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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

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Amendment No. 2  
to  
**FORM S-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**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)*

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**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)*

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**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:  \_\_\_\_\_

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**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.**

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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 SEPTEMBER 26, 2006**



**Common Stock  
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 \$ \_\_\_\_\_ and \$ \_\_\_\_\_ 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 \_\_\_\_\_ 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. Individuals who participate in this offering are urged to read this prospectus in its entirety. 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,

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placebo-controlled study involving approximately 375 patients. In addition, we will also 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. 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 Food and Drug Administration, or 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 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.

Notwithstanding the positive results of these pilot studies, 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.
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**The Offering**

Common stock offered: shares

Common stock outstanding after this offering: 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 6,281,900 shares outstanding as of the date of this prospectus, and excludes as of that date:

- 1,500,000 shares of common stock reserved for future grants under our 2006 Stock Incentive Plan;
- 1,603,000 shares of common stock reserved for issuance upon the exercise of outstanding stock options having a weighted exercise price of \$1.67 per share.

Unless otherwise stated, all information in this prospectus assumes:

- no exercise of the underwriters’ over-allotment option; and
- the automatic conversion of all of our outstanding preferred stock into 1,464,400 shares of our common stock immediately upon the completion of this offering.

**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	\$ (0.14)	\$ (0.35)	\$ (0.42)	\$ (0.27)	\$ (0.21)	
Weighted average shares outstanding — basic and diluted	4,720,000	3,767,033	4,252,219	2,000,000	2,000,000	
Pro forma basic and diluted net loss per share <sup>(1)</sup>	\$ (0.12)		\$ (0.36)			
Pro forma weighted average shares outstanding — basic and diluted <sup>(1)</sup>	5,420,000		4,952,219			

(1) Pro forma gives effect to the conversion of issued shares of our Series A Preferred Stock into 700,000 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.

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

(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 764,400 shares of our common stock, the automatic conversion of our outstanding Series A Preferred Stock into 700,000 shares of our common stock on the closing of this offering, and the issuance of 97,500 shares of our common stock in July 2006 relating to services performed for us by certain of our consultants and scientific advisors during 2004, 2005 and the first six months of 2006.

(2) Pro forma information as adjusted gives further effect to our sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share and our receipt of an estimated \$ \_\_\_\_\_ 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

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.

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 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

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;

- 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.

In the United States, where vigabatrin is not currently approved for use, we intend to commence during the fourth quarter of 2006 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.

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

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 40.0% of our outstanding common stock. Following this offering, we expect that Mr. McEnany will beneficially own approximately % 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 % of the total amount that has been invested to fund our operations, but only receive % 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 \_\_\_\_\_ shares of our common stock outstanding, of which \_\_\_\_\_ shares will be restricted securities. The holders of \_\_\_\_\_ % 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 the underwriters. We also intend to register for future sale the 1,500,000 shares of common stock that we may issue under our 2006 Stock Incentive Plan and the 1,603,000 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 \$ , assuming an initial public offering price of \$ , and after deducting underwriting discounts and commissions and estimated offering expenses. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the net proceeds to us from this offering by approximately \$ , 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 \$ .

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

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 764,400 shares of our common stock, the automatic conversion upon the closing of this offering of the outstanding Series A Preferred Stock into 700,000 shares of our common stock, and the issuance of 97,500 shares of our common stock in July 2006 relating to services performed for us by certain of our consultants and scientific advisors during 2004, 2005 and the first six months of 2006; and
- on a pro forma as adjusted basis to give further effect to our sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share and our receipt of an estimated \$ \_\_\_\_\_ 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 <sup>(1)</sup>
Cash and cash equivalents	\$ 324,154	\$ 3,549,294	\$ _____
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: 4,720,000 shares actual, 6,281,900 shares pro forma; and _____ shares pro forma as adjusted	47,200	62,819	_____
Additional paid-in capital	3,579,447	6,984,668	_____
Accumulated deficit	(3,696,585)	(3,696,585)	_____
<b>Total stockholders’ equity (deficit)</b>	<b>(69,238)</b>	<b>3,350,902</b>	<b>_____</b>
<b>Total capitalization</b>	<b>\$ (69,238)</b>	<b>\$ 3,350,902</b>	<b>\$ _____</b>

(1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital, total shareholders’ equity and total capitalization by approximately \$ \_\_\_\_\_ 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 1,603,000 shares of common stock underlying options outstanding on the date of this prospectus at a weighted average exercise price of \$1.67 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 97,500 shares of our common stock for services and the automatic conversion, upon completion of this offering, of all outstanding shares of our convertible preferred stock into an aggregate of 1,464,400 shares of our common stock, our pro forma net tangible book value as of June 30, 2006, would have been \$3,350,902, or \$0.53 per share.

After giving further effect to the sale of shares of common stock in this offering, at an assumed initial public offering price of \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_, or approximately \$ \_\_\_\_\_ per share. This represents an immediate increase in net tangible book value of approximately \$ \_\_\_\_\_ to our existing stockholders and an immediate dilution of \$ \_\_\_\_\_ per share to new investors in this offering.

The following table illustrates this calculation.

Assumed public offering price per share		\$ _____
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 common shares issued after June 30, 2006	\$	0.54
Pro forma net tangible book value per share at June 30, 2006	\$	0.53
Increase in pro forma net tangible book value per share attributable to this offering	\$	_____
Pro forma net tangible book value per share after this offering		\$ _____
Dilution in pro forma net tangible book value per share to investors in this offering		\$ _____

Each \$1.00 increase (decrease) in the assumed initial offering price of \$ \_\_\_\_\_ per share would increase (decrease) our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_, or approximately \$ \_\_\_\_\_ per share, and dilution to new investors by \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_ per share, representing an increase to existing stockholders of approximately \$ \_\_\_\_\_ per share, and there will be an immediate dilution of approximately \$ \_\_\_\_\_ per share to new investors.



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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:

	Shares Purchased		Total Consideration Paid		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	6,281,900	%	\$ 5,334,140	%	\$ 0.85
New investors					
Total		100%	\$	100%	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) total consideration paid by new investors, total consideration paid by all stockholders and the average price per share paid by all stockholders by \$ , \$ and \$ , respectively, 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 % , and the number of shares held by new investors will increase to , or approximately % .

## 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.

	Six Months Ended June 30,		Year Ended December 31,			Period from	Cumulative period
	2006	2005	2005	2004	2003	January 4, 2002 (date of inception) through December 31, 2002 (unaudited)	from January 4, 2002 (date of inception) through June 30, 2006 (unaudited)
<b>Statement of Operations 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	\$ (0.14)	\$ (0.35)	\$ (0.42)	\$ (0.27)	\$ (0.21)	\$ (0.16)	
Weighted average shares outstanding — basic and diluted	4,720,000	3,767,033	4,252,219	2,000,000	2,000,000	1,616,438	
Pro forma basic and diluted net loss per share <sup>(1)</sup>	\$ (0.12)		\$ (0.36)				
Pro forma weighted average shares outstanding — basic and diluted <sup>(1)</sup>	5,420,000		4,952,219				

(1) Pro forma gives effect to the conversion of shares of our Series A Preferred Stock into 700,000 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.

	Pro forma June 30,		December 31,			
	2006(1)	June 30,	2005	2004	2003	2002
	(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 764,400 shares of our common stock, the automatic conversion of our outstanding Series A Preferred Stock into 700,000 shares of our common stock on the closing of this offering, and the issuance of 97,500 shares of our common stock in July 2006 relating to services performed for us by certain of our consultants and scientific advisors during 2004, 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 \$1.66, \$1.46 and \$1.44, 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 \$2.00 per share as of December 31, 2005 and \$4.35 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 1,503,000

shares of our common stock, of which options to purchase 1,403,000 were vested and 100,000 were unvested. We also had 97,500 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 \$ 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 \$3,100,140 (after paying our Chief Executive Officer \$125,000 of deferred compensation then due to him), increasing our cash and cash equivalents to \$3,424,294. We have used these funds 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.



*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

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 will also 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. 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 Food and Drug Administration, or 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 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 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.

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.

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 GABA<sub>B</sub> 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 with 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,

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



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, and 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

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.

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 duplicated in future larger studies.

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.

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 (which because of the small size of the study and the number of patients who dropped out of the studies, these results 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 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
  - progabide, marketed as Gabrene 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



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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, Pharmaceutics International, Inc. ("PII"), to formulate and manufacture CPP-109 for use in our upcoming clinical trials. We also intend in the future to contract with PII 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 infections with other drugs. Based on the known side effects of VEDs associated with vigabatrin when used in the treatment of epilepsy, our clinical studies will also seek to determine if VEDs 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 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.

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

*Robert D. Fechtner, M.D.* is Professor of Ophthalmology and Director, Glaucoma Division at the Institute of Ophthalmology and Visual Science UMDNJ — New Jersey Medical School, Newark, New Jersey. Dr. Fechtner received his B.S. in Biomedical Science and his medical degree from the University of Michigan School of Medicine. He completed his residency at Albert Einstein College of Medicine in New York. This was followed by a fellowship in glaucoma at the University of California, San Diego under a National Research Service Award from the National Institutes of Health. After several years on the faculty at University of Louisville, he and his family returned home to New Jersey where he joined the faculty at New Jersey Medical School. Dr. Fechtner has published over 70 articles and chapters and is on the editorial boards of American Journal of Ophthalmology and Journal of Glaucoma.



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*Eugene Laska, Ph.D.* is Professor of Psychiatry at the Department of Psychiatry at New York University Medical Center. Dr. Laska received a Ph.D. in Mathematics at New York University, and then completed a PHS Postdoctoral Fellowship at the Department of Statistics at Stanford University. Dr. Laska is the Director of the Statistical Sciences 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. <sup>(1)</sup>	75	Co-Founder and Director
Charles B. O’Keeffe <sup>(2)(3)</sup>	66	Senior Advisor and Director
Philip H. Coelho <sup>(2)(3)</sup>	62	Director
David S. Tierney, M.D. <sup>(1)(3)</sup>	43	Director
Milton J. Wallace <sup>(1)(3)</sup>	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

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 \$2.00 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 15,000 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 250,000 shares of our common stock to each of Mr. McEnany and Dr. Huckel (options to purchase 1,000,000 shares in the aggregate). These options are currently vested, expire ten years after their grant dates, and have an exercise price of \$1.00 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 200,000 shares of our common stock at an exercise price of \$2.00 per share. Mr. O'Keeffe's options expire in January 2010. Mr. Weinstein holds options to purchase 300,000 shares of our common stock, 200,000 of which are at an exercise price of \$2.00 per share (100,000 expire in October 2009 and 100,000 expire in March 2010) and 100,000 of which are at an exercise price of \$4.35 per

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share (50,000 expire in October 2009 and 50,000 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 100,000 shares of our common stock to Mr. Winship. These options will vest over a four-year period and have an exercise price of \$4.35 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 \$ 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 \$(1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Patrick J. McEnany	500,000	—		
Jack Weinstein	200,000	100,000		

(1) Based upon an assumed initial public offering price of \$ 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 1,500,000 shares for issuance under the 2006 plan. Options to acquire 15,000 shares have been granted to date 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

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 6,281,900 shares of common stock outstanding as of the date of this prospectus and \_\_\_\_\_ 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>	2,706,750	39.9%	
Hubert Huckel, M.D. <sup>(2)</sup>	1,287,500	19.0%	
Jonathan Brodie	315,000	5.0%	
Philip H. Coelho	150,000	2.4%	
Charles B. O’Keeffe <sup>(3)</sup>	222,500	3.4%	
David S. Tierney, M.D.	125,000	2.0%	
Milton J. Wallace <sup>(5)</sup>	215,000	3.4%	
Jack Weinstein <sup>(4)</sup>	300,000	4.6%	
M. Douglas Winship <sup>(6)</sup>	—	—	
Officers & directors as a group (8 persons)	5,006,750	64.3%	

(1) Includes 100,000 shares owned by Mr. McEnany’s wife.

(2) Includes options to purchase 500,000 shares of our common stock at a price of \$1.00 per share.

(3) Includes options to purchase 200,000 shares of our common stock at a price of \$2.00 per share.

(4) Includes options to purchase 300,000 shares of our common stock, of which options to purchase 200,000 shares are exercisable at a price of \$2.00 per share and options to purchase 100,000 shares are exercisable at a price of \$4.35 per share.

(5) Includes 20,000 shares owned by Biscayne National Corp. Mr. Wallace is the president of Biscayne National Corp.

(6) Excludes options to purchase 100,000 shares of our common stock exercisable at a price of \$4.35 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 300,000 shares of our common stock, all of which are currently exercisable. Options to purchase 200,000 shares of our common stock have an exercise price of \$2.00 per share, and options to purchase 100,000 shares of our common stock have an exercise price of \$4.35 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 6,281,900 shares of common stock outstanding, of which 4,817,500 are issued shares of our common stock and 1,464,400 are shares of our common stock issuable upon the automatic conversion at the closing of this offering of our Series A and B Preferred Stock. At this date, 70,000 shares of our Series A Preferred Stock and 7,544 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 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 \_\_\_\_\_ shares of our common stock outstanding. Of the shares which will be outstanding after the offering:

- all \_\_\_\_\_ shares of common stock sold in the offering will be freely tradeable;
- \_\_\_\_\_ shares will be “restricted securities” held by non-affiliates; and
- \_\_\_\_\_ 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 \_\_\_\_\_ 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 \_\_\_\_\_ % 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.

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	

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 \_\_\_\_\_ 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 shares:

Per share		
	No Exercise	Full Exercise
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

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.

**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 90,000 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

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

	<u>December 31,</u>	
	<u>2005</u>	<u>2004</u>
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 771,127	\$ 183,911
Prepaid insurance	440	-
<b>Total current assets</b>	<b>771,567</b>	<b>183,911</b>
Property and equipment, net	4,031	1,465
Deposits	13,852	-
<b>Total assets</b>	<b>\$ 789,450</b>	<b>\$ 185,376</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 67,753	\$ 30,734
Accrued expenses	275,235	37,066
<b>Total current liabilities</b>	<b>342,988</b>	<b>67,800</b>
Commitments and contingencies (See notes)	-	-
<b>Stockholders' equity</b>		
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, 4,720,000 shares issued and outstanding at December 31, 2005 and 2,000,000 shares issued and outstanding at December 31, 2004	47,200	20,000
Additional paid-in capital	3,428,322	1,321,256
Deficit accumulated during the development stage	(3,029,760)	(1,224,380)
<b>Total stockholders' equity</b>	<b>446,462</b>	<b>117,576</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 789,450</b>	<b>\$ 185,376</b>

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	1,822,168	542,958	434,312	3,055,383
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	\$ (1,805,380)	\$ (539,820)	\$ (428,615)	\$ (3,029,760)
Loss per share-basic and diluted	\$ (0.42)	\$ (0.27)	\$ (0.21)	
Weighted Average Shares outstanding — basic and diluted	4,252,219	2,000,000	2,000,000	

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>	\$ -	\$ 15,000	\$ 85,000	\$ -	\$ 100,000
Issuance of common stock	-	5,000	120,000	-	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>	<u>-</u>	<u>20,000</u>	<u>280,833</u>	<u>(255,945)</u>	<u>44,888</u>
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>	<u>700</u>	<u>20,000</u>	<u>1,026,423</u>	<u>(684,560)</u>	<u>362,563</u>
Issuance of stock options for services	-	-	294,833	-	294,833
Net loss	-	-	-	(539,820)	(539,820)
<b>Balance at December 31, 2004</b>	<u>700</u>	<u>20,000</u>	<u>1,321,256</u>	<u>(1,224,380)</u>	<u>117,576</u>
Issuance of common stock	-	27,100	1,019,416	-	1,046,516
Issuance of common stock and stock options for services	-	100	1,087,650	-	1,087,750
Net loss	-	-	-	(1,805,380)	(1,805,380)
<b>Balance at December 31, 2005</b>	<u>\$ 700</u>	<u>\$ 47,200</u>	<u>\$ 3,428,322</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.



- 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 \$1.66, \$1.46 and \$1.44, 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	\$ (2,313,297)	\$ (615,653)	\$ (504,448)
Loss per share — basic and diluted, as reported	(0.42)	(0.27)	(0.21)
Loss per share — basic and diluted, pro forma	\$ (0.54)	\$ (0.31)	\$ (0.25)

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 700,000 shares of common stock as well as stock options to purchase up to 1,500,000 shares of common stock at exercise prices ranging from \$1.00 to \$4.35. In addition, on July 24, 2006, the Company completed a private placement of 7,644 shares of Series B preferred stock convertible into 764,400 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.

**3. Property and Equipment**

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

	2005	2004
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:

	2005	2004
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

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 \$2 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 52,500 shares of common stock were issued in July 2006 related to this accrual. In addition, an additional 45,000 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 250,000 shares of the Company's common stock (500,000 shares in the aggregate) at an exercise price of \$1.00 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 150,000 shares of the Company's common stock. The exercise price of 100,000 of these options is \$2.00 per share. The exercise price of the remaining 50,000 options is the offering price of the next private placement to raise more than \$2 million (\$4.35 based on the private placement that closed on July 24, 2006). Of these 150,000 options, 50,000 vested immediately, 50,000 vested on October 1, 2005 and 50,000 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 200,000 shares of the Company's common stock at an exercise price of \$2.00 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 250,000 shares of the Company's common stock (500,000 shares in the aggregate ) at an exercise price of \$1.00 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 150,000 shares of the Company's common stock. The exercise price of 100,000 of these options is \$2.00 per share. The exercise price of the remaining 50,000 options is the offering price of the next private placement to raise more than \$2 million (\$4.35 based on the private placement that closed on July 24, 2006). 100,000 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 100,000 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 \$4.35 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	650,000	\$ 1.41	500,000	\$ 1.00	500,000	\$ 1.00
Granted	850,000	1.55	150,000	2.78	-	-
Exercised	-	-	-	-	-	-
Forfeited	-	-	-	-	-	-
Outstanding at end of year	1,500,000	\$ 1.49	650,000	\$ 1.41	500,000	\$ 1.00
Exercisable at end of year	1,400,000	\$ 1.29	433,333	\$ 1.23	166,667	\$ 1.00

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	
\$1.00 — \$2.00	1,400,000	8.57 years	\$ 1.29	1,400,000	\$ 1.29	
\$4.35	100,000	5 years	\$ 4.35	-	\$ -	
	1,500,000			1,400,000		

**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 500,000 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 2,710,000 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, 4,720,000 and 2,000,000 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 ten 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 ten 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 100 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 100 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, 1,500,000 shares of the Company's Common Stock have been reserved for issuance. No grants have been made to date under the Plan.

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

	June 30, 2006 (unaudited)	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	<u>434,351</u>	<u>342,988</u>
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, 4,720,000 shares issued and outstanding at June 30, 2006 and December 31, 2005	47,200	47,200
Additional paid-in capital	3,579,447	3,428,322
Accumulated deficit	<u>(3,696,585)</u>	<u>(3,029,760)</u>
Total stockholders' equity (deficit)	<u>(69,238)</u>	<u>446,462</u>
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	\$ (666,825)	\$ (1,321,672)	\$ (3,696,585)
Loss per share – basic and diluted	\$ (0.14)	\$ (0.35)	
Weighted average shares outstanding – basic and diluted	4,720,000	3,767,033	

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

	Preferred Stock	Common Stock	Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at December 31, 2005</b>	\$ 700	\$ 47,200	\$ 3,428,322	\$ (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>\$ 47,200</u>	<u>\$ 3,579,447</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 (unaudited)
	2006 (unaudited)	2005	
<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	<u>(12,446)</u>	<u>(3,940)</u>	<u>(18,218)</u>
<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	<u>-</u>	<u>1,046,516</u>	<u>1,821,973</u>
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	-	-	-
<b>Non-cash financing activities:</b>			

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 1,500,000 shares of common stock of which stock options to purchase 1,400,000 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	1,500,000	\$ 1.49	8.33	\$ 2,615,000
Granted	0			
Exercised	0			
Forfeited	0			
Options outstanding at June 30, 2006	1,500,000	\$ 1.49	8.33	\$ 2,615,000
Options exercisable at June 30, 2006	1,400,000	\$ 1.29	8.57	\$ 2,447,500

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Shares	Weighted-Average Remaining Contractual Life	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	
\$1.00 — \$2.00	1,400,000	8.57 years	\$ 1.29	1,400,000	\$	1.29
\$4.35	100,000	5 years	\$ 4.35	—	\$	—
	1,500,000			1,400,000		

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 \$1.66 per share.

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	\$	(0.35)
<b>Loss per share — basic and diluted, pro forma</b>	<b>\$</b>	<b>(0.48)</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, 4,720,000 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 ten 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 ten 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 \$4.35 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 45,000 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 100 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 100 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, 1,500,000 shares of the Company's common stock have been reserved for issuance. No options have been granted to date under the Plan.



**Common Stock  
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>

\* To be furnished by amendment.

**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.

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- 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, 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 2,710,000 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 97,500 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*
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*
5.1	Opinion of Akerman Senterfitt(2)
10.1	Form of Employment Agreement between the Company and Patrick J. McEnany*
10.2	Form of Employment Agreement between the Company and Jack Weinstein*
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 Pharmaceutics 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.

(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. 2 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 September 25, 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)	September 25, 2006
<u>/s/ Jack Weinstein</u> Jack Weinstein	Vice President, Treasurer and Chief Financial Officer (Principal Financial and Accounting Officer)	September 25, 2006
<u>/s/ Hubert E. Huckel, M.D.*</u> Hubert E. Huckel, M.D.	Director	September 25, 2006
<u>/s/ Charles B. O’Keeffe*</u> Charles B. O’Keeffe	Director	September 25, 2006
<u>/s/ Philip H. Coelho*</u> Philip H. Coelho	Director	September 25, 2006
<u>/s/ David S. Tierney, M.D.*</u> David S. Tierney, M.D.	Director	September 25, 2006
<u>/s/ Milton J. Wallace*</u> Milton J. Wallace	Director	September 25, 2006
<u>*/s/ Patrick J. McEnany</u>		

By: Patrick J. McEnany, under power of attorney dated July 25, 2006.

CATALYST PHARMACEUTICAL PARTNERS, INC.

\_\_\_\_\_ Shares

Common Stock

UNDERWRITING AGREEMENT

Dated \_\_\_\_\_, 2006

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First Albany Capital Inc.  
Stifel, Nicolaus & Company, Incorporated  
As Representatives of the several Underwriters

c/o First Albany Capital Inc.  
One Penn Plaza  
New York, New York 10119

Ladies and Gentlemen:

Catalyst Pharmaceutical Partners, Inc., a Delaware corporation (the "Company"), proposes to issue and sell to the underwriters listed on Schedule A hereto (the "Underwriters") \_\_\_\_\_ shares (the "Firm Shares") of its common stock, par value \$0.001 per share (the "Common Stock"), and also proposes to issue and sell to the Underwriters, at the option of the Underwriters, an aggregate of not more than additional shares (the "Additional Shares") of its Common Stock as set forth below. The Firm Shares and the Additional Shares are herein collectively called the "Shares."

The terms, "herein," "hereof," "hereto," "hereinafter" and similar terms, as used in this Agreement, shall in each case refer to this Agreement as a whole and not to any particular section, paragraph, sentence or other subdivision of this Agreement.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "Act"), with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-1 (File No. 333-136039), including a prospectus, relating to the offer and sale of the Shares. Except where the context otherwise requires, "Registration Statement," as used herein, means such registration statement, as amended at the time of such registration statement's effectiveness for purposes of Section 11 of the Act, as such section applies to the respective Underwriters (the "Effective Time"), including (i) all documents filed as a part thereof, (ii) any information contained in a prospectus filed with the Commission pursuant to Rule 424(b) under the Act and deemed to be part of such registration statement at the time of effectiveness pursuant to Rule 430(A) or Rule 430(C) under the Act, and (iii) any registration statement filed by the Company to register the offer and sale of Shares pursuant to Rule 462(b) under the Act in connection with the offering of the Shares (a "462(b) Registration Statement"). If it is contemplated, at the time this Agreement is executed and delivered, that a post-effective amendment to the aforesaid registration statement will be filed and must be declared effective before the offering of the Shares may commence, the term "Registration Statement" shall include the aforesaid registration statement as amended by said post-effective amendment.

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The Company has furnished to you, for use by the Underwriters and by dealers in connection with the offering of the Shares, copies of one or more preliminary prospectuses relating to the Shares. Except where the context otherwise requires, "Preliminary Prospectus," as used herein, means each such preliminary prospectus, in the form so furnished.

Except where the context otherwise requires, "Prospectus," as used herein, means the prospectus filed by the Company with the Commission pursuant to Rule 424(b) under the Act on or before the second business day after the date hereof (or such earlier time as may be required under the Act), or, if no such filing is required, the prospectus included in the Registration Statement at the time it became effective under the Act, in each case in the form furnished by the Company to you, for use by the Underwriters and by dealers in connection with the offering of the Shares.

"Permitted Free Writing Prospectuses," as used herein, means the documents listed on Schedule C attached hereto and each "road show" (as defined in Rule 433 under the Act), if any, related to the offering of the Shares contemplated hereby that is a "written communication" (as defined in Rule 405 under the Act) (each such road show, a "Road Show").

"Disclosure Package," as used herein, means (i) the Preliminary Prospectus dated [ ], which is the form of preliminary prospectus most recently furnished to the Underwriters for use by the Underwriters and dealers in connection with the offering of the Shares and (ii) the Permitted Free Writing Prospectuses listed on Schedule B attached hereto.

"Applicable Time," as used herein, means \_\_\_ [AM/PM] (Eastern time) on \_\_\_\_\_, 2006 or such other time as agreed by the Company and First Albany.

"Issuer Free Writing Prospectus," as used herein, means any "written communication" (as defined in Rule 405 under the Securities Act), created by the Company for use by, or with the permission of, the Company that constitutes an offer to sell or solicitation of an offer to buy the Securities, including any Permitted Free Writing Prospectus listed on Schedule B attached hereto.

The Company and the Underwriters agree as follows:

1. Purchase, Sale and Delivery of Shares. On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to sell to the Underwriters, and the Underwriters agree, severally and not jointly, to purchase from the Company, at a purchase price of \$\_\_\_\_\_ per share, the respective numbers of Firm Shares set forth opposite the names of the Underwriters on Schedule A hereto, subject to adjustment in accordance with Section 7 hereof.

The Company will deliver the Firm Shares to you through the facilities of The Depository Trust Company ("DTC") for the accounts of the several Underwriters



against payment of the purchase price therefor in Federal (same day) funds by official bank check or checks or wire transfer to an account at a bank identified by the Company to First Albany Capital Inc. ("First Albany") drawn to the order of the Company, at the office of Dewey Ballantine LLP, 1301 Avenue of the Americas, New York, New York 10019, at 9:00 A.M., New York time, on \_\_\_\_\_, 2006, or at such other time not later than seven full business days thereafter as First Albany and the Company determine, such time being herein referred to as the "time of purchase." As used herein, "business day" shall mean a day on which the New York Stock Exchange (the "NYSE") is open for trading. The certificates for the Firm Shares so to be delivered will be in the form of one or more global securities in definitive form deposited with DTC and registered in the name of Cede & Co., as nominee for DTC, and will be made available for checking at least 24 hours prior to the time of purchase.

In addition, upon written notice from First Albany given to the Company on or before the close of business, New York time, on the 30th day subsequent to the date of the Prospectus, the Underwriters may purchase all or less than all of the Additional Shares at the same purchase price per Additional Share as that to be paid for the Firm Shares. The Company agrees to sell to the Underwriters the number of Additional Shares specified in such notice, and the Underwriters agree, severally and not jointly, to purchase such Additional Shares. Such Additional Shares shall be purchased for the account of each Underwriter in the same proportion as the number of Firm Shares set forth opposite such Underwriter's name on Schedule A hereto bears to the total number of Firm Shares (subject to adjustment by First Albany to eliminate fractions and subject to adjustment in accordance with Section 7 hereof) and may be purchased by the Underwriters only for the purpose of covering over-allotments, if any, made in connection with the sale of the Firm Shares. No Additional Shares shall be sold or delivered unless the Firm Shares previously have been, or simultaneously are, sold and delivered. The right to purchase the Additional Shares or any portion thereof may be exercised from time to time and, to the extent not previously exercised, may be surrendered and terminated at any time upon notice by First Albany to the Company.

Each time for the delivery of and payment for the Additional Shares, being herein referred to as an "additional time of purchase," which may be the time of purchase, shall be determined by First Albany but shall be not later than five full business days after written notice of election to purchase Additional Shares is given. The Company will deliver the Additional Shares being purchased at each additional time of purchase to you through the facilities of DTC for the accounts of the several Underwriters against payment of the purchase price therefor in Federal (same day) funds by official bank check or checks or wire transfer to an account at a bank identified by the Company to First Albany drawn to the order of the Company, at the above office of Dewey Ballantine LLP at 9:00 A.M., New York time. The certificates for the Additional Shares being purchased at each additional time of purchase will be in the form of one or more global securities in definitive form deposited with DTC and registered in the name of Cede & Co., as nominee for DTC, and will be made available for checking at a reasonable time in advance of such additional time of purchase.

It is understood that the several Underwriters propose to offer the Shares for sale to the public as set forth in the Prospectus.

2. Representations and Warranties of the Company. The Company represents and warrants to each of the Underwriters that:

(a) The Company has been duly organized and is validly existing as a corporation in good standing under the laws of Delaware, with the requisite corporate power and authority to own, lease and operate its properties and conduct its business as described in the Registration Statement, the Disclosure Package or the Prospectus. The Company is duly qualified to do business as a foreign corporation and is in good standing in each jurisdiction where the ownership or leasing of its properties or the conduct of its business requires such qualification, except where the failure to so qualify would not, individually or in the aggregate, either (i) have a material adverse effect on the business, operations, properties, prospects, management, condition (financial or other) or results of operation of the Company and the Subsidiaries (as defined herein) taken as a whole or (ii) prevent or materially interfere with consummation of the transactions contemplated hereby (the occurrence of such effect or such prevention described in the foregoing clauses (i) or (ii) being herein referred to as a "Material Adverse Effect"). Complete and correct copies of the charter and bylaws or other organizational documents of the Company have been delivered to you, and, except as set forth in the exhibits to the Registration Statement, no changes therein will be made on or after the Applicable Time or on or before the time of purchase or, if applicable, any additional time of purchase.

(b) This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company, enforceable against the Company in accordance with its terms. The Shares have been duly and validly authorized by the Company and, when issued and delivered by the Company against payment therefor as provided herein, will be validly issued, fully paid and non-assessable and will not have been issued in violation of any preemptive, subscription or similar right.

(c) No approval, authorization, consent or order of or filing with any federal, state, local or other governmental commission, board, body, authority or agency, or of or with any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq Stock Market, Inc. ("Nasdaq"), or approval of the stockholders of the Company, is required to be obtained or made by the Company in connection with the issuance and sale of the Shares or the consummation by the Company of the other transactions contemplated hereby, other than (i) registration of the offer and sale of the Shares under the Act, which has been effected (or, with respect to any registration statement to be filed hereunder pursuant to Rule 462(b) under the Act, will be effected in accordance herewith), or (ii) any necessary qualification under the securities or blue sky laws of the various jurisdictions in which the Shares are being offered by the Underwriters.

(d) The execution and delivery by the Company of this Agreement and the performance by the Company of its obligations hereunder, including the issuance and sale of the Shares and the consummation of the other transactions contemplated hereby does not and will not conflict with, result in any breach or violation of or constitute a default under (or constitute any event which with notice, lapse of time or both would result in any breach or violation of or constitute a default under or give the holder of any indebtedness the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under), nor result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to (i) any provisions of the charter, bylaws or other organizational documents of the Company, (ii) any provision of any license, permit, indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any lease, contract or other agreement or instrument to which the Company is a party or by which it or any of its properties may be bound or affected, (iii) any federal, state, local or foreign law, regulation or rule, or any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq), or (iv) any decree, judgment or order applicable to the Company or any of its respective properties.

(e) The Registration Statement has heretofore become effective under the Act or, with respect to any registration statement to be filed to register the offer and sale of Shares pursuant to Rule 462(b) under the Act, will be filed with the Commission and become effective under the Act no later than 10:00 PM, New York City time, on the date of determination of the public offering price for the Shares; no stop order of the Commission preventing or suspending the use of the Prospectus or any Preliminary Prospectus or Permitted Free Writing Prospectus or the effectiveness of the Registration Statement has been issued, and no proceedings for such purpose have been instituted or, to the Company's knowledge, are contemplated by the Commission; the Exchange Act Registration Statement has become effective as provided in Section 12 of the Exchange Act.

(f) The Registration Statement complied when it became effective, complies as of the Applicable Time and, as amended or supplemented, at the time of purchase, each additional time of purchase, if any, and at all times during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172 under the Act or any similar rule) in connection with any sale of Shares, will comply, in all material respects, with the requirements of the Act; the Registration Statement did not, as of the Effective Time, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; each Preliminary Prospectus complied, at the time it was filed with the Commission, and complies as of the Applicable Time, in all material respects with the requirements

of the Act; the Disclosure Package, when considered together with the pricing information set forth on Schedule B hereto, does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; the Prospectus will comply, as of its date, and as of the date the Prospectus is filed with the Commission, and as of the time of purchase, each additional time of purchase, if any, in all material respects, with the requirements of the Act; the Prospectus will not, as of its date, and as of the date the Prospectus is filed with the Commission, and the time of purchase, any additional time of purchase, as then amended or supplemented, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that the Company makes no representation or warranty with respect to any statement contained in the Registration Statement, any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus in reliance upon and in conformity with information concerning any Underwriter furnished in writing by or on behalf of such Underwriter through First Albany to the Company expressly for use in the Registration Statement, such Preliminary Prospectus, the Prospectus or such Permitted Free Writing Prospectus.

(g) Prior to the execution of this Agreement, the Company has not, directly or indirectly, offered or sold any Shares by means of any "prospectus" (within the meaning of the Act), or used any "prospectus" (within the meaning of the Act) in connection with the offer or sale of the Shares, in each case other than any Preliminary Prospectus and any Permitted Free Writing Prospectus, if any; the Company has not, directly or indirectly, prepared, used or referred to any Permitted Free Writing Prospectus except in compliance with Rules 164 and 433 under the Act; assuming that such Permitted Free Writing Prospectus is accompanied or preceded by the most recent Preliminary Prospectus that contains a price range, and that such Permitted Free Writing Prospectus is so sent or given after the Registration Statement was filed with the Commission (and after such Permitted Free Writing Prospectus was, if required pursuant to Rule 433(d) under the Act, filed with the Commission), the sending or giving, by any Underwriter, of any Permitted Free Writing Prospectus will satisfy the provisions of Rule 164 or Rule 433 (without reliance on subsections (b), (c) and (d) of Rule 164 each of the Preliminary Prospectuses dated \_\_\_\_\_, 2006 is a prospectus that, other than by reason of Rule 433 or Rule 431 under the Act, satisfies the requirements of Section 10 of the Act, including a price range where required by rule; neither the Company nor the Underwriters are disqualified, by reason of subsection (f) or (g) of Rule 164 under the Act, from using, in connection with the offer and sale of the Shares, "free writing prospectuses" (as defined in

Rule 405 under the Act) pursuant to Rules 164 and 433 under the Act; the Company is not an “ineligible issuer” (as defined in Rule 405 under the Act) as of the eligibility determination date for purposes of Rules 164 and 433 under the Act with respect to the offering of the Shares contemplated by the Registration Statement; the parties hereto agree and understand that the content of any and all “road shows” (as defined in Rule 433 under the Act) related to the offering of the Shares contemplated hereby is solely the property of the Company; the Company has caused there to be made available at least one version of a “*bona fide* electronic road show” (as defined in Rule 433 under the Act) in a manner that, pursuant to Rule 433(d)(8)(ii) under the Act, causes the Company not to be required, pursuant to Rule 433(d) under the Act, to file, with the Commission, any Road Show.

(h) No person has a contractual or other right to act as an underwriter, or as a financial advisor to the Company, in connection with the offer and sale of the Shares or, except as described in the Registration Statement, the Disclosure Package and the Prospectus, and except for such rights as have been validly waived, to cause the Company to register under the Act the offer and sale of any shares of Common Stock or shares of any other capital stock or other equity interests of the Company, or to include any such shares or interests in the Registration Statement or the offering contemplated thereby.

(i) The capital stock of the Company, including the Shares, conforms in all material respects to the description thereof contained in the Registration Statement, the Disclosure Package and the Prospectus. As of the date of this Agreement, the Company’s capitalization is as set forth under the heading “Actual” in the section of the Registration Statement, any Preliminary Prospectus and the Prospectus entitled “Capitalization,” and as of the time of purchase and any additional time of purchase, as the case may be, the Company’s capitalization shall be as set forth under the heading “As Adjusