

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

*(Exact name of registrant as specified in its charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**2834**  
*(Primary Standard Industrial  
Classification Code Number)*

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

**220 Miracle Mile  
Suite 234  
Coral Gables, Florida 33134  
(305) 529-2522**

*(Name, address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)*

**Patrick J. McEnany  
Chief Executive Officer  
Catalyst Pharmaceutical Partners, Inc.  
220 Miracle Mile  
Suite 234  
Coral Gables, Florida 33134  
(305) 529-2522**

*(Name, address, including zip code, and telephone number, including area code,  
of agent for service)*

**Copies To:**

**Philip B. Schwartz, Esq.  
Akerman Senterfitt  
One Southeast Third Avenue  
Miami, Florida 33131  
(305) 374-5600**

**Donald J. Murray, Esq.  
Dewey Ballantine LLP  
1301 Avenue of the Americas  
New York, New York 10019-6092  
(212) 259-8000**

**Approximate date of commencement of proposed sale to public:** As soon as practicable after this registration becomes effective

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box:

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

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

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

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Proposed maximum aggregate offering price (1)	Amount of registration fee
Common Stock, par value \$0.001 per share	\$44,850,000	\$4,798.95(2)

(1) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

(2) \$4,306.75 was previously paid with the original filing of the Registration Statement.

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

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED OCTOBER 4, 2006**



## **Common Stock 3,000,000 Shares**

This is the initial public offering of our common stock and no public market currently exists for our shares. We expect that the public offering price will be between \$11.00 and \$13.00 per share.

<b>The Offering</b>	<b>Per Share</b>	<b>Total</b>
Public Offering Price	\$	\$
Underwriting Discounts and Commissions	\$	\$
Proceeds, Before Expenses, to Catalyst	\$	\$

We have applied to have our common stock included for quotation on the Nasdaq Global Market under the symbol "CPRX."

**Investing in our common stock involves a high degree of risk.  
See "Risk Factors" beginning on page 10.**

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

We have granted the underwriters the right to purchase up to 450,000 additional shares from us within 30 days after the date of this prospectus to cover over-allotments, if any. The underwriters expect to deliver shares of common stock to purchasers on or about \_\_\_\_\_, 2006.

**First Albany Capital**

**Stifel Nicolaus**

The date of this prospectus is \_\_\_\_\_, 2006

You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer and sale is not permitted. You should assume that the information in this prospectus is accurate as of the date on the front cover of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

Sabril is a registered trademark of Sanofi-Aventis.

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## PROSPECTUS SUMMARY

*The following summary is qualified in its entirety by the more detailed information appearing elsewhere in this prospectus. You are urged to read this prospectus in its entirety before investing in this offering. An investment in the shares offered hereby involves a high degree of risk. This prospectus 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 "Risk Factors." "We," "our," "ours," "us," or the "company" when used herein, refers to Catalyst Pharmaceutical Partners, Inc.*

We are a specialty pharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of addiction. Our initial product candidate is CPP-109, which is based on the chemical compound *gamma-vinyl-GABA*, commonly referred to as vigabatrin. We intend to begin in the first quarter of 2007 a U.S. Phase II clinical trial evaluating CPP-109 for the treatment of cocaine addiction. We also intend to develop CPP-109 to treat methamphetamine addiction. We believe that our CPP-109 platform has the potential to produce therapies for other addictions, including addictions to nicotine, prescription pain medications, alcohol, and marijuana, as well as treatments for related addictive disorders, such as obesity and compulsive gambling.

Drug abuse and addiction, including cocaine and methamphetamine abuse, comprise a worldwide health problem that affects millions of people and has wide-ranging negative social consequences. 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. In 2005, an estimated 19.7 million people in the United States suffered from dependence on illicit drugs, according to the National Survey on Drug Use and Health, published by the Substance Abuse and Mental Health Services Administration, or SAMHSA. According to the same source, approximately 2.4 million people used cocaine in the month preceding the survey, approximately 900,000 were new users in 2004, and approximately 797,000 patients sought treatment for cocaine abuse in 2005. Also according to the SAMHSA survey, approximately 512,000 people used methamphetamine in the month preceding the survey, approximately 192,000 were new users in 2004, and approximately 351,000 patients sought treatment for methamphetamine and other stimulant abuse in 2005. According to the United Nations Office on Drugs and Crime, in 2004 there were approximately 3.5 million users of cocaine and 2.7 million users of amphetamine-type stimulants across Europe. Despite the significance of cocaine and methamphetamine abuse as a worldwide public health problem, there are no currently approved pharmaceutical therapies for cocaine and methamphetamine abuse.

Many addictive drugs, including cocaine and methamphetamine, produce feelings of euphoria by increasing the concentration of the chemical neurotransmitter dopamine in specific areas of the brain. Under normal conditions, dopamine levels are relatively constant, increasing temporarily as a result of experiences such as eating or sexual arousal. Over time, the feeling of pleasure is decreased by a reduction in dopamine to its pre-arousal level and through the action of *gamma-aminobutyric acid*, or GABA, a chemical neurotransmitter that inhibits the effect of dopamine. Substances such as cocaine and methamphetamine cause enormous amounts of dopamine buildup, producing feelings of euphoria. CPP-109 increases the amount of GABA present, which suppresses the responses to the dramatic increase in dopamine levels produced by cocaine and methamphetamine, thereby preventing the perception of pleasure that is associated with their use.

We have been granted an exclusive worldwide license from Brookhaven National Laboratory to nine U.S. patents and two 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 2020. Additionally, we have received approval from the European Union with respect to one of our principal patents, which will allow us to seek approval for this patent in each of the EU member states.

We intend to commence in the first quarter of 2007 a U.S. Phase II clinical trial to evaluate CPP-109 for the treatment of cocaine addiction. While the final design of this clinical trial and the number of patients to be included has not yet been finalized, we currently anticipate that this trial will be a double-blind, randomized,

placebo-controlled study involving approximately 375 patients. In addition, we plan to conduct certain Phase I clinical trials with CPP-109, including pharmacokinetics, cardiac function, drug-drug interaction studies and studies in special populations. If the data from these trials are sufficiently compelling, we intend to submit a New Drug Application, or NDA, seeking marketing approval from the U.S. Food and Drug Administration, or FDA. However it is most likely that additional clinical trials, including a U.S. Phase III clinical trial, will be required before we are permitted to file an NDA for CPP-109. In order to further the available research on the use of vigabatrin to treat cocaine addiction, we are also supporting a 100 patient double-blind, placebo-controlled clinical trial in Mexico. We expect that this trial will be the equivalent of a Phase II study in the United States, and will start in the fourth quarter of 2006. See “Risk Factors” and “Our Business — Our Clinical Research” and “— Clinical Studies That We Support.”

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

Our intention to advance CPP-109 as a potential treatment for cocaine and methamphetamine addiction is based on the results of two open-label pilot studies conducted in Mexico in 2003 and 2004 under the supervision of Jonathan Brodie, M.D., Ph.D., a member of our Scientific Advisory Board and a member of the faculty of New York University. In one study, of the 30 patients enrolled, 18 completed the study and 16 tested negative for methamphetamine and cocaine addiction during the last six weeks of the trial. In the other study, of the 20 patients enrolled, eight completed the study and remained drug free for periods ranging from 46-58 days. During and for at least six weeks following the completion of these trials, many of the completers reported reduced cravings, beneficial weight gain and other positive behavioral changes.

These were open-label studies involving only a small number of participants, and neither study provides sufficient data regarding safety and efficacy to support an NDA for CPP-109. Further, because these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol, there can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these pilot studies. We cannot assure you that future clinical trials will be successful or that we will obtain approval of an NDA for CPP-109. See “Risk Factors” and “Our Business — Pilot Studies.”

We were incorporated in Delaware in July 2006. We are the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation, (“CPP-Florida”), which commenced operations in January 2002.

Our principal executive offices are located at 220 Miracle Mile, Suite 234, Coral Gables, Florida 33134, our telephone number is (305) 529-2522 and our website is [www.catalystpharma.com](http://www.catalystpharma.com). The information contained on our website is not part of this prospectus.

### **Our Business Strategy**

To facilitate our business development and growth, we plan to:

- *Focus on CPP-109 for cocaine addiction.* We intend to commence a Phase II clinical trial for the use of CPP-109 as a treatment for cocaine addiction. Treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status 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. We plan next to develop CPP-109 for the treatment of methamphetamine addiction. Further, 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 related addictive disorders, including obesity and compulsive gambling.
- *Acquire or license additional addiction therapies.* We know of other product candidates that may have potential for the treatment of addiction. We may seek to acquire or license one or more of these product candidates to expand our development programs. We have entered into no such agreements to date.
- *Develop second generation of CPP-109.* We plan to develop a new 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 formulation in the United States.
- *Leverage the services of thought leaders in addiction treatment.* We believe that 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.

### **Risks Affecting Our Business**

Our business is subject to numerous risks, as more fully described herein and in the section entitled "Risk Factors" immediately following this Summary. A few of these risks are described below:

- We have a limited operating history, currently have no products approved for sale and have incurred operating losses of approximately \$3.7 million from inception through June 30, 2006. We expect to incur operating losses for the foreseeable future.
- Our product candidate, CPP-109 is at an early stage of development and has not yet been approved for use in the treatment of cocaine addiction, methamphetamine addiction or any other type of addiction. Failure can occur at any stage of development of a pharmaceutical product such as CPP-109, and it may be years (if ever) before our product development efforts produce viable products that we can commercialize.
- We may never generate any product revenues, achieve profitability or achieve our business objectives.

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- We may not be able to acquire or license other product candidates that have the potential for the treatment of addiction or that other product candidates will be available for us to acquire on acceptable terms, or at all. Further, we may not have the funds for any such acquisition, even if we believe the terms of such acquisition to be favorable. Further, any product we acquire is likely to require substantial additional development, requiring significant funding, and we may not have the funds for such purpose. Finally, any product we acquire may not ultimately be determined to be safe and effective for the treatment of addiction. As a result, we may not be able to commercialize any product we acquire.
- We may not be able to successfully develop a new version of CPP-109. In such event, we may not obtain any exclusive marketing rights with respect to such product.
- We may not be able to retain access to the expertise of our scientific advisors. Without our scientific advisors, our product development efforts may be delayed or frustrated.

### The Offering

Common stock offered 3,000,000 shares  
Common stock outstanding after this offering 12,166,667 shares

Use of proceeds We plan to use the net proceeds from this offering:

- to fund our planned U.S. Phase II clinical trial of CPP-109 for use in treating cocaine addiction;
- to conduct, if required, a U.S. Phase III clinical trial of CPP-109 for use in treating cocaine addiction, to submit and seek approval of an NDA for CPP-109 for use in treating cocaine addiction and to pay for any other required clinical and non-clinical testing of CPP-109;
- to conduct clinical studies and trials for the use of CPP-109 in treating methamphetamine addiction, and to submit such regulatory filings as are required to seek approval for CPP-109 for use in treating methamphetamine addiction;
- to organize clinical studies of CPP-109 for use in treating nicotine addiction and to initiate clinical studies and trials needed to commercialize CPP-109 in Europe; and
- for working capital and other general corporate purposes.

In addition, we may use a portion of the net proceeds to license or acquire one or more products that show promise in the treatment of addiction. No agreements with respect to any acquisition have been entered into to this date.

Proposed Nasdaq Global Market symbol CPRX

Risk factors You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding whether to invest in our common stock.

The number of shares of our common stock outstanding after this offering is based on the 7,029,787 shares outstanding as of the date of this prospectus, and excludes as of that date:

- 2,339,128 shares of common stock reserved for issuance upon the exercise of outstanding stock options having a weighted average exercise price of \$1.14 per share; and
- 2,188,828 additional shares of common stock reserved for future grants under our 2006 Stock Incentive Plan.

Unless otherwise stated, all information in this prospectus:

- gives retroactive effect to a forward stock split of our common stock of approximately 1.4592-to-one (effected in the form of a stock dividend) declared and effective on October 3, 2006;
- gives effect to the automatic conversion of all of our outstanding preferred stock into 2,136,880 shares of our common stock immediately upon the completion of this offering; and
- assumes no exercise of the underwriters' over-allotment option.



### Summary Financial Data

The following table sets forth our summary financial data for the three years ended December 31, 2005, which have been derived from our audited financial statements included elsewhere in this prospectus. In addition, the table includes summary financial data for the six months ended June 30, 2006 and 2005, and as of June 30, 2006, which have been derived from our unaudited financial statements included elsewhere in this prospectus. Our unaudited financial statements have been prepared on a basis substantially consistent with our audited financial statements and, in the opinion of management, include all adjustments (consisting of normally recurring adjustments) necessary for a fair presentation of results under those periods. It is important that you read this information together with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and our financial statements and the related notes and schedules to these financial statements beginning on Page F-1 of this prospectus. Our interim financial results are not necessarily indicative of our financial results for the full year, and our historical results presented below are not necessarily indicative of results to be expected in future periods.

	Six Months Ended June 30,		Year Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through June 30, 2006 (unaudited)
	2006 (unaudited)	2005	2005	2004	2003	
<b>Statement of Operations Data:</b>						
Revenues	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Operating costs and expenses:						
Research and development	432,764	1,200,769	1,462,889	378,254	268,829	2,680,416
General and administrative	242,194	126,811	359,279	164,704	165,483	1,049,925
Total operating expenses	674,958	1,327,580	1,822,168	542,958	434,312	3,730,341
Loss from operations	(674,958)	(1,327,580)	(1,822,168)	(542,958)	(434,312)	(3,730,341)
Interest income	8,133	5,908	16,788	3,138	5,697	33,756
Loss before income taxes	(666,825)	(1,321,672)	(1,805,380)	(539,820)	(428,615)	(3,696,585)
Provision for income taxes	-	-	-	-	-	-
Net loss	\$ (666,825)	\$ (1,321,672)	\$ (1,805,380)	\$ (539,820)	\$ (428,615)	\$ (3,696,585)
Basic and diluted net loss per share	\$ (0.10)	\$ (0.24)	\$ (0.29)	\$ (0.18)	\$ (0.15)	
Weighted average shares outstanding — basic and diluted	6,887,513	5,496,925	6,204,918	2,918,438	2,918,438	
Pro forma basic and diluted net loss per share <sup>(1)</sup>	\$ (0.08)		\$ (0.25)			
Pro forma weighted average shares outstanding — basic and diluted <sup>(1)</sup>	7,908,966		7,226,371			

(1) Pro forma gives effect to the conversion of issued shares of our Series A Preferred Stock into 1,021,453 shares of our common stock as if such shares of Series A Preferred Stock had been converted into common stock as of the earlier of January 1, 2005 or the beginning of the reporting period. Such shares of Series A Preferred Stock will automatically convert into common stock at the closing of this offering.

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	June 30, 2006		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 324,154	\$ 3,549,294	\$ 36,029,294
Working capital (deficiency)	(107,516)	3,312,624	35,792,624
Total assets	365,113	3,590,253	36,070,253
Total liabilities	434,351	239,351	239,351
Stockholders' equity (deficit)	(69,238)	3,350,902	35,830,902

(1) Pro forma gives effect to our completion of a private placement on July 24, 2006 of 7,644 shares of our Series B Preferred Stock from which we received net proceeds of \$3,225,140, the automatic conversion of these Series B preferred shares upon the closing of this offering into 1,115,427 shares of our common stock, the automatic conversion of our outstanding Series A Preferred Stock into 1,021,453 shares of our common stock on the closing of this offering, and the issuance of 142,274 shares of our common stock in July 2006 as payment of \$195,000 of previously deferred compensation for services performed for us by certain of our consultants and scientific advisors during 2005 and the first six months of 2006.

(2) Pro forma information as adjusted gives further effect to our sale of 3,000,000 shares of common stock in this offering at an assumed initial public offering price of \$12.00 per share and our receipt of an estimated \$32,480,000 in net proceeds therefrom, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

## RISK FACTORS

*Any investment in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, and all information contained in this prospectus, before you decide whether to purchase our securities. The occurrence of any of the following risks could cause our business, results of operations, financial condition and prospects to materially suffer and the market price of our stock to decline, and you may lose part or all of your investment.*

### **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 \$1,805,380 for the year ended December 31, 2005 and \$666,825 for the six months ended June 30, 2006, and as of June 30, 2006 we had an accumulated deficit of \$3,696,585. We may not obtain approval of an NDA for CPP-109 and may never achieve profitability.

#### **Our business may require additional capital.**

Our business goals include developing CPP-109 for use in treating various addictions, including cocaine and methamphetamine addiction. While we expect that the proceeds of this offering will allow us to complete all of the clinical and non-clinical trials required to seek approval of an NDA for CPP-109 to treat cocaine and methamphetamine addiction, our expectation, which is based on information available to us at the date of this prospectus, may not be correct. Further, we intend to develop clinical studies to seek commercialization of CPP-109 for nicotine addiction and to commercialize CPP-109 for sale in Europe. While we have allocated a portion of the proceeds of the offering to develop and commence these studies, these studies have not yet been developed and we do not know the ultimate costs of these studies. If we need additional funds to complete required studies on CPP-109 to treat cocaine addiction and methamphetamine addiction, or as we move closer to organizing studies regarding nicotine addiction or relating to our efforts to obtain approvals for CPP-109 in Europe, we will require additional funding to pay such costs. Required funds may not be available, or even if they are available, they may not be available on terms acceptable to us. Further, to the extent that we raise such funds through collaborative arrangements, it may be necessary to relinquish some of the rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to raise required funds, our business and prospects would be adversely affected.

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

There is currently little scientific evidence indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, two open-label pilot clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine and methamphetamine addiction. Only 26 persons in

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the aggregate completed these trials. Additionally, some of the study results described in this prospectus, such as evidence regarding beneficial weight gain, employment or other behavioral changes, have little scientific correlation to the safety or efficacy of CPP-109 as a treatment for addiction, and therefore are not reliable as evidence of safety or efficacy. Further, because these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol, there can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these pilot studies. The results of these pilot studies are not necessarily predictive of results that will be obtained in later stages of clinical testing in the United States or ensure success in later stage clinical trials and neither study provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA.

**Our product development efforts may fail.**

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

- CPP-109 may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;
- CPP-109, even if found to be safe and effective, could prove difficult or impossible to manufacture on a large scale or on a cost-effective basis;
- CPP-109 may be uneconomical to market or take substantially longer to obtain necessary regulatory approvals than anticipated; or
- competitors may market equivalent or superior products.

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

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

We will only obtain regulatory approval to commercialize CPP-109 if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well-controlled clinical studies that the drug is safe and effective for its intended use and that it otherwise meets approval requirements. A failure of one or more preclinical 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;
- we may be unable to reach agreements on acceptable terms with prospective clinical research organizations;
- the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;

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- our third-party contractors 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 clinical trials may be greater than we anticipate.

### **We are dependent on a single chemical compound, vigabatrin.**

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

### **Vigabatrin, the single chemical compound on which we depend, has known side effects that may hinder our ability to produce safe and commercially viable products.**

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

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

These known side effects, as well as other side effects that may be discovered during our clinical trials, may cause the FDA or other governmental agencies to halt clinical trials prior to their completion, prevent the initiation of further clinical trials, or deny the approval of CPP-109 as a treatment for addiction. These known side effects may also cause the FDA to impose marketing restrictions on CPP-109. For example, the FDA may require specialized training for, or otherwise limit the ability of, physicians to prescribe CPP-109 and of pharmacists to fill prescriptions for CPP-109, may restrict our ability to advertise CPP-109, and may require us to keep a registry of patients who are prescribed CPP-109 to prevent such patients from using CPP-109 over an extended period of time.

### **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, corporate partners such as Brookhaven, and other third parties 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 these 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 rely on third parties to manage the data from these clinical trials, we are responsible for confirming that each clinical trial is conducted in accordance with its general investigational plan and protocol.

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Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practice, for conducting, recording and reporting the results of clinical trials to assure that the data and the results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for CPP-109 if these requirements are not met.

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

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

### **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 a contract manufacturer, Pharmaceuticals International, Inc. ("PII"), for the manufacture of CPP-109 for use in our U.S. Phase II clinical trial. We also intend in the future to enter into an agreement with PII 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.

### **Our business is subject to substantial competition.**

The development and commercialization of new drugs is highly competitive worldwide. Although there is no currently approved prescription drug treatment for cocaine or methamphetamine addiction, there are a significant number of other companies that are pursuing the development of drugs that, if approved and commercialized, would be competitive with CPP-109. Some of these other drugs have already begun or even completed Phase II clinical trials. In addition, some or all of these drugs may not have the side effects currently

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associated with vigabatrin, including VFDs. Therefore, these competitive drugs may be approved by the FDA instead of, or more quickly than, CPP-109, and if approved may be more acceptable to health care providers. Further, we expect that the number of companies seeking to develop prescription drugs to treat drug addiction will increase. Other products may be developed that either render CPP-109 obsolete or have advantages that significantly outweigh those of CPP-109. See “Our Business — Competition” for information about products that are currently under development that may be competitive with CPP-109.

Many of our competitors have substantially greater financial, technical, and human resources than we do. In addition, many of our competitors have significantly greater experience than we do in conducting clinical studies and obtaining regulatory approvals of prescription drugs. Accordingly, our competitors may succeed in obtaining FDA approval for products more rapidly than we can. Furthermore, if we are permitted to commence commercial sales of 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 only four employees 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 future growth, or hire, train, motivate, and manage the required personnel. Our failure to manage growth effectively could limit our ability to achieve our goals.

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

### **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. While we intend to carry liability insurance during our clinical trials with an aggregate annual coverage limit of \$10,000,000, with a deductible of \$50,000 per occurrence and \$500,000 in the aggregate, we do not currently have such a policy. We may not be able to obtain a policy for these amounts at a reasonable cost, or at all. Even if we obtain sufficient liability coverage, our insurance may not reimburse us, or this 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 may be able to obtain may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

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

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

**We have no experience as a public company, and the obligations incident to being a public company will place significant demands on our management.**

Since our inception, we have operated as a private company, not subject to the requirements applicable to public companies. While we plan to expand our finance and accounting staff when we become public by adding a Controller/Chief Accounting Officer, we currently have only two persons in our accounting department, one of whom is our Chief Financial Officer and the other of whom is a clerk. We may encounter substantial difficulty attracting a Controller/Chief Accounting Officer with requisite experience due to the high level of competition for experienced financial professionals.

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

As a public reporting company, we will need to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of Sarbanes-Oxley, the SEC adopted rules requiring public companies to include a report of management on a company's internal control over financial reporting in their Annual Report on Form 10-K. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment of the effectiveness of our internal control over financial reporting. If we close this offering as planned during 2006, this requirement will first apply to our Annual Report on Form 10-K for the fiscal year ending December 31, 2007. If we are unable to conclude that we have effective internal control over our financial reporting at December 31, 2007, and future year-ends as required by Section 404 of Sarbanes-Oxley, 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 Science Associates, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy, or Brookhaven. Pursuant to this license agreement, we have licensed rights under nine patents and two 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 2020. We also have the right to future patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. See “Our 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 two pending U.S. patent applications. These applications may not result in issued patents. If patents are issued, any such patents might not provide any commercial benefit to us.

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

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

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

There may be third-party patents whose claims we infringe. 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 United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

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

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

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- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product so that it does not infringe others' patent rights, which may not be possible or could require substantial funds or time.

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 two principal members of our Scientific Advisory Board. If our employees, consultants, contractors or others disclose our data to others or use data belonging to others in connection with our business, it could lead to disputes over the ownership of inventions derived from that information or expose us to potential damages or other penalties.

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

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

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

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

Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. For example, Ovation Pharmaceuticals, Inc., or Ovation, which holds rights in North America to Sabril for the treatment of epilepsy, has indicated its intent to seek to develop Sabril for the treatment of cocaine addiction. We believe that Ovation would infringe our patent rights if they seek to commercialize vigabatrin to treat cocaine addiction, and we have advised Ovation of our belief in that regard. We intend to pursue infringement claims against Ovation if it seeks to commercialize Sabril for this indication. 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 federal, state and local government 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, we must show that the facilities used to produce the product candidate are in compliance with applicable manufacturing regulations, which under FDA regulations are called current Good Manufacturing Practices, or cGMP. In general, these requirements mandate that manufacturers follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. The process of obtaining regulatory approvals typically takes several years and requires the expenditure of substantial capital and other resources. Despite the time, expense and resources invested by us in the approval process, we may not be able to demonstrate that our product candidates are safe and effective, in which event we would not receive the regulatory approvals required to market them.

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

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

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

**If our non-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 must conduct, at our own expense, extensive non-clinical tests to demonstrate the safety of CPP-109 in animals and clinical trials to demonstrate the safety and efficacy of CPP-109 in humans. Non-clinical testing is expensive, difficult to design and implement, can take several years to complete and is uncertain as to outcome. Our non-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 non-clinical testing.

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In the United States, where vigabatrin is not currently approved for use, we intend to commence during the first quarter of 2007 a Phase II clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction. We will also be required to conduct one or more Phase I clinical trials for CPP-109. While the scope of the required Phase I clinical trials are currently uncertain, it is likely that we will be required to perform studies of pharmacokinetics, cardiac function, drug-drug interaction and the effect of the drug on special populations. We may also develop and implement additional studies (including a U.S. Phase III clinical trial, if required) in order to seek approval to commercialize CPP-109 for the treatment of cocaine addiction. However, even if the results of clinical trials are promising, a drug may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Future clinical trials for CPP-109 may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, an inability to recruit clinical trial participants at the expected rate, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays.

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

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

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

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

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

We may encounter difficulties in our clinical trials due to the nature of the addiction mechanism and our resulting target patient population. We do not know how long it will take to recruit patients for our Phase II clinical trial. Trial participants will be required to meet specific clinical standards for cocaine 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, and will not be eligible to participate in our study if they meet the DSM-IV criteria for dependence with respect to other addictive substances. 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. In addition, 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 be adversely affected.

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

The FDA will require us to submit extensive non-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, may require several years to conduct. Some pre-clinical testing has previously been performed with respect to Sabril, and some of the data from such testing is publicly available. However, we do not yet know whether the FDA will consider such public data in reviewing any NDA we may file, what non-clinical tests will be required or whether any non-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 non-clinical tests that we undertake, if conducted, will be acceptable to the FDA.

**If the FDA does not accept an NDA from us based on the results of our Phase II clinical trial, our development and commercialization activities would be significantly delayed.**

Generally, the process of seeking approval of an NDA requires multiple clinical trials, including at least one pivotal Phase III clinical trial. However, if the results of our Phase II clinical trial in the United States are sufficiently compelling, we may elect to submit an NDA on the basis of the U.S. Phase II trial and seek FDA review under its accelerated approval process. Accelerated approval provides the opportunity for regulatory approval based on achieving endpoints in our proposed trial, which we believe will be designed to show the safety and efficacy of CPP-109 to the FDA's satisfaction. However, the FDA may not accept our endpoints, we may not succeed in reaching our endpoints or we may be forced to end our trial if we find that trial participants are exposed to significant health risks, or we otherwise may not successfully complete our Phase II trial. Even if our Phase II clinical trial data are compelling, it is most likely that the FDA will still require additional trials, including a U.S. Phase III trial, before we will be permitted to file an NDA for CPP-109. Failure to obtain review on the basis of a single study or to obtain accelerated approval could require us to complete additional and more extensive clinical trials, which would be costly and time-consuming and would delay potential FDA approval of CPP-109 for several years.

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

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

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

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

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

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

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

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

Regulatory authorities have broad enforcement power, and any failure by us to comply with manufacturing or marketing regulations could result in penalties, including warning letters, fines, total or partial 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 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 federal, state and local laws, 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

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the operating environment for healthcare companies. We cannot predict the likelihood of all future changes in the healthcare industry in general, or the addiction treatment industry in particular, or what impact they may have on our earnings, financial condition or business. Government regulations applicable to our proposed products or the interpretation thereof might change and thereby prevent us from marketing some or all of our products and services for a period of time or indefinitely.

**Risks Related to this Offering and 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 that will become effective upon completion of this offering with Patrick J. McEnany, our Chairman and Chief Executive Officer, and Jack Weinstein, our Chief Financial Officer, with respect to their services, and the consulting agreements we have with one of our board members and one 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.

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

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

Prior to this offering, our Chairman and Chief Executive Officer, Patrick J. McEnany, beneficially owns approximately 40% of our outstanding common stock. Following this offering, we expect that Mr. McEnany will beneficially own approximately 31% of our outstanding common stock. As a result, it is likely that Mr. McEnany will continue to own sufficient shares of our common stock to be 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.

**There has been no prior market for our common stock, and it may trade at prices below the initial public offering price.**

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which a trading market for our common stock will develop or be sustained after this offering. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters based on factors that may not be indicative of future performance, and may not bear any relationship to the price at which our common stock will trade upon completion of this offering. You may be unable to sell your shares of common stock at or above the initial public offering price.

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

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

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

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

**You will experience immediate and substantial dilution as a result of this offering.**

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares in prior offerings. In addition, you will experience immediate and substantial dilution insofar as the initial public offering price will be substantially greater than the tangible book value per share of our outstanding common stock after giving effect to this offering. As a result, investors who purchase common stock in the offering will:

- pay a price that substantially exceeds the value of our tangible assets after subtracting our liabilities; and
- contribute 87% of the total amount that has been invested to fund our operations, but only receive 25% of the outstanding shares of our common stock and related voting rights.

Additionally, we may in the future require additional financing, and we may seek such financing by means of additional equity issuances. If this occurs, your interests in our common stock may experience further dilution.



**We have broad discretion in the use of the proceeds from this offering. Our use of the offering proceeds may not yield a favorable return on your investment.**

We expect to use the net proceeds from this offering to develop and fund clinical studies of our product candidates and for general corporate purposes, including the potential acquisition or in-license of products that may have potential applications in treating addiction. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you do not agree. Pending the use of the proceeds in this offering, we plan to invest them. However, the proceeds may not be invested effectively or in a manner that yields a favorable or any return, and consequently, this could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates.

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

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

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

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

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

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

After this offering, we will have 12,166,667 shares of our common stock outstanding, of which 9,166,667 shares will be restricted securities. The holders of approximately 96% of our restricted shares have entered into lock-up agreements with the underwriters under which they have agreed not to sell their shares of common stock for 180 days from the date of this prospectus without the prior written consent of First Albany Capital Inc. We also intend to register for future sale the 2,188,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and the 2,339,128 shares of common stock underlying our outstanding stock options. 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. Our common stock may not appreciate in value after the offering or even maintain the price at which investors purchased shares.

## FORWARD-LOOKING STATEMENTS

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

- our ability to successfully complete clinical trials required to file and obtain approval of an NDA for the commercialism of CPP-109, and the timing of any such filing and approval;
- our ability to protect our intellectual property rights;
- market acceptance of any products as to which we may receive approval for commercialization;
- the ability of others to develop, obtain approval of, and commercialize competitive products; and
- the information contained in the “Risk Factors” section.

Our current plans and objectives are based on assumptions involving the growth and expansion 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 in this prospectus, which reflect our views only as of the date of this prospectus, you should not place undue reliance upon such statements.

## USE OF PROCEEDS

The net proceeds to us from the sale of the securities offered hereby are estimated to be approximately \$32,480,000, assuming an initial public offering price of \$12.00, and after deducting underwriting discounts and commissions and estimated offering expenses. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) the net proceeds to us from this offering by approximately \$2,790,000, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds will be approximately \$37,502,000.

We expect to use approximately \$26.0 million of the net proceeds of this offering to complete the clinical studies and non-clinical studies that we believe, based on currently available information will be required for us to file an NDA for the use of CPP-109 to treat cocaine addiction and methamphetamine addiction, as follows:

- approximately \$7.0 million will be used to fund our U.S. Phase II clinical trial to evaluate CPP-109 for the treatment of cocaine addiction;
- approximately \$7.5 million will be used to fund a U.S. Phase III clinical trial to evaluate CPP-109 for the treatment of cocaine addiction, if required;
- up to approximately \$4.0 million will be used to fund other costs relating to our filing of an NDA for CPP-109 to treat cocaine addiction, including any Phase I clinical trials and other non-clinical studies that may be required; and
- approximately \$7.5 million will be used to fund required clinical studies and trials to evaluate CPP-109 as a treatment for methamphetamine addiction and to fund costs relating to our regulatory filings to seek approval for the use of CPP-109 to treat methamphetamine addiction.

We also expect to use approximately \$5.0 million of the net proceeds of this offering to organize clinical studies and trials to evaluate CPP-109 as a treatment for nicotine addiction and to initiate the clinical studies and trials needed to seek approvals to commercialize CPP-109 in Europe. We have not yet developed any of the studies required for these purposes, do not yet have estimates of their costs and expect that we will need to raise additional funding to complete these studies.

Additional net proceeds will be used for general corporate purposes, including rent payments for our office facility, compensation payments to our executive officers and employees and professional fees.

The above amounts represent our estimate of the costs to fund the above clinical programs. However, we cannot assure you that we will be able to complete our trials with the amounts specified, and the costs we incur may be well in excess of the above amounts.

In addition, we may use a portion of the net proceeds from this offering to acquire or license one or more products that show promise in treating addiction. However, we currently have no commitments, agreements, or understandings relating to any such acquisition.

We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will be sufficient to meet our projected operating requirements for the next 30 months.

The allocation of the net proceeds of this offering described above represents our best current estimate of our projected operating requirements. However, the exact amount and timing of our expenditures will depend on several factors, including the success of our commercialization activities and the progress of our clinical trials and other development efforts as well as the amount of cash used in our operations. Accordingly, our

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management will have broad discretion in the application of the net proceeds and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. We reserve the right to change the use of these proceeds as a result of certain contingencies such as the results of our commercialization efforts, competitive developments, opportunities to acquire or in-license products, and other factors.

Pending the uses described above, we plan to invest the net proceeds of this offering in short and medium-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

**DIVIDEND POLICY**

We have not in the past and do not intend in the foreseeable future to pay cash dividends. We expect to retain future earnings, if any, to fund the development and growth of our business. The declaration of dividends is subject to the discretion of our board of directors and will depend on various factors, including our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors. In addition, the terms of any future debt or credit facility may preclude us from paying dividends on our common stock.

## CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2006:

- on an actual basis;
- on a pro forma basis to give effect to our completion on July 24, 2006 of a private placement of 7,644 shares of our Series B Preferred Stock from which we received net proceeds of \$3,225,140, the automatic conversion of these Series B preferred shares upon the closing of this offering into 1,115,427 shares of our common stock, the automatic conversion upon the closing of this offering of the outstanding Series A Preferred Stock into 1,021,453 shares of our common stock, and the issuance of 142,274 shares of our common stock in July 2006 as payment of previously deferred compensation for services performed for us by certain of our consultants and scientific advisors during 2005 and the first six months of 2006; and
- on a pro forma as adjusted basis to give further effect to our sale of 3,000,000 shares of common stock in this offering at an assumed initial public offering price of \$12.00 per share and our receipt of an estimated \$32,480,000 in net proceeds therefrom, after deducting underwriting discounts and commissions and estimated offering expenses to be paid by us.

This table should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and the financial statements and the related notes and schedules thereto, included elsewhere in this prospectus.

	June 30, 2006		
	Actual	Pro forma	Pro forma as adjusted(1)
Cash and cash equivalents	\$ 324,154	\$ 3,549,294	\$ 36,029,294
Stockholders’ equity (deficit):			
Preferred stock, \$.01 par value, 5,000,000 shares authorized; 70,000 shares actual, no shares pro forma and pro forma as adjusted	\$ 700	\$ –	\$ –
Common stock, \$.01 par value, 100,000,000 shares authorized; issued and outstanding: 6,887,513 shares actual, 9,166,667 shares pro forma; and 12,166,667 shares pro forma as adjusted	68,875	91,667	121,667
Additional paid-in capital	3,557,772	6,955,820	39,405,820
Accumulated deficit	(3,696,585)	(3,696,585)	(3,696,585)
Total stockholders’ equity (deficit)	(69,238)	3,350,902	35,830,902
Total capitalization	\$ (69,238)	\$ 3,350,902	\$ 35,830,902

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total shareholders’ equity and total capitalization by approximately \$2.8 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus. The pro forma as adjusted information discussed above is illustrative only and following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

The above table excludes 2,339,128 shares of common stock underlying options outstanding on the date of this prospectus at a weighted average exercise price of \$1.14 per share.

## DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share you pay in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. We had a net tangible book value at June 30, 2006 of \$(69,238), or \$(0.01) per share. Net tangible book value per share represents our tangible assets less total liabilities divided by the number of shares of common stock outstanding. On a pro forma basis, after giving effect to the conversion of our Series A Preferred Stock into shares of common stock, our tangible net worth at June 30, 2006 would have been \$(0.01) per share.

After giving effect to completing our private placement in July 2006, in which we sold 7,644 shares of Series B Preferred Stock for net proceeds of \$3,225,140, and after adjusting for the issuance in July 2006 of 142,274 shares of our common stock as payment of previously deferred compensation for services performed for us by certain of our consultants and scientific advisors during 2005 and the first six months of 2006 and the automatic conversion, upon completion of this offering, of all outstanding shares of our convertible preferred stock into an aggregate of 2,136,880 shares of our common stock, our pro forma net tangible book value as of June 30, 2006, would have been \$3,350,902, or \$0.37 per share.

After giving further effect to the sale of 3,000,000 shares of common stock in this offering, at an assumed initial public offering price of \$12.00 per share, and after deducting the estimated offering expenses, our pro forma as adjusted net tangible book value at June 30, 2006 would have been approximately \$35,830,902, or approximately \$2.95 per share. This represents an immediate increase in net tangible book value of approximately \$2.58 to our existing stockholders and an immediate dilution of \$9.05 per share to new investors in this offering.

The following table illustrates this calculation.

Assumed public offering price per share		\$ 12.00
Historical net tangible book value	\$ (0.01)	
Change in value attributable to conversion of preferred stock outstanding at June 30, 2006 (pro forma)	—	
Increase in value attributable to preferred stock issued after June 30, 2006 (assuming conversion) and payment of compensation through issuance of common stock after June 30, 2006	0.38	
Pro forma net tangible book value per share at June 30, 2006	0.37	
Increase in pro forma net tangible book value per share attributable to this offering	2.58	
Pro forma net tangible book value per share after this offering		2.95
Dilution in pro forma net tangible book value per share to investors in this offering		<u>\$ 9.05</u>

Each \$1.00 increase (decrease) in the assumed initial offering price of \$12.00 per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately \$2,790,000, or approximately \$.23 per share, and dilution to new investors by approximately \$0.77 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus.

If the underwriters exercise their over-allotment option in full, our pro forma as adjusted net tangible book value as of June 30, 2006 will increase to approximately \$3.24 per share, representing an increase to

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existing stockholders of approximately \$2.87 per share, and there will be an immediate dilution of approximately \$8.76 per share to new investors.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2006, the total number of shares of our common stock purchased from us and the total consideration and average price per share paid by existing stockholders and by new investors:

	<u>Shares Purchased</u>		<u>Total Consideration Paid</u>		<u>Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders	9,166,667	75%	\$ 5,334,140	13%	\$ 0.58
New investors	3,000,000	25	36,000,000	87	12.00
Total	<u>12,166,667</u>	<u>100%</u>	<u>\$ 41,334,140</u>	<u>100%</u>	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$12.00 per share would increase (decrease) total consideration paid by new investors and total consideration paid by all stockholders by \$3,000,000 and the average price per share paid by all stockholders by approximately \$0.25 assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Depending on market conditions at the time of pricing of this offering and other considerations, we may sell fewer or more shares than the number set forth on the cover page of this prospectus.

If the underwriters exercise their over-allotment option in full, the percentage of shares held by existing stockholders will decrease to approximately 73%, and the number of shares held by new investors will increase to 3,450,000, or approximately 27%.



**SELECTED FINANCIAL DATA**

The following table sets forth our selected financial data for each of the three years ended December 31, 2005 and as of December 31, 2005 and 2004, which have been derived from our audited financial statements included elsewhere in this prospectus. In addition, the table includes selected financial data for the six months ended June 30, 2006 and 2005, and as of June 30, 2006, which have been derived from our unaudited interim financial statements included elsewhere in this prospectus. The table also includes unaudited data for the year ended December 31, 2002 and as of December 31, 2003 and 2002, which are not included in this prospectus. Our predecessor company was incorporated in 2002. It is important that you read this information together with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Risk Factors" and our financial statements and the related notes and schedules to these financial statements beginning on Page F-1 of this prospectus. The results presented below are not necessarily indicative of results to be expected in any future periods.

	<u>Six Months Ended June 30,</u>		<u>Year Ended December 31,</u>			<u>Period from</u>	<u>Cumulative period</u>
	<u>2006</u>	<u>2005</u>	<u>2005</u>	<u>2004</u>	<u>2003</u>	<u>January 4, 2002</u> <u>(date of inception)</u> <u>through</u> <u>December 31, 2002</u>	<u>from January 4,</u> <u>2002 (date of</u> <u>inception) through</u> <u>June 30, 2006</u>
	(unaudited)					(unaudited)	(unaudited)
<b>Statement of Operations</b>							
<b>Data:</b>							
Revenues	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Operating costs and expenses:							
Research and development	432,764	1,200,769	1,462,889	378,829	268,829	137,680	2,680,416
General and administrative	242,194	126,811	359,279	164,704	165,483	118,265	1,049,925
Total operating expenses	674,958	1,327,580	1,822,168	542,958	434,312	255,945	3,730,341
Loss from operations	(674,958)	(1,327,580)	(1,822,168)	(542,958)	(434,312)	(255,945)	(3,730,341)
Interest income	8,133	5,908	16,788	3,138	5,697	-	33,756
Loss before income taxes	(666,825)	(1,321,672)	(1,805,380)	(539,820)	(428,615)	(255,945)	(3,696,585)
Provision for income taxes	-	-	-	-	-	-	-
Net loss	\$ (666,825)	\$ (1,321,672)	\$ (1,805,380)	\$ (539,820)	\$ (428,615)	\$ (255,945)	\$ (3,696,585)
Basic and diluted net loss per share	\$ (0.10)	\$ (0.24)	\$ (0.29)	\$ (0.18)	\$ (0.15)	\$ (0.11)	
Weighted average shares outstanding — basic and diluted	6,887,513	5,496,926	6,204,918	2,918,438	2,918,438	2,358,737	
Pro forma basic and diluted net loss per share <sup>(1)</sup>	\$ (0.08)		\$ (0.25)				
Pro forma weighted average shares outstanding — basic and diluted <sup>(1)</sup>	7,908,966		7,226,371				

(1) Pro forma gives effect to the conversion of shares of our Series A Preferred Stock into 1,021,453 shares of our common stock as if such shares of Series A Preferred Stock had been converted into common stock as of the earlier of January 1, 2005 or the beginning of the reporting period. Such shares of Series A Preferred Stock will automatically convert into common stock on the closing of this offering.

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	Pro forma June 30, 2006(1)	June 30, 2006	December 31,			
			2005	2004	2003	2002
	(unaudited)	(unaudited)			(unaudited)	(unaudited)
<b>Balance Sheet Data:</b>						
Cash and cash equivalents	\$ 3,549,294	\$ 324,154	\$ 771,127	\$ 183,911	\$ 416,262	\$ 107,089
Working capital (deficiency)	3,312,624	(107,516)	428,579	116,111	362,563	40,388
Total assets	3,590,253	365,113	789,450	185,376	416,262	111,589
Total liabilities	239,351	434,351	342,988	67,800	53,699	66,701
Stockholders' equity (deficit)	3,350,902	(69,238)	446,462	117,576	362,563	44,888

- (1) Pro forma gives effect to our completion of a private placement on July 24, 2006 of 7,644 shares of our Series B Preferred Stock from which we received net proceeds of \$3,225,140, the automatic conversion of these Series B preferred shares upon the closing of this offering into 1,115,427 shares of our common stock, the automatic conversion of our outstanding Series A Preferred Stock into 1,021,453 shares of our common stock on the closing of this offering, and the issuance of 142,274 shares of our common stock in July 2006 relating to services performed for us by certain of our consultants and scientific advisors during 2005 and the first six months of 2006.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with our financial statements and the related notes and schedule thereto appearing elsewhere in this prospectus. This discussion and analysis may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially as a result of various factors, including those set forth in "Risk Factors" or elsewhere in this prospectus.*

### Overview

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

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

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

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

Research and development expenses, in the aggregate, represented approximately 64%, 81%, 70% and 62% of our total operating expenses for the six months ended June 30, 2006 and the years ended December 31, 2005, 2004 and 2003, respectively. Research and development expenses consist primarily of costs incurred for clinical trials 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 planned U.S. Phase II clinical trial, our anticipated costs related to the clinical trial to be conducted in Mexico, and any required Phase I studies that we undertake. We estimate that we will incur approximately \$18.5 million in expenses, in addition to costs previously incurred, for our further clinical trials and development costs for CPP-109 to treat cocaine addiction. These estimates assume that a U.S. Phase III clinical trial will be required by the FDA before we are able to obtain approval of an NDA for CPP-109. A portion of the net proceeds of this offering will be used to fund all such expenses. We do not expect that we will be able to commercialize CPP-109 for at least two to three years following this offering.

The above costs include assumptions about events that may be outside of our control. For example, the FDA could require us to alter or delay our clinical trials at any stage, which may significantly increase the costs of that trial, as well as delay our commercialization of CPP-109 and our future revenue.

## **Basis of Presentation**

### *Revenues*

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

### *Research and development expenses*

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

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

### *Selling and marketing expenses*

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

### *General and administrative expenses*

Our general and administrative expenses consist primarily of salaries, consulting fees for members of our Scientific Advisory Board, information technology, and corporate administration functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal and accounting services.

### *Stock-based compensation*

We recognize costs related to the issuance of common stock to employees and consultants by using the estimated fair value of the stock at the date of grant, in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation" (SFAS 123). We further account for the issuance of employee stock options using the intrinsic value method. Accordingly, compensation cost for stock options issued is measured as the excess, if any, of the fair value of our common stock at the date of grant over the exercise price of the options.

### *Income taxes*

We have incurred operating losses since inception. As of December 31, 2005 and 2004, we had net operating loss carryforwards of \$588,326 and \$385,928, respectively. The related deferred tax asset has a 100% valuation allowance as of December 31, 2005 and 2004, as we believe it is more likely than not that the deferred tax asset will not be realized. There are no other significant temporary differences. The net operating loss carry-forwards will expire at various dates beginning in 2022 through 2025. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of these carry-forwards may be subject to limitation.

## **Critical Accounting Policies and Estimates**

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

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

### *Non-clinical study and clinical trial expenses*

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

### *Stock-based compensation*

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

## **Results of Operations**

*Revenues.* We had no revenues for the six month periods ended June 30, 2006 and 2005 or for the years ended December 31, 2005, 2004, and 2003.

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*Research and Development Expenses.* Research and development expenses for the six months ended June 30, 2006 and 2005 were \$432,764 and \$1,200,769, respectively. Research and development expenses for the years ended December 31, 2005, 2004, and 2003 were \$1,462,889, \$378,254, and \$268,829, respectively. Expenses to date include costs associated with the filing of our IND, payments with respect to clinical studies that we support, and payments to consultants and members of our Scientific Advisory Board and other service providers who have assisted us with respect to these matters.

We recorded non-cash compensation in each of the six-month periods in 2006 and 2005, and in 2005, 2004 and 2003. Such non-cash compensation, which was part of our research and development expenses, related to shares of common stock issued to several of our consultants and scientific advisors for services rendered and the value of stock options granted to non-employees. In 2005, 2004, 2003 and the period from January 4, 2002 (date of inception) through December 31, 2005, we recorded compensation expense of \$1,067,750, \$294,833, \$75,833 and \$1,514,249, respectively, related to the issuance of stock options to nonemployees. The weighted average fair value of the stock options granted in 2005, 2004 and the period from January 4, 2002 (date of inception) through December 31, 2005 was \$1.14, \$1.00 and \$0.99, respectively. There were no stock options granted in 2003.

We expect that research and development activities will increase substantially as we receive the vigabatrin that will be used in our upcoming clinical trials, as we pay the costs associated with our ongoing clinical studies and trials, and as we expand our product development activities generally. Our historical research and development expenses have been very low. This is due to the fact that much of the early stage development costs associated with the development of vigabatrin to treat addiction were incurred by Brookhaven in connection with their ongoing animal studies into the use of vigabatrin to treat addiction. We benefit from their research by reason of our license.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the six months ended June 30, 2006 and 2005 or during the 2005, 2004 and 2003 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 \$242,194 and \$126,811, respectively, for the six months ended 2006 and 2005. General and administrative expenses were \$359,279, \$164,704 and \$165,483, respectively, for the years ended December 31, 2005, 2004 and 2003. General and administrative expenses include office expenses, legal and accounting fees and travel expenses for our employees, consultants and members of our Scientific Advisory Board. We expect general and administrative expenses to increase in future periods as we incur general non-research expenses relating to the monitoring and oversight of our clinical trials, add staff, expand our infrastructure to support the requirements of being a public company and otherwise expend funds to continue to develop our business as set forth in this prospectus.

*Stock-Based Compensation.* We issued (i) stock options to non-employees in late 2004 and early 2005, (ii) stock options to our Chief Executive Officer in early 2005, and (iii) shares of our common stock to several of our scientific advisors and consultants in 2005 and in the first half of 2006. See "*Research and Development*" above. The measurement date for all these equity instruments, 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 non-employee guarantee has fully vested in the award. 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 value of \$1.37 per share as of December 31, 2005 and \$2.98 per share as of June 30, 2006, which we believed to be the fair value of such securities as of each of these dates. As of June 30, 2006, we had outstanding stock options to purchase 2,188,828

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shares of our common stock, of which options to purchase 2,042,906 were vested and 145,922 were unvested. We also had 142,274 shares of common stock payable at June 30, 2006, which we issued in July 2006.

Our belief as to the fair value of our securities as of December 31, 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 as of June 30, 2006 was based on the substantial advancement of our product development efforts that occurred during the first half of fiscal 2006 and on the common-equivalent per share price paid by unrelated investors who purchased securities in our private placement that closed in July 2006. We did not obtain a contemporaneous valuation by an unrelated valuation specialist because we believed that this current market transaction represented the best indicator of fair value of our common stock.

After this offering, we anticipate that we will calculate the value of our stock-based compensation by reference to the market price of our common stock. We believe that the public market for companies seeking to develop pharmacologic treatments for substance abuse has positively changed in the last few months and that the assumed initial public offering price of \$12.00 per share is consistent with the valuations of other public biopharmaceutical companies at similar points of product development. As a result, we believe that the price paid by investors in this offering is likely to be substantially higher than the fair value ascribed to our equity during prior periods. Further, we expect that the completion of this offering will add value to our shares because they will have increased liquidity and marketability. However, the amount of such additional value cannot be measured with precision or certainty.

*Interest Income.* We reported interest income in all periods relating to our investment of funds received from our private placements in 2003 and 2005. All such funds were invested in short and medium-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. As of June 30, 2006, we had received total net proceeds of approximately \$1.9 million from private placements of our securities. Subsequent to June 30, 2006, we completed a private placement of our securities in which we raised net proceeds of \$3,225,140.

At June 30, 2006, we had cash and cash equivalents of \$324,154 and had a working capital deficit of \$107,516. Subsequent to June 30, 2006, we closed a private placement in which we received net proceeds of \$3,225,140. We used a portion of the proceeds from that offering to pay our Chief Executive Officer \$125,000 in deferred compensation then due to him. We also used a portion of these proceeds for the following purposes:

- approximately \$100,000 to purchase the active pharmaceutical ingredient required to manufacture batches of CPP-109 for use in our U.S. Phase II clinical trial; and
- approximately \$600,000 to pay a contract manufacturer for services in connection with the development and manufacture of our formulation of vigabatrin and to pay for required bioequivalency studies with respect to the chemical composition of CPP-109.

The balance is being used to fund our support of the upcoming clinical study in Mexico, and for working capital and general corporate purposes in our business.

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### *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. We anticipate using a significant portion of the proceeds from this offering to finance these activities. It may take several years to obtain the necessary regulatory approvals to commercialize CPP-109 in the United States.

We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will be sufficient to meet our projected operating requirements for the next 30 months, including our requirements relating to obtaining necessary regulatory approvals and to the commercialization of CPP-109 for use in treating cocaine and methamphetamine addiction.

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

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

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

To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or sales and marketing initiatives.

### *Cash Flows*

Net cash used in operations was \$434,527 and \$244,111, respectively, for the six months ended June 30, 2006 and 2005, respectively and \$455,360, \$230,520 and \$365,784, respectively for 2005, 2004 and 2003. Net cash used in each of these periods primarily reflects that portion of the net loss for these periods not attributed to non-cash compensation.

Net cash used in investing activities was \$12,446 and 3,940 for the six months ended June 30, 2006 and 2005, respectively, and \$3,940, \$1,831 and \$0, respectively, for 2005, 2004 and 2003. Such funds were used primarily to purchase computer equipment.



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Net cash provided by financing activities was \$0 and \$1,046,516 for the six months ended June 30, 2006 and 2005, respectively, and \$1,046,516, \$0 and \$674,957 in 2005, 2004 and 2003, respectively. Net cash from financing activities is comprised of the net proceeds of the two private placements that we completed in April 2003 and March 2005. Such funds were used to fund our research and development costs and our general and administrative costs in 2005, 2004, 2003 and during the first half of 2006.

### *Contractual Obligations*

As of June 30, 2006, we had contractual obligations as follows:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Debt	\$ —	\$ —	\$ —	\$ —	\$ —
Capital leases	—	—	—	—	—
Operating leases	33,285	17,736	15,549	—	—
Total	<u>\$33,285</u>	<u>\$ 17,736</u>	<u>\$ 15,549</u>	<u>\$ —</u>	<u>\$ —</u>

We are also obligated to make the following payments:

- *Payment to Brookhaven under our license agreement.* We have agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval for CPP-109, \$250,000 in each of the second and third years following approval, and \$500,000 per year thereafter until the last patent expires.
- *Payments to our contract manufacturer.* We are obligated to pay our contract manufacturer approximately \$513,200, with payments to be based on the achievement of milestones relating to the schedule of work that it has agreed to perform for us.
- We intend to enter into employment agreements with two of our executive officers, which will become effective on the closing of this offering and will require aggregate base salary payments of \$515,000 per year following this offering.

### *Off-Balance Sheet Arrangements*

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

### **Recent Accounting Pronouncements**

In May 2005, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 154, "Accounting Changes and Error Corrections — a replacement of APB Opinion No. 20 and FASB Statement No. 3," or SFAS 154. SFAS 154 replaces APB Opinion No. 20, "Accounting Changes," and FASB Statement No. 3, "Reporting Accounting Changes in Interim Financial Statements," and changes the requirements relating to the accounting for and reporting of any changes in accounting principles. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. SFAS 154 applies to all voluntary changes in accounting principles. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed.

APB Opinion No. 20 previously required that most voluntary changes in accounting principles be recognized by including, in net income of the period of the change, the cumulative effect of changing to the new accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the

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cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change in one or more individual prior periods presented, SFAS 154 requires that the new accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable, and that a corresponding adjustment be made to the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) for that period, rather than being reported in an income statement. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, SFAS 154 requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. We do not believe that the adoption of SFAS 154 will have a significant effect on our financial statements.

In March 2006, the FASB issued SFAS 156 — “Accounting for Servicing of Financial Assets — an amendment of FASB Statement No. 140,” or SFAS 156. SFAS 156 is effective for the first fiscal year beginning after September 15, 2006. SFAS 156 changes the way entities account for servicing assets and obligations associated with financial assets acquired or disposed of. We have not yet completed our evaluation of the impact of adopting SFAS 156 on our results of operations or financial position, but do not expect that the adoption of SFAS 156 will have a material impact.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

**Quantitative and Qualitative Disclosures About Market Risk**

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

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

## OUR BUSINESS

### Overview

We are a specialty pharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of addiction. Our initial product candidate is CPP-109, which is based on the chemical compound *gamma-vinyl-GABA*, commonly referred to as vigabatrin. We intend to begin in the first quarter of 2007 a Phase II clinical trial evaluating CPP-109 for the treatment of cocaine addiction. We also intend to develop CPP-109 to treat methamphetamine addiction. We believe that our CPP-109 platform has the potential to produce therapies for other addictions, including addictions to nicotine, prescription pain medications, alcohol, and marijuana, as well as treatments for related addictive disorders, such as obesity and compulsive gambling.

Many addictive drugs, including cocaine and methamphetamine, produce feelings of euphoria by increasing the concentration of the chemical neurotransmitter dopamine in specific areas of the brain. Under normal conditions, dopamine levels are relatively constant, increasing temporarily as a result of experiences such as eating or sexual arousal. Over time, the feeling of pleasure is decreased by a reduction in dopamine to its pre-arousal level and through the action of *gamma-aminobutyric acid*, or GABA, a chemical neurotransmitter that inhibits the effect of dopamine. Substances such as cocaine and methamphetamine cause enormous amounts of dopamine buildup, producing feelings of euphoria. CPP-109 increases the amount of GABA present, which suppresses the responses to the dramatic increase in dopamine levels produced by cocaine and methamphetamine, thereby preventing the perception of pleasure that is associated with their use.

We have been granted an exclusive worldwide license from Brookhaven National Laboratory, which we refer to as Brookhaven, to nine U.S. patents and two 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 2020. Additionally, we have received approval from the European Union with respect to one of our principal patents, which will allow us to seek approval for this patent in each of the EU member states.

We intend to commence in the first quarter of 2007 a U.S. Phase II clinical trial to evaluate CPP-109 for the treatment of cocaine addiction. While the final design of this clinical trial and the number of patients to be included has not yet been finalized, we currently anticipate that this trial will be a double-blind, randomized, placebo-controlled study involving approximately 375 patients. In addition, we plan to conduct certain Phase I clinical trials with CPP-109, including pharmacokinetics, cardiac function, drug-drug interaction studies and studies in special populations. If the data from these trials are sufficiently compelling, we intend to submit an NDA seeking marketing approval from the FDA. However, it is most likely that additional clinical trials, including a U.S. Phase III clinical trial, will be required before we are permitted to file an NDA for CPP-109. We are also supporting a 100 patient double-blind, placebo-controlled clinical trial in Mexico. We expect that this trial will be the equivalent of a Phase II study in the United States, and will start in the fourth quarter of 2006.

In December 2004, the FDA accepted our IND for CPP-109 for the treatment of cocaine addiction. We have been granted Fast Track status by the FDA for CPP-109. Fast Track designation means, among other things, that the FDA recognizes cocaine addiction as an unmet medical need for which no pharmacological products are currently approved for marketing, and consequently the FDA may initiate review of sections of an 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 less stringent. Further, Fast Track status may be withdrawn at any time and does not guarantee that we will qualify for, or be able to take advantage of, priority review procedures following submission of an NDA. Notwithstanding, we believe that our receipt of Fast Track status may accelerate the regulatory approval process, although we cannot assure you that our clinical trials will be successful or that we will obtain approval of an NDA for CPP-109.

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Our intention to advance CPP-109 as a potential treatment for cocaine and methamphetamine addiction is based on the results of two open-label pilot studies conducted in Mexico in 2003 and 2004 by a member of our Scientific Advisory Board. In one study, of the 30 patients enrolled, 18 completed the study and 16 tested negative for methamphetamine and cocaine during the last six weeks of the trial. In another study, of the 20 patients enrolled, eight completed the study and remained drug-free for periods ranging from 46-58 days. These studies strongly supported our intention to advance CPP-109 as a potential treatment for cocaine and methamphetamine addiction. However, these studies only involve a small number of patients and neither study provided enough evidence regarding safety and efficacy to support an NDA filing with the FDA. In addition, because these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol, there can be no assurance that the results of subsequent clinical trials will corroborate the results of these pilot studies.

### **Our Business Strategy**

To facilitate our business development and growth we plan to:

- *Focus on CPP-109 for cocaine addiction.* We intend to commence a U.S. Phase II clinical trial evaluating the use of CPP-109 as a treatment for cocaine addiction. Treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status 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. We plan next to develop CPP-109 for the treatment of methamphetamine addiction. Further, 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 related addictive disorders, including obesity and compulsive gambling.
- *Acquire or license additional addiction therapies.* We know of other product candidates that may have the potential for the treatment of addiction. We may seek to acquire or license one or more of these product candidates to expand our development programs. We have entered into no such agreements to date.
- *Develop second generation of CPP-109.* We plan to develop a new 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 formulation in the United States.
- *Leverage the services of thought leaders in addiction treatment.* We believe that 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.

### **Industry Background — Substance Abuse and Addiction**

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

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

amphetamine-type stimulants across Europe. We believe that the direct and indirect costs of cocaine and methamphetamine use are indicative of a significant global public health problem, representing a significant unmet medical need for which no adequate pharmaceutical therapies exist.

*Cocaine Addiction.* According to the SAMHSA survey, an estimated 2.4 million people had used cocaine in the month preceding the survey. Additionally, in 2005, approximately 900,000 people had used cocaine for the first time within the preceding 12 months, an average of approximately 2,400 new users per day. According to the same study, approximately 797,000 patients received treatment for cocaine abuse in 2005. According to the National Institute of Drug Abuse, or NIDA, there are no pharmacologic treatments for cocaine addiction currently approved for marketing by the FDA. We believe that other therapies being developed for the treatment of cocaine addiction, but not yet approved for marketing, suffer from significant limitations which have not been exhibited to date by CPP-109.

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

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

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

#### **Limitations of Current Approaches to Addiction Treatment: Our Market Opportunity**

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.

Historically, addicted individuals have been treated primarily through behavioral modification, which has a high rate of relapse. According to the SAMHSA survey, 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 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; and
- they are often ineffective at eliminating drug cravings or responding to increasing levels of drug use.

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

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

### **Pharmacodynamics of Addictive Drugs**

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

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

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

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

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dopamine effects are moderated by GABA, which in turn is moderated by GABA-T, maintaining the brain in a balanced, pre-arousal state.

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

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

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

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

*Mechanism of Action of Nicotine.* Nicotine has a similar chemical structure to the neurotransmitter acetylcholine. Acetylcholine and its receptors are involved in many activities, including respiration, maintenance of heart rate, memory, alertness, and muscle movement. Once nicotine enters the brain, it activates receptors that normally respond to acetylcholine, called cholinergic receptors. Regular use of nicotine causes a decrease in the number of cholinergic receptors and a decrease in the sensitivity of these receptors to nicotine and acetylcholine. Recent research has also shown that nicotine causes an increased release of dopamine resulting in the pleasurable sensation triggered by its use. We believe that the increase in dopamine levels is similar, although less intense, than that observed in cocaine and methamphetamine users.

## **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.

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

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relaxation and sleep, and contributes to functions such as motor control and vision. An enzyme known as GABA-T is responsible for the eventual breakdown of GABA once the feeling of euphoria has faded.

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

*History and Side Effect Profile.* Vigabatrin has been marketed over the past decade in over 30 countries by Sanofi-Aventis under the brand name Sabril as a secondary treatment for adult epilepsy and as a primary treatment for the management of infantile spasms, known as West Syndrome. The composition of matter patents for Sabril expired in 1993. Neither vigabatrin nor Sabril has been approved in the United States for any indication.

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

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

*Brookhaven's Research.* Our initial interest in vigabatrin was based on Brookhaven's research with it regarding the pathology and treatment of cocaine and other addictions. Brookhaven scientists have shown that the dopamine pathway responds similarly to drugs of abuse. In 1997, scientists at Brookhaven harnessed an emerging technology, positron emission tomography scans, or PET scans, and became the first to image the effects of addicting substances in living human 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.

*Platform Technology.* We believe that vigabatrin is potentially suitable for the treatment of many addictions due to its ability to block the euphoria associated with heightened levels of dopamine. These include our initial focus areas of cocaine and methamphetamine addictions and addictions to other substances including nicotine, prescription pain medications, alcohol and marijuana, as well as related addictive disorders such as obesity and compulsive gambling. Brookhaven has licensed to us patents relating to the use of CPP-109 as a treatment for all abused drugs. Consequently, if CPP-109 is determined to be a safe and effective treatment for cocaine and methamphetamine addiction, we may pursue additional clinical trials to determine whether CPP-109 can be used to treat addiction to other substances.

## **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 FDCA, the FDA is directed to facilitate the development and expedite review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designation emphasizes communication between us and the FDA and affords us benefits that



may help to expedite the approval process. For example, Fast Track designation affords us the opportunity to submit an NDA for CPP-109 on a rolling, or modular, basis, allowing the FDA to review sections of the NDA in advance of receiving our full submission. The designation also means that we may have increased communications with the FDA regarding the design of our clinical studies, which we hope will expedite the development and review of our application for the approval of CPP-109 and provide greater certainty overall in the regulatory pathway.

We intend to commence a Phase II clinical trial in the first quarter of 2007 to evaluate CPP-109 for the treatment of cocaine addiction. While the final design of this clinical trial and the number of patients to be included has not yet been finalized, we currently anticipate that this trial will be a double-blind, randomized, placebo-controlled trial involving approximately 375 patients at multiple treatment sites in the United States and Canada. To be eligible to participate in the trial, participants must meet specific clinical standards for cocaine dependence, as specified in DSM-IV, a set of diagnosis guidelines established for clinical professionals. Additionally, trial participants cannot meet the DSM-IV criteria for dependence on other addictive substances. The trial is expected to be 26 weeks in duration, with subjects divided into three equal groups. One group will receive vigabatrin for a 26-week period. A second group will receive vigabatrin for a nine-week period, followed by a placebo for 17 weeks. The third group will receive a placebo for the full 26 weeks. The primary endpoint of this study is three weeks of abstinence from cocaine at nine weeks and again at 26 weeks. A secondary endpoint measures abstinence for three-week periods at 18 weeks and a reduction in cocaine use from baseline at 18 weeks. Further, eye safety studies will be conducted on all trial participants to determine the extent of any VFDs among such participants.

If the data from this clinical trial are compelling, we may file an NDA and seek regulatory approval in the United States to commercialize CPP-109. However, it is most likely that we will have to complete a U.S. Phase III clinical trial before we are permitted to file an NDA seeking regulatory approval to sell CPP-109 in the United States.

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 require one or more Phase I clinical trials. While the scope of the required clinical trials is currently uncertain, it is likely that we will be required to include studies of pharmacokinetics, cardiac function, drug-drug interaction and the effect of the drug on special populations. We expect to conduct the required Phase I trial during the pendency of our Phase II clinical trial or thereafter. We believe that the proceeds from this offering will be sufficient to fund the Phase I clinical trials that are ultimately determined to be required.

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

#### **Clinical Studies That We Support**

The primary focus of our product development efforts is on our clinical studies; however, we have in the past supported and will continue in the future to support clinical studies of the use of vigabatrin for the treatment of addiction by investigators, including members of our Scientific Advisory Board and the academic institutions with which they are affiliated. In most cases, these studies have been funded in the past and will be funded in the future by third parties, such as the particular academic institution or a governmental agency, such as the National Institute on Drug Abuse. In some cases, we provide unrestricted sponsorship funds for these types of studies. In other cases, we provide other assistance to the investigator. We expect to continue to support investigator studies in the future to the extent that they meet the criteria described below. The clinical trial in Mexico that we are currently supporting is an example of such a study. Our support for these studies is intended to further the available research on the use of vigabatrin to treat addiction, to assist investigators in designing

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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.

We believe that the clinical trial that we are currently supporting in Mexico will be considered a Phase II study, because it is designed to evaluate the safety and efficacy of vigabatrin as a treatment for cocaine addiction. We have received approval from Mexican authorities to begin enrollment, which we expect to begin in the fourth quarter of 2006. The principal investigators of this trial are Jonathan Brodie, Ph.D., M.D., a professor of Psychiatry at New York University and a member of our Scientific Advisory Board, and Emilia Figueroa, M.D., a physician addiction specialist who directs several addiction treatment clinics in Mexico. Dr. Brodie designed the protocol for this trial, which is a double-blind, placebo-controlled study and involves 100 patients at a single location in Mexico City. Subjects will be selected from a pool of cocaine-dependent prison parolees who meet the specific clinical standards for cocaine dependence, as specified in DSM-IV. The trial is expected to continue for one year. The primary endpoint of the trial is patient abstinence from cocaine for a period of 21 days following treatment. In addition to the primary endpoints, eye safety studies may be conducted to determine the extent of any visual field defects among the trial participants.

We have been advised by the FDA that the study to be conducted in Mexico may be considered by the FDA as pivotal support for an NDA filing by us if it is conducted under Good Clinical Practice Guidelines. Additionally, we will be required to provide evidence in an NDA addressing the applicability of the foreign data to the U.S. population. However, because the study is being conducted in Mexico and is not subject to FDA oversight in any respect, including study design and protocol, there can be no assurance that this study will ultimately be considered by the FDA as evidence supporting approval of an NDA for CPP-109 by the FDA. We anticipate that while investigator studies such as the Mexican study may support an NDA filing by us, our U.S. clinical trials will be the primary clinical trials considered by the FDA in determining whether to approve any NDA we are ultimately permitted to file.

### **Pilot Studies**

Our intention to advance CPP-109 as a potential treatment for cocaine and methamphetamine addiction is based on two open-label human pilot studies conducted in 2003 and 2004 in Mexico by a member of our Scientific Advisory Board. We believe these pilot studies support the therapeutic potential of vigabatrin as a treatment for cocaine and methamphetamine addiction. However, both studies involved a small number of patients and neither study provided enough evidence regarding safety and efficacy to support an NDA filing with the FDA. In addition, because these studies were conducted in Mexico and were not subject to FDA oversight in any respect, including study design and protocol, there can be no assurance that the results of subsequent clinical trials in the United States will corroborate the results of these pilot studies. These pilot studies are described below:

#### *Cocaine Pilot Study 2003 — Mexico.*

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

- **Study design.** The protocol was designed as an outpatient, open-label, fixed-dose, time-limited trial in a setting with psychotherapeutic support and intervention. A total of 20 subjects, consisting of 19 men and one woman were enrolled.
- **Enrollment criteria.** Subjects were primarily daily cocaine abusers meeting DSM-IV criteria for cocaine dependence with a minimum of three years of continuous use. Most of the subjects were polydrug abusers whose cocaine use was often supplemented with methamphetamine, marijuana, and/or alcohol. As a prerequisite for inclusion, all subjects indicated that they were interested in

breaking their drug dependence and gave informed, signed consent. Exclusion criteria included intravenous drug use and subjects treated within the past year for substance abuse. At the beginning of the study, the average age of the subjects was 29, with an average 12-year history of cocaine abuse and an average daily consumption of 1.7 grams of cocaine.

- **Dosing.** Following an admission physical examination and screening for medical exclusion criteria, all subjects were given a screening urinalysis and a craving questionnaire and were then placed on vigabatrin. Each subject was given escalating doses of vigabatrin. Vigabatrin was administered on day 1 at two grams, consisting of one gram twice daily. After 3 days, the dosage was increased to 1.5 grams twice daily and on day seven vigabatrin was administered at a continuing dose of two grams twice daily. All dosing was done under observation in the clinic. Subjects who had a negative drug screen for four successive weeks, or 28 days in total, were then tapered down by one gram of vigabatrin per day per week.
- **Testing.** All subjects were encouraged to participate in group and individual counseling programs and were required to twice weekly provide urine samples in addition to filling out a daily questionnaire of drug use and craving. The drug screen included cocaine, heroin, methamphetamine, tetrahydrocannabinol, or THC, and phencyclidine, or PCP.
- **Results.** Of the 20 subjects enrolled in the study:
  - eight remained in the program and were drug-free for periods ranging from 46 to 58 days at the end of the study. Only two subjects had a single “slip” or relapse into cocaine use once the craving stopped. A slip restarted the consecutive days “clean” or drug-free value.
  - Of the 12 subjects who failed to complete the program, eight requested termination within 10 days, stating that they did not wish to stop their cocaine use. The other four subjects stayed in the protocol for periods of 25 to 43 days but continued to use cocaine, although in reduced amounts: two out of the four had an 80% reduction, one out of the four had a 50% reduction, and the other did not reduce at all, according to self-reports by the subjects, despite their claim that the drug did not engender the usual “high.”

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

The trial completers did not differ significantly from the non-completers in age, duration of cocaine abuse, or average daily use. The consecutive days “clean” for the completers averaged 48.5 days, compared to an average of 1.9 days for non-completers, with a P-value, which is a measure of statistical significance, of less than 0.0001. There was also a clear distinction between the two groups on the basis of weight gained during the trial: an average of 18.2 pounds for the completers, compared to an average of 0.2 pounds for non-completers, with a P-value of less than 0.0001. A “P-value” of less than .05 indicates that the different results between treatment groups was not random. No subject who continued cocaine use during their participation in the study reported increased appetite or experienced weight gain. In order for the study’s outcomes to be convincing in light of concerns about vigabatrin’s safety and efficacy, an outcome measure of 28 consecutive days clean, in which the subject tested negative for cocaine, was utilized. We believe this measure was particularly stringent for an outpatient setting and in the field of addiction therapy where statistical significance often exceeds therapeutic reality.

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

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

\* Not statistically significant.

Subjects in this study were all cocaine users who consumed cocaine five to seven days per week and had been doing so for three to 15 years. Nevertheless, 40% of those who entered the study completed it without relapse. Once cocaine use ceased, six of the eight completers were entirely drug free for the duration of the study, or seven weeks. The others had a single “slip” and were again clean for greater than four weeks. On the other hand, the mean time to relapse of all 12 non-completers was less than 2 days. Significantly, all of the trial completers gained weight, while none of the non-completers gained any. Weight gain precisely paralleled cessation of cocaine use by self-report as well as by the twice weekly drug screen and daily observation. We believe that this is not surprising in view of the well-known appetite-suppressing effects of cocaine.

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

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

- **Side Effects Observed.** Overall, vigabatrin was well tolerated. No subjects reported visual disturbances of any kind throughout their exposure to vigabatrin or admitted to vision changes of any kind upon questioning. The major side effects were transient somnolence, or drowsiness, in the first 10 days, observed in 17 of the 20 subjects, and an intermittent low-grade headache, observed in 9 of the 20 subjects, that occasionally persisted for several weeks, although never severe enough for the subject to request termination on that basis.

*Cocaine and Methamphetamine Pilot Study 2004 — Mexico.* The second pilot study was conducted in Mexico between November 2003 and January 2004 under Dr. Brodie’s supervision and with our financial

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

- **Study design.** All subjects, consisting of 29 men and one woman, met DSM-IV criteria for drug dependence. The protocol for this study was reviewed and approved by the Government of Mexico according to the standards of the Helsinki Convention as currently modified.
- **Enrollment criteria.** Subjects abused methamphetamine, cocaine, or both on a daily basis, but were otherwise in good health. The average duration of drug dependence for all subjects was 12.8 years. All 30 subjects enrolled met DSM-IV criteria for substance abuse, three met the criteria for dependence on cocaine alone, 10 met the criteria for methamphetamine dependence alone, and 17 met the criteria for dependence on both cocaine and methamphetamine. A complete preadmission history and physical examination for all test subjects were obtained.
- **Ophthalmologic Measurement.** The baseline ophthalmologic examination consisted of funduscopy, in which a doctor examines the back of the eye with an ophthalmoscope in order to assess any damage to the blood vessels that supply the retina. In addition, visual acuity was determined by conventional ophthalmic techniques, and measurements of the subject's visual field were performed utilizing a measurement technique known as an automated Humphreys VF60-4 protocol. These tests were repeated in the middle and end of treatment and again at one to two months following treatment cessation. Ophthalmic measurements were performed at the Codet Eye Institute, Tijuana, B.C. Mexico. In addition, these data were independently evaluated by a Board Certified Ophthalmologist at the University of Medicine and Dentistry, Newark, New Jersey, who had no knowledge of each subject's identity.
- **Dosing.** Vigabatrin administration was initiated at 500 milligrams twice daily for three days, then 1.5 grams per day for the next four days and two grams per day for the next week. On day 15, subjects were placed on three grams per day, maintained at that dose for the next 28 days, and then tapered to zero over the next three weeks. Completers received a cumulative dose of vigabatrin of 137 grams, which is less than 10% of the 1,500 gram lifetime exposure that we believe is associated with an increase in the incidence of visual field defects.
- **Testing.** Twice-weekly urine samples were obtained under direct observation and tested for cocaine, methamphetamine, marijuana, heroin, and alcohol. Daily vital signs were monitored, and all subjects were encouraged to participate in weekly group therapy.
- **Results.** Of the 30 volunteers enrolled:
  - 11 subjects dropped out before completing 4 weeks,
  - One subject completed 8 weeks; and
  - 18 subjects completed all nine weeks, consisting of all three cocaine-only users, 6 of the 10 methamphetamine-only users, and 9 of the 17 users of both methamphetamine and cocaine.

Completers did not differ significantly from non-completers in either the pre-study daily usage or years of dependence. Further administration of vigabatrin did not have an effect on vital signs, even with continued use of cocaine and methamphetamine. Further, there were no VFDs or other changes in visual acuity detected in any subject, regardless of whether the subject completed the study or not.

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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 (because of the small size of the study and the number of patients who dropped out of the studies, these results may not be reliable or repeatable, and may not be duplicated in future trials). Fifteen completers were methamphetamine-free and/or cocaine-free for four consecutive weeks, with no slips, while two were never drug-free although use was markedly reduced according to self-reports by the users. The average drug-free interval was 40.1 consecutive days, with an average use of 0.03 grams of cocaine or methamphetamine over the last three weeks of the study.

### **Nicotine Animal Studies**

A member of our Scientific Advisory Board working at Brookhaven has conducted preclinical studies using primates to evaluate the effects of vigabatrin on nicotine addiction. In these studies, the administration of vigabatrin inhibited the ability of nicotine to increase dopamine levels in varying degrees based on dosage level and time elapsed since administration of vigabatrin. When vigabatrin was administered 12 or 24 hours prior to the introduction of nicotine, researchers observed no increase in dopamine levels. Based upon these findings, we intend to commence clinical studies evaluating CPP-109 as a treatment for nicotine addiction in 2008.

### **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 below, relapse rates for traditional counseling treatments are very high, while clinical studies of vigabatrin to date have shown low relapse rates among the 26 patients who completed treatment. There can be no assurance, however, that the relapse rates over wider studies or in general use will remain as low.
- If approved, we believe that the use of CPP-109 in conjunction with counseling will potentially offer a more efficacious and cost-effective addiction treatment than is currently available.
- Unlike other compounds, we believe that CPP-109 has no abuse liability; that is, we believe that CPP-109 does not substitute addiction to one drug for addiction to another drug. As a result, we believe it will be easier for patients to cease using CPP-109 after treatment without withdrawal effects.
- CPP-109's mechanism of action potentially allows it to be used to treat most types of substance addiction and abuse.
- We have been granted Fast Track status for CPP-109 by the FDA, which allows us an expedited review process with the FDA of any NDA we may file for CPP-109.

### **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, methamphetamine, and nicotine 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

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impacted if our competitors' present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payors.

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

- *Cocaine-mimetics*. The mechanism of action of these drugs is similar to cocaine. None of these approaches have, to our knowledge, shown any efficacy. These compounds include:
  - methylphenidate, which is marketed as Ritalin by Novartis, and
  - GBR-12909, which is known as vanoxerine and is currently in Phase II clinical trials sponsored by the National Institute of Drug Abuse.
- *Cocaine-antagonists*. These compounds are intended to selectively target GABA, moderating dopamine levels in the brain. We believe that many of these compounds are receptor active and require increasing dosing over time. None of these compounds are presently approved for marketing to treat addiction. These compounds include:
  - baclofen, marketed as Lioresal by Novartis,
  - topiramate, marketed as Topamax by Ortho-McNeil Neurologics,
  - tiagabine, marketed as Gabitril by Cephalon,
  - gabapentin, marketed as Neurontin by Pfizer, and
  - pregabalin, marketed as Lyrica by Sanofi-Aventis.
- *Addiction Vaccines*. These vaccines are designed to block cocaine transport into the brain. They do not address issues relating to craving or other behaviors associated with cocaine addiction. We also believe that they can be overwhelmed by increasing dosages of cocaine. These compounds include:
  - TA-CD is a cocaine vaccine currently in Phase II clinical trials sponsored by Celtic Pharma Development U.K. Plc.

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

Finally, Ovation Pharmaceuticals, Inc., which holds the North American rights to Sabril as an adjunctive therapy for the treatment of epilepsy and as a primary treatment for West Syndrome, has indicated its intent to undertake studies with respect to the use of Sabril in treating cocaine addiction. 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 assert our intellectual property rights if Ovation sought to market Sabril for the treatment of cocaine addiction. There can be no assurance we would be successful in that regard.

Most therapies to treat nicotine addiction can be classified into two groups, nicotine replacement therapies and prescription-only neurotransmitter modulators. Numerous over-the-counter, or OTC, therapies currently exist to treat nicotine addiction such as transdermal nicotine patches, inhalation sprays, nicotine gum, lozenges and oral dose drugs. Although there are a wide variety of OTC products for nicotine addiction, the only currently marketed prescription product specific to smoking cessation is Zyban, marketed by GlaxoSmithKline plc.

## Patents and Intellectual Property Rights

### *Brookhaven license agreement*

We have been granted an exclusive, worldwide license from Brookhaven Science Associates, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (which we refer to as Brookhaven), to nine patents and two 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 2020. Additionally, we recently received approval from the European Union with respect to one of our principal patents, which will allow us to seek approval for this patent in each of the EU member states.

The license agreement, which is dated as of April 30, 2006 and which supercedes a previous license agreement that was entered into in 2002, grants us an exclusive worldwide license, including the right to sublicense, to make, have made, use, and/or sell licensed products and practice the licensed process with respect to the medical application in humans of vigabatrin under certain patent rights. These rights are subject to the United States government's rights to practice the licensed process for its own use. The purpose of this agreement is to permit us to commercialize products upon the receipt of government regulatory approval for the use of vigabatrin for the treatment of human drug addiction and addiction-related behavior. In exchange for such rights, we paid Brookhaven an initial fee of \$50,000 and have agreed to pay a fee of \$100,000 in the year of NDA approval for CPP-109, \$250,000 in each of the second and third years following approval, and \$500,000 per year thereafter until the last patent expires. In addition, we have agreed to reimburse Brookhaven for all reasonable and customary expenses it incurs from the beginning of our agreement in connection with the filing, prosecution and maintenance of all patents and patent applications included in the patent rights we have licensed. We are obligated to reimburse Brookhaven \$69,352, as of September 30, 2005, for such expenses upon our filing of an NDA.

We have also agreed to consult with Brookhaven not less frequently than quarterly with respect to drug development steps taken and progress made toward the objective of gaining marketing approval from the FDA for any licensed product from the beginning of our agreement through the date the FDA grants us its approval to sell any licensed product. We have also agreed to have in effect and maintain a liability insurance policy in an amount of at least \$1,000,000 to cover claims arising out of the manufacture and use of licensed products and such policy shall designate Brookhaven as an additional insured. We have agreed to increase and maintain, throughout the life of the agreement and for five years after its termination, liability insurance coverage in the amount of at least \$5,000,000 upon acceptance by the FDA of our application to commence Phase III clinical trials involving licensed products. Our agreement with Brookhaven expires simultaneously with the expiration of the last to expire patent it has licensed to us.

### *General*

Protection of our intellectual property and proprietary technology is a strategic priority for our business. We rely on a combination of patent, trademark, copyright and trade secret laws along with institutional know-how and continuing technological advancement to develop and maintain our competitive position. Our ability to protect and use our intellectual property rights in the continued development and commercialization of our technologies and products, operate without infringing the proprietary rights of others, and prevent others from infringing our proprietary rights, is crucial to our continued success. We will be able to protect our products and technologies from 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.



## **Manufacturing, Marketing and Reimbursement**

Since the composition of matter patent for vigabatrin has expired, we will not 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 clinical trial requirements. We also have an agreement with a contract manufacturer, Pharmaceuticals 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 or another contract manufacturer to manufacture commercial quantities of CPP-109 if the FDA approves an NDA for CPP-109.

Under our current agreement with PII, they have agreed to manufacture for us CPP-109 in quantities that we believe will be sufficient to conduct our planned Phase II clinical study for the treatment of cocaine addiction, along with a matching placebo for study purposes. The contract is for the manufacture of a specific number of tablets of CPP-109 and contains no renewal provisions. Pursuant to the agreement, we will make payments to PII, aggregating \$513,200, based on achievement of milestones related to the schedule of work PII has agreed to perform for us.

Under our contract with PII, we have agreed to indemnify PII against:

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

PII has agreed to indemnify us against:

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

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

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

Since we intend to contract with a third party to manufacture our products, our contract manufacturer will be obligated to comply with all applicable environmental laws and regulations that affect the manufacturing process. As a result, we do not believe that we will have any significant exposure to environmental issues.

We do not currently have any in-house marketing, distribution, or production capabilities. In order to generate sales of CPP-109 or any other product candidates we may develop, we must either acquire or develop an internal marketing force with technical expertise and with supporting documentation capabilities, or make arrangements with third parties to perform these services for us. The acquisition and development of a marketing and distribution infrastructure will require substantial resources, which may divert the attention of our

management and key personnel away from our product development efforts. To the extent that we enter into marketing and distribution arrangements with third parties, our revenues will depend on the efforts of others. If we fail to enter into such agreements, or if we fail to develop our own marketing and distribution channels, we would experience delays in product sales and incur increased costs.

## Government Regulation

### *United States*

Governmental authorities in the United States and other countries extensively regulate the testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. In the United States, the FDA, under the FDCA, and other federal statutes and regulations, subjects pharmaceutical products to review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products, our products may be seized and we may be criminally prosecuted.

*FDA Approval Process.* To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory and animal testing in compliance with FDA regulations;
- submission of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- submission and approval of an NDA by the FDA.

The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap. In Phase I clinical trials, the product is tested in a small number of patients or healthy volunteers, primarily for safety at one or more dosages. In Phase II clinical trials, in addition to safety, the sponsor evaluates the efficacy of the product on targeted indications, and identifies possible adverse effects and safety risks in a patient population. Phase III clinical trials typically involve testing for safety and clinical efficacy in an expanded population at geographically-dispersed test sites. The FDA closely monitors the progress of each phase of clinical testing and may, at its discretion, reevaluate, alter, suspend or terminate testing based on the data accumulated to that point and its assessment of the risk/benefit ratio to the patient. Total time required for carrying out such clinical testing varies between two and ten years. Additional clinical testing is often required for special classes of patients, e.g., such as the elderly, or those with kidney impairment, and to test for interactions with other drugs. Based on the known side effects of VFDs associated with vigabatrin when used in the treatment of epilepsy, our clinical studies will also seek to determine if VFDs are associated with vigabatrin when dispensed in the dosages and for the limited periods proposed for the treatment of cocaine and methamphetamine addiction.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the partial, 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 institutional review board, or IRB of each

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clinical site, generally must approve the clinical trial design and patient informed consent at that site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the non-clinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant, and six months to complete its initial review of a priority NDA. The priority review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months of the PDUFA goal date. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA and issue a not approvable letter.

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

*Section 505(b)(2) New Drug Applications.* As an alternate path to FDA approval for new indications, improved formulations of previously-approved products, or new chemical entities, a company may submit a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA filing under Section 505(b)(1) as described above. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Amendments permit the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product, or on published literature reports, or both. The FDA may also require companies to perform additional studies or measurements to support approval.

To the extent that a Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication, which is the FDA's list of approved drug products and the indications for which they are approved. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application may also 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.

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If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send a notice of the paragraph IV certification to the NDA and the holder of the underlying patent once the NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the 30-month stay period is extended by such amount of time so that 7.5 years has elapsed since the approval of the NDA with five-year exclusivity. This period could be extended by six months if the NDA sponsor obtains pediatric exclusivity. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay. Vigabatrin has not yet been approved by the FDA for the treatment of addiction, Ovation has indicated its intent to pursue development of Sabril, its branded version of vigabatrin, for treatment of cocaine addiction. As such, at this time we do not anticipate submitting a paragraph IV certification. However, other applicants submitting 505(b)(2) applications for vigabatrin that rely on CPP-109, if approved, as well as an applicant that submits an abbreviated new drug application, or ANDA, that cites CPP-109 as the reference listed drug, would be required to submit patent certifications for any patents listed in the Orange Book for CPP-109.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If these companies successfully challenge the FDA's interpretation of Section 505(b)(2), the FDA may be required to change its interpretation of Section 505(b)(2). This could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

*The Hatch-Waxman Act.* Under the Hatch-Waxman Amendments, newly-approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments provide five-year marketing exclusivity to the first applicant to gain approval of an NDA for a chemical entity, meaning that the FDA has not previously approved any other drug containing the same active ingredients. The Hatch-Waxman Amendments prohibit the submission of an ANDA, or a Section 505(b)(2) NDA for another version of such drug during the five-year exclusive period; however, as explained above, submission of an ANDA or Section 505(b)(2) NDA containing a paragraph IV certification is permitted after four years, which may trigger a 30-month stay of approval of the ANDA or Section 505(b)(2) NDA. Protection under Hatch-Waxman will not prevent the submission or approval of another "full" or "stand-alone" NDA; however, the applicant would be required to conduct its own non-clinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Amendments also provide three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application.

If the FDA approves another company's version of vigabatrin before it approves CPP-109, and awards that company five-year marketing exclusivity, then we could not submit a 505(b)(2) application for CPP-109 for at least four years. If, however, we submit a "full" or "stand-alone" NDA for CPP-109 under Section 505(b)(1) of the FDCA, then any competitor's five-year marketing exclusivity will not block approval of CPP-109.

In addition to non-patent marketing exclusivity, the Hatch-Waxman Amendments amended the FFDCA to require each NDA sponsor to submit with its application information on any patent that claims the drug for which the applicant submitted the NDA or that claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Generic applicants that wish to rely on the approval of a drug listed

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in the Orange Book must certify to each listed patent, as discussed above. We intend to submit for Orange Book listing all relevant patents for our product candidate.

Finally, the Hatch-Waxman Amendments amended the patent laws so that certain patents related to products regulated by the FDA are eligible for a patent term extension if patent life was lost during a period when the product was undergoing regulatory review, and if certain criteria are met. We intend to seek patent term extensions, provided our patents and products, if they are approved, meet applicable eligibility requirements.

*Fast Track Designation.* The FDA's Fast Track program is intended to facilitate the development and to expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition and that demonstrate the potential to address unmet medical needs. Under the Fast Track program, applicants may seek traditional approval for a product based on data demonstrating an effect on a clinically meaningful endpoint, or approval based on a well-established surrogate endpoint. The sponsor of a new drug candidate may request the FDA to designate the drug candidate for a specific indication as a Fast Track drug at the time of original submission of its IND, or at any time thereafter prior to receiving marketing approval of a marketing application. The FDA has granted fast track status to CPP-109.

Fast track designation permits the FDA to initiate review of sections of an NDA before the application is complete. This so-called "rolling review" is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant has paid applicable user fees. The FDA's PDUFA review clock for both a standard and priority NDA for a fast track product does not begin until the complete application is submitted. Additionally, fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by emerging data, or if the designated drug development program is no longer being pursued. A product approved under the FDA's Fast Track program is subject to expedited withdrawal of approval if required post-approval studies are not conducted with due diligence, if the studies fail to verify the clinical benefit of the product, or if the sponsor disseminates false or misleading materials with respect to the product.

*Other Regulatory Requirements.* We may also be subject to a number of post-approval regulatory requirements. If we seek to make certain changes to an approved product, such as promoting or labeling a product for a new indication, making certain manufacturing changes or product enhancements or adding labeling claims, we will need FDA review and approval of an NDA supplement before the change can be implemented. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications or product enhancements and, in some cases, for manufacturing and labeling claims, is generally a time-consuming and expensive process that may require us to conduct clinical trials under the FDA's IND regulations. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all. In addition, adverse experiences associated with use of the products must be reported to the FDA, and FDA rules govern how we can label, advertise or otherwise commercialize our products.

There are current post-marketing safety surveillance requirements that we will need to meet to continue to market an approved product. The FDA also may, in its discretion, require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products.

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 health care 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 health care item or service reimbursable under Medicare, Medicaid or other federally financed health care 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-

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kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal health care 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 health care companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we and the manufacturers on which we rely for the manufacture of our products are subject to requirements that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practice, or cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, record-keeping and other requirements. The FDA periodically inspects drug manufacturing facilities to evaluate compliance with cGMP requirements.

Also, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record-keeping and control procedures.

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

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

Outside of the European Union, we are subject to widely varying foreign obligations, which may be quite different from those of the FDA, governing clinical studies, product registration and approval and pharmaceutical sales. Whether or not FDA approval has been received, we must obtain separate approval for products by the comparable regulatory authorities of foreign countries prior to the commencement of marketing CPP-109 in

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those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. In addition, under current U.S. law, there are significant restrictions on the export of products not approved by the FDA, depending on the country involved and the status of the product in that country.

### **Our Employees**

We currently employ five persons, including our Chief Financial Officer, who is currently a consultant but will be an employee upon completion of this offering. We also utilize the services of consultants, including members of our board of directors and 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 quantitate 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 for vigabatrin to treat addiction.

*Jonathan Brodie, Ph.D., M.D.* is the Marvin Stern Professor of Psychiatry at New York University School of Medicine. Dr. Brodie completed his B.S. in Chemistry as a Ford Foundation Scholar and his Ph.D. in Physiological Chemistry (Organic Chemistry minor) at the University of Wisconsin-Madison. He was an NIH postdoctoral Fellow in Biochemistry at Scripps Clinic and Research Foundation and a tenured associate professor of Biochemistry at the School of Medicine at SUNY at Buffalo. He then received his M.D. at New York University School of Medicine and joined the faculty after completing his residency in psychiatry at NYU/ Bellevue Medical Center. He is a 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 for 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

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best drug on the market to treat patients who are addicted to heroin. Dr. Jasinski has agreed to be the principal investigator for our upcoming U.S. Phase II clinical trial.

*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.

**Facilities**

We currently operate our business in leased office space in Coral Gables, Florida. We pay annual rent on our office space of approximately \$17,900. In anticipation of the expansion of our operations, we plan to obtain additional leased space in the near future.

**Legal Proceedings**

We are not a party to any legal proceedings.



## OUR MANAGEMENT

### Officers and Directors

The following table shows information about our officers and directors as of the date of this prospectus:

Name	Age	Position(s)
Patrick J. McEnany	59	Co-Founder, Chairman, President and Chief Executive Officer
Hubert E. Huckel, M.D.(1)	75	Co-Founder and Director
Charles B. O’Keeffe(2)(3)	66	Senior Advisor and Director
Philip H. Coelho(2)(3)	62	Director
David S. Tierney, M.D.(1)(3)	43	Director
Milton J. Wallace(1)(3)	70	Director
Jack Weinstein	50	Vice President, Treasurer and Chief Financial Officer
M. Douglas Winship	57	Vice President of Regulatory Operations
Charles W. Gorodetzky, M.D., Ph.D.	69	Chief Medical Officer

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

**Patrick J. McEnany** is our Co-Founder, Chairman, President and Chief Executive Officer. Mr. McEnany has been Chief Executive Officer and a director since our formation in January 2002. He became Chairman and President in April 2006. From 1999 to 2002, Mr. McEnany was a consultant in the pharmaceutical industry. From 1991 to 1997, Mr. McEnany was Chairman and Chief Executive Officer of Royce Laboratories, Inc., a generic pharmaceutical manufacturer. From 1997 to 1998, after the merger of Royce into Watson Pharmaceuticals, Inc., Mr. McEnany served as president of the wholly-owned Royce Laboratories subsidiary and vice president of corporate development for Watson Pharmaceuticals, Inc. From 1993 to 1997, he also served as vice chairman and a director of the National Association of Pharmaceutical Manufacturers. He currently serves on the board of directors for ThermoGenesis Corp., Renal CarePartners, Inc. and the Jackson Memorial Hospital Foundation.

**Hubert E. Huckel, M.D.** is our Co-Founder and is a member of our board of directors. Dr. Huckel was Chairman of the Board until April 2006. Dr. Huckel spent 29 years with The Hoechst Group (now part of Sanofi-Aventis), and was at the time of his retirement in 1992, executive chairman of the board of Hoechst-Roussel Pharmaceuticals, Inc. Dr. Huckel has continued his involvement in the prescription drug industry and currently serves on the boards of directors of Titan Pharmaceuticals, Inc., ThermoGenesis Corp., Valera Pharmaceuticals, Inc., and Concordia Pharmaceuticals, Inc. Dr. Huckel received his M.D. degree from the University of Vienna, Austria and is a member of the Rockefeller University Council.

**Charles B. O’Keeffe** became a consultant to us in December 2004 and has served as our Senior Advisor since that time. Mr. O’Keeffe has also served as a member of our board of directors since December 2004. Mr. O’Keeffe is a Professor in the Department of Epidemiology and Community Health at Virginia Commonwealth University, and has served in such capacity since January 1, 2004. Mr. O’Keeffe joined VCU after retiring as President and chief executive officer of Reckitt Benckiser Pharmaceuticals, Inc., a position Mr. O’Keeffe held from 1991 until 2003. As President of Drug Abuse Rehabilitation Services (from 1970 until 1971), he developed the first child-resistant, abuse-resistant vehicle for dispensing methadone. He served as president of Washington Reference Laboratories from 1972 until 1975, which provided toxicology services to the Department of Defense during the Vietnam War. He has served in the White House (from 1970 until 1973 and from 1976 until 1980) for three presidents — as advisor, special assistant for international health and deputy

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director for international affairs in the Office of Drug Abuse Policy — and has served on U.S. delegations to the World Health Assembly and the U.N. Commission on Narcotic Drugs. Mr. O’Keeffe played a significant role in helping Congress reach consensus on the Drug Addiction Treatment Act of 2000.

**Philip H. Coelho** has been a member of our board of directors since October 2002. Mr. Coelho has been employed with ThermoGenesis Corp., a company focused on the blood processing and hospital/woundcare markets, since October 1986. Since November 1997, Mr. Coelho has served as chairman and chief executive officer of ThermoGenesis; from December 1989 to November 1997, Mr. Coelho was president and chief executive officer of ThermoGenesis; and from October 1986 to September 1989, Mr. Coelho served as vice president and director of research and development of ThermoGenesis. Prior to this, from October 1983 to October 1986, Mr. Coelho was president of Castleton, Inc., a company that developed and licensed the ultra-rapid heat transfer technology to ThermoGenesis. Mr. Coelho holds a Bachelor of Science degree in Mechanical Engineering from the University of California, Davis.

**David S. Tierney, M.D.** has served as a member of our board of directors since October 2002. Dr. Tierney has served as the president and chief executive officer of Valera Pharmaceuticals, Inc. a specialty pharmaceutical company, since 2000 and has served as a director since 2001. From January 2000 to August 2000, Dr. Tierney served as President of Biovail Technologies, a division of Biovail Corporation, a Canadian drug delivery company, where he was responsible for all of Biovail’s research and development, regulatory and clinical activities. From March 1997 to January 2000, Dr. Tierney was Senior Vice President of Drug Development at Roberts Pharmaceutical Corporation, where he was responsible for all research and development activities, and for drug development, medical affairs, worldwide regulatory affairs and chemical process development, as well as being part of the executive management team. From December 1989 to March 1997, Dr. Tierney was employed by Élan Corporation, a pharmaceutical company, in a variety of management positions. Dr. Tierney received his medical degree from the Royal College of Surgeons in Dublin, Ireland and was subsequently trained in internal medicine.

**Milton J. Wallace** became a member of our board of directors in October 2002. Mr. Wallace was a practicing attorney in Miami, Florida for over 40 years until 2005, when he retired. Mr. Wallace served as co-founder and chairman of Renex Corporation, a provider of kidney dialysis services, from July 1993 to February 2000, when that company was acquired by National Nephrology Associates, Inc. Mr. Wallace also was the co-founder and a director of Home Intensive Care, Inc., a provider of home infusion and dialysis services, from 1985 to July 1993, when that company was acquired by W.R. Grace & Co. Mr. Wallace was chairman of the board of directors of Med/Waste, Inc., an entity engaged in the business of medical waste, from June 1993 until February 13, 2002, when that company filed a voluntary bankruptcy petition under federal bankruptcy laws. Mr. Wallace currently serves as chairman of the board of directors of Renal CarePartners, Inc., as Vice Chairman of Preferred Care Partners, and as a member of the board of directors of Imperial Industries, Inc.

**Jack Weinstein** has served as a consultant to us and as our Chief Financial Officer since October 2004. For the last 20 years Mr. Weinstein has primarily been employed as an investment banker with various firms. From 2002 to 2004, Mr. Weinstein was with, and he currently is a licensed agent of, The Avalon Group, Ltd., a broker-dealer. From 1999 to 2002, Mr. Weinstein was employed by Ladenburg Thalmann & Co., Inc. From 1994 to 1999, Mr. Weinstein was employed by Gruntal & Co., LLC. Mr. Weinstein earned a Bachelors Degree from the University of Miami in 1979 and a Masters in Business Administration from Harvard University Graduate School of Business Administration in 1983.

**M. Douglas Winship** joined us in July 2006 as our Vice President of Regulatory Operations. Mr. Winship has worked in regulatory affairs in the healthcare industry for 30 years. From 2004 to 2005, Mr. Winship was vice president — quality assurance and regulatory affairs for Argos Therapeutics, Inc., a biotechnology company developing immuno therapy treatments for cancer, in Durham, North Carolina. Previously, Mr. Winship was employed by CEL-SCI Corp., a biotechnology company developing immune system based treatments, in Vienna, VA, from 1998 to 2002 as senior vice president — regulatory affairs and

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quality assurance, and from 1994 through 1998 as vice president — regulatory affairs and quality assurance. From 1998 to 1994, Mr. Winship was employed by Curative Technologies, Inc., a health-care company involved in the wound-healing market, first as director of regulatory affairs and quality assurance and later as vice president of Regulatory Affairs and Quality Assurance. Mr. Winship earned his Bachelor of Science in chemistry from Upsala College in 1971.

**Charles W. Gorodetzky, M.D., Ph.D.**, became our Chief Medical Officer in September 2006. Dr. Gorodetzky has more than 43 years of experience in pharmacology, drug development, clinical trials and addiction medicine. From 1999 to 2005, Dr. Gorodetzky was employed by Quintiles, Inc. in a variety of management positions, including serving as a Vice President in the Medical and Scientific Services Department. While at Quintiles, he had extensive experience with designing, organizing and managing large multi-center clinical trials in a variety of central-nervous system (CNS) indications, abuse liability, substance abuse treatment and smoking cessation. Prior to joining Quintiles, from 1994 to 1998 Dr. Gorodetzky was a Vice President of Hoechst Marion Roussel, Inc. (formerly Marion Merrell Dow), serving as Global Head of CNS Development, Head of Clinical Research North America and North American Medical Advisor. Dr. Gorodetzky has been directly involved in the clinical development of vigabatrin since 1995, first as the primary responsible development person at Hoechst Marion Rousell (HMR) (now Sanofi Aventis) and then as the person at Quintiles working with HMR in the development of vigabatrin. Prior to joining HMR, Dr. Gorodetzky was employed by several pharmaceutical companies in management positions, with an emphasis on developing smoking cessation therapies and anti-epileptic drugs. From 1963 to 1984, Dr. Gorodetzky was on the staff at the National Institute on Drug Abuse, Addiction Research Center, serving in his last position as the final director of NIDA's Lexington facility.

### **Board Composition**

Our board of directors consists of six directors, each serving a one-year term expiring at the next annual meeting of stockholders. The board will satisfy all criteria for independence established by the Nasdaq Global Market, or Nasdaq, and other governing laws and regulations. No director will be deemed to be independent unless the board affirmatively determines that the director has no material relationship with us directly, or as an officer, stockholder or partner of an organization that has a relationship with us.

### **Board Committees**

Upon the completion of this offering, the standing committees of our board of directors will consist of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. These committees are described below. Our board of directors may also establish various other committees to assist it in its responsibilities.

### **Audit Committee**

The Audit Committee is primarily concerned with the accuracy and effectiveness of the audits of our financial statements by our independent auditors. Its duties include:

- selecting independent auditors;
- reviewing the scope of the audit to be conducted by them and the results of their audit;
- approving non-audit services provided to us by the independent auditor;
- reviewing the integrity, adequacy and effectiveness of our financial reporting process and internal controls; assessing our financial reporting practices, including the disclosures in our annual and quarterly reports and the accounting standards and principles followed; and
- conducting other reviews relating to compliance by our employees with our policies and applicable laws.

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Currently, the Audit Committee is comprised of Messrs. Wallace, Huckel and Tierney, each of whom is independent as defined under Nasdaq rules. Mr. Wallace currently serves as Chairman of the committee. The board of directors has determined that Mr. Wallace qualifies as "audit committee financial expert" as that term is defined under the rules of the Securities and Exchange Commission, or SEC.

### **Compensation Committee**

This Compensation Committee's primary responsibility is to discharge our board of director's responsibilities relating to compensation of our senior executives. Its duties include:

- developing guidelines and reviewing the compensation and performance of our executive officers;
- setting the compensation of the chief executive officer and evaluating his performance based on corporate goals and objectives;
- making recommendations to the board of directors with respect to incentive compensation plans, equity-based plans and deferred compensation plans; and
- reviewing director compensation levels and practices, and recommending, from time to time, changes in such compensation levels and practices to the board of directors.

Currently, the Compensation Committee is comprised of Messrs. O'Keeffe and Coelho, each of whom is independent as defined under Nasdaq rules.

### **Nominating and Corporate Governance Committee**

The Nominating and Corporate Governance Committee's responsibilities include the selection of potential candidates for our board of directors and the development and annual review of our governance principles. This committee also annually reviews director compensation and benefits, and oversees the annual self-evaluations of our board of directors and its committees. It also makes recommendations to our board of directors concerning the structure and membership of the other board committees.

The Nominating and Corporate Governance Committee is comprised of all of our outside directors, each of whom is independent as defined under Nasdaq rules.

### **Compensation Committee Interlocks and Insider Participation**

None of the members of our Compensation Committee were at any time an officer or employee of ours. In addition, none of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or Compensation Committee, except that Mr. McEnany serves on the compensation committee of ThermoGenesis, the Chief Executive Officer of which is Mr. Coelho.

### **Compensation of Directors**

Our directors currently do not receive, and have not received, any cash compensation for serving on our board. Directors are eligible to receive stock options and restricted share grants of our common stock under our 2006 Stock Incentive Plan. No options or restricted shares have been granted to our directors to date.

### **Executive Compensation**

#### *Current and historic compensation paid to executives and consultants*

Prior to 2005, Mr. McEnany received no compensation for serving as our Chief Executive Officer. In January 2005, we entered into an employment agreement with Mr. McEnany under which he was to receive an annual salary of \$100,000 per annum. We also agreed to pay for Mr. McEnany's health insurance, which costs

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us less than \$10,000 per year. However, Mr. McEnany agreed to defer 50% of his annual salary until such time as we procured financing and raised gross proceeds of at least \$2.0 million; Mr. McEnany subsequently agreed to defer 100% of his compensation until such financing was obtained. In fact, Mr. McEnany received no compensation in 2002, 2003, 2004 and 2005 for his services. However, in July 2006, after we completed our private placement, Mr. McEnany was paid all deferred compensation, aggregating \$125,000. We intend to enter into a new employment agreement with Mr. McEnany which shall become effective upon the completion of this offering.

In October 2004, we entered into a consulting agreement with Mr. Weinstein. Under the terms of the consulting agreement, as amended, Mr. Weinstein receives a monthly consulting fee of \$7,500. In addition, Mr. Weinstein will receive a fee in the amount of approximately \$150,000 from the proceeds of this offering. See "Certain Relationships and Related Transactions." We intend to enter into an employment agreement with Mr. Weinstein which will become effective upon the completion of this offering.

In January 2005, we entered into a consulting agreement with Mr. O'Keeffe under which we pay him a monthly consulting fee of \$5,000, payable \$2,500 in cash and \$2,500 in shares of our common stock valued at \$1.37 per share. We also pay consulting fees to several members of our scientific advisory board, as follows: Dr. Dewey (\$1,500 per month), Dr. Jasinski (\$1,500 per month), and Dr. Brodie (\$1,000 per month).

Mr. Winship is paid a base salary of \$180,000 per annum for serving as our Vice President of Regulatory Operations. He also will have the opportunity to earn bonuses of up to 20% of his base salary by meeting performance objectives approved by the Compensation Committee of the Board.

In September 2006, we entered into an employment agreement with Mr. Gorodetzky. Mr. Gorodetzky's contract provides that he will contribute at least 10 hours per week to our business, a minimum of 40 hours per month or 120 hours per quarter. Mr. Gorodetzky is paid \$250 per hour for his services. Mr. Gorodetzky is paid \$200 per hour for services above and beyond 120 hours per quarter. In addition, Mr. Gorodetzky has been granted stock options under our 2006 Stock Incentive Plan to purchase 21,888 shares of our common stock, at an exercise price equal to the public offering price in this offering. These options will vest in equal installments over a 3-year period beginning on September 1, 2007.

### *Post-offering compensation for Messrs. McEnany and Weinstein*

We intend to enter into employment agreements with Messrs. McEnany and Weinstein which shall become effective upon completion of this offering. Under these agreements, Messrs. McEnany and Weinstein will receive base salaries of \$315,000 and \$200,000, respectively, and bonus compensation based on performance. Each employment agreement will also contain a "change of control" severance arrangement if the employee is not retained in our employment after a change of control.

## **Stock Options and Stock Incentive Plans**

### *Currently outstanding stock options*

In each of July 2002 and March 2005, we issued options to purchase 364,805 shares of our common stock to each of Mr. McEnany and Dr. Huckel (options to purchase 1,459,220 shares in the aggregate). These options are currently vested, expire ten years after their grant dates, and have an exercise price of \$0.69 per share.

In 2004 and 2005, we issued options to purchase shares of our common stock to Messrs. Weinstein and O'Keeffe. Mr. O'Keeffe holds options to purchase 291,844 shares of our common stock at an exercise price of \$1.37 per share. Mr. O'Keeffe's options expire in January 2010. Mr. Weinstein holds options to purchase 437,766 shares of our common stock, 291,844 of which are at an exercise price of \$1.37 per share (145,922 expire in October 2009 and 145,922 expire in March 2010) and 145,922 of which are at an exercise price of \$2.98 per

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share (72,961 expire in October 2009 and 72,961 expire in March 2010). All of the options held by Messrs. Weinstein and O’Keeffe are fully vested.

In July 2006, we issued five-year options to purchase 145,922 shares of our common stock to Mr. Winship. These options will vest over a four-year period and have an exercise price of \$2.98 per share.

The following table sets forth the number and value of securities underlying unexercised options held by our named executive officers at December 31, 2005. Because there was no public market for our common stock as of December 31, 2005, amounts described in the following table under the heading “Value of Unexercised In-the-Money Options at December 31, 2005” are determined by multiplying the number of shares issued or issuable upon exercise of the option by the difference between the assumed initial public offering price of \$12.00 per share, which is the midpoint of the range set forth on the cover, and the per share option exercise price. In 2005, none of our named executive officers exercised any options.

Name	Number of Unexercised Options at December 31, 2005		Value of Unexercised In-the-money Options at December 31, 2005 (\$) <sup>(1)</sup>	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Patrick J. McEnany	729,609	–	8,251,878	–
Jack Weinstein	291,844	145,922	3,102,302	1,316,216

(1) Based upon an assumed initial public offering price of \$12.00 per share, which is the midpoint of the range set forth on the cover of this prospectus.

*The 2006 Stock Incentive Plan*

*Overview.* Our board of directors has recently approved the 2006 Stock Incentive Plan (the “2006 plan”), and we anticipate that our stockholders will approve the 2006 plan prior to this offering. We have reserved 2,188,828 shares for issuance under the 2006 plan. To date, options to acquire 21,888 shares have been granted under the 2006 plan. The purpose of the 2006 plan is to continue to advance our interests by allowing us to attract, retain, reward, and motivate individuals eligible under the 2006 plan to strive for our continued success by giving them additional opportunities to purchase further equity stakes in our company.

*Administration.* The Compensation Committee of our board of directors will administer the 2006 plan and will determine which persons will receive grants of awards and the type of award to be granted to such persons. The Compensation Committee will also interpret the provisions of the 2006 plan and make all other determinations that it deems necessary or advisable for the administration of the 2006 plan.

*Eligibility.* All eligible individuals will be able to participate in the 2006 plan. Eligible individuals include our directors, officers, employees, independent contractors and consultants, as well as individuals who have accepted an offer of employment with us.

*Transferability of awards.* Awards are non-transferable other than by will or by the laws of descent and distribution or as otherwise expressly allowed by the Compensation Committee pursuant to a gift to members of an eligible person’s immediate family. The gift may be directly or indirectly transferred, by means of a trust, partnership, or otherwise. Stock options and SARs may be exercised only by the optionee, any such permitted transferee or a guardian, legal representative or beneficiary.

*Change of control.* If there is a change in control of Catalyst Pharmaceutical Partners, Inc., any award that is not exercisable and vested may immediately become exercisable and vested in the sole and absolute discretion of the Compensation Committee. Vested awards will be deemed earned and payable in full. The Compensation Committee may also terminate the awards, entitling participants to a cash payment. If we are liquidated or dissolved, awards may also be converted into the right to receive liquidation proceeds. In the event that the Compensation Committee does not terminate or convert an award upon a change of control, then the

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award will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation.

*Amendments, modifications and termination.* Our board of directors may, at any time, amend, suspend or terminate the 2006 plan, but the board may not impair the rights of holders of outstanding awards without the holder's consent. No amendment to the 2006 plan may be made without consent of our stockholders. In the event that an award is granted to a person residing outside of the United States, the board may, at its discretion, modify the terms of the agreement to comply with the laws of the country of which the eligible individual is a resident. The 2006 plan will terminate 10 years after its effective date.

**OUR PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding the beneficial ownership of our common stock as of the date of this prospectus by:

- each person or entity who we know beneficially owns more than 5% of our outstanding common stock;
- each of our directors and executive officers; and
- all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the U.S. Securities and Exchange Commission and includes voting or investment power with respect to the shares. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days of the date of this prospectus are deemed outstanding and included in the number of shares beneficially owned, while those shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Except as otherwise indicated, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Applicable percentage ownership in this table is based on 9,166,667 shares of common stock outstanding as of the date of this prospectus, giving pro forma effect to the automatic conversion of all outstanding shares of our preferred stock into 2,136,880 shares of common stock, and 12,166,667 shares of common stock outstanding immediately after the completion of this offering. The address for each shareholder listed in the table is c/o Catalyst Pharmaceutical Partners, Inc., 220 Miracle Mile, Suite 234, Coral Gables, Florida 33134.

	Shares Owned	Percentage Owned	
		Before Offering	After Offering
Patrick J. McEnany <sup>(1)(2)</sup>	3,949,741	39.9%	30.6%
Hubert Huckel, M.D. <sup>(2)</sup>	1,878,744	19.0	14.6
Jonathan Brodie	459,654	5.0	3.8
Philip H. Coelho	218,883	2.4	1.8
Charles B. O’Keeffe <sup>(3)</sup>	324,676	3.4	2.6
David S. Tierney, M.D.	182,402	2.0	1.5
Milton J. Wallace <sup>(5)</sup>	313,732	3.4	2.6
Jack Weinstein <sup>(4)</sup>	437,766	4.6	3.6
M. Douglas Winship <sup>(6)</sup>	—	—	—
All officers and directors as a group (8 persons)	7,305,944	64.3	50.9

(1) Includes 145,922 shares owned by Mr. McEnany’s wife.

(2) Includes options to purchase 729,609 shares of our common stock at a price of \$0.69 per share.

(3) Includes options to purchase 291,844 shares of our common stock at a price of \$1.37 per share.

(4) Includes options to purchase 437,766 shares of our common stock, of which options to purchase 291,844 shares are exercisable at a price of \$1.37 per share and options to purchase 145,922 shares are exercisable a price of \$2.98 per share.

(5) Includes 29,184 shares owned by Biscayne National Corp. Mr. Wallace is the president of Biscayne National Corp.

(6) Excludes options to purchase 145,922 shares of our common stock exercisable at a price of \$2.98 per share, none of which have vested or will vest within 60 days of the date of this prospectus.



#### **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Effective May 2006, we amended our consulting agreement with Jack Weinstein, our Chief Financial Officer. Pursuant to the consulting agreement, as amended, Mr. Weinstein receives a monthly consulting fee of \$7,500. As part of Mr. Weinstein's consulting arrangement with us, he also received five-year options to purchase an aggregate of 437,766 shares of our common stock, all of which are currently exercisable. Options to purchase 291,844 shares of our common stock have an exercise price of \$1.37 per share, and options to purchase 145,922 shares of our common stock have an exercise price of \$2.98 per share.

In addition, Mr. Weinstein will receive a success fee of approximately \$150,000 upon the completion of this offering. Pursuant to the agreement, \$2,500 of the monthly consulting fees payable to Mr. Weinstein after April 30, 2006 are being applied towards this fee. The May 2006 consulting agreement amended the previous agreement dated October 2004 pursuant to which Mr. Weinstein received a monthly consulting fee of \$5,000, in addition to the stock options described above.

## DESCRIPTION OF OUR CAPITAL STOCK

Our authorized capital currently consists of 100,000,000 shares of common stock, par value \$.001 per share, and 5,000,000 shares of preferred stock, par value \$.001 per share. As of the date of this prospectus, we had 9,166,667 shares of common stock outstanding giving pro forma effect to the automatic conversion of all outstanding shares of our preferred stock into 2,136,880 shares of common stock. At this date, 70,000 shares of our Series A Preferred Stock and 7,644 shares of our Series B Preferred Stock are outstanding. All share and per share information contained in this prospectus assumes conversion of the currently outstanding Series A Preferred Stock and Series B Preferred Stock into common stock at the closing of this offering.

We were incorporated in Delaware in July 2006. We are the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation ("CPP-Florida"), which was incorporated in the State of Florida in January 2002. Our merger with CPP-Florida was completed on September 7, 2006.

The description below of our capital stock reflects information about Catalyst Pharmaceutical Partners, Inc., a Delaware corporation. Such information is a summary and is qualified in its entirety by our Certificate of Incorporation and our By-laws. Copies of our Certificate of Incorporation and By-laws are filed as exhibits to our registration statement, of which this prospectus forms a part.

### Common Stock

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

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

### Preferred Stock

Our board of directors is authorized, without further stockholder action, to divide any or all shares of the authorized preferred stock into series and fix and determine the designations, preferences and relative rights and qualifications, limitations, or restrictions thereon of any series so established, including voting powers, dividend rights, liquidation preferences, redemption rights and conversion privileges.

Any further issuances of preferred stock with voting rights or conversion rights may adversely affect the voting power of common stock, including the loss of voting control to others. The issuance of preferred stock may have the effect of delaying, deferring, or preventing a change of control.

### Provisions of the Certificate and the By-laws

A number of provisions of our certificate of incorporation and by-laws concern matters of corporate governance and the rights of stockholders. Certain of these provisions, as well as the ability of our board of directors to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof, may be deemed to have an anti-takeover effect and may discourage takeover attempts not first approved by the board of directors (including takeovers which certain stockholders may deem to be in their best interests). To the

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extent takeover attempts are discouraged, temporary fluctuations in the market price of the common stock, which may result from actual or rumored takeover attempts, may be inhibited. These provisions, together with the classified board of directors (which we are proposing to declassify) and the ability of the board to issue preferred stock without further stockholder action, also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders, even if such removal or assumption would be beneficial to our stockholders. These provisions also could discourage or make more difficult a merger, tender offer or proxy contests, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of the common stock. The board of directors believes that these provisions are appropriate to protect the interest of us and all of our stockholders.

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

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

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

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

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

## **Provisions of Delaware Law**

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

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

Section 203 defines "business combination" to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

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

## **Transfer Agent**

The transfer agent for our common stock is Continental Stock Transfer & Trust Company, 17 Battery Place, 8th Floor, New York, New York 10004. Continental Stock Transfer & Trust Company can be reached at (212) 509-4000.

## SHARES ELIGIBLE FOR FUTURE SALE

### General

Upon completion of this offering, there will be 12,166,667 shares of our common stock outstanding. Of the shares which will be outstanding after the offering:

- all 3,000,000 shares of common stock sold in the offering will be freely tradeable;
- 4,059,551 shares will be “restricted securities” held by non-affiliates; and
- 5,117,116 shares will be held by our executive officers and directors.

The restricted securities described above are eligible for sale in the public market, subject to volume limitations, manner of sale provisions and other requirements of Rule 144, from time to time.

### Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned “restricted securities” for at least one year, including an affiliate, is entitled to sell, within any three-month period, a number of shares that does not exceed the greater of:

- one percent of the then outstanding shares of our common stock (approximately 121,667 shares immediately following the offering); or
- the average weekly trading volume during the four calendar weeks preceding filing of notice of such sale.

A person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the 90 days preceding a sale and who owns shares that were acquired from us or an affiliate of ours for at least two years prior to the proposed sale is entitled to sell such shares pursuant to Rule 144(k) without regard to the volume limitations, manner of sale provisions or other limitations of Rule 144.

Shares held by our executive officers and directors may be sold in the public market, subject to the volume, manner of sale and other limitations of Rule 144, but may not be sold in reliance upon Rule 144(k).

### Lock-up Agreements

In addition to the limits placed on the sale of shares of our common stock by operation of Rule 144 and other provisions of the Securities Act of 1933, as amended, we, our directors and executive officers and holders of approximately 96% of our common stock (assuming the automatic conversion of all of our shares of Series A Preferred Stock and Series B Preferred Stock upon the closing of this offering), have entered into lock-up agreements with the underwriters. Under these agreements, subject to certain, limited exceptions, we may not issue any new shares of common stock, and those holders of stock may not, directly or indirectly, offer, sell, contract to sell, pledge or otherwise dispose of or hedge any common stock or securities convertible into or exchangeable for shares of common stock, or publicly announce the intention to do any of the foregoing, without the prior written consent of First Albany Capital, Inc. for a period of 180 days from the date of this prospectus. This consent may be given at any time without public notice. If we issue an earnings release or material news or a material event relating to us occurs during the 15 calendar days plus 3 business days before the last day of the lock-up period, or if prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16 days following the last day of the lock-up period, the restrictions provided in the lock-up agreements will continue to apply until 15 calendar days plus 3 business days after the issuance of the earnings release or the occurrence of material news or a material event. Also, during this 180-day period, we have agreed not to file any registration statement for, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock without the prior written consent of First Albany Capital Inc.

## **MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following is a general discussion of the material U.S. federal income and estate tax consequences of the ownership and disposition of our common stock by a non-U.S. holder that acquires our common stock pursuant to this offering. The discussion is based on provisions of the Internal Revenue Code of 1986, as amended (the "Code"), applicable U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations, all as in effect on the date of this prospectus, and all of which are subject to change, possibly on a retroactive basis. The discussion is limited to non-U.S. holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). As used in this discussion, the term "non-U.S. holder" means a beneficial owner of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (including any entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any State of the United States or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (1) if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust, or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If a partnership or other pass-through entity holds common stock, the tax treatment of a partner or member in the partnership or other entity will generally depend on the status of the partner or member and upon the activities of the partnership or other entity. This discussion does not address the U.S. federal income or estate tax consequences applicable to any person who holds our common stock through a partnership or other entity treated as a partnership, or any other form of pass-through-through entity, for U.S. federal tax purposes or the tax consequences to such partnership or other entity. Accordingly, we urge partnerships and other pass-through entities which hold our common stock and partners and members in these partnerships and other entities to consult their tax advisors.

This discussion also does not consider:

- U.S. federal gift tax consequences, or any U.S. state or local or non-U.S. tax consequences;
- the tax consequences for the stockholders or beneficiaries of a non-U.S. holder;
- any U.S. federal tax considerations that may be relevant to a non-U.S. holder in light of its particular circumstances or to non-U.S. holders that may be subject to special treatment under U.S. federal tax laws, such as financial institutions, insurance companies, tax exempt organizations, certain trusts, hybrid entities, certain former citizens or residents of the United States, holders subject to the U.S. federal alternative minimum tax, broker-dealers, controlled foreign corporations, passive foreign investment companies, and dealers and traders in securities; or
- special tax rules that may apply to a non-U.S. holder that holds our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security," or other integrated investment.

**This discussion is for general purposes only. Prospective investors are urged to consult their own tax advisors regarding the application of the U.S. federal income and estate tax laws to their particular situations and the consequences under U.S. federal gift tax laws, as well as foreign, state, and local laws and tax treaties.**

## **Dividends**

As previously discussed, we do not anticipate paying dividends on our common stock. See “Dividend Policy.” If we pay dividends on our common stock, those payments will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those dividends exceed our current and accumulated earnings and profits, for U.S. federal income tax purposes, the dividends will constitute a return of capital and first reduce the non-U.S. holder’s basis, but not below zero, and then will be treated as gain from the sale of stock.

We will be required to withhold U.S. federal income tax at a rate of 30%, or a lower rate under an applicable income tax treaty, from the gross amount of amounts constituting dividends as determined under U.S. federal income tax principles (as described above) paid to a non-U.S. holder, unless the dividend is effectively connected with the conduct of a trade or business of the non-U.S. holder within the United States and, if an income tax treaty applies, attributable to a permanent establishment of the non-U.S. holder within the United States. Under applicable U.S. Treasury regulations, a non-U.S. holder (including, in certain cases of non-U.S. holders that are entities, the owner or owners of such entities) will be required to satisfy certain certification requirements in order to claim a reduced rate of withholding pursuant to an applicable income tax treaty. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are effectively connected with a non-U.S. holder’s conduct of a trade or business in the United States and, if an income tax treaty applies, attributable to a permanent establishment in the United States, are taxed on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if the non-U.S. holder were a resident of the United States. In such cases, we will not have to withhold U.S. federal income tax if the non-U.S. holder complies with applicable certification and disclosure requirements. In addition, a “branch profits tax” may be imposed at a 30% rate, or a lower rate under an applicable income tax treaty, on dividends received by a foreign corporation that are effectively connected with the foreign corporation’s conduct of a trade or business in the United States.

In order to claim the benefit of an income tax treaty or to claim exemption from withholding because the income is effectively connected with the conduct of a trade or business in the United States (or, if an income tax treaty applies, because the income is effectively connected with the conduct of a trade or business of the non-U.S. holder within the United States through a permanent establishment situated in the United States), the non-U.S. holder must provide a properly executed IRS Form W-8BEN, for treaty benefits, or W-8ECI, for effectively connected income, respectively (or such successor forms as the IRS designates), prior to the payment of dividends. These forms must be periodically updated.

A non-U.S. holder that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for a refund together with the required information with the IRS.

## **Gain on Disposition of Common Stock**

A non-U.S. holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock unless one of the following applies

- the gain is effectively connected with the non-U.S. holder’s conduct of a trade or business in the United States and, if an income tax treaty applies, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the regular graduated rates and in the manner applicable to U.S. persons and, if the non-U.S. holder is a foreign corporation, the “branch profits tax” referred to above may also apply;

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- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met; in this case, unless an applicable income tax treaty provides otherwise, the non-U.S. holder generally will be subject to a 30% U.S. federal income tax on the gain derived from the disposition; or
- our common stock constitutes a United States real property interest by reason of our status as a “United States real property holding corporation,” or a “USRPHC,” for U.S. federal income tax purposes at any time during the shorter of the 5 year period ending on the date of such disposition or the period that the non-U.S. holder held our common stock. While we believe that we are not currently, and will not become, a USRPHC, the determination of whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our other business assets, and accordingly there can be no assurance that we will not become a USRPHC in the future. However, as long as our common stock is “regularly traded on an established securities market” within the meaning of Section 897(c)(3) of the Code, a non-U.S. holder would be subject to U.S. federal income tax on any gain from the sale, exchange or other disposition of our shares of common stock, by reason of USRPHC status, only if such non-U.S. holder, actually or constructively, owned more than 5% of our common stock at some time during the shorter of the periods described above. On the other hand, if we are or were to become a USRPHC and were to fail to qualify as “regularly traded on an established securities market,” then a non-U.S. holder generally would be subject to U.S. federal income tax on net gain derived from the disposition of our common stock at regular graduated rates and may be subject to U.S. federal income tax withholding on the gross proceeds realized with respect to such disposition. A non-U.S. holder may obtain a refund of any such amounts withheld in excess of the non-U.S. holder’s federal income tax liability.

### **Federal Estate Tax**

Shares of our common stock owned or treated as owned by an individual who is a non-U.S. holder at the time of death (including by reason of certain lifetime transfers of interests therein) will be included in the individual’s gross estate for U.S. federal estate tax purposes and, unless an applicable estate tax or other treaty provides otherwise, may be subject to U.S. federal estate tax.

### **Information Reporting and Backup Withholding Tax**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to that holder and the tax withheld from those dividends.

These reporting requirements apply regardless of whether withholding was reduced or eliminated by an applicable income tax treaty. Copies of the information returns reporting those dividends and withholding may also be made available under the provisions of an applicable income tax treaty or agreement to the tax authorities in the country in which the non-U.S. holder is a resident. Under some circumstances, U.S. Treasury regulations require backup withholding and additional information reporting on reportable payments on common stock. The gross amount of dividends paid to a non-U.S. holder that fails to certify its non-U.S. holder status in accordance with applicable U.S. Treasury regulations generally will be reduced by backup withholding at the applicable rate (currently 28%).

In general, backup withholding and information reporting will not apply to the payment of the proceeds of sale or other disposition of common stock made to a non-U.S. holder if the non-U.S. holder provides any required certifications.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder’s U.S. federal income tax liability, if any, provided that the required information is furnished to the IRS in a timely manner.



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These backup withholding and information reporting rules are complex and non-U.S. holders are urged to consult their own tax advisors regarding the application of these rules to them.

**The foregoing discussion of U.S. federal income and estate tax considerations is not tax advice. Accordingly, each prospective non-U.S. holder of our common stock should consult that holder's own tax advisor with respect to the federal, state, local and non-U.S. tax consequences of the ownership and disposition of our common stock.**

## UNDERWRITING

We are offering the shares of our common stock through the underwriters named below. We have applied to have our common stock included for quotation on the Nasdaq Global Market under the symbol "CPRX."

### The Underwriters and the Underwriting Agreement

We and the underwriters named below have entered into an underwriting agreement relating to this offering. First Albany Capital Inc. and Stifel, Nicolaus & Company, Incorporated are the representatives of the underwriters.

The underwriters have severally agreed, subject to the terms and conditions of the underwriting agreement, to purchase from us the number of shares indicated in the following table:

Underwriter	Number of Shares
First Albany Capital Inc. Stifel, Nicolaus & Company, Incorporated	
Total	<u>3,000,000</u>

Except for the underwriters' over-allotment option described below, the underwriters must take and pay for all of the shares, if they take any shares.

We have granted to the underwriters the option to purchase from us up to an additional 450,000 shares of our common stock to cover over-allotments, if any, made in connection with this offering. First Albany Capital Inc., on behalf of the underwriters, may exercise this option at any time, from time to time, on or before the 30th day after the date of this prospectus. If First Albany Capital Inc. exercises this option, the underwriters will each severally purchase shares in approximately the same proportion as set forth in the table above. The underwriters are not obligated to purchase any of these additional shares if they do not exercise their over-allotment option.

We have agreed to indemnify the underwriters and their partners, directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act of 1933, as amended. If we are unable to provide this indemnification, we have agreed to contribute to payments the underwriters and these persons may be required to make in respect of those liabilities.

### Public Offering Price, Commissions and Discounts and Offering Expenses

The underwriters will initially offer the shares to the public at the public offering price set forth on the cover of this prospectus. If all the shares are not sold at this public offering price, the representatives may change the public offering price or any other selling term.

Shares sold by the underwriters to securities dealers may be sold at a discount of up to \$            per share from the public offering price. Any of these securities dealers may resell any shares purchased from the underwriters to other brokers or dealers at a discount of up to \$            per share from the public offering price.

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The table below shows the per share and total underwriting discounts and commissions we will pay to the underwriters, assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 450,000 shares:

	<u>No Exercise</u>	<u>Full Exercise</u>
Per share		
Total		

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately \$1.0 million.

**Lock-Up Agreements**

We, each of our officers and directors, and stockholders owning substantially all of our outstanding common stock have entered into lock-up agreements with the underwriters. Subject to certain exceptions, these lock-up agreements generally prohibit us and each of these persons, without the prior written consent of First Albany Capital Inc., from selling, offering to sell, contracting to sell, hypothecating, pledging, granting an option to purchase or otherwise disposing of any shares of our common stock or securities convertible into or exchangeable or exercisable for common stock or any warrants or other rights to purchase common stock or such securities. These restrictions will be in effect for 180 days after the date of this prospectus. However, if we issue an earnings release or significant news or a significant event relating to us occurs, or if we announce during the 16-day period beginning on the last day the restrictions would otherwise apply, then the restrictions applicable to our officers, directors and stockholders will continue to apply for 15 calendar days plus three business days from the date we issue the earnings release or the date the significant news or event occurs. At any time and without public notice, First Albany Capital Inc. may in its sole discretion release all or some of the securities from these lock-up agreements.

**Stabilization and Short Positions**

In connection with this offering, the underwriters may engage in activities that stabilize, maintain or otherwise affect the price of our common stock. These activities include stabilizing transactions, syndicate short covering and penalty bids. The underwriters may carry out these activities on the Nasdaq Global Market, in the over-the-counter market or otherwise. As a result of these activities, the price of our common stock may be higher than the price that may otherwise exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time.

*Stabilizing Transactions and Syndicate Short Covering.* Stabilizing transactions consist of placing a bid or effecting a purchase for the purpose of pegging, fixing or maintaining the price of a security. Stabilizing activities may include purchases to cover short positions created by short sales. Short sales are sales by the underwriters in excess of the number of shares they are obligated to purchase from us in this offering. Short sales create short positions that can be either "covered" or "naked." A covered short position is a short position in an amount that does not exceed the number of shares the underwriters may purchase from us by exercising their over-allotment option described above. A naked short position is a short position in excess of that amount.

The underwriters may close out a covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In determining the source of shares to close out a covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares by exercising their over-allotment option. The underwriters must close out a naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there

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may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchased shares in this offering.

*Penalty Bids.* The underwriters may impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of that underwriter in stabilizing or short covering transactions.

### **Determination of Offering Price**

Prior to this offering, there was no public market for our common stock. The initial public offering price will be determined by negotiation between us and the representatives of the underwriters. The principal factors to be considered in determining the initial public offering price include:

- the information set forth in this prospectus and otherwise available to representatives;
- our history and prospects, and the history of and prospects for the industry in which we compete;
- our past and present financial performance and an assessment of our management;
- our prospects for future earnings and the present state of our development;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

### **Affiliations**

Certain of the underwriters and their respective affiliates have from time to time performed and may in the future perform various commercial banking, financial advisory and investment banking services for us, for which they have received or will receive customary fees.

## NOTICE TO INVESTORS

### European Economic Area

In relation to the Member States of the European Economic Area (“EEA”), each of which, with the exception of Italy, has implemented the Prospectus Directive, with effect from and including the date on which the Prospectus Directive is implemented in that Member State (the “Relevant Implementation Date”), our common stock will not be offered to the public in that Member State prior to the publication of a prospectus in relation to our common stock that has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, our common stock may be offered to the public in that Member State at any time:

- (a) to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts; or
- (c) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

As used above, the expression “offered to the public” in relation to any of our common stock in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common stock to be offered so as to enable an investor to decide to purchase or subscribe for our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Member State. The “EEA” consists of all of the member states of the European Union, Norway, Iceland and Liechtenstein.

The EEA selling restriction is in addition to any other selling restrictions set out below.

### United Kingdom

Our common stock may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than to persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000 (“FSMA”) with respect to anything done in relation to our common stock in, from or otherwise involving the United Kingdom. In addition, each underwriter has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. Without limitation to the other restrictions referred to herein, this prospectus is directed only at (1) persons outside the United Kingdom; (2) persons having professional experience in matters relating to investments who fall within the definition of “investment professionals” in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005; or (3) high net worth bodies corporate, unincorporated associations and partnerships and trustees of high value trusts as described in Article 49(2) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Without limitation to the other restrictions referred to herein, any investment or investment activity to which this prospectus relates is available only to, and will be engaged in only with, such persons, and persons within the United Kingdom who received this communication (other than persons who fall within (2) or (3) above), should not rely or act upon this communication.

## France

No prospectus (including any amendment or replacement thereto) has been prepared in connection with the offering of our common stock that has been approved by the *Autorité des marchés financiers* or by the competent authority of another State that is a contracting party to the Agreement on the European Economic Area and notified to the *Autorité des marchés financiers*; no common stock has been offered or sold and will be offered or sold, directly or indirectly, to the public in France except to permitted investors ("Permitted Investors") consisting of persons licensed to provide the investment service of portfolio management for the account of third parties, qualified investors (*investisseurs qualifiés*) acting for their own account and/or corporate investors meeting one of the four criteria provided in Article 1 of Decree N° 2004-1019 of September 28, 2004 and belonging to a limited circle of investors (*cercle restreint d'investisseurs*) acting for their own account, with "qualified investors" and "limited circle of investors" having the meaning ascribed to them in Article L. 411-2 of the French *Code Monétaire et Financier* and applicable regulations thereunder; none of this prospectus or any other materials related to the offer or information contained therein relating to our common stock has been released, issued or distributed to the public in France except to Permitted Investors; and the direct or indirect resale to the public in France of any common stock acquired by any Permitted Investors may be made only as provided by articles L. 412-1 and L. 621-8 of the French *Code Monétaire et Financier* and applicable regulations thereunder.

## Italy

The offering of shares of our common stock has not been cleared by the Italian Securities Exchange Commission (*Commissione Nazionale per le Società e la Borsa*, the "CONSOB") pursuant to Italian securities legislation and, accordingly, shares of our common stock may not and will not be offered, sold or delivered, nor may or will copies of this prospectus or any other documents relating to shares of our common stock or the offering be distributed in Italy other than to professional investors (*operatori qualificati*), as defined in Article 31, paragraph 2 of CONSOB Regulation No. 11522 of July 1, 1998, as amended ("Regulation No. 11522").

