Catalyst Pharmaceutical Partners, Inc.
Form 10-K
March 25, 2008

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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, 2007

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

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

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

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

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

Indicate by check mark if registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 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 check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No o

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

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company þ

As of June 30, 2007, the last business day of the Registrant s most recently completed second quarter, the aggregate market value of all voting, and non-voting common equity held by non-affiliates was $29,829,280.

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: 12,564,437 shares of common stock, $0.001 par value per share, were outstanding as of March 14, 2008.

Part III incorporates certain information by reference from the registrant s definitive proxy statement for the 2008 annual meeting of stockholders. The proxy statement with respect to the 2008 annual meeting of stockholders will be filed no later than 120 days after the close of the registrants fiscal year ended December 31, 2007.

CATALYST PHARMACEUTICAL PARTNERS, INC.
FORM 10-K ANNUAL REPORT
For the Fiscal Year Ended December 31, 2007
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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 the preclinical and clinical trials required for us to file a new drug application (NDA) for our product candidate CPP-109;

our ability to complete such trials on a timely basis and within the budgets we establish for such trials;

our ability to protect our intellectual property;

whether others develop and commercialize products competitive to our products;

changes in the regulations affecting our business;

our ability to attract and retain skilled employees;

our having sufficient financial resources to complete the trials required to file and obtain approval of an NDA for CPP-109; and

changes in general economic conditions and interest rates.

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.

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Item 1. Business

Overview

We are a biopharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of addiction. Our initial product candidate is CPP-109, which is our version of the chemical compound *gamma-vinyl-GABA,* commonly referred to as vigabatrin. We are currently conducting a clinical study of CPP-109 for use in the treatment of cocaine addiction, and we intend to conduct clinical studies of CPP-109 for use in the treatment of 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 obsessive-compulsive disorders such as obesity and compulsive gambling. We intend to develop CPP-109 to treat other forms of addiction, such as those described above, subject to the availability of funding for such purposes.

We have initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with cocaine addiction. We have retained Health Decisions, Inc. as the Contract Research Organization (CRO) to oversee the trial on our behalf. We estimate that the cost of this trial will be approximately $5,400,000. The trial is expected to enroll 180 cocaine addicted patients at not less than 10 addiction treatment clinical centers in the United States. Patients will be treated for a period of 12 weeks, with an additional 12 weeks of follow-up. The primary endpoint of the trial is to demonstrate that a larger proportion of CPP-109-treated subjects than placebo-treated subjects will be cocaine-free during their last two weeks of treatment (weeks 11 and 12). Additionally, we will be measuring several secondary endpoints based on reductions of cocaine use and craving. To be eligible to participate in this trial, participants must meet specific clinical standards for cocaine addiction, 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 most other addictive substances. Further, eye safety studies will be conducted on all trial participants before and after the trial to determine the extent of visual field defects among such participants, if any. We began the process of enrolling patients in our trial in January 2008 after the protocol for our trial was accepted by the U.S. Food and Drug Administration (FDA). We expect to have initial top-line results from this trial in the fourth quarter of 2008. Additional detailed information about our trial can be found at www.clinicaltrials.gov.

We also intend to conduct a similar randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We currently estimate that the cost of this trial will be approximately $5,400,000. We currently expect to initiate this study during the second quarter of 2008 and to have initial top-line results from this trial during the third quarter of 2009.

During the first quarter of 2007, we completed a bioequivalence study demonstrating that CPP-109 is bioavailable and bioequivalent to Sabril®, the branded version of vigabatrin marketed in Europe by Sanofi-Aventis. In the study, investigators randomized 30 healthy male and female subjects to either of two treatments a 500 mg. tablet of Sabril® or a 500 mg. tablet of CPP-109. The researchers dispensed the assigned medication tablet to the participants after an overnight fast and collected blood plasma samples before dosing. An additional 21 blood plasma samples were collected after dosing over a period of 36 hours. After a washout period of eight days, each participant was crossed over to receive the alternate tablet, and plasma samples were collected according to the same schedule. A total of 28 subjects completed both arms of the study. This study was conducted as recommended by the FDA s Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products General Considerations.

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In December 2007, we were advised of the positive top-line results from an investigator-initiated Phase II, randomized double-blind, placebo-controlled trial, in which vigabatrin met its primary efficacy endpoint of abstinence during the last weeks of treatment for cocaine addiction. One hundred and three (103) community-based, non-hospitalized cocaine addicted individuals participated in this trial conducted at a single site in Mexico City, Mexico. Of the 103 participants in the trial, 50 were treated with vigabatrin and 53 received placebo. A total of 50 subjects completed the 9 week treatment period. Twice-weekly urine screening tests were obtained from each subject in order to objectively evaluate each subject s cocaine use. All subjects were also offered one group counseling session per week. The primary outcome measure of the trial was no positive urine tests for cocaine use during the last three weeks of the nine-week trial.

Eighteen subjects fulfilled the criteria for the primary outcome measure. Fourteen of the 50 subjects treated with vigabatrin (28.0%) versus four of the 53 subjects treated with placebo (7.5%) met the primary endpoint. A logistic regression utilizing years of cocaine use and average amount per day at baseline yielded statistically significant treatment differences and a p-value of 0.009 (P-value of less than 0.05 indicates that the different results between treatment groups was unlikely to be random). We have been advised by the investigators that they are analyzing the data from this trial to determine the results with respect to secondary endpoints, and we expect such data will be made available to us in the near future.

If the results of our upcoming U.S. clinical trials are compelling, we intend to conduct the follow-on pivotal U.S. Phase III clinical trial for cocaine addiction 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 one or more additional Phase III studies, 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 has allowed us to seek registration for this patent in eighteen EU member states.

In December 2004, the 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. The purpose of a Fast Track designation is to authorize the FDA to take actions to facilitate the development and expedite the review of an application for such product. Fast Track status means, among other things, that the FDA recognizes cocaine addiction as a serious or life threatening condition for which there exists an unmet medical need, 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, rolling 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.

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Our Strategy

Our goal is to be a leading biopharmaceutical 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. During the third quarter of 2007, we initiated a U.S. Phase II clinical trial evaluating the use of CPP-109 as a treatment for cocaine addiction and commenced enrollment for the trial in January 2008. During the second quarter of 2008, 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 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 CPP-109 for one or more of these additional indications, subject to the availability of funding.

Develop second generation of CPP-109. Subject to the availability of additional funding, we plan to develop a new optically pure form 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 form in the United States.

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.

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.

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

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.

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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 due to development of tolerance; and
- they are often ineffective at eliminating drug cravings or responding to increasing levels of drug use.

We believe that CPP-109 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.

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 that 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.

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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.

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.

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 2006, an estimated 20.4 million people in the United States aged 12 or over suffered from dependence on illicit drugs, according to the National Survey on Drug Use and Health, published by SAMHSA, which we refer to as the SAMHSA survey. According to the Office of National Drug Control Policy, costs of drug abuse to society were an estimated $180 billion in 2002 in the United States.

Addiction is not only a U.S. health problem. For example, according to the United Nations Office on Drugs and Crime, in 2005 there were approximately 4.1 million users of cocaine and 2.8 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 2006, approximately 977,000 people aged 12 or over had used cocaine for the first time within the preceding 12 months, an average of approximately 2,675 new users per day. According to the same study, approximately 928,000 patients received treatment for cocaine abuse in 2006. According to the National Institute on 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.

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Methamphetamine Addiction. According to the SAMHSA survey, an estimated 700,000 people aged 12 or over had used methamphetamine in the month preceding the survey. Additionally, an estimated 259,000 people had used methamphetamine for the first time within the preceding 12 months, an average of 710 new users per day. Additionally, according to the SAMHSA survey, 535,000 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.

Other Addictions. According to the SAMHSA survey, in 2006 an estimated 7.0 million people aged 12 or over took prescription drugs for non-medical purposes, including approximately 5.2 million who abused prescription pain relievers in the month preceding the survey. Further, according to the SAMHSA survey, approximately 17 million people aged 12 or over in the United States were classified as heavy drinkers. Additionally, according to the SAMHSA survey there are approximately 14.8 million persons aged 12 or over who used marijuana in the month preceding the survey and approximately 1.2 million persons sought treatment in 2006. 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.

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.

CPP-109 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 CPP-109 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. CPP-109 administration does not appear to affect the baseline levels of dopamine, nor those variations in dopamine levels caused by normal stimuli.

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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 names Sabril®, Sabrilex® and Sabrilan® (hereinafter referred to as Sabril®) as a secondary treatment for adult epilepsy and as a primary treatment for the management of infantile spasms, known as West Syndrome. The composition of matter patents for Sabril® expired in 1993. No forms of vigabatrin, including Sabril®, have been approved in the United States for any indication. However, 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 recently announced the submission of NDAs for these indications with an FDA Action date of June 2008.

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 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, using positron emission tomography scans, or PET scans, became the first researchers 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 potential to submit an NDA for CPP-109 on a rolling, or modular, basis, allowing the FDA to review sections of the NDA in advance of receiving our full submission. The designation also means that we may have increased communications with the FDA regarding the design of our clinical studies, which we hope will expedite the development and review of our application for the approval of CPP-109 for cocaine addiction and provide greater certainty overall in the regulatory pathway. There can be no assurance that our receipt of Fast Track status will assist us in the regulatory process for CPP-109.

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During July 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with cocaine addiction. We have retained Health Decisions, Inc. as the CRO to oversee the trial on our behalf. We estimate that the cost of this trial will be approximately $5,400,000. The trial is expected to enroll 180 cocaine addicted patients at not less than 10 addiction treatment clinical centers in the United States. Patients will be treated for a period of 12 weeks, with an additional 12 weeks of follow-up. The primary endpoint of the trial is to demonstrate that a larger proportion of CPP-109-treated subjects than placebo-treated subjects will be cocaine-free during their last two weeks of treatment (weeks 11 and 12). Additionally, we will be measuring several secondary endpoints based on reductions of cocaine use and craving. To be eligible to participate in this trial, participants must meet specific clinical standards for cocaine addiction, 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 most other addictive substances. Further, eye safety studies will be conducted before and after the trial on all trial participants to determine the extent of visual field defects among such participants, if any. We began enrolling patients in January 2008 after the protocol for our trial was accepted by the FDA, and we expect to have initial top-line results from our trial during the fourth quarter of 2008. Additional detailed information about our trial can be found at www.clinicaltrials.gov.

We also intend to conduct a similar randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We currently estimate that the cost of this trial will be approximately $5,400,000. We currently expect to initiate this trial during the second quarter of 2008 and we expect to have initial top-line results from this trial during the third quarter of 2009.

During the first quarter of 2007, we completed a bioequivalence study demonstrating that CPP-109 is bioavailable and bioequivalent to Sabril®, the branded version of vigabatrin marketed in Europe by Sanofi-Aventis. In this study, investigators randomized 30 healthy male and female subjects to either of two treatments a 500 mg. tablet of Sabril® or a 500 mg. tablet of CPP-109. The researchers dispensed the assigned medication tablet to the participants after an overnight fast and collected blood plasma samples before dosing. An additional 21 blood plasma samples were collected after dosing over a period of 36 hours. After a washout period of eight days, each participant was crossed over to receive the alternate tablet, and plasma samples were collected according to the same schedule. A total of 28 subjects completed both arms of the study. This study was conducted as recommended by the FDA s Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products General Considerations.

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 Phase I studies of pharmacokinetics, cardiac function, drug-drug interaction and/or the effect of the drug on special populations. We intend to initiate discussions with the FDA during 2008 to discuss the scope of the Phase I testing that will be required before we are permitted to file an NDA for CPP-109 and 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 file an NDA seeking FDA approval to market CPP-109.

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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 may provide unrestricted sponsorship funds for these types of studies. In other cases, we may provide alternative assistance to the investigator. We expect to continue to support investigator studies in the future to the extent that they meet criteria acceptable to us. Such criteria 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.

Recent double-blind, placebo-controlled study in Mexico

In December 2007, we were advised of the positive top-line results from an investigator-initiated Phase II, randomized double-blind, placebo-controlled trial, in which vigabatrin met its primary efficacy endpoint of abstinence, defined as two clean urine samples obtained during each of the last three weeks of treatment for cocaine addiction. The principal investigators of this trial were 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. We supported this study through an unrestricted gift to the NYU School of Medicine. The trial s protocol was approved by NYU s Institutional Review Board in May 2006 and the Federal Commission for Sanitary Risks Protection (Mexico) in September 2006, and was registered on www.clinicaltrials.gov with the identifier NCT00527683.

One hundred and three (103) community-based, non-hospitalized cocaine addicted individuals participated in this trial conducted at a single site in Mexico City, Mexico. All subjects had ready access to cocaine and were self-motivated to stop their use. The trial was designed to show whether vigabatrin treatment could significantly increase abstinence compared to placebo. Subjects were randomly assigned to either a placebo or vigabatrin and were treated for a period of nine weeks. Of the 103 participants in the trial, 50 were treated with vigabatrin and 53 received placebo. Twice-weekly urine screening tests were obtained from each subject in order to objectively evaluate each subject s cocaine use. All subjects were also offered one group counseling session per week. The primary outcome measure of the trial was abstinence, defined as no positive urine tests for cocaine use during the last three weeks of the nine-week trial.

The initial results reported for this trial are as follows:

50 subjects completed 9 weeks of treatment

14 of the 50 subjects on vigabatrin (28.0%) vs four of the 53 subjects on placebo (7.5%) had no positive urine tests evidencing cocaine use during the last three weeks of treatment ($p = 0.009$)

17 of the 50 subjects on vigabatrin (34.0%) vs five of the 53 subjects on placebo (9.4%) were either abstinent or, at most, had one positive urine test evidencing cocaine use during last three weeks of treatment ($p = 0.002$)

We have been advised by the investigators that they are analyzing the data from this trial to determine the results with respect to secondary endpoints, and we expect such data will be made available to us in the near future.

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This study was conducted in Mexico and was not subject to FDA oversight, including study design and protocol. There can be no assurance that our ongoing U.S. Phase II clinical trial will corroborate the results of this trial.

Pilot Studies

Our efforts to advance CPP-109 as a potential treatment for cocaine addiction and methamphetamine addiction were originally based on two open-label human pilot studies conducted in 2003 and 2004 in Mexico by Drs. Brodie and Figueroa. The results of these trials were published in the peer-reviewed journal, *Synapse*. Both pilot studies involved a small number of patients. A high number of patients dropped out of both studies, which is consistent with the experiences reported by other researchers conducting clinical trials in cocaine and methamphetamine-dependent subjects. Further these studies were open label studies, and therefore the results may or may not reliably predict the results that we will obtain in multicenter, randomized, double-blind, placebo-controlled trials. These pilot studies are discussed below:

Cocaine Pilot Study 2003 Mexico.

The first pilot study of vigabatrin for treating cocaine addiction was conducted in Mexico in 2003. The study was a 9-week outpatient, open-label, fixed-dose, time-limited trial in a setting with psychotherapeutic support and intervention. A total of 20 subjects meeting DSM-IV criteria for cocaine addiction were enrolled. Most of the subjects were polydrug abusers whose cocaine use was often supplemented with methamphetamine, marijuana, and/or alcohol. 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.

The results of the study are described below:

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.

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 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 increased appetite and 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. 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.

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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 study enrolled 30 subjects dependent on methamphetamine and/or cocaine by DSM-IV criteria. The study evaluated the efficacy of vigabatrin for treatment of cocaine and methamphetamine abuse and examined whether short-term usage of vigabatrin caused visual field defects (VFD). The study was designed as a 9-week outpatient open label study. The protocol for this study was reviewed and approved by the Government of Mexico. The average duration of drug addiction for all subjects was 12.8 years. 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.

Because of the previously reported safety concern regarding the occurrence of VFDs due to long-term vigabatrin administration, baseline ophthalmologic examinations were conducted, visual acuity was determined and measurements of the subject s visual field were performed in Mexico. These tests were repeated in the middle and end of treatment and again at one to two months following treatment cessation. 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.

The results of the study are described below:

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.

15 subjects were cocaine and/or methamphetamine free for the last three weeks of treatment.

there were no VFDs or other changes in visual acuity detected in any subject, regardless of whether the subject completed the study or not.

there were no significant adverse events.

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. 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.

However, because of the design and small size of the two open-label studies, these results may not be reliable or repeatable, and may not be duplicated in future trials.

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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 2022. Additionally, we received approval from the European Union with respect to one of our principal patents, which has allowed us to seek registration for this patent in eighteen EU member states.

The license agreement, which is dated as of April 30, 2006 and which 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, upon the filing of an NDA for CPP-109 and the approval of an NDA for CPP-109 we will be obligated to reimburse Brookhaven for certain expenses it incurs in connection with the filing, prosecution and maintenance of all patents and patent applications included in the patent rights we have licensed.

We have also agreed to consult with Brookhaven 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.

In November 2007, Brookhaven formally advised us that they believe that the amount potentially due for patent related expenses as of that date is approximately $1,000,000. We believe that we are potentially only liable to Brookhaven for approximately $166,000 as of December 31, 2007, and we have advised Brookhaven that we dispute their determination of patent-related expenses due under the license agreement. We intend to consult with Brookhaven in an effort to resolve this dispute. However, there can be no assurance as to the outcome of this matter. In any event, the total amount of patent-related expenses due to Brookhaven under the license agreement is only payable at the earliest upon our submission of an NDA for CPP-109.

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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 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 CPP-109 for us in quantities that we believe will be sufficient to conduct our U.S. Phase II clinical trials evaluating CPP-109 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 conduct our contemplated U.S. Phase II clinical trials.

Our contract with PII contains no renewal provisions. Pursuant to the agreement, we will make payments to PII, aggregating approximately $830,000 based on achievement of milestones related to the schedule of work PII has agreed to perform for us. Approximately $674,000 of this amount had been paid through December 31, 2007. 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.

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Because CPP-109 is not presently approved in the United States for any indication, we must submit an NDA for CPP-109 as 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.

Since we intend to contract with a third party to manufacture our products, if the FDA approves an NDA for CPP-109, our contract manufacturer will be 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 payers.

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.

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.

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

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 recently announced the submission of NDAs for these indications with an FDA Action date of June 2008. Ovation also recently announced that they have been granted Fast Track status by the FDA with respect to Sabril® for the treatment of cocaine and methamphetamine addiction. Ovation has also 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 Ovation with respect to NIDA 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 any addictive or obsessive compulsive conditions covered by our patents. 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 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 may allow us the potential for a rolling review process with the FDA of any NDA we may file for CPP-109 relating to its use in treating cocaine and/or methamphetamine addiction.

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Government Regulation

The FDA Approval Process

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

Pharmaceutical product development in the U.S. typically 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

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particular indication or indications, dosage tolerance and optimum dosage, and identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

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

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

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The Hatch-Waxman Act

The approval process described above is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a full or stand-alone NDA, is governed by Section 505(b)(1) of the 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 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.

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Other Regulatory Requirements

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

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

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Priority Review

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

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

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

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

Physician Drug Samples

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

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

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Agency leads to an approval granted by the European Commission which permits marketing of the product throughout the European Union. The decentralized procedure provides for mutual recognition of nationally approved decisions and is used for products that do not comply with requirements for the centralized procedure. Under the decentralized procedure, the holders of national marketing authorization in one of the countries within the European Union may submit further applications to other countries within the European Union, who will be requested to recognize the original authorization based on an assessment report provided by the country in which marketing authorization is held.

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

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

Employees

As of March 14, 2008 we had seven 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 quantify 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.

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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.

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

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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 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. The content on our website is not, nor should it be deemed to be, incorporated by reference into this Form 10-K.

Item 1A. Risk Factors

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

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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 $4,139,493 for the year ended December 31, 2007, and as of December 31, 2007 we had a deficit accumulated during the development stage of $9,898,707. 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. At the present time, we estimate that we will require additional funding to complete the Phase III clinical trial that we believe we will be required to complete before we are in a position to file an NDA for CPP-109. We will also require additional working capital to support our operations during periods after the middle of 2009. Further, we intend to develop 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 theses studies, and we will need additional funding to pay such costs.

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

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

There is currently limited clinical evidence indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, one double-blind, placebo controlled study and two open-label clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine addiction and methamphetamine addiction. Only 76 persons in the aggregate completed these trials. 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 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.

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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 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;
- conditions may be imposed upon us by the FDA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for reinspection due to changes in the regulatory environment;
- the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and
- the costs of our pre-clinical or clinical trials may be greater than we anticipate.

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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 as part of our clinical studies and trials. We do not yet know whether our ultimate formulation for and dosing of vigabatrin will cause VFDs or how the potential for this known side effect will affect our ability to obtain marketing approval for CPP-109.

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

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.

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

Our current plans for 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. The FDA may not agree that we can market CPP-109 for additional indications. If we are required to generate substantial additional data beyond what we have planned to support approval, our product development and commercialization efforts will be delayed and we may suffer significant harm to our future financial performance. In addition, submission of supplemental NDAs for additional indications, conducting new research and development and generating additional data to support FDA approval will require that we obtain additional financing, and we can provide no assurance that we will be able to obtain such financing on acceptable terms, or at all.

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

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 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 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.

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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 payers.

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 recently announced the submission of NDAs for these indications with an FDA Action date of June 2008. Ovation also recently announced that they have been granted Fast Track status by the FDA with respect to Sabril® for the treatment of cocaine and methamphetamine addiction. Ovation has also has 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 Ovation with respect to NIDA 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 seven employees and nine 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.

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

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

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and 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 payers control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. In particular, the rising costs of pharmaceutical products are a subject of considerable attention and debate. Third-party payers are increasingly altering reimbursement levels and challenging the price and cost-effectiveness of pharmaceutical products. The reimbursement status of newly approved pharmaceutical products in particular is generally uncertain. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for CPP-109 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.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of Sarbanes-Oxley, the SEC adopted rules requiring public companies to include a report of management on a company s internal control over financial reporting in their Annual Report on Form 10-K. In addition, the independent registered public

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accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Based on current rules, we are required to comply with Section 404a of Sarbanes-Oxley, management s assessment of the effectiveness of our company s internal controls over financial reporting. Currently, we will be required to come into compliance with Section 404b requiring attestation of an independent registered public accounting firm on management s assessment for the year ended December 31, 2008. However, the SEC is considering delaying the implementation of this requirement an additional year. If 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.

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.

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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.

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.

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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 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 Sabril® 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 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.

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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. We may be required to conduct costly, post-marketing follow-up studies if FDA requests additional information.

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

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

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

Before we can obtain regulatory approval for the sale of our product candidates, we will have to conduct, at our own expense, pre-clinical tests in animals order to support the safety of CPP-109. 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.

Additionally, we will need to conduct clinical trials demonstrating the efficacy and safety of CPP-109 in humans. In the United States, where vigabatrin is not currently approved for use, we commenced in July 2007 a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction and expect to commence in the second quarter of 2008 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/or the effect of the drug on special populations. We will also 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, CPP-109 may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Future clinical trials for CPP-109 may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, an inability to recruit clinical trial participants at the expected rate, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays.

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

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

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

We may encounter difficulties in our 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 most other addictive substances. 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 abuse. If these third-party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected.

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

The FDA will require us to submit data from pre-clinical testing for CPP-109 before approving our product. Some testing, such as carcinogenicity studies, which seek to identify the potential of a drug to cause tumors in animals and to assess the relevant risk in humans, will take, if required, several years to complete. We do not yet know what pre-clinical tests will be required or whether any pre-clinical tests will begin as planned, will need to be restructured or will be completed on schedule, if at all. We do not know whether the pre-clinical tests that we undertake, if conducted, will be acceptable to the FDA. The Company intends to initiate discussions with the FDA during 2008 to obtain agreement on the preclinical testing program they will require from us to support an NDA for CPP-109.

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

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

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

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

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

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

If any of our contract manufacturers fail to achieve and maintain appropriate manufacturing standards, patients using our product candidates could be injured or die, resulting in product liability claims. Even absent patient inquiry, we may be subject to product recalls, product seizures or withdrawals, delays or failures in testing or delivery, cost overruns or other problems that could seriously harm our business or profitability.

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

Even if our products receive regulatory approvals, we will be subject to extensive ongoing government regulation. The FDA or other regulatory authorities may impose 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. 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 results of operations, financial condition or business. Government regulations applicable to our proposed products or the interpretation thereof might change and thereby prevent us from marketing some or all of our products and services for a period of time or indefinitely.

Risks Related to Our Common Stock

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

We are highly dependent on our officers, on our Board of Directors and on our scientific advisors. The loss of the services of any of these individuals could significantly impede the achievement of our scientific and business objectives. Other than employment agreements with Patrick J. McEnany, our Chairman, President 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 Patrick J. McEnany, 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, President 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.

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In addition, equity markets in general, and the market for emerging pharmaceutical and life sciences companies in particular, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. In addition, changes in economic conditions in the United States, Europe or globally could impact our ability to grow profitably. Adverse economic changes are outside our control and may result in material adverse impacts on our business or financial results. These broad market and industry factors may materially affect the market price of our shares, regardless of our own development and operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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.

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

As of March 14, 2008 we had 12,564,437 shares of our common stock outstanding, of which 5,333,439 shares are restricted securities. 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 2,352,254 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. Sales of restricted shares or shares underlying stock options, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

Item 2. Properties

We currently operate our business in leased office space in Coral Gables, Florida and Upper Saddle River, New Jersey. We pay annual rent on our office space of approximately $74,000.

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 2007.

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PART II

Item 5. Market for Registrant s Common Equity, Restricted 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 (from November 8, 2006)	$6.15	$4.25
Year Ended December 31, 2007		
First Quarter	$6.83	$3.80
Second Quarter	$4.65	$3.48
Third Quarter	$4.00	$2.70
Fourth Quarter	$3.51	$2.50
Year Ended December 31, 2008		
First Quarter (through March 14, 2008)	$3.87	$2.94

The closing sale price for the common stock on March 14, 2008 was $3.57. As of March 14, 2008, there were approximately 77 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.

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Performance Graph

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

COMPARISON OF 14 MONTH CUMULATIVE TOTAL RETURN*

Among Catalyst Pharmaceutical Partners, Inc, The NASDAQ Composite Index

And The NASDAQ Biotechnology Index

* 100 invested on 11/08/06 in stock or 10/31/06 in index including reinvestment of dividends. Fiscal year ending December 31.

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Item 6. Selected Financial Data

The selected statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the period from January 4, 2002 (inception) through December 31, 2007, and the balance sheet data as of December 31, 2007 and 2006, have been derived from our audited financial statements included elsewhere in this Form 10-K. The income statement data for 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 have been derived from financial statements that are not included in this Form 10-K. Historical results are not necessarily indicative of future results. This selected financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes included elsewhere in this Form 10-K.

	Year Ended December 31,					Cumulative period from inception (January 4, 2002) through December 31,
	2007	2006	2005	2004	2003	2007
Statement of Operations Data:						
Revenues	$	$	$	$	$	$
Operating costs and expenses:						
Research and development	2,990,659	1,087,144	1,330,515	378,254	268,829	6,095,081
General and administrative	2,036,470	1,815,183	491,653	164,704	165,483	4,889,758
Total operating cost and expenses	5,027,129	2,902,327	1,822,168	542,958	434,312	10,984,839
(Loss) from operations	(5,027,129)	(2,902,327)	(1,822,168)	(542,958)	(434,312)	(10,984,839)
Interest income	887,636	172,873	16,788	3,138	5,697	1,086,132
Loss before income taxes	(4,139,493)	(2,729,454)	(1,805,380)	(539,820)	(428,615)	(9,898,707)
Provision for income taxes						
Net loss	$ (4,139,493)	$ (2,729,454)	$ (1,805,380)	$ (539,820)	$ (428,615)	$ (9,898,707)
Net loss per share basic and diluted	$ (0.33)	$ (0.36)	$ (0.29)	$ (0.18)	$ (0.15)	

Weighted average shares outstanding basic and diluted	12,525,405	7,687,630	6,204,918	2,918,438	2,918,438

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	As of December 31,				
	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash and cash equivalents	$ 15,943,896	$ 20,434,702	$ 771,127	$ 183,911	$ 416,262
Working capital	16,228,401	19,814,976	428,579	116,111	362,563
Total assets	16,679,922	20,619,479	789,450	185,376	416,262
Total liabilities	357,165	772,846	342,988	67,800	53,699
Stockholders equity	16,322,757	19,846,633	446,462	117,576	362,563

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 development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of drug addiction. Our initial product candidate is CPP-109, which has been confirmed to be bioequivalent to the chemical compound *gamma-vinyl-GABA,* commonly referred to as vigabatrin.

In November 2006, we completed an initial public offering (the IPO) in which we raised net proceeds of approximately $17.6 million. We are using these proceeds to complete clinical and non-clinical studies evaluating the use of CPP-109 to treat cocaine and methamphetamine addiction. We may also seek to conduct a proof-of-concept study evaluating the effectiveness of CPP-109 in treating certain eating disorders, although no such trial has been organized to this date.

During July 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial in patients with cocaine addiction (see Recent Developments section). We intend to commence a U.S. Phase II clinical trial evaluating CPP-109 as a treatment for methamphetamine addiction in the second quarter of 2008.

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.

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Research and development expenses, in the aggregate, represented approximately 60%, 38%, and 73% of our total operating expenses for the years ended December 31, 2007, 2006 and 2005, 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, an anticipated U.S. Phase III clinical trial, and any required Phase I studies of CPP-109 that we determine are necessary.

We currently estimate that we will require additional funding to complete the Phase III clinical trial that we believe will be required before we are in a position to file an NDA for CPP-109. There can be no assurance that such funding will be available when required or on terms acceptable to us. See Liquidity and Capital Resources below.

Basis of presentation

Revenues

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

Research and development expenses

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

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

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Clinical trial activities require significant up front expenditures. We anticipate paying significant portions of a trial s cost before it 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 personnel expenses for accounting, corporate and administrative functions. Other costs include administrative facilities costs, regulatory fees, and professional fees for legal, information technology, accounting and consulting services.

Stock-based compensation

We recognize costs related to the issuance of stock-based awards to employees and consultants by using the estimated fair value of the award at the date of grant, in accordance with SFAS 123R.

Income taxes

We have incurred operating losses since inception. As of December 31, 2007 and 2006, we had net operating loss carryforwards of approximately $3,232,000 and $1,008,000, respectively. Our net deferred tax asset has a 100% valuation allowance as of December 31, 2007 and 2006, 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 2023 through 2027. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitation.

We have adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* , (FIN 48), on January 1, 2007. Previously, we had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* . As required by FIN 48, which clarifies SFAS No. 109, *Accounting for Income Taxes* , we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely sustain the position following the audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, we applied FIN 48 to all tax positions for which the statute of limitation remained open. No resulting unrecognized tax benefits were identified in connection with the implementation of FIN 48.

Critical Accounting Policies and Estimates

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

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

Pre-clinical study and clinical trial expenses

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

Stock-based compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123R, "*Share-Based Payment* . We utilize 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. Our expected volatility is based on the historical volatility of other publicly traded development stage companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated expected life of our stock options awards. For the fiscal year ended December 31, 2007 and 2006, respectively, the assumptions used were an estimated annual volatility of 100%, average expected holding periods of four to five years, and risk-free interest rates ranging from 3.50% to 4.90% and 5.50%, respectively.

Results of Operations

Revenues. We had no revenues for the years ended December 31, 2007, 2006, and 2005.

Research and Development Expenses. Research and development expenses for the years ended December 31, 2007, 2006, and 2005 were $2,990,659, $1,087,144, and $1,330,515, respectively. Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2007 grew significantly compared to amounts expended in the same period in 2006, as we paid for services related to the initiation of our Phase II clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction, paid for certain expenses in preparation for the initiation of our clinical trial evaluating CPP-109 for use in the treatment of methamphetamine addiction, raw materials and finished products for use in our upcoming clinical trials, made an unrestricted grant to the sponsor of a clinical trial that is being conducted in Mexico and conducted our bioequivalence study comparing CPP-109 to a version of Sabril® marketed in Europe by Sanofi-Aventis.

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In our research and development activities for 2007, 2006 and 2005, we recorded stock-based compensation relating to shares of our common stock issued to several of our consultants and scientific advisors for services rendered and the value of stock options granted to employee and non-employees. The amount of stock-based compensation recorded in 2007, 2006 and 2005 relating to our research and development activities was $365,107, $344,649 and $881,000, respectively. Further, the weighted average fair value of the stock options granted in 2007, 2006 and 2005 was $2.65, $5.05, and $1.14, respectively.

We expect that research and development activities will continue to increase substantially now that we have initiated our U.S. Phase II cocaine clinical trial, are in the planning stages for the commencement of our contemplated U.S. Phase II methamphetamine clinical trial, and plan to expand our product development activities generally.

Selling and Marketing Expenses. We had no selling and marketing expenses during the 2007, 2006, and 2005 fiscal years. 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 $2,036,470, $1,815,183, and $491,653, respectively, for the years ended December 31, 2007, 2006, and 2005. Included in general and administrative expenses in each of these years was stock-based compensation expense of $191,236, $876,090, and $291,750, respectively. General and administrative expenses includes, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our employees, consultants and members of our Scientific Advisory Board. The increase in general and administrative expenses for the year ended December 31, 2007 from the year ended December 31, 2006 is primarily due to the addition of several executives in early 2007 that were not previously employees and the administrative expenses related to our being a publicly held entity commencing in November 2006. These increased expenditures were partially offset by a decrease in stock-based compensation expense. We expect general and administrative efforts to further increase in future periods as we incur general non-research expenses relating to the monitoring and oversight of our clinical trials and otherwise expend funds to continue to develop our business as described herein.

Stock-Based Compensation. We issued (i) stock options to non-employee consultants in 2005, (ii) stock options to our Chief Executive Officer in 2005, (iii) shares of our common stock and stock options to several of our scientific advisors and consultants in 2007, 2006 and 2005, and (iv) stock options and restricted stock to employees in 2007 and 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 commitment, as defined in EITF 96-18, 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 the quoted market value of our common stock on dates subsequent to our IPO in November 2006.

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Our belief as to the fair value of our securities in 2005 and 2006 (prior to our IPO) 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;
- 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 and during 2007 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. Interest income increased substantially in the year ended December 31, 2007 when compared to the same period in 2006 due to the investment of the proceeds of our IPO. Substantially all such funds were invested in short-term interest bearing obligations, certificates of deposit and direct or guaranteed obligations of the United States government.

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

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, 2007, we had cash and cash equivalents of $15.9 million and working capital of $16.2 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 through the middle of 2009.

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;

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the cost and timing of regulatory approvals;

the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;

the cost and timing of establishing sales, marketing and distribution capabilities;

the effect of competition and market developments;

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

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

At the present time, we estimate that we will require additional funding to complete the Phase III clinical trial that we believe we will be required to complete before we are in a position to file an NDA for CPP-109. We will also require additional working capital to support our operations in periods after the middle of 2009.

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

Cash Flows

Net cash used in operations was $4,424,934, $1,178,532, and $455,360, respectively, for 2007, 2006 and 2005. During the year ended December 31, 2007, net cash used in operating activities was primarily attributable to our net loss of $4,139,493, an increase in prepaid expenses and deposits of $465,696 and decreases of $228,206 in accounts payable and $185,721 in accrued expenses. This was offset in part by $572,104 of non-cash expenses and a decrease of $22,078 in interest receivable. Non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities was $65,872, $21,053, and $3,940, respectively, for 2007, 2006 and 2005. Such funds were used primarily for purchases of computer equipment, furniture and leasehold improvements

Net cash provided by financing activities was $0, $20,863,160, and $1,046,516, respectively, for 2007, 2006 and 2005. Net cash from financing activities is comprised of the net proceeds of our IPO in November 2006 and the private placements that were completed in March 2005 and July 2006. Such funds have been used to fund our research and development costs and our general and administrative costs in 2007 and 2006.

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Contractual Obligations

As of December 31, 2007, we had contractual obligations as follows:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 Years
Long-term obligations	$	$	$	$	$
Capital lease obligations					
Operating lease obligations	330,016	73,687	127,594	128,735	
Purchase obligations					
Other long-term obligations reflected on the registrant s balance sheet under GAAP					
Total	$ 330,016	$ 73,687	$ 127,594	$ 128,735	$

We have entered into the following contractual arrangements:

Payments to Brookhaven under our license agreement. We have agreed to pay Brookhaven a fee of $100,000 in the year of NDA approval for CPP-109, $250,000 in each of the second and third years following approval, and $500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed product for certain of their patent-related expenses. We believe that such potential obligation is approximately $166,000 as of December 31, 2007. See *Dispute with Brookhaven* below.

Payments to our contract manufacturer. We estimate that we will pay our contract manufacturer approximately $830,000 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, 2007, we had paid approximately $674,000 of this amount.

Payments to our CRO. We estimate that we will pay our CRO approximately $5,080,000 and $4,915,000, respectively, with respect to our U.S. Phase II cocaine trial and US Phase II methamphetamine trial, with payments to be based on the achievement of milestones relating to the agreed upon service agreement. At December 31, 2007, we had paid approximately $768,000 and $315,000, respectively, of these amounts. Of these payments, approximately $315,000 has been advanced to the CRO for future expenses and as such, have been included in prepaid expenses in the accompanying balance sheet at December 31, 2007.

Payments for laboratories and other trial related tests. We estimate that we will pay approximately $567,000, in connection with laboratories and other tests related to our U.S. Phase II cocaine trial during the next 13 months. At December 31, 2007, we had paid approximately $157,000 of this amount, $111,303 of which have been advanced upon signing of the contracts and as such have been included in prepaid expenses in the accompanying balance sheet as of December 31, 2007. In addition, we are obligated to pay approximately $274,000 during the next 12 months in connection with laboratories related to our U.S. Phase II methamphetamine trial.

Employment agreements. We have entered into employment agreements with two of our executive officers, which require aggregate base salary payments of $530,000 per year.

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Dispute with Brookhaven.

During November 2007, Brookhaven formally advised us that they believe that the amount potentially due for patent related expenses as of that date is approximately $1,000,000. We believe that we are potentially only liable to Brookhaven for approximately $166,000 as of December 31, 2007, and we have advised Brookhaven that we dispute their determination of patent-related expenses due under the license agreement. We intend to consult with Brookhaven in an effort to resolve this dispute. However, there can be no assurance as to the outcome of this matter. In any event, the total amount of patent-related expenses due to Brookhaven under the license agreement is only payable upon our submission of an NDA for CPP-109.

Off-Balance Sheet Arrangements

We currently have no debt. Capital lease obligations as of December 31, 2007 were not material. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Recent Accounting Pronouncements

In 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 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 February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities,* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The provisions of SFAS No. 159 will be effective for us beginning January 1, 2008. We do not expect the adoption of SFAS No. 159 to have a material impact on our financial statements.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities.* The guidance in EITF Issue 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. We intend to adopt EITF Issue 07-3 effective January 1, 2008. We do not expect the adoption of EITF Issue 07-3 to have a material impact on our financial statements.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

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

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of December 31, 2007, 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.

Management s Assessment of Internal Control Over Financial Reporting

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

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

Under the supervision and with the participation of our principal executive officer and our principal financial officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2007 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and in accordance with the interpretive guidance issued by the SEC in Release No. 34-55929. Based on that evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2007.

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.

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

Item 9B. Other Information

Not applicable.

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PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this item will be contained in our definitive proxy statement, or Proxy Statement, to be filed with the Securities and Exchange Commission in connection with our 2008 Annual Meeting of Stockholders. Our Proxy Statement for the 2008 Annual Meeting of Stockholders is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2007 and is incorporated into this report by this reference.

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

Item 11. Executive Compensation

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

Item 12. Security Ownership of Certain Beneficial Owners and Management

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

Item 13. Certain Relationships and Related Transactions

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

Item 14. Principal Accounting Fees and Services

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

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this report.

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

Report of Grant Thornton LLP, Independent Registered Public Accounting Firm
Balance Sheets as of December 31, 2007 and 2006
Statements of Operations for the years ended December 31, 2007, 2006 and 2005 and the period from inception (January 4, 2002) through December 31, 2007
Statement of Stockholders Equity for the period from inception (January 4, 2002) through December 31, 2007
Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 and the period from inception (January 4, 2002) through December 31, 2007.
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(2)
10.2	Employment Agreement between the Company and Jack Weinstein(2)
10.3	License Agreement, as amended, between the Company and Brookhaven National Laboratories(1)
10.4	Stock Option Agreement between the Company and Patrick J. McEnany(1)

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Exhibit No.	Description of Exhibit
10.5	Stock Option Agreement between the Company and Hubert Huckel(1)
10.6	Stock Option Agreement between the Company and Jack Weinstein(1)
10.7	Stock Option Agreement between the Company and Charles O Keeffe(1)
10.8	Stock Option Agreement between the Company and M. Douglas Winship(2)
10.9	2006 Stock Incentive Plan(1)
10.10	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
10.11	Consulting Agreement between the Company and Charles O Keeffe(1)
10.12	Consulting Agreement between the Company and Donald R. Jasinski(1)
10.13	Agreement between the Company and Charles Gorodetzky(1)
10.14	Agreement between the Company and Pharmaceutics International, Inc.(1)
10.15	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)
10.17	Lease Agreement between the Company and 335 Alhambra Plaza, Ltd. (4)
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

(4) Filed by reference to the Company s Quarterly Report on Form 10-Q for the period ended March 31, 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 25th day of March, 2008.

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 25, 2008
/s/ Jack Weinstein Jack Weinstein	Vice President, Treasurer and Chief Financial Officer (Principal Financial Officer)	March 25, 2008
/s/ Alicia Grande Alicia Grande	Corporate Controller/Chief Accounting Officer	March 25, 2008
/s/ Hubert E. Huckel, M.D. Hubert E. Huckel, M.D.	Director	March 25, 2008
/s/ Charles B. O Keeffe Charles B. O Keeffe	Director	March 25, 2008
/s/ Philip H. Coelho Philip H. Coelho	Director	March 25, 2008
/s/ David S. Tierney, M.D. David S. Tierney, M.D.	Director	March 25, 2008
/s/ Milton J. Wallace Milton J. Wallace	Director	March 25, 2008

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Years ended December 31, 2007, 2006, and 2005

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REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Catalyst Pharmaceutical Partners, Inc.

We have audited the accompanying balance sheets of Catalyst Pharmaceutical Partners, Inc. (a Development Stage Company) (the Company) as of December 31, 2007 and 2006, and the related statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2007 and the period from January 4, 2002 (date of inception) through December 31, 2007. 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, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 and the period from January 4, 2002 (date of inception) through December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company has adopted Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* in 2007. In addition, as discussed in Note 2 to the financial statements, the Company has adopted Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* in 2006.

/s/ Grant Thornton LLP
GRANT THORNTON LLP

Miami, Florida
March 11, 2008

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

	December 31, 2007	December 31, 2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,943,896	$ 20,434,702
Interest receivable	63,709	85,787
Prepaid expenses	524,081	67,333
Total current assets	16,531,686	20,587,822
Property and equipment, net	127,788	20,157
Deposits	20,448	11,500
Total assets	$ 16,679,922	$ 20,619,479
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 219,866	$ 448,072
Accrued expenses and other liabilities	83,419	324,774
Total current liabilities	303,285	772,846
Accrued expenses and other liabilities, non-current	53,880	
Total liabilities	357,165	772,846
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $.001 par value, 5,000,000 shares authorized:		
Series A Preferred Stock, no shares issued and outstanding, at December 31, 2007 and 2006		
Series B Preferred Stock, no shares issued and outstanding, at December 31, 2007 and 2006		
Common stock, $.001 par value, 100,000,000 shares authorized at December 31, 2007 and 2006, 12,527,564 shares and 12,516,620 shares issued and outstanding at December 31, 2007 and 2006, respectively	12,528	12,517
Additional paid-in capital	26,208,936	25,593,330
Deficit accumulated during the development stage	(9,898,707)	(5,759,214)
Total stockholders equity	16,322,757	19,846,633
Total liabilities and stockholders equity	$ 16,679,922	$ 20,619,479

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,
	2007	2006	2005	2007
Revenues	$	$	$	$
Operating costs and expenses:				
Research and development	2,990,659	1,087,144	1,330,515	6,095,081
General and administrative	2,036,470	1,815,183	491,653	4,889,758
Total operating costs and expenses	5,027,129	2,902,327	1,822,168	10,984,839
Loss from operations	(5,027,129)	(2,902,327)	(1,822,168)	(10,984,839)
Interest income	887,636	172,873	16,788	1,086,132
Loss before income taxes	(4,139,493)	(2,729,454)	(1,805,380)	(9,898,707)
Provision for income taxes				
Net loss	$ (4,139,493)	$ (2,729,454)	$ (1,805,380)	$ (9,898,707)
Net loss per share basic and diluted	$ (0.33)	$ (0.36)	$ (0.29)	
Weighted average shares outstanding basic and diluted	12,525,405	7,687,630	6,204,918	

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, 2007

	Preferred Stock Series A	Preferred Stock Series B	Common Stock	Paid-In And Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total
Balance at January 4, 2002 (date of inception)	$	$	$ 21,888	$ 78,112	$	$ 100,000
Issuance of common stock			7,296	117,704		125,000
Issuance of stock options for services				75,833		75,833
Net loss					(255,945)	(255,945)
Balance at December 31, 2002			29,184	271,649	(255,945)	44,888
Issuance of preferred stock	700			669,757		670,457
Issuance of stock options for services				75,833		75,833
Net loss					(428,615)	(428,615)
Balance at December 31, 2003	700		29,184	1,017,239	(684,560)	362,563
Issuance of stock options for services				294,833		294,833
Net loss					(539,820)	(539,820)
Balance at December 31, 2004	700		29,184	1,312,072	(1,224,380)	117,576
Issuance of common stock			39,545	1,006,971		1,046,516
Issuance of common stock and stock options for services			146	1,087,604		1,087,750
Net loss					(1,805,380)	(1,805,380)
Balance at December 31, 2005	700		68,875	3,406,647	(3,029,760)	446,462
Change in par value	(630)		(61,988)	62,618		

Issuance of preferred stock Series B , net		8		3,225,132		3,225,140
Issuance of common stock (IPO), net			3,350	17,634,670		17,638,020
Conversion of preferred stock Series A into common stock, upon closing of IPO	(70)		1,022	(952)		
Conversion of preferred stock Series B into common stock, upon closing of IPO		(8)	1,116	(1,108)		
Issuance of common stock and stock options for services			142	1,266,323		1,266,465
Net loss					(2,729,454)	(2,729,454)
Balance at December 31, 2006			12,517	25,593,330	(5,759,214)	19,846,633
Issuance of common stock and stock options for services			11	579,676		579,687
Amortization of restricted stock for services				35,930		35,930
Net loss					(4,139,493)	(4,139,493)
Balance at December 31, 2007	$	$	$ 12,528	$ 26,208,936	$ (9,898,707)	$ 16,322,757

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

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CATALYST PHARMACEUTICAL PARTNERS, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS

	Year Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through December 31,
	2007	2006	2005	2007
Operating Activities:				
Net loss	$ (4,139,493)	$ (2,729,454)	$ (1,805,380)	$ (9,898,707)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation and amortization	15,761	4,927	1,374	22,428
Stock-based compensation	556,343	1,220,739	1,172,750	3,436,331
Decrease (increase) in interest receivable	22,078	(85,787)		(63,709)
(Increase) in other prepaid expenses and deposits	(465,696)	(64,541)	(14,292)	(544,529)
(Decrease) increase in accounts payable	(228,206)	380,319	37,019	219,865
(Decrease) increase in accrued expenses	(185,721)	95,265	153,169	79,780
Net cash used in operating activities	(4,424,934)	(1,178,532)	(455,360)	(6,748,541)
Investing Activities:				
Capital expenditures	(65,872)	(21,053)	(3,940)	(92,696)
Net cash used in investing activities	(65,872)	(21,053)	(3,940)	(92,696)
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 (decrease) increase in cash and cash equivalents	(4,490,806)	19,663,575	587,216	15,843,896
Cash and cash equivalents beginning of period	20,434,702	771,127	183,911	100,000
Cash and cash equivalents end of period	$ 15,943,896	$ 20,434,702	$ 771,127	$ 15,943,896

Supplemental disclosure of non-cash investing and financing activities:				
Non-cash incentive received from lessor	$ 52,320	$	$	$ 52,320

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

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CATALYST PHARMACEUTICAL PARTNERS, INC.
(a development stage company)
NOTES TO FINANCIAL STATEMENTS

1. Organization and Description of Business

Catalyst Pharmaceutical Partners, Inc. (the Company) is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs 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 which commenced operations in January 2002.

