a Controller/Chief Accounting Officer with experience in preparing financial statements in accordance with generally accepted accounting principles.

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

Item 9B. ***Other Information***

Not applicable.

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PART III

Item 10. ***Directors and Executive Officers of the Registrant***

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of our Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2006, and is incorporated in this report by 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 in this report by 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 in this report by 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 in this report by 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 in this report by 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, 2006 and 2005

Statements of Operations for the years ended December 31, 2006, 2005 and 2004 and the period from January 4, 2002 (inception) through December 31, 2006

Statements of Stockholders Equity for the period from January 4, 2002 (inception) through December 31, 2006

Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004 and the period from January 4, 2002 (inception) through December 31, 2006

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
3.1	Certificate of Incorporation(1)
3.2	Amendment to Certificate of Incorporation(1)
3.3	By-laws(1)
4.1	Specimen stock certificate for common stock(1)
10.1	Employment Agreement between the Company and Patrick J. McEnany(1)
10.2	Employment Agreement between the Company and Jack Weinstein(1)
10.3	License Agreement, as amended, between the Company and Brookhaven National Laboratories(1)
10.4	Stock Option Agreements between the Company and Patrick J. McEnany(1)
10.5	Stock Option Agreements between the Company and Hubert Huckel(1)

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Exhibit No.	Description of Exhibit
10.6	Stock Option Agreements between the Company and Jack Weinstein(1)
10.7	Stock Option Agreement between the Company and Charles O Keeffe(1)
10.8	2006 Stock Incentive Plan(1)
10.9	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
10.10	Consulting Agreement, as amended, between the Company and Jack Weinstein(1)
10.11	Consulting Agreement between the Company and Charles O Keeffe(1)
10.12	Consulting Agreement between the Company and Donald R. Jasinski(1)
10.13	Agreement between the Company and Charles Gorodetzky(1)
10.14	Agreement between the Company and Pharmaceutics International, Inc.(1)
10.15	Stock Option Agreement between the Company and M. Douglas Winship (2)
10.16	Amendment No. 1 to Consulting Agreement between Charles O Keeffe and the Company (3)
31.1	Section 302 CEO Certification*
31.2	Section 302 CFO Certification*
32.1	Section 906 CEO Certification*
32.2	Section 906 CFO Certification*

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

(2) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2006

(3) Filed by reference to the Company s Current Report on Form 8-K

dated January 3, 2007

* Filed herewith

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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, 2007.

CATALYST PHARMACEUTICAL PARTNERS, INC.

By: /s/ Patrick J. McEnany
Patrick J. McEnany, Chairman, President and CEO

Pursuant to the requirements of the Securities Act of 1933, 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, 2007
/s/ Jack Weinstein Jack Weinstein	Vice President, Treasurer and Chief Financial Officer (Principal Financial Officer)	March 30, 2007
/s/ Alicia Grande Alicia Grande	Corporate Controller/Chief Accounting Officer	March 30, 2007
/s/ Hubert E. Huckel, M.D. Hubert E. Huckel, M.D.	Director	March 30, 2007
/s/ Charles B. O Keeffe Charles B. O Keeffe	Director	March 30, 2007
/s/ Philip H. Coelho Philip H. Coelho	Director	March 30, 2007
/s/ David S. Tierney, M.D. David S. Tierney, M.D.	Director	March 30, 2007
/s/ Milton J. Wallace	Director	March 30, 2007

Milton J. Wallace

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Years ended December 31, 2006, 2005 and 2004

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors
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, 2006 and 2005, and the related statements of operations, stockholders equity and cash flows for each of the three years in the period ended December 31, 2006 and the period from January 4, 2002 (date of inception) through December 31, 2006. 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, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2006 and the period from January 4, 2002 (date of inception) through December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As described in Notes 2 and 11 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based compensation to adopt Statement of Financial Accounting Standard No. 123(R), Share-Based Payment.

/s/ Grant Thorton LLP
Miami, Florida
March 16, 2007

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CATALYST PHARMACEUTICAL PARTNERS, INC.
(a development stage company)
BALANCE SHEETS

	December 31, 2006	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,434,702	$ 771,127
Interest receivable	85,787	
Prepaid expenses	67,333	440
Total current assets	20,587,822	771,567
Property and equipment, net	20,157	4,031
Deposits	11,500	13,852
Total assets	$ 20,619,479	$ 789,450
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 448,072	$ 67,753
Accrued expenses	324,774	275,235
Total current liabilities	772,846	342,988
Commitments and contingencies		
Stockholders equity		
Preferred stock, $.001 par value and $.01 par value at December 31, 2006 and 2005, respectively; 5,000,000 shares authorized:		
Series A Preferred Stock, no shares and 70,000 shares issued and outstanding, at December 31, 2006 and 2005, respectively		700
Series B Preferred Stock, no shares issued and outstanding, at December 31, 2006 and 2005		
Common stock, $.001 par value, 100,000,000 shares authorized at December 31, 2006; $0.01 par value, 30,000,000 shares authorized at December 31, 2005; 12,516,620 shares and 6,887,513 shares issued and outstanding at December 31, 2006 and 2005, respectively	12,517	68,875
Additional paid-in capital	25,593,330	3,406,647
Deficit accumulated during the development stage	(5,759,214)	(3,029,760)
Total stockholders equity	19,846,633	446,462
Total liabilities and stockholders equity	$ 20,619,479	$ 789,450

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, 2006
	2006	2005	2004	
Revenues	$	$	$	$
Operating costs and expenses:				
Research and development	989,144	1,330,515	378,254	3,104,422
General and administrative	1,913,183	491,653	164,704	2,853,288
Total operating expenses	2,902,327	1,822,168	542,958	5,957,710
Loss from operations	(2,902,327)	(1,822,168)	(542,958)	(5,957,710)
Interest income	172,873	16,788	3,138	198,496
Loss before income taxes	(2,729,454)	(1,805,380)	(539,820)	(5,759,214)
Provision for income taxes				
Net loss	$ (2,729,454)	$ (1,805,380)	$ (539,820)	$ (5,759,214)
Basic and diluted net loss per share	$ (0.36)	$ (0.29)	$ (0.18)	
Weighted average shares outstanding basic and diluted	7,687,630	6,204,918	2,918,438	

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, 2006

	Preferred Stock Series A	Preferred Stock Series B	Common Stock	Paid-in Capital	Deficit Accumulated During the Development Stage	Total
Balance at January 4, 2002 (date of inception)	$	$	$ 21,888	$ 78,112	$	$ 100,000
Issuance of common stock			7,296	117,704		125,000
Issuance of stock options for services				75,833		75,833
Net loss					(255,945)	(255,945)
Balance at December 31, 2002			29,184	271,649	(255,945)	44,888
Issuance of preferred stock	700			669,757		670,457
Issuance of stock options for services				75,833		75,833
Net loss					(428,615)	(428,615)
Balance at December 31, 2003	700		29,184	1,017,239	(684,560)	362,563
Issuance of stock options for services				294,833		294,833
Net loss					(539,820)	(539,820)
Balance at December 31, 2004	700		29,184	1,312,072	(1,224,380)	117,576
Issuance of common stock			39,545	1,006,971		1,046,516
Issuance of common stock and stock options for services			146	1,087,604		1,087,750
Net loss					(1,805,380)	(1,805,380)
Balance at December 31, 2005	700		$ 68,875	$ 3,406,647	$ (3,029,760)	$ 446,462

Change in par value	(630)		(61,988)	62,618		
Issuance of preferred stock Series B, net		8		3,225,132		3,225,140
Issuance of common stock (IPO), net			3,350	17,634,670		17,638,020
Conversion of preferred stock Series A into common stock, upon closing of IPO	(70)		1,022	(952)		
Conversion of preferred stock Series B into common stock, upon closing of IPO		(8)	1,116	(1,108)		
Issuance of common stock and stock options for services			142	1,266,323		1,266,465
Net loss					(2,729,454)	(2,729,454)
Balance at December 31, 2006	$	$	$ 12,517	$ 25,593,330	$ (5,759,214)	$ 19,846,633

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

	For the Years Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through December 31,
	2006	2005	2004	2006
Operating Activities:				
Net loss	$ (2,729,454)	$ (1,805,380)	$ (539,820)	$ (5,759,214)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation	4,927	1,374	366	6,667
Stock-based compensation	1,220,739	1,172,750	294,833	2,879,988
(Increase) in interest receivable	(85,787)			(85,787)
(Increase) in other prepaid expenses and deposits	(64,541)	(14,292)		(78,833)
Increase in accounts payable	380,319	37,019	14,436	448,071
Increase (decrease) in accrued expenses	95,265	153,169	(335)	265,501
Net cash used in operating activities	(1,178,532)	(455,360)	(230,520)	(2,323,607)
Investing Activities:				
Capital expenditures	(21,053)	(3,940)	(1,831)	(26,824)
Net cash used in investing activities	(21,053)	(3,940)	(1,831)	(26,824)
Financing Activities:				
Proceeds from issuance of common stock, net	17,638,020	1,046,516		18,789,536
Proceeds from issuance of preferred stock, net	3,225,140			3,895,597
Net cash provided by financing activities	20,863,160	1,046,516		22,685,133
Net increase in cash and cash equivalents	19,663,575	587,216	(232,351)	20,334,702
Cash and cash equivalents beginning of period	771,127	183,911	416,262	100,000
Cash and cash equivalents end of period	$ 20,434,702	$ 771,127	$ 183,911	$ 20,434,702

Supplemental disclosures of cash flow information:				
Cash paid during the year for interest				
Cash paid during the year for income taxes				

Non-cash financing activities:

In 2006, 2005, 2004 and during the period from January 4, 2002 (date of inception) through December 31, 2006, the Company recorded compensation expense of $1,220,739, $1,172,750, $294,833, and $2,879,988, respectively, related to the issuance of common stock, stock options to non-employees and stock options granted to an employee in 2006.

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 acquisition, development and commercialization of prescription drugs for the treatment of drug addiction. The Company was incorporated in Delaware in July 2006. It is the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation that commenced operations in January 2002.

The Company has incurred operating losses in each period from inception through December 31, 2006. The Company has funded its cash needs to date through an initial funding from its founders, four subsequent private placements and an initial public offering (IPO) of its common stock.

Merger

On September 7, 2006, the Company completed a merger with Catalyst Pharmaceutical Partners, Inc., a Florida corporation (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 has been made to capital stock and additional paid in capital on the accompanying balance sheet at December 31, 2006 to reflect this change.

2. Basis of Presentation and Significant Accounting Policies

a. **DEVELOPMENT STAGE COMPANY.** Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage and the Company s financial statements are presented in accordance with Statement of Financial Accounting Standard No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company s primary focus is on the development and commercialization of the chemical compound gamma-vinyl-GABA, commonly referred to as vigabatrin, as a potential treatment for addictions.

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. The Company has substantially all of its cash and cash equivalents deposited with one financial institution.

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

d. **PROPERTY AND EQUIPMENT.** Property and equipment is stated at cost, less accumulated depreciation and is depreciated using the straight-line method over the estimated useful life of the respective asset. Useful lives generally range from three years for computer equipment to five to seven years for furniture and equipment.

e. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company s financial instruments, including cash and cash equivalents, accounts payables and accrued liabilities are carried at cost which approximates fair value due to the relative short-term maturities of these instruments.

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

g. **STOCK BASED COMPENSATION.** Through July 2006, the Company did not have a formal stock option plan. In July 2006 the Company adopted the 2006 Stock Incentive Plan (the Plan). The Plan provides for the Company to issue options, restricted stock, stock appreciation rights and restricted stock units to employees, directors and consultants of the Company. Under the Plan, 2,188,828 shares of the Company s Common Stock have been reserved for issuance. Additionally, prior to the adoption of the Plan, the Company had issued options pursuant to written agreements.

As of December 31, 2006 there were outstanding options to purchase 2,374,149 shares of common stock, including options to purchase 21,888 shares granted under the Plan, of which options to purchase 2,201,961 shares were exercisable as of December 31, 2006.

For the years ended December 31, 2006, 2005 and 2004, the Company recorded stock compensation expense as follows:

	2006	2005	2004
Research & development	$ 344,649	$ 881,000	$ 75,833
General & administrative	876,090	291,750	219,000
Total stock based compensation	$ 1,220,739	$ 1,172,750	$ 294,833

Prior to January 1, 2006, the Company recognized share-based compensation using the intrinsic value method. Under this method, share-based compensation expense related to stock options was not recognized in the results of operations if the exercise price was equal to or greater than the market value of the common stock on the measurement date, in accordance with Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No.123). Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123R, *Share-Based Payment* .

The Company has elected to use the modified prospective transition method for adopting SFAS No. 123R, which requires the recognition of stock-based compensation cost on a prospective basis; therefore, prior period financial statements have not been restated. Under this method the provisions of SFAS No. 123R are applied to all awards granted after the adoption date and to awards not yet vested with unrecognized expense at the adoption date based on the estimated fair value at grant date as determined under the original provisions of SFAS No. 123. The impact of forfeitures that may occur prior to vesting is also estimated and considered in the amount recognized. In addition, the realization of tax benefits in excess of amounts recognized for financial reporting purposes, if any, will be recognized as a financing activity rather than an operating activity

as in the past. Pursuant to the requirements of SFAS No. 123R, the Company will continue to present the pro forma information for periods prior to the adoption date.

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

No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets. The Company elected to adopt the alternative method of calculating the historical pool of windfall tax benefits as permitted by FASB Staff Position (FSP) No. SFAS 123R-c, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*. This is a simplified method to determine the pool of windfall tax benefits that is used in determining the tax effects of stock compensation in the results of operations and cash flow reporting for awards that were outstanding as of the adoption of SFAS No. 123R.

The fair value of the stock option and common stock awards which are subject to graded vesting, granted after January 1, 2006, is expensed on a straight-line basis over the vesting period of the awards. The Company had no unvested stock options to employees as of January 1, 2006.

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 expected stock price volatility, expected option life, risk-free interest rate and dividend yield. Due to the Company s short history as a public entity, the Company s expected volatility is based on the historical volatility of other publicly traded development stage companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated life of the stock options awards. For the period ended December 31, 2006 the assumptions used were an estimated annual volatility of 100%, expected average holding periods of five years, and a risk-free interest rate of 5.5%. The expected dividend rate is zero and no forfeiture rate was applied, as it was not considered material.

Had compensation cost for the stock-based compensation plans been determined based on the fair value method at the grant dates for awards of employee stock options consistent with the method of SFAS No. 123, pro forma net loss and loss per share would be as follows:

	Years ended December 31,	
	2005	2004
Net loss, as reported	$ (1,805,380)	$ (539,820)
Stock-based compensation expense determined under the fair value-based method, net of $0 tax	(507,917)	(75,833)
Net loss, pro forma	$ (2,313,297)	$ (615,653)
Loss per share basic and diluted, as reported	$ (0.29)	$ (0.18)
Loss per share basic and diluted, pro forma	$ (0.37)	$ (0.21)

The Company has recognized in the income statement the costs related to employee and consultant services in share-based payment transactions by using the estimated fair value of the stock at the date of grant, in accordance with SFAS No. 123.

h. **DEFERRED COMPENSATION.** Prior to July 2006, the Company had an agreement with one of the executive officers to defer payment of a portion of his compensation due to him until the Company had completed an equity financing raising gross proceeds of at least $2.0 million. This contingency was satisfied

at the closing of a private placement in July 2006 (See Note 5) and the full amount due to this executive officer for services has been recognized in the income statement for each period for which compensation was accrued subject to the contingency (See Note 8). All such deferred compensation was paid in full in 2006.

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

i. **CONCENTRATION OF CREDIT RISK.** The financial instrument that potentially subjects the Company to concentration of credit risk is cash. The Company places its cash with high-credit quality financial institutions.

j. **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.

k. **COMPREHENSIVE INCOME (LOSS).** SFAS No. 130, *Reporting Comprehensive Income (Loss),* requires that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly into stockholders equity. The Company has reported comprehensive income (loss) in the statement of stockholders equity as net loss.

l. **EARNINGS (LOSS) PER SHARE**. Basic earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net earnings (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 and stock options. For all periods presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive. Potentially dilutive common stock equivalents as of December 31, 2006 include stock options to purchase up to 2,374,149 shares of common stock at exercise prices ranging from $0.69 to $6.00. Potentially dilutive common stock equivalents as of December 31, 2005 include 70,000 shares of Series A Preferred Stock convertible into 1,021,453 shares of common stock as well as stock options to purchase up to 2,188,828 shares of common stock at exercise prices ranging from $0.69 to $2.98.

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

n. **RECENT ACCOUNTING PRONOUNCEMENTS.**

In July 2006, the FASB issued Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109* (FIN No. 48). This interpretation which clarifies SFAS No. 109, *Accounting for Income Taxes* , establishes the criterion that an individual tax position has to meet for some or all of the benefits of that position to be recognized in the Company s financial statements. Upon initial application, FIN No. 48 will be applied to all tax positions for which the statute of limitations remains open. Only tax positions that meet the more-likely-than-not recognition threshold at the adoption date will be recognized or continue to be recognized. The cumulative effect of applying FIN No. 48 will be reported as an adjustment to retained earnings at the beginning of the period in which it is adopted. FIN No. 48 is effective for fiscal years beginning after December 15, 2006 and will be adopted by the Company on January 1, 2007. The Company has not been able to complete its evaluation of the impact of adopting FIN No. 48 and as a result, is not able to estimate the effect the adoption will have on its financial position and results of operations.

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

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS No. 157). This statement provides a single definition of fair value, a framework for measuring fair value, and expanded disclosures concerning fair value. Previously, different definitions of fair value were contained in various accounting pronouncements creating inconsistencies in measurement and disclosures. SFAS No. 157 applies under those previously issued pronouncements that prescribe fair value as the relevant measure of value, except SFAS No. 123(R) and related interpretations and pronouncements that require or permit measurement similar to fair value but are not intended to measure fair value. This pronouncement is effective for fiscal years beginning after November 15, 2007. The Company is evaluating the impact of SFAS No. 157, but does not expect the adoption of SFAS No. 157 to have a material impact on its financial position, results of operations, or cash flows.

In September 2006, the SEC issued Staff Accounting Bulletin (SAB) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements. SAB No. 108 addresses how the effects of prior year uncorrected misstatements should be considered when quantifying misstatements in current year financial statements. SAB No. 108 requires companies to quantify misstatements using a balance sheet and income statement approach and to evaluate whether either approach results in quantifying an error that is material in light of relevant quantitative and qualitative factors. SAB No. 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the dual approach had always been used or (ii) recording the cumulative effect of initially applying the dual approach as adjustments to the carrying value of assets and liabilities as of January 1, 2006 with an offsetting adjustment recorded to the opening balance of retained earnings. Use of the cumulative effect transition method requires detailed disclosure of the nature and amount of each individual error being corrected through the cumulative adjustment and how and when it arose. The adoption of SAB No. 108 did not have a material impact on our financial statements.

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

3. Property and Equipment

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

	2006	2005
Computer equipment	$ 18,368	$ 3,303
Furniture and equipment	8,457	2,468
Accumulated depreciation	(6,668)	(1,740)
Total property and equipment, net	$ 20,157	$ 4,031

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4. Accrued Expenses

Accrued expenses consist of the following as of December 31:

	2006	2005
Common stock issuable	$ 59,274	$ 105,000
Deferred compensation		83,327
Accrued license fee	165,869	69,352
Accrued professional fees	72,571	15,000
Accrued compensation & benefits	21,198	
Other	5,862	2,556
Total accrued expenses	$ 324,774	$ 275,235

5. Deferred Compensation

In January 2005, the Company entered into an agreement with Patrick McEnany, to act as the Company s Chief Executive Officer. The agreement called for an annual salary of $100,000 per year commencing on March 1, 2005. The agreement stipulated that half of Mr. McEnany s salary was to be deferred until the Company raised equity in the amount of not less than $2,000,000. Mr. McEnany also deferred the other half of his compensation until the equity minimum was met. The condition requiring full payment of this obligation was satisfied in July 2006 when the Company closed a private placement. As of December 31, 2006 and 2005, $0 and $83,327, respectively was payable to Mr. McEnany for deferred compensation. All deferred compensation was paid to Mr. McEnany from the proceeds of the private placement completed during July 2006. (See Note 10.)

6. Lease Obligations

The Company has executed noncancellable operating lease agreements for its corporate offices. As of December 31, 2006, future minimum lease payments under the noncancellable operating lease agreements are as follows:

2007	$ 31,547
2008	6,579
	$ 38,126

Rent expense was $18,977, $16,041, and $10,914 as of December 31, 2006, 2005, and 2004, respectively. The Company s office leases expire on various dates from December 2007 to May 2008.

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7. Agreements

a. **LICENSE AGREEMENT WITH BROOKHAVEN.** The Company has entered into a license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven), whereby the Company has obtained an exclusive license for several patents and patent applications in the U.S. and outside the U.S. relating to the use of vigabatrin as a treatment for cocaine and other addictions. This license agreement runs concurrently with the term of the last to expire of the licensed patents, the last of which currently expires in 2021. The Company paid a fee to obtain the license in the amount of $50,000. In addition the Company is required to reimburse Brookhaven for the costs they have incurred relative to the related patents. The amount of such costs incurred as of December 31, 2006 and 2005 was $165,869 and $69,352, respectively, which have been included in accrued expenses in the accompanying balance sheets. These costs will become payable in six monthly installments at the time the Company submits a new drug application (NDA) to the U.S. Food and Drug Administration (FDA). The license agreement also calls for annual royalty payments of $100,000 in the year of FDA approval of an NDA relating to the licensed patents, $250,000 in the second and third year after the approval and $500,000 for each subsequent year until the expiration of the license agreement. 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, which is when the last patent expires.

b. **AGREEMENT WITH CONTRACT MANUFACTURER.** The Company has entered into an agreement with a contract manufacturer under which such manufacturer will develop for the Company its version of vigabatrin for use by the Company in its clinical trials. The contract manufacturer will progress bill under this agreement pursuant to a schedule of payments to run concurrent with the work they will be performing. The payments will be due 30 days from the time of invoicing of the schedule procedure. During the year ended December 31, 2006 the Company paid approximately $207,000 of costs due under this agreement, which was recorded as research and development costs in the statement of operations.

8. Related Party Transactions

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers and a member 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, 2006, 2005 and 2004, the Company paid approximately $170,000, $203,000 and $15,000, respectively, in consulting fees to related parties. In addition, as of December 31, 2006 and 2005, the Company accrued $59,274 and $105,000 related to common stock issuable under certain of these consulting agreements for 10,944 shares and 76,609 shares, which were issued in March 2007 and July 2006, respectively. Fair values ranging from $2.98 to $6.00 per share were used in 2006 to determine the related expense. A fair value of $1.37 per share was used to determine the related expense in 2005 and 2004. This fair value was based on an internal valuation performed by Company management based on the fair value of similar entities and current market conditions. In addition 65,665 shares of common stock were issued in July 2006 for services performed from January 1, 2006 through June 30, 2006.

Prior to its IPO, the Company had a consulting agreement with its Chief Financial Officer, which required a bonus payment upon the completion of a U.S. initial public offering of at least $10 million. The Company paid the required bonus in the amount of $140,575 in November 2006 upon the successful completion of the IPO, which was recorded as general and administrative costs in the statement of operations for the year ended December 31, 2006.

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8. Related Party Transactions (continued)

At the closing of the IPO, the Company entered into employment agreements with Patrick J. McEnany, its Chairman, President and Chief Executive Officer, and Jack Weinstein, its Vice President, Treasurer and Chief Financial Officer. Under these agreements, Messrs. McEnany and Weinstein will receive annual base salaries of $315,000 and $200,000, respectively, and bonus compensation based on performance.

9. Income Taxes

As of December 31, 2006 and 2005 the Company had deferred tax assets of approximately $2,002,000 and $1,151,000, respectively, of which approximately $1,120,000 and $576,000 represent net operating loss carryforwards and start-up costs. The remaining temporary differences represent nondeductible stock option expense. The related deferred tax asset has a 100% valuation allowance as of December 31, 2006 and 2005, 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 $851,000, $686,000 and $205,000 in 2006, 2005, and 2004, respectively. There are no other significant temporary differences. The net operating loss carry-forwards of $2,947,000 as of December 31, 2006 will expire at various dates beginning in 2022 and expiring in 2026. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitation.

The effective tax rate of 0% in all periods presented differs from the statutory rate of 35% due to the valuation allowance and because the Company had no taxable income.

10. Stockholder s 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 have been 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, 2006 and 2005, 12,516,620 and 6,887,513 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

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10. Stockholder s Equity (continued)

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 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.

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share at December 31, 2006 and $0.01 par value per share at December 31, 2005.

i. *Series A Preferred Stock.* At December 31, 2006 and 2005, the Company had no shares and 70,000 shares of Series A Preferred Stock issued and outstanding, respectively. Each share of outstanding Series A Preferred Stock had a liquidation preference of $1.00 per share and voted with the Common Stock on the basis of approximately fifteen votes for each share of Series A Preferred Stock outstanding. Each share of Series A Preferred Stock was convertible, at the option of the holder, into approximately 15 shares of common stock; provided, however, that all of the outstanding shares of Series A Preferred Stock were to automatically convert into shares of the Company s Common Stock under certain circumstances, including the completion of an initial public offering. In November 2006, all outstanding shares of Series A Preferred Stock were converted into common stock upon completion of the IPO.

ii. *Series B Preferred Stock.* At December 31, 2006 and 2005, the Company had no shares of Series B Preferred Stock issued and outstanding. The Company issued 7,644 shares of Series B Preferred Stock in July 2006. Each share of outstanding Series B Preferred Stock had a liquidation preference of $435 per share and voted with the Common Stock on the basis of approximately 145 votes for each share of Series B Preferred Stock outstanding. Each share of Series B Preferred Stock was convertible, at the option of the holder, into approximately 145 shares of common stock; provided, however, that all of the outstanding shares of Series B Preferred Stock were to automatically convert into shares of the Company s Common Stock under certain circumstances. In November 2006, all outstanding shares of Series B Preferred Stock shares were converted into common stock upon completion of the IPO.

11. Stock Compensation Plans

Through July 2006, the Company did not have a formal stock option plan, although stock options were granted pursuant to written agreements. During July 2006, the Company adopted the 2006 Stock Incentive Plan (the Plan). The Plan provides for the Company to issue options, restricted stock, stock appreciation rights and restricted stock units (collectively, the Awards) to employees, directors and consultants of the Company (see Note 2). The measurement date for all these equity instruments issued prior to 2006, other than options granted to the Company s Chief Executive Officer, is based on the guidance of EITF 96-18, and accordingly the options are marked to their fair value at the end of each period until the non-employee guarantee has fully vested in the award. Share awards generally vest over a period of 3 to 4 years of continuous service and have contractual terms with a maximum of 10 years. Certain awards provide for accelerated vesting if there is a change in control.

Total share based compensation included in the net loss for the years ended December 31, 2006, 2005 and 2004 was $1,220,739, $1,172,750 and $294,833, respectively. The number of shares available for future issuance under the Plan at December 31, 2006 was 2,166,940 shares. The Company issues new shares as shares are required to be delivered upon exercise of all outstanding stock options.

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11. Stock Compensation Plan (continued)

On July 1, 2002, the Company entered into two Non-Qualified Stock Option Agreements with the Company s founders, Hubert Huckel and Patrick McEnany. These agreements provided an option to purchase 364,805 shares of the Company s common stock (729,610 shares in the aggregate) at an exercise price of $0.69 per share. These options expire ten years from their date of grant and previously vested over three years.

On October 1, 2004, the Company entered into an agreement with Jack Weinstein, who was then a consultant to the Company. Pursuant to this agreement, Mr. Weinstein received an option to purchase 218,883 shares of the Company s common stock. The exercise price of 145,922 of these options is $1.37 per share. The exercise price of the remaining 72,961 is $2.98 per share. Of these 218,883 options, 72,961 vested immediately, 72,961 vested on October 1, 2005 and 72,961 vested upon completion of the July 2006 private placement. These options expire five years from their date of grant.

On January 3, 2005, the Company entered into a Non-Qualified Stock Option Agreement with Charles O Keeffe. This agreement included the right to purchase 291,844 shares of the Company s common stock at an exercise price of $1.37 per share. These options vested immediately and expire five years from their date of grant.

On March 4, 2005, the Company entered into two Non-Qualified Stock Option Agreements with Hubert Huckel and Patrick McEnany. These agreements provided an option to purchase 364,805 shares of the Company s common stock (729,610 shares in the aggregate) at an exercise price of $0.69 per share. These options vested immediately and expire ten years from their date of grant.

On March 4, 2005, an additional Non-Qualified Stock Option Agreement was entered into with Jack Weinstein. This agreement provided an option to purchase 218,883 shares of the Company s common stock. The exercise price of 145,922 of these options is $1.37 per share. The exercise price of the remaining 72,961 options is $2.98 per share. Of these 218,883 options 145,922 vested immediately and the remaining vested upon the completion of the July 2006 private placement. These options expire five years from their date of grant.

In July 2006, the Company granted five-year options to purchase 145,922 shares of the Company s common stock to M. Douglas Winship, its Vice President of Regulatory Operations. These options vest over four-years and are exercisable at an exercise price of $2.98 per share. These options expire five years from their date of grant.

Stock option activity under the Company s written stock option agreements and the Plan for the years ended December 31, 2006, 2005 and 2004 is summarized as follows:

	2006		2005		2004	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at beginning of year	2,188,828	$ 1.02	948,492	$ 0.97	729,609	$ 0.69
Granted	185,321	3.19	1,240,336	1.06	218,883	1.91
Exercised						
Forfeited						
Outstanding at end of year	2,374,149	$ 1.19	2,188,828	$ 1.02	948,492	$ 0.97
Exercisable at end of year	2,201,961	$ 1.02	2,042,906	$ 0.88	632,327	$ 0.84

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11. Stock Compensation Plan (continued)

The following table summarizes information about the Company s options outstanding at December 31, 2006:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.69 - $1.37	2,060,417	5.72	$ 0.89	2,056,039	$ 0.88
$2.98	291,844	3.54	$ 2.98	145,922	$ 2.98
$6.00	21,888	4.67	$ 6.00		
	2,374,149	5.45	$ 1.19	2,201,961	$ 1.02

The aggregate intrinsic value of outstanding options and exercisable options at December 31, 2006 was $8,641,902 and $8,389,471, respectively. The weighted-average grant-date fair value of stock options granted during 2006, 2005 and 2004 was $5.05, $1.14 and $1.00, respectively.

As of December 31, 2006, there was approximately $755,000 of unrecognized compensation expense related to non-vested stock compensation awards granted under the Plan. That cost is expected to be recognized over a weighted average period of approximately 4.51 years.

12. Quarterly Financial Information (unaudited)

The following table presents unaudited supplemental quarterly financial information for the years ended December 31, 2006 and December 31, 2005:

	Quarter ended			
	March 31, 2006	June 30, 2006	September 30, 2006(1)	December 31, 2006
Revenues	$	$	$	$
Loss from operations	(317,997)	(356,960)	(1,342,219)	(885,151)
Loss before income taxes	(312,829)	(353,996)	(1,321,388)	(741,241)
Net loss	(312,829)	(353,996)	(1,321,388)	(741,241)
Loss per share basic and diluted	$ (0.05)	$ (0.05)	$ (0.19)	$ (0.07)

(1) $828,818 of stock-based compensation was recorded in the quarter ended September 30, 2006.

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12. Quarterly Financial Information (unaudited) (continued)

	Quarter ended			
	March 31, 2005(1)	June 30, 2005	September 30, 2005	December 31, 2005
Revenues	$	$	$	$
Loss from operations	(1,058,880)	(268,700)	(233,955)	(260,633)
Loss before income taxes	(1,057,293)	(264,379)	(227,771)	(255,937)
Net loss	(1,057,293)	(264,379)	(227,771)	(255,937)
Loss per share basic and diluted	$ (0.26)	$ (0.04)	$ (0.03)	$ (0.04)

(1) $950,375 of stock-based compensation was recorded in the quarter ended March 31, 2005.

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