Any offer, sale or delivery of shares of our common stock or distribution of copies of this prospectus or any other document relating to shares of our common stock or the offering in Italy may and will be effected in accordance with all Italian securities, tax, exchange control and other applicable laws and regulations, and, in particular, will be: (i) made by an investment firm, bank or financial intermediary permitted to conduct such activities in Italy in accordance with the Legislative Decree No. 385 of September 1, 1993, as amended (the "Italian Banking Law"), Legislative Decree No. 58 of February 24, 1998, as amended, Regulation No. 11522, and any other applicable laws and regulations; (ii) in compliance with Article 129 of the Italian Banking Law and the implementing guidelines of the Bank of Italy; and (iii) in compliance with any other applicable notification requirement or limitation which may be imposed by CONSOB or the Bank of Italy.

Any investor purchasing shares of our common stock in the offering is solely responsible for ensuring that any offer or resale of shares of common stock it purchased in the offering occurs in compliance with applicable laws and regulations.

This prospectus and the information contained herein are intended only for the use of its recipient and are not to be distributed to any third party resident or located in Italy for any reason. No person resident or located in Italy other than the original recipients of this document may rely on it or its content.

In addition to the above (which shall continue to apply to the extent not inconsistent with the implementing measures of the Prospective Directive in Italy), after the implementation of the Prospectus Directive in Italy, the restrictions, warranties and representations set out under the heading "European Economic Area" above shall apply to Italy.

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**Spain**

Neither the common stock nor this prospectus have been approved or registered in the administrative registries of the Spanish National Securities Exchange Commission (*Comisión Nacional del Mercado de Valores*). Accordingly, our common stock may not be offered in Spain except in circumstances which do not constitute a public offer of securities in Spain within the meaning of articles 30bis of the Spanish Securities Markets Law of 28 July 1988 (*Ley 24/1988, de 28 de Julio, del Mercado de Valores*), as amended and restated, and supplemental rules enacted thereunder.

**Sweden**

This is not a prospectus under, and has not been prepared in accordance with the prospectus requirements provided for in, the Swedish Financial Instruments Trading Act (*lagen (1991:980) om handel med finansiella instrument*) nor any other Swedish enactment. Neither the Swedish Financial Supervisory Authority nor any other Swedish public body has examined, approved, or registered this document.

**Switzerland**

The common stock may not and will not be publicly offered, distributed or re-distributed on a professional basis in or from Switzerland and neither this prospectus nor any other solicitation for investments in our common stock may be communicated or distributed in Switzerland in any way that could constitute a public offering within the meaning of Articles 1156 or 652a of the Swiss Code of Obligations or of Article 2 of the Federal Act on Investment Funds of March 18, 1994. This prospectus may not be copied, reproduced, distributed or passed on to others without the underwriter's prior written consent. This prospectus is not a prospectus within the meaning of Articles 1156 and 652a of the Swiss Code of Obligations or a listing prospectus according to article 32 of the Listing Rules of the Swiss Exchange and may not comply with the information standards required thereunder. We will not apply for a listing of our common stock on any Swiss stock exchange or other Swiss regulated market and this prospectus may not comply with the information required under the relevant listing rules. The common stock offered hereby has not and will not be registered with the Swiss Federal Banking Commission and has not and will not be authorized under the Federal Act on Investment Funds of March 18, 1994. The investor protection afforded to acquirers of investment fund certificates by the Federal Act on Investment Funds of March 18, 1994 does not extend to acquirers of our common stock.

**LEGAL MATTERS**

Our counsel, Akerman Senterfitt, in Miami, Florida, will pass on the validity of shares of common stock offered by this prospectus. Philip B. Schwartz, a shareholder of Akerman Senterfitt, is our corporate secretary and currently owns 131,330 shares of our outstanding common stock. Dewey Ballantine LLP, New York, New York is counsel to the underwriters in connection with this offering.

**EXPERTS**

Grant Thornton LLP, our independent registered public accounting firm, has audited our financial statements as set forth in their report, which is included herein. We have included our financial statements in this prospectus in reliance on such report, given on the authority of Grant Thornton LLP as experts in accounting and auditing in giving said report.

#### **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act that registers the shares of our common stock to be sold in this offering. This prospectus does not contain all of the information set forth in the registration statement with the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessary complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed with the SEC. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

The reports and other information we file with the SEC can be read and copied at the SEC's Public Reference Room at 100 F. Street, N.E., Washington, D.C. 20549. Copies of these materials can be obtained at prescribed rates from the SEC's Public Reference Room at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. The SEC also maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. Upon completion of this offering, we will become subject to the reporting and information requirements of the Securities Exchange Act of 1934, and, as a result, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspecting and copying at the SEC's public reference room and the website of the SEC referred to above.



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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors  
Catalyst Pharmaceutical Partners

We have audited the accompanying balance sheets of Catalyst Pharmaceutical Partners, Inc. (a Development Stage Company) (the "Company") as of December 31, 2005 and 2004, and the related statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005 and the period from January 4, 2002 (date of inception) through December 31, 2005. 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. An audit includes 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, 2005 and 2004, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2005 and the period from January 4, 2002 (date of inception) through December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

Miami, Florida  
July 24, 2006  
(except for Note 13(c) as to which  
the date is October 3, 2006)

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

	December 31,	
	2005	2004
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 771,127	\$ 183,911
Prepaid insurance	440	-
Total current assets	771,567	183,911
Property and equipment, net	4,031	1,465
Deposits	13,852	-
Total assets	<u>\$ 789,450</u>	<u>\$ 185,376</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 67,753	\$ 30,734
Accrued expenses	275,235	37,066
Total current liabilities	342,988	67,800
Commitments and contingencies (See notes)	-	-
Stockholders' equity		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, 70,000 shares Series A Preferred Stock issued and outstanding	700	700
Common stock, \$.01 par value, 30,000,000 shares authorized, 6,887,513 shares issued and outstanding at December 31, 2005 and 2,918,438 shares issued and outstanding at December 31, 2004	68,875	29,184
Additional paid-in capital	3,406,647	1,312,072
Deficit accumulated during the development stage	(3,029,760)	(1,224,380)
Total stockholders' equity	446,462	117,576
Total liabilities and stockholders' equity	<u>\$ 789,450</u>	<u>\$ 185,376</u>

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

**CATALYST PHARMACEUTICAL PARTNERS, INC.**  
**(a development stage company)**  
**STATEMENTS OF OPERATIONS**

	Years Ended December 31,			Cumulative Period from January 4, 2002 (date of inception) through December 31, 2005
	2005	2004	2003	
Revenues	\$ —	\$ —	\$ —	\$ —
Operating costs and expenses:				
Research and development	1,462,889	378,254	268,829	2,247,652
General and Administrative	359,279	164,704	165,483	807,731
Total operating costs and expenses	<u>1,822,168</u>	<u>542,958</u>	<u>434,312</u>	<u>3,055,383</u>
Loss from operations	(1,822,168)	(542,958)	(434,312)	(3,055,383)
Interest income	16,788	3,138	5,697	25,623
Loss before income taxes	(1,805,380)	(539,820)	(428,615)	(3,029,760)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (1,805,380)</u>	<u>\$ (539,820)</u>	<u>\$ (428,615)</u>	<u>\$ (3,029,760)</u>
Loss per share-basic and diluted	<u>\$ (0.29)</u>	<u>\$ (0.18)</u>	<u>\$ (0.15)</u>	
Weighted Average Shares outstanding — basic and diluted	<u>6,204,918</u>	<u>2,918,438</u>	<u>2,918,438</u>	

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

**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, 2005

	Preferred Stock	Common Stock	Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at January 4, 2002 (date of inception)</b>	\$ —	\$ 21,908	\$ 78,092	\$ —	\$ 100,000
Issuance of common stock	—	7,276	117,724	—	125,000
Issuance of stock options for services	—	—	75,833	—	75,833
Net loss	—	—	—	(255,945)	(255,945)
<b>Balance at December 31, 2002</b>	—	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)
<b>Balance at December 31, 2003</b>	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)
<b>Balance at December 31, 2004</b>	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)
<b>Balance at December 31, 2005</b>	<u>\$ 700</u>	<u>\$ 68,875</u>	<u>\$ 3,406,647</u>	<u>\$ (3,029,760)</u>	<u>\$ 446,462</u>

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

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

	For the Years Ended December 31,			Cumulative period from January 4, 2002 (date of inception) through December 31, 2005
	2005	2004	2003	
<b>Operating Activities:</b>				
Net loss	\$ (1,805,380)	\$ (539,820)	\$ (428,615)	\$ (3,029,760)
Reconciliation of net loss to net cash used in operating activities:				
Depreciation	1,374	366	-	1,740
Stock-based compensation	1,172,750	294,833	95,733	1,659,249
(Increase) in other prepaid expenses and deposits	(14,292)	-	-	(14,292)
(Decrease) increase in Accounts Payable	37,019	14,436	(50,403)	67,752
Increase (decrease) in accrued expenses	153,169	(335)	17,501	170,236
Net cash used in operating activities	<u>(455,360)</u>	<u>(230,520)</u>	<u>(365,784)</u>	<u>(1,145,075)</u>
<b>Investing Activities:</b>				
Capital Expenditures	(3,940)	(1,831)	-	(5,771)
Net cash used in investing activities	<u>(3,940)</u>	<u>(1,831)</u>	<u>-</u>	<u>(5,771)</u>
<b>Financing Activities:</b>				
Proceeds from issuance of common stock	1,046,516	-	4,500	1,151,516
Proceeds from issuance of preferred stock	-	-	670,457	670,457
Net cash provided by financing activities	<u>1,046,516</u>	<u>-</u>	<u>674,957</u>	<u>1,821,973</u>
Net increase in cash and cash equivalents	587,216	(232,351)	309,173	671,127
Cash and cash equivalents — beginning of period	183,911	416,262	107,089	100,000
Cash and cash equivalents — end of period	<u>\$ 771,127</u>	<u>\$ 183,911</u>	<u>\$ 416,262</u>	<u>\$ 771,127</u>
Supplemental disclosures of cash flow information:				
Cash paid during the year for interest	-	-	-	-
Cash paid during the year for income taxes	-	-	-	-

**Non-cash financing activities:**

In 2005, 2004, 2003, and during the period from January 4, 2002 (date of inception) through December 31, 2005, the Company recorded compensation expense of \$1,067,750, \$294,833, \$75,833 and \$1,514,249, respectively, related to the issuance of stock options to non-employees.

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

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

**1. Organization and Description of Business**

Catalyst Pharmaceutical Partners, Inc. (the "Company") is a development-stage specialty pharmaceutical company focused on the acquisition, development and commercialization of prescription drugs for the treatment of drug addiction. The Company was incorporated in the State of Florida on January 4, 2002.

The Company has incurred operating losses in each period from inception through December 31, 2005. The Company has been able to fund its cash needs to date through an initial funding from its founders and four subsequent private placements. The Company's management intends to raise additional equity funds through an initial public offering of its equity securities.

**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 chemical compound gamma-vinyl-GABA, commonly referred to as vigabatrin as a potential treatment for addictions.
- b. **USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.
- c. **CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company has substantially all of its cash and cash equivalents deposited with one financial institution.
- d. **PROPERTY AND EQUIPMENT.** Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years.
- e. **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. Total research and development expenses were \$1,462,889, \$378,254, and \$268,829 in 2005, 2004, and 2003, respectively.
- f. **LICENSES AND OTHER PURCHASED PRODUCT RIGHTS.** The costs of acquired licenses and other purchased product rights are capitalized and amortized over their respective useful lives, generally the actual life of the license agreement. The Financial Accounting Standards Board ("FASB") has issued Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). The provisions of SFAS 142 provide that the carrying value of intangible assets that have finite useful lives are to be amortized over their respected useful lives.

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- g. **STOCK BASED COMPENSATION.** The Company has recognized in the income statement the costs related to employee/consultant services in share-based payment transactions by using the estimated fair value of the stock at the date of grant, in accordance with Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation" (SFAS 123).

The Company accounts for the issuance of employee stock options using the intrinsic value method. Accordingly, compensation cost for stock options issued is measured as the excess, if any, of the fair value of the Company's common stock at the date of grant over the exercise price of the options. In 2005, 2004, 2003 and during the period from January 4, 2002 (date of inception) through December 31, 2005, the Company recorded compensation expense of \$1,067,750, \$294,833, \$75,833 and \$1,514,249, respectively, related to the issuance of stock options to nonemployees. The weighted average fair value of the stock options granted in 2005, 2004 and during the period from January 4, 2002 (date of inception) through December 31, 2005 was \$1.14, \$1.00 and \$0.99, respectively. There were no stock options granted in 2003. The fair values were determined using the Black-Scholes option-pricing model with an estimated annual volatility of 100% for all periods, expected holding periods of five to ten years, and a risk-free interest rate of 5% in all periods through 2004 and a risk free rate of 5.5% in 2005.

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

	Years ended December 31,		
	2005	2004	2003
Net loss, as reported	\$ (1,805,380)	\$ (539,820)	\$ (428,615)
Stock-based compensation expense determined under the fair value-based method, net of tax	(507,917)	(75,833)	(75,833)
Net loss, pro forma	<u>\$ (2,313,297)</u>	<u>\$ (615,653)</u>	<u>\$ (504,448)</u>
Loss per share — basic and diluted, as reported	\$ (.29)	\$ (.18)	\$ (.15)
Loss per share — basic and diluted, pro forma	<u>\$ (.37)</u>	<u>\$ (.21)</u>	<u>\$ (.17)</u>

The above pro forma disclosures may not be representative of the effects on reported net (loss) earnings for future years as options vest over several years and the Company may continue to grant options to employees.

- h. **DEFERRED COMPENSATION.** The Company has an agreement with one of the executive officers to defer payment of a portion of his compensation due to him until the Company has completed an equity financing raising gross proceeds of at least \$2.0 million. This contingency was satisfied at the closing of the recently completed private placement (See Note 10) and the full amount due to this executive officer for services has been recognized in the income statement for each period for which compensation was accrued subject to the contingency (See Note 7).
- i. **CONCENTRATION OF CREDIT RISK.** The financial instrument that potentially subjects the Company to concentration of credit risk is cash. The Company places its cash with high-credit quality financial institutions.
- j. **INCOME TAXES.** The Company utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation



allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

- k. **EARNINGS (LOSS) PER SHARE.** Basic earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common stock equivalents, such as convertible preferred stock and stock options. For all periods presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive. Potentially dilutive common stock equivalents as of December 31, 2005 include 70,000 shares of Series A Preferred Stock convertible into 1,021,453 shares of common stock as well as stock options to purchase up to 2,188,828 shares of common stock at exercise prices ranging from \$0.69 to \$2.98. In addition, on July 24, 2006, the Company completed a private placement of 7,644 shares of Series B preferred stock convertible into 1,115,427 shares of common stock.
- l. **NEW ACCOUNTING PRONOUNCEMENTS.** In December 2004, the FASB issued Statement 123(R) which addresses the accounting for share-based payment transactions (for example, stock options and awards of restricted stock) in which an employer receives employee-services in exchange for equity securities of the company or liabilities that are based on a fair value of the company's equity securities. This proposal eliminates use of APB Opinion No. 25, Accounting for Stock Issued to Employees, and requires such transactions to be accounted for using a fair value-based method and recording compensation expense rather than optional pro forma disclosure. The new standard substantially amends SFAS 123. Statement 123(R) is effective on January 1, 2006 and will require the Company to recognize an expense for the fair value of its unvested outstanding stock options in future financial statements. The Company had no unvested stock options to employees as of January 1, 2006.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections," which changes the requirements for the accounting and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle as well as to changes required by an accounting pronouncement that does not include specific transition provisions. SFAS No. 154 requires that changes in accounting principle be retrospectively applied. SFAS No. 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The Company does not expect the adoption of this standard to have a material effect on the Company's financial statements.

A variety of proposed or otherwise potential accounting standards are currently under study by standard-setting organizations and various regulatory agencies. Because of the tentative and preliminary nature of these proposed standards, management has not determined whether implementation of such proposed standards would be material to our condensed consolidated financial statements.

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**3. Property and Equipment**

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

	<u>2005</u>	<u>2004</u>
Computer equipment	\$ 3,303	\$ 1,831
Furniture and equipment	2,468	-
Accumulated depreciation	(1,740)	(366)
Total property and equipment	<u>\$ 4,031</u>	<u>\$ 1,465</u>

**4. Lease Obligations**

The Company has executed a noncancellable operating lease agreement for its corporate office. As of December 31, 2005, future minimum lease payments under the noncancellable operating lease agreement are as follows:

2006	\$ 17,736
2007	18,268
2008	6,149
	<u>\$ 42,153</u>

Rent expense was \$16,041, \$10,914, and \$0 as of December 31, 2005, 2004 and 2003, respectively. Deferred rent liability as of December 31, 2005 was immaterial.

**5. Accrued Expenses**

Accrued expenses consist of the following as of December 31:

	<u>2005</u>	<u>2004</u>
Common stock payable	\$ 105,000	\$ 20,000
Deferred payroll	83,327	-
Accrued license fee	69,352	-
Accrued professional fees	15,000	15,000
Other	2,556	2,066
	<u>\$ 275,235</u>	<u>\$ 37,066</u>

**6. 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 2020. The Company paid a fee to obtain the license in the amount of \$50,000. In addition the Company is required to reimburse Brookhaven for the costs they have incurred relative to the related patents. The amount of costs incurred prior to September 30, 2005 is \$69,352, which will become payable in six monthly installments at the time the Company submits a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA"). Costs incurred after September 30, 2005 will also be due after the submission of the

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NDA. The license agreement also calls for annual royalty payments of \$100,000 in the year of FDA approval of an NDA relating to the licensed patents, \$250,000 in the second and third year after the approval and \$500,000 for each subsequent year until the expiration of the license agreement. The Company also has the right to enter into sub-license agreements, and if it does, a royalty of 20% of any sub-license fees will be payable to Brookhaven.

- b. **AGREEMENT WITH CONTRACT MANUFACTURER.** The Company has entered into an agreement with a contract manufacturer under which such manufacturer will develop for the Company its version of vigabatrin for use by the Company in its clinical trials. The gross minimum costs related to this agreement are estimated at \$513,200. The contract manufacturer will progress bill under this agreement pursuant to a schedule of payments to run concurrent with the work they will be performing. The payments will be due 30 days from the time of invoicing of the schedule procedure.

### **7. Deferred Compensation**

In January 2005, the Company entered into an agreement with Patrick McEnany, to act as the Company's Chief Executive Officer. The agreement calls for an annual salary of \$100,000 per year to commence as of March 1, 2005. The agreement stipulates that half of Mr. McEnany's salary is to be deferred until the Company raises equity in the amount of not less than \$2,000,000. Mr. McEnany has also deferred the other half of his compensation until the equity minimum has been met. As of December 31, 2005 and 2004, the amount payable to Mr. McEnany for his deferred compensation was \$83,327 and \$0, respectively. All deferred compensation was earned and paid to Mr. McEnany from the proceeds of the recently completed private placement. (See Note 13.)

### **8. Related Party Transactions**

Since its inception in 2002, the Company has entered into various Consulting Agreements with nonemployee officers and a member of the Company's Scientific Advisory Board, a portion of which were with related parties under common ownership and control. During the years ended December 31, 2005 and 2004, the Company paid approximately \$203,000 and \$15,000 in consulting fees to related parties. There were no consulting fees paid to related parties for the year ended December 31, 2003. In addition, as of December 31, 2005, the Company accrued \$105,000 related to common stock payable under certain consulting agreements. A fair value of \$1.37 per share was used to determine the related expense in 2004 and 2005. This fair value was based on an internal valuation performed by Company management based on the fair value of similar entities and current market conditions. An aggregate of 76,609 shares of common stock were issued in July 2006 related to this accrual. In addition, an additional 65,665 shares of common stock were issued in July 2006 for services performed from January 1, 2006 through June 30, 2006.

The Company's consulting agreement with its CFO requires a bonus payment of approximately \$150,000 upon the Company's completion of a U.S. initial public offering of at least \$10 million.

### **9. Stock Options Granted**

Through July 2006, the Company did not have a formal stock option plan.

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

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On October 1, 2004, the Company entered into an agreement with Jack Weinstein, a consultant to the Company. Pursuant to this agreement, Mr. Weinstein received an option to purchase 218,883 shares of the Company's common stock. The exercise price of 145,922 of these options is \$1.37 per share. The exercise price of the remaining 72,961 options is the offering price of the next private placement to raise more than \$2 million (\$2.98 based on the private placement that closed on July 24, 2006). Of these 218,583 options, 72,961 vested immediately, 72,961 vested on October 1, 2005 and 72,961 vested upon completion of the July 2006 private placement. These options expire five years from their date of grant.

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

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

On March 4, 2005, an additional "Non-Qualified Stock Option Agreement" was entered into with Jack Weinstein, a consultant to the Company. This agreement provided an option to purchase 218,883 shares of the Company's common stock. The exercise price of 145,922 of these options is \$1.37 per share. The exercise price of the remaining 72,961 options is the offering price of the next private placement to raise more than \$2 million (\$2.98 based on the private placement that closed on July 24, 2006). 145,922 of these options vested immediately and the remaining vested upon the completion of the July 2006 private placement. These options expire five years from their date of grant.

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

A summary of the Company's stock option activity and related information for the years ended December 31, 2005, 2004, and 2003:

	2005		2004		2003	
	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	948,492	\$ .97	729,609	\$ .69	729,609	\$ .69
Granted	1,240,336	1.06	218,883	1.91	-	-
Exercised	-	-	-	-	-	-
Forfeited	-	-	-	-	-	-
Outstanding at end of year	<u>2,188,828</u>	<u>\$ 1.02</u>	<u>948,492</u>	<u>\$ .97</u>	<u>729,609</u>	<u>\$ .69</u>
Exercisable at end of year	<u>2,042,906</u>	<u>\$ .88</u>	<u>632,327</u>	<u>\$ .84</u>	<u>243,203</u>	<u>\$ .69</u>

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The following information applies to options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
\$0.69 — \$1.37	2,042,906	8.57 years	\$ .88	2,042,906	\$ .88
\$2.98	145,922	5 years	\$ 2.98	—	\$ —
	2,188,828			2,042,906	

## 10. 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 the Company's common stock.

## 11. Capitalization

- a. **COMMON STOCK.** The Company has 30,000,000 shares of authorized common stock with a par value of \$0.01 per share. At December 31, 2005 and 2004, 6,887,513 and 2,918,438 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.
- b. **PREFERRED STOCK.** The Company has 5,000,000 shares of authorized preferred stock outstanding, \$0.01 par value per share.
  - i. *Series A Preferred Stock.* At December 31, 2005, the Company had 70,000 shares of Series A Preferred Stock issued and outstanding. Each share of outstanding Series A Preferred Stock has a liquidation preference of \$1.00 per share and votes with the Common Stock on the basis of approximately fifteen votes for each share of Series A Preferred Stock outstanding. Each share of Series A Preferred Stock is convertible, at the option of the holder, into approximately 15 shares of common stock; provided, however, that all of the outstanding shares of Series A Preferred Stock will automatically convert into shares of the Company's Common Stock under certain circumstances, including the completion of an initial public offering.

## 12. Income Taxes

As of December 31, 2005 and 2004 the Company had deferred tax assets of approximately \$1,151,000 and \$465,000, respectively, of which approximately \$576,000 and \$296,000 represent net operating loss carryforwards. The remaining deferred tax assets represent nondeductible stock option expense. The related deferred tax asset has a 100% valuation allowance as of December 31, 2005 and 2004, 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 \$686,000, \$205,000 and \$163,000 in 2005, 2004, and 2003, respectively. There are no other significant temporary differences. The net operating loss carry-forwards will expire at various dates beginning in 2022 and expiring in 2025. 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.

**13. Subsequent Events**

- a. **PRIVATE PLACEMENT.** 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 the Company's Series B Preferred Stock. Each share of outstanding Series B Preferred Stock has a liquidation preference of \$435 per share and votes with the Common Stock on the basis of approximately 145 votes for each share of Series B Preferred Stock outstanding. Each share of Series B Preferred Stock is convertible, at the option of the holder, into approximately 145 shares of common stock; provided, however, that all of the outstanding shares of Series B Preferred Stock will automatically convert into shares of common stock under certain circumstances, including the completion of an initial public offering.
- b. **2006 STOCK INCENTIVE PLAN.** In July 2006 the Company adopted the 2006 Stock Incentive Plan (the "Plan"). The Plan provides for the Company to issue options, restricted stock, stock appreciation rights and restricted stock units (collectively, the "Awards") 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. No grants have been made to date under the Plan.
- c. **STOCK SPLIT.** On October 3, 2006, the Company's board of directors approved an approximate 1.4592 forward stock split (effected in the form of a stock dividend). All stock value, common shares outstanding and per share amounts set forth in these financial statements have been adjusted retroactively to reflect this split.

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

	June 30, 2006 <i>(unaudited)</i>	December 31, 2005
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 324,154	\$ 771,127
Prepaid insurance	2,681	440
Total current assets	326,835	771,567
Property and equipment, net	14,426	4,031
Deposits	23,852	13,852
Total assets	<u>\$ 365,113</u>	<u>\$ 789,450</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 24,946	\$ 67,753
Accrued expenses	409,405	275,235
Total current liabilities	434,351	342,988
Commitments and Contingencies (See notes)	-	-
Stockholders' equity (deficit)		
Preferred stock, \$.01 par value, 5,000,000 shares authorized, 70,000 shares Series A Preferred Stock outstanding	700	700
Common stock, \$.01 par value, 30,000,000 shares authorized, 6,887,513 shares issued and outstanding at June 30, 2006 and December 31, 2005	68,875	68,875
Additional paid-in capital	3,557,772	3,406,647
Accumulated deficit	(3,696,585)	(3,029,760)
Total stockholders' equity (deficit)	(69,238)	446,462
Total liabilities and stockholders' equity (deficit)	<u>\$ 365,113</u>	<u>\$ 789,450</u>

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

**CATALYST PHARMACEUTICAL PARTNERS, INC.**  
**(a development stage company)**  
**STATEMENTS OF OPERATIONS**

	For the Six Months Ended June 30,		Cumulative Period from January 4, 2002 (date of inception) to June 30, 2006
	2006	2005	(unaudited)
Revenues	\$ —	\$ —	\$ —
Operating costs and expenses:			
Research and development	432,764	1,200,769	2,680,416
General and administrative	242,194	126,811	1,049,925
Total operating costs and expenses	674,958	1,327,580	3,730,341
Loss from operations	(674,958)	(1,327,580)	(3,730,341)
Interest income	8,133	5,908	33,756
Loss before income taxes	(666,825)	(1,321,672)	(3,696,585)
Provision for income taxes	—	—	—
Net loss	<u>\$ (666,825)</u>	<u>\$ (1,321,672)</u>	<u>\$ (3,696,585)</u>
Loss per share – basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.24)</u>	
Weighted average shares outstanding – basic and diluted	<u>6,887,513</u>	<u>5,496,925</u>	

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



**CATALYST PHARMACEUTICAL PARTNERS, INC.**  
**(a development stage company)**  
**STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (unaudited)**  
**For the six months ended June 30, 2006**

	<u>Preferred Stock</u>	<u>Common Stock</u>	<u>Paid-in Capital</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total</u>
<b>Balance at December 31, 2005</b>	\$ 700	\$ 68,875	\$ 3,406,647	\$ (3,029,760)	\$ 446,462
Issuance of stock options for services	-	-	151,125	-	151,125
Net loss	-	-	-	(666,825)	(666,825)
<b>Balance at June 30, 2006</b>	<u>\$ 700</u>	<u>\$ 68,875</u>	<u>\$ 3,557,772</u>	<u>\$ (3,696,585)</u>	<u>\$ (69,238)</u>

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

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

	For the Six Months Ended June 30,		Cumulative period from January 4, 2002 (date of inception) through June 30, 2006
	2006	2005	2006
	(unaudited)		(unaudited)
<b>Operating Activities:</b>			
Net loss	\$ (666,825)	\$ (1,321,672)	\$ (3,696,585)
Reconciliation of net loss to net cash used in operating activities:			
Depreciation	2,051	687	3,791
Stock-based compensation	241,125	1,013,374	1,900,374
(Increase) in other prepaid expenses and deposits	(12,241)	(16,100)	(26,533)
(Decrease) increase in accounts payable	(42,806)	90	24,946
Increase (decrease) in accrued expenses	44,169	79,510	214,406
Net cash used in operating activities	<u>(434,527)</u>	<u>(244,111)</u>	<u>(1,579,601)</u>
<b>Investing Activities:</b>			
Capital expenditures	(12,446)	(3,940)	(18,218)
Net cash used in investing activities	(12,446)	(3,940)	(18,218)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock	—	1,046,516	1,151,516
Proceeds from issuance of preferred stock	—	—	670,457
Net cash provided by financing activities	—	1,046,516	1,821,973
Net increase in cash and cash equivalents	(446,973)	798,465	224,154
Cash and cash equivalents — January 1	771,127	183,911	100,000
Cash and cash equivalents — June 30	<u>\$ 324,154</u>	<u>\$ 982,376</u>	<u>\$ 324,154</u>
Supplemental disclosures of cash flow information:			
Cash paid during the year for interest	—	—	—
Cash paid during the year for income taxes	—	—	—

**Non-cash financing activities:**

During the six months ended June 30, 2006 and 2005, the Company recorded compensation expense of \$151,125 and \$998,375, respectively, related to the issuance of stock options to nonemployees.

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

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

**1. Organization and Description of Business**

Catalyst Pharmaceutical Partners, Inc. ("Company") is a development-stage specialty pharmaceutical company focused on the acquisition, development and commercialization of prescription drugs for the treatment of drug addiction. The Company was incorporated in the State of Florida on January 4, 2002.

The Company has incurred operating losses in each period from inception through June 30, 2006. The Company has been able to fund its cash needs to date through an initial funding from its founders and four subsequent private placements. The Company's management intends to raise additional equity funds through an initial public offering of its equity securities.

**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."
- b. **INTERIM FINANCIAL STATEMENTS.** The accompanying unaudited interim condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. The accompanying unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements and the notes thereto included elsewhere in this prospectus.

In the opinion of management, the accompanying unaudited interim condensed financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of June 30, 2006, the results of its operations for the six month periods ended June 30, 2006 and 2005 and its cash flows for the six month periods ended June 30, 2006 and 2005. The results of operations and cash flows for the six month period ended June 30, 2006 are not necessarily indicative of the results of operations or cash flows which may be reported for the year ending December 31, 2006.

- c. **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.
- d. **STOCK COMPENSATION PLANS.** Through July 2006, the Company did not have a formal stock option plan. As of June 30, 2006, there were outstanding stock options to purchase 2,188,828 shares of common stock of which stock options to purchase 2,042,906 shares of common stock were exercisable as of June 30, 2006. There was no stock option activity during the six-month period ended June 30, 2006 or effect on cash flows.

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For the six month periods ended June 30, 2006 and 2005, the Company recognized expense of \$241,125 and \$1,013,375, respectively, in stock-based compensation costs, which is reflected in research and development expenses. No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for substantially 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. As of June 30, 2006, the Company has no unrecognized compensation costs related to non-vested employee stock option awards.

The following information applies to options outstanding and exercisable at June 30, 2006:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2006	2,188,828	\$ 1.02	8.33	\$ 2,615,000
Granted	0			
Exercised	0			
Forfeited	0			
Options outstanding at June 30, 2006	<u>2,188,828</u>	<u>\$ 1.02</u>	<u>8.33</u>	<u>\$ 2,615,000</u>
Options exercisable at June 30, 2006	<u>2,042,906</u>	<u>\$ .88</u>	<u>8.57</u>	<u>\$ 2,447,500</u>

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Shares	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
\$ .69 — \$1.37	2,042,906	8.57 years	\$ .88	2,042,906	\$ .88
\$2.98	145,922	5 years	\$ 2.98	—	\$ —
	<u>2,188,828</u>			<u>2,042,906</u>	

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. 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 term of the Company's stock options awards. For the period ended June 30, 2006 the assumptions used were an estimated annual volatility of 100%, expected holding periods of five to ten years, and a risk-free interest rate of 5.5%. The expected dividend rate is zero and no forfeiture rate was applied. As of June 30, 2006, the unrecognized compensation costs related to non-vested stock option is immaterial. There were no stock options granted during the six month period ended June 30, 2006. For the six month period ended June 30, 2005, the weighted average fair value of stock options granted was \$1.14 per share.

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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:

	For the Six Months Ended June 30, 2005	
Net loss, as reported	\$	(1,321,672)
Total stock-based employee compensation expense determined under fair value-based method		(488,959)
Net loss, pro forma	\$	(1,810,631)
Loss per share — basic and diluted, as reported	\$	(.24)
<b>Loss per share — basic and diluted, pro forma</b>	<b>\$</b>	<b>(.33)</b>

The above pro forma disclosures may not be representative of the effects on reported net (loss) earnings for future years as options vest over several years and the Company may continue to grant options to employees.

**3. Property and Equipment**

Property and equipment, net consists of the following:

	June 30, 2006	December 31, 2005
Computer equipment	\$ 11,715	\$ 3,303
Furniture and equipment	6,502	2,468
Accumulated depreciation	(3,791)	(1,740)
Total property and equipment	\$ 14,426	\$ 4,031

**4. Capitalization**

- a. **COMMON STOCK.** The Company has 30,000,000 shares of authorized common stock with a par value of \$0.01 per share. At June 30, 2006 and December 31, 2005, 6,887,513 shares, respectively, of common stock were issued and outstanding. Each holder of common stock is entitled to one vote of each share of common stock held of record on all matters on which stockholders generally are entitled to vote.
- b. **PREFERRED STOCK.** The Company has 5,000,000 shares of authorized preferred stock outstanding, \$0.01 par value per share.
  - i. *Series A Preferred Stock.* At December 31, 2005, the Company had 70,000 shares of Series A Preferred Stock outstanding. Each share of outstanding Series A Preferred Stock has a liquidation preference of \$1.00 per share and votes with the Common Stock on the basis of approximately 15 votes for each share of Series A Preferred Stock outstanding. Each share of Series A Preferred Stock is convertible, at the option of the holder, into approximately 15 shares of common stock; provided, however, that all of the outstanding shares of Series A Preferred Stock will automatically convert into shares of the Company's Common Stock under certain circumstances, including the completion of an initial public offering.

**5. Related Party Transactions.**

Since its inception in 2002, the Company has entered into various Consulting Agreements with non-employee officers, and a member of the Company's Scientific Advisory Board, a portion of which were with related parties under common ownership and control. During the six months ended June 30, 2006 and 2005, the Company paid approximately \$65,000 and \$93,000 in consulting fees to related parties. In addition, as of June 30, 2006, the Company accrued \$195,000 related to common stock payable under certain consulting arrangements. A fair value of \$2.98 per share was used to determine the related expense for the six months ended June 30, 2006. This fair value was based on an internal valuation performed by Company management based on the fair value of similar entities and current market conditions. An aggregate of 65,665 shares of common stock were issued in July 2006 related to this accrual.

The Company's consulting agreement with its CFO requires a bonus payment of approximately \$150,000 upon the completion of a U.S. initial public offering of at least \$10 million.

**6. Subsequent Events**

- a. **PRIVATE PLACEMENT.** 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 the Company's Series B Preferred Stock. Each share of outstanding Series B Preferred Stock has a liquidation preference of \$435 per share and votes with the Common Stock on the basis of approximately 145 votes for each share of Series B Preferred Stock outstanding. Each share of Series B Preferred Stock is convertible, at the option of the holder, into approximately 145 shares of common stock; provided, however, that all of the outstanding shares of Series B Preferred Stock will automatically convert into shares of common stock under certain circumstances, including the completion of an initial public offering.
- b. **2006 STOCK INCENTIVE PLAN.** In July 2006 the Company adopted the 2006 Stock Incentive Plan (the "Plan"). The Plan provides for the Company to issue options, restricted stock, stock appreciation rights and restricted stock units (collectively, the "Awards") 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. No options have been granted to date under the Plan.
- c. **STOCK SPLIT.** On October 3, 2006, the Company's board of directors approved an approximate 1.4592 forward stock split (effected in the form of a stock dividend). All stock value, common shares outstanding and per share amounts set forth in these financial statements have been adjusted retroactively to reflect this split.



**Common Stock  
3,000,000 Shares**

**First Albany Capital**

**Stifel Nicolaus**

The date of this prospectus is \_\_\_\_\_, 2006

Through and including \_\_\_\_\_, 2006 (the 25th day after the date of this prospectus), all dealers that effect transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or provisions.

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**PART II**  
**Information Not Required In Prospectus**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the various costs and expenses to be incurred in connection with the issuance and distribution of the securities registered under this Registration Statement, other than underwriting discounts and commissions. All such expenses are estimates, except for the SEC registration fee, the NASD filing fee, and the Nasdaq Global Market listing fee. The following expenses will be borne solely by the Registrant.

SEC Registration Fee	\$	4,306.75
NASD Filing Fee		4,525.00
Nasdaq Global Market Listing Fee		100,000.00
Printing and Engraving Expenses		200,000.00
Legal Fees and Expenses		450,000.00
Accounting Fees and Expenses		100,000.00
Transfer Agent and Registrar Fees		20,000.00
Miscellaneous Expenses		121,168.25
<b>Total</b>	<b>\$</b>	<b>1,000,000.00</b>

**Item 14. Indemnification of Officers and Directors**

Section 145 of the Delaware General Corporation Law permits, in general, a Delaware corporation to indemnify any person who was or is a party to any proceeding (other than an action by, or in the right of, the corporation) by reason of the fact that he or she is or was a director or officer of the corporation, or served another business enterprise in any capacity at the request of the corporation, against liability incurred in connection with such proceeding, including the estimated expenses of litigating the proceeding to conclusion and the expenses actually and reasonably incurred in connection with the defense or settlement of such proceeding, if such person acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, in criminal actions or proceedings, additionally had no reasonable cause to believe that his or her conduct was unlawful. A Delaware corporation's power to indemnify applies to actions brought by or in the right of the corporation as well, but only to the extent of expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of the action or suit, provided that no indemnification shall be provided in such actions in the event of any adjudication of negligence or misconduct in the performance of such person's duties to the corporation, unless a court believes that in light of all the circumstances indemnification should apply. Section 145 of the Delaware General Corporation Law also permits, in general, a Delaware corporation to purchase and maintain insurance on behalf of any person who is or was a director or officer of the corporation, or served another entity in any capacity at the request of the corporation, against liability incurred by such person in such capacity, whether or not the corporation would have the power to indemnify such person against such liability.

The Registrant's By-Laws implement the indemnification provisions permitted by Section 145 of the Delaware General Corporation Law by providing that:

- The Registrant shall indemnify any person that was or is a party to any proceeding by reason of the fact that he or she is or was a director or an officer of the Registrant, to the fullest extent permitted by the Delaware General Corporation Law.
- The Registrant shall prepay expenses, including attorneys' fees, incurred by a director or an officer in connection with defending a proceeding for which the Registrant is required to provide indemnification,



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provided that the director or the officer shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification for such expenses.

- The Registrant shall pay a claim for indemnification or advancement of expenses within 30 days after it receives a written claim from an indemnified director or officer. Such director or officer may file suit to recover the unpaid claim amount, and the corporation shall have the burden of proving that the director or officer is not entitled to the requested claim amount.
- The grant of indemnification rights by the registrant shall not be exclusive of any other rights that an indemnified director or officer may have or hereafter acquire under any statute, agreement, vote of stockholders or disinterested directors, or provision of the Certificate of Incorporation or the by-laws of the Registrant.
- The Registrant's obligation, if any, to indemnify or to advance expenses to any indemnified person who was or is serving another corporation, partnership, joint venture, trust, enterprise or non-profit enterprise shall be reduced by any amount such employee may collect as indemnification or advancement of expenses from the other corporation, partnership, joint venture, trust, enterprise or non-profit enterprise.
- The Registrant may, in its discretion, indemnify and advance expenses to employees and agents, to the extent and manner permitted by law, under circumstances where indemnification is not required by law.

In addition, as permitted by Section 102 of the Delaware General Corporation Law, the Registrant's Certificate of Incorporation includes a provision that eliminates the personal liability of its directors for monetary damages for breach of their fiduciary duty as directors to the fullest extent permitted by the Delaware General Corporation Law.

These indemnification provisions may be sufficiently broad to permit indemnification of the Registrant's directors and officers for liabilities (including reimbursement of expenses incurred) arising under the Securities Act. Pursuant to the Underwriting Agreement to be filed as Exhibit 1.1 to this Registration Statement, the underwriters have agreed to indemnify the Registrant's directors, officers, and controlling persons, and the Registrant has agreed to indemnify the underwriters, against certain civil liabilities that may be incurred in connection with the offering of securities pursuant to this Registration Statement (including certain liabilities under the Securities Act) as a result of any statement or omission in this Registration Statement, in the related prospectus, in any preliminary prospectus, or in any amendment or supplement thereto, in each case to the extent that the statement or omission was made in reliance upon and in conformity with written information furnished by the underwriters expressly for use therein.

**Item 15. Recent Sales of Unregistered Securities**

The following is information furnished with regard to all securities sold by the Registrant within the past three years that were not registered under the Act.

On February 28, 2005, the Registrant completed a rights offering of shares of its authorized but unissued common stock to holders of its common stock and holders of its Series A Preferred Stock. In the rights offering, the Registrant issued 3,954,483 shares of its common stock to its stockholders. No commissions were paid in connection with the issuance of the foregoing shares, all of which were issued pursuant to an exemption from registration under Section 4(2) of the Act. This offering resulted in proceeds of approximately \$1,000,000 to the Registrant, net of expenses.

On July 24, 2006, the Registrant completed the sale of 7,644 shares of its Series B Preferred Stock, par value \$0.01 per share at a price of \$435 per share. The foregoing securities were issued to 51 accredited investors and were issued pursuant to an exemption from registration under Section 4(2) of the Act.

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In July 2006, the Registrant issued an aggregate of 142,274 shares of its common stock to five of its advisors for services performed during 2005 and through June 30, 2006. These shares were issued pursuant to an exemption from registration under Section 4(2) of the Act.

None of these transactions involved any underwriters, underwriting discounts, or any public offering. The recipients of securities in each transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients received adequate information regarding the Registrant and the stock sold.

**Item 16. Exhibits and Financial Statement Schedules**

(a) Exhibits

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
1.1	Form of Underwriting Agreement between Catalyst Pharmaceutical Partners, Inc. and the underwriters named therein(1)
3.1	Certificate of Incorporation(1)
3.2	Amendment to Certificate of Incorporation(1)
3.3	By-laws(1)
4.1	Specimen stock certificate for common stock(1)
5.1	Opinion of Akerman Senterfitt(2)
10.1	Form of Employment Agreement between the Company and Patrick J. McEnany(1)
10.2	Form of Employment Agreement between the Company and Jack Weinstein(1)
10.3	License Agreement, as amended, between the Company and Brookhaven National Laboratories(1)
10.4	Stock Option Agreements between the Company and Patrick J. McEnany(1)
10.5	Stock Option Agreements between the Company and Hubert Huckel(1)
10.6	Stock Option Agreements between the Company and Jack Weinstein(1)
10.7	Stock Option Agreement between the Company and Charles O’Keeffe(1)
10.8	2006 Stock Incentive Plan(1)
10.9	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
10.10	Consulting Agreement, as amended, between the Company and Jack Weinstein(1)
10.11	Consulting Agreement between the Company and Charles O’Keeffe(1)
10.12	Consulting Agreement between the Company and Donald R. Jasinski(1)
10.13	Agreement between the Company and Charles Gorodetzky(1)
10.14	Agreement between the Company and Pharmaceuticals International, Inc.(1)
23.1	Consent of Grant Thornton LLP*
23.2	Consent of Akerman Senterfitt (included as Exhibit 5.1)
24.1	Power of Attorney (included on Page II-5)

(1) Previously filed.

(2) To be filed by amendment.

\* Filed herewith.

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(b) Financial Statement Schedules

None.

**Item 17. Undertakings**

(1) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser

(2) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or a controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(3) The undersigned registrant hereby undertakes that:

- (a) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of the prospectus filed as a part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be a part of this registration statement at the time it was declared effective.
- (b) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 3 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in City of Miami, State of Florida on October 3, 2006.

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

By: \_\_\_\_\_ /s/ Patrick J. McEnany

Patrick J. McEnany  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 2 to Registration Statement on Form S-1 has been signed by the following persons, in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Patrick J. McEnany</u> Patrick J. McEnany	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	October 3, 2006
<u>/s/ Jack Weinstein</u> Jack Weinstein	Vice President, Treasurer and Chief Financial Officer (Principal Financial and Accounting Officer)	October 3, 2006
<u>/s/ Hubert E. Huckel, M.D.*</u> Hubert E. Huckel, M.D.	Director	October 3, 2006
<u>/s/ Charles B. O'Keeffe*</u> Charles B. O'Keeffe	Director	October 3, 2006
<u>/s/ Philip H. Coelho*</u> Philip H. Coelho	Director	October 3, 2006
<u>/s/ David S. Tierney, M.D.*</u> David S. Tierney, M.D.	Director	October 3, 2006
<u>/s/ Milton J. Wallace*</u> Milton J. Wallace	Director	October 3, 2006
<u>*/s/ Patrick J. McEnany</u> By: Patrick J. McEnany, under power of attorney dated July 25, 2006.		

CONSENT OF INDEPENDENT  
REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated July 24, 2006 (except for Note 13(c) as to which the date is October 3, 2006), accompanying the financial statements of Catalyst Pharmaceutical Partners, Inc. (a Development Stage Company) contained in the Registration Statement and Prospectus. We consent to the use of the aforementioned report in the Registration Statement and Prospectus, and to the use of our name as it appears under the caption "Experts."

/s/ Grant Thornton LLP

Miami, Florida  
October 3, 2006