The Company has incurred operating losses in each period from inception through December 31, 2007. The Company has been able to fund 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 was made to capital stock and additional paid-in capital during 2006 to reflect this change.

Capital Resources

At the present time, the Company estimates that it will require additional funding to complete the Phase III clinical trial that its management believes the Company will be required to complete before the Company is in a position to file a new drug application, or NDA for our product initial candidate, CPP-109. The Company will also require additional working capital to support its operations in periods after the middle of 2009.

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1. Organization and Description of Business (continued)

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

2. Basis of Presentation and Significant Accounting Policies

a. **DEVELOPMENT STAGE COMPANY.** Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage and the Company s financial statements are presented in accordance with Statement of Financial Accounting Standards No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company s primary focus is on the development and commercialization of CPP-109, which is the chemical compound gamma-vinyl-GABA, commonly referred to as vigabatrin, as a potential treatment for drug addiction, including cocaine addiction, methamphetamine addiction, and certain obsessive compulsive disorders.

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. The Company had cash balances at certain financial institutions in excess of federally insured limits periodically throughout the year.

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

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

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

f. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company s financial instruments consist of cash and cash equivalents, interest receivable, accounts payables and accrued liabilities. At December 31, 2007 the fair value of these instruments approximated their carrying value.

g. **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.

h. **STOCK BASED COMPENSATION.** Through July 2006, the Company did not have a formal stock option plan. During periods prior to July 2006, the Company granted options pursuant to written agreements to purchase an aggregate of 2,352,261 shares of common stock. 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.

As of December 31, 2007 there were outstanding options to purchase 2,568,149 shares of common stock, including options to purchase 215,888 shares granted under the Plan, of which options to purchase 2,320,781 shares were exercisable as of December 31, 2007.

For the years ended December 31, 2007, 2006 and 2005, the Company recorded stock compensation expense as follows:

	2007	2006	2005
Research and development	$ 365,107	$ 344,649	$ 881,000
General & administrative	191,236	876,090	291,750
Total stock-based compensation	$ 556,343	$ 1,220,739	$ 1,172,750

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* .

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

The Company 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.

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 periods ended December 31, 2007 and 2006 the assumptions used were an estimated annual volatility of 100%, expected average holding periods of five years, and risk-free interest rates ranging from 3.50% to 4.90% and 5.50%, respectively. 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:

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

		Year Ended December 31, 2005
Net loss, as reported	$	(1,805,380)
Stock-based compensation expense determined under the fair value based method, net of $0 tax		(507,917)
Net loss, pro forma	$	(2,313,297)
Loss per share basic and diluted, as reported	$	(0.29)
Loss per share basic and diluted, pro forma	$	(0.37)

The Company has recognized in the statement of operations 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.

i. **DEFERRED COMPENSATION.** Prior to July 2006, the Company had an agreement with one of the executive officers to defer payment of a portion of 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 10) and the full amount due to this executive officer for services has been recognized in the statement of operations 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.

j. **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.

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

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), on January 1, 2007. Previously, the Company had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies* . As required by FIN 48, which clarifies FASB Statement No. 109, *Accounting for Income Taxes* , the Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, the Company applied FIN 48 to all tax positions for which the statute of limitation remained open. No resulting unrecognized tax benefits were identified in connection with the implementation of FIN 48.

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

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

l. **COMPREHENSIVE INCOME (LOSS).** 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.

m. **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, stock options and restricted stock units. For all periods presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive. Potentially dilutive common stock equivalents as of December 31, 2007 include (i) stock options to purchase up to 2,568,149 shares of common stock at exercise prices ranging from $0.69 to $6.00 and (ii) 25,484 shares of restricted common stock that will vest over the next 2 years. 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.

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

o. **RECENT ACCOUNTING PRONOUNCEMENTS.**

In 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 does not expect the adoption of SFAS No. 157 to have a material impact on the Company s financial statements.

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

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS No. 159). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The provisions of SFAS No. 159 will be effective for the Company beginning January 1, 2008. The Company does not expect the adoption of SFAS No. 159 to have a material impact on the Company s financial statements.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force (EITF) on EITF Issue 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities. The guidance in EITF Issue 07-3 requires the entity to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the entity would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is to be applied prospectively to new contracts entered into on or after December 15, 2007. The Company intends to adopt EITF Issue 07-3 effective January 1, 2008. The Company does not expect the adoption of EITF Issue 07-3 to have a material impact on the Company s financial statements.

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

3. Prepaid Expenses

Prepaid expenses consist of the following as of December 31:

	2007	2006
Advances to CRO	$ 314,503	$
Prepaid clinical research fees	121,303	
Prepaid insurance	82,162	66,183
Prepaid rent	5,043	1,150
Other	1,070	
Total prepaid expenses	$ 524,081	$ 67,333

4. Property and Equipment

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

	2007	2006
Computer equipment	$ 25,866	$ 18,368
Furniture and equipment	44,175	8,457
Leasehold improvements	80,176	
	150,217	26,825
Less: Accumulated depreciation	(22,429)	(6,668)
Total property and equipment, net	$ 127,788	$ 20,157

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4. Property and Equipment (continued)

Depreciation and amortization expense was $15,761, $4,927 and $1,374, for the years ended December 31, 2007, 2006 and 2005, respectively. During the year ended December 31, 2007, approximately $52,000 of tenant build-out costs were funded, and paid by the landlord, directly through lease incentives and therefore, excluded from the cash flow statement as a non-cash investing and financing activity. The lease incentive will be amortized over the term of the lease as a reduction of rent expense.

5. Accrued Expenses and Other Liabilities

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

	2007	2006
Deferred rent and lease incentive	$ 9,470	$
Accrued compensation and benefits	40,831	21,198
Accrued professional fees	10,000	72,571
Common Stock issuable		59,274
Other (See notes 13)	23,118	171,731
Current accrued expense and other liabilities	83,419	324,774
Deferred rent & lease incentive- non-current	53,880	
Non-current accrued expense and other liabilities	53,880	
Total accrued expenses and other liabilities	$ 137,299	$ 324,774

6. Commitments

The Company has contracted with a CRO, various drug manufacturers, and other vendors to assist in clinical trial work, analysis, and the filing of an NDA with the FDA. The contracts are cancelable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

The Company has executed noncancellable operating lease agreements for its corporate offices. Certain of these leases have free or escalating rent payment provisions. The Company recognizes rent expense under such leases on a straight-line basis over the term of the lease. As of December 31, 2007, future minimum lease payments under the noncancellable operating lease agreements are as follows:

2008	$ 73,687
2009	62,860
2010	64,734
2011	66,296
2012	62,439
	$ 330,016

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6. Commitments (continued)

During the quarter ended March 31, 2007, the Company entered into a new lease for its corporate offices in Coral Gables, Florida. The lease provides for fixed increases in minimum annual rent payments, as well as rent free periods. The total amount of rental payments due over the lease term is being charged to rent expense on the straight-line method over the term of the lease. The differences between rent expense recorded and the amount paid is credited or charged to accrued expenses in the accompanying balance sheet. Rent expense was $44,169, $18,977, and $16,041 for the years ended December 31, 2007, 2006, and 2005, respectively. The Company s leases expire on various dates from December 2008 to November 2012.

Obligations under capital leases are not significant.

For commitments related to the Company s license agreement with Brookhaven see Note 7.

7. Agreements

a. **LICENSE AGREEMENT WITH BROOKHAVEN.** The Company has entered into a license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven), whereby the Company has obtained an exclusive license for several patents and patent applications in the U.S. and outside the U.S. relating to the use of vigabatrin as a treatment for cocaine and other addictions. 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. Under the license agreement, the Company has agreed to pay Brookhaven a fee of $100,000 in the year of NDA approval of CPP-109, $250,000 in each of the second and third year following approval and $500,000 per year thereafter until the license agreement expires. The Company is also obligated to reimburse Brookhaven for certain of their patent related expenses. The Company believes that as of December 31, 2007 it had a contingent liability of approximately $166,000, related to this obligation. Of these costs approximately $69,000 will become payable in six equal monthly installments at the time the Company submits a new drug application (NDA) to the U.S. Food and Drug Administration (FDA), and the remaining $97,000 will be due commencing within 60 days of obtaining FDA regulatory approval to sell any product. The Company also has the right to enter into sub-license agreements, and if it does, a royalty of 20% of any sub-license fees will be payable to Brookhaven, which is when the last patent expires.

During November 2007, Brookhaven formally advised the Company that they believe that the amount potentially due for patent related expenses as of that date was approximately $1,000,000. The Company believes that it is potentially only liable to Brookhaven for the approximately $166,000 described above, and it has advised Brookhaven that it disputes their determination of patent-related expenses due under the license agreement. The Company intends to consult with Brookhaven in an effort to resolve this dispute. However, there can be no assurance as to the outcome of this matter. In any event, the total amount of patent-related expenses due to Brookhaven under the license agreement is only payable upon the submission by the Company of an NDA for CPP-109. As the Company has not filed an NDA for CPP-109, no amounts are accrued for these matters in the accompanying December 31, 2007 balance sheet.

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7. Agreements (continued)

b. **AGREEMENT WITH CONTRACT MANUFACTURER.** The Company has entered into an agreement with a contract manufacturer under which such manufacturer has developed for the Company its version of vigabatrin for use by the Company in its clinical trials. The contract manufacturer is progress billing the Company under this agreement pursuant to a schedule of payments running concurrently with the work they are performing. The payments are due 30 days from the time of invoicing of the scheduled procedure. During the years ended December 31, 2007 and 2006, the Company paid approximately $467,000 and $207,000, respectively, of costs due under this agreement, which was recorded as research and development costs in the statement of operations.

c. **AGREEMENT WITH CONTRACT RESEARCH ORGANIZATION**. The Company has entered into an agreement with a CRO to oversee the Company s U.S. Phase II cocaine and methamphetamine clinical trials. The agreements require certain advances as well as payments based on the achievement of milestones. During the year ended December 31, 2007, the Company paid approximately $1,083,000 of costs due under this agreement. Of these payments $314,503 has been advanced for future expenses and as such has been included in prepaid expenses in the accompanying balance sheet at December 31, 2007.

8. Related Party Transactions

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers and members of the Company s Scientific Advisory Board, a portion of which were with related parties under common ownership and control. During the years ended December 31, 2007, 2006 and 2005, the Company paid approximately $56,000, $170,000, and $203,000, respectively, in consulting fees to related parties. In addition, as of December 31, 2006, the Company accrued $59,274 related to common stock issuable under certain of these consulting agreements for 10,944 shares, which were issued in March 2007. Fair values ranging from $2.98 to $6.00 per share were used to determine the related expense in 2006. These fair values were based on internal valuations 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 raising 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.

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.

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9. Income Taxes

As of December 31, 2007 and 2006, the Company had deferred tax assets of approximately $3,112,000 and $1,521,000, respectively, of which approximately $2,541,000 and $1,017,000 represent net operating loss carryforwards and start-up costs. The remaining temporary differences represent nondeductible stock option and equity expense. The related deferred tax asset has a 100% valuation allowance as of December 31, 2007 and 2006, 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 $1,591,000, $1,032,000 and $278,000 in 2007, 2006 and 2005, respectively. There are no other significant temporary differences. The net operating loss carry-forwards of $3,232,000 as of December 31, 2007 will expire at various dates beginning in 2023 and expiring in 2027. 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 were adjusted retroactively to reflect this split.

Private Placements

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

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

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

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

Common Stock

The Company has 100,000,000 shares of authorized common stock with a par value of $0.001 per share. At December 31, 2007 and 2006, 12,527,564 and 12,516,620 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.

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

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10. Stockholder s Equity (continued)

Preferred Stock

The Company has 5,000,000 shares of authorized preferred stock, $0.001 par value per share at December 31, 2007 and 2006. No shares of preferred stock were outstanding at December 31, 2007 and 2006.

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 the options granted to the Company s Chief Executive Officer in 2002 and 2005, 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 is 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.

The number of shares available for future issuance under the Plan at December 31, 2007 was 1,947,456 shares. The Company issues new shares as shares are required to be delivered upon exercise of all outstanding stock options.

Stock Options

The Company has granted stock options to employees, officers, directors and scientific advisors generally at exercise prices equal to the market price of the stock at grant date. The options generally vest ratably over three or four years, based on continued employment, with a maximum term of five to 10 years. During the years ended December 31, 2007, 2006 and 2005 the Company recorded non-cash stock-based compensation related to stock options totaling $520,413, $948,090 and $1,067,750, respectively.

Stock option activity under the Company s written stock option agreements and the Plan for the years ended December 31, 2007, 2006 and 2005 is summarized as follows:

	2007		2006		2005	
	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	2,374,149	$ 1.19	2,188,828	$ 1.02	948,492	$ 0.97
Granted	194,000	4.20	185,321	3.19	1,240,336	1.06
Exercised						
Forfeited or expired						
Outstanding at end of year	2,568,149	$ 1.42	2,374,149	$ 1.19	2,188,828	$ 1.02
Exercisable at end of year	2,320,781	$ 1.15	2,201,961	$ 1.02	2,042,906	$ 0.88

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11. Stock Compensation Plans (continued)

The following table summarizes information about the Company s options outstanding at December 31, 2007:

	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	4.73	$ 0.89	2,060,417	$ 0.89
$2.98	291,844	3.98	$ 2.98	182,402	$ 2.98
$3.60- $4.00	154,000	4.96	$ 3.74	70,666	$ 3.81
$6.00	61,888	5.18	$ 6.00	7,296	$ 6.00
	2,568,149	4.66	$ 1.42	2,320,781	$ 1.15

The aggregate intrinsic value of outstanding options and exercisable options at December 31, 2007 was $5,219,223 and $5,326,209, respectively. The weighted-average grant-date fair value of stock options granted during 2007, 2006 and 2005 was $2.65, $5.05 and $1.14, respectively. The total fair value of vested stock options during 2007, 2006 and 2005 was $433,736, $410,451 and $1,246,516, respectively.

As of December 31, 2007, there was approximately $718,000 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 1.16 years.

Restricted Stock Units

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

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Nonvested balance at December 31, 2006		$
Granted	25,484	3.61
Vested		
Forfeited		
Nonvested balance at December 31, 2007	25,484	$ 3.61

During the years ended December 31, 2007, 2006 and 2005, the Company recorded non-cash stock-based compensation related to restricted stock units totaling $35,930, $0 and $0, respectively. As of December 31, 2007, there was $56,077 of total restricted stock unit compensation expense related to non-vested awards not yet recognized, which is expected to be recognized over a weighted average period of 0.7 years.

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12. Benefit Plan

During 2007, the Company established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code. Subject to certain dollar limits, all eligible employees may contribute up to 15% of their pre-tax annual compensation to the plan. Commencing in 2008, the Company has elected to make discretionary matching contributions of employee contributions up to 4% of an employee s gross salary.

13. Quarterly Financial Information (unaudited)

The following table presents unaudited supplemental quarterly financial information for the years ended December 31, 2007 and December 31, 2006:

	Quarter Ended			
	March 31, 2007	June 30, 2007	September 30, 2007 (2)	December 31, 2007
Revenues	$	$	$	$
Loss from operations	(1,497,146)	(1,436,988)	(950,426)	(1,142,569)
Net loss	(1,252,078)	(1,208,130)	(734,347)	(944,938)
Loss per share basic and diluted	$ (0.10)	$ (0.10)	$ (0.06)	$ (0.08)

	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)
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

(2) During the quarter ended September 30, 2007, the Company revised its estimate of accrued license fees, and as a result research and development expenses were

reduced by approximately $166,000.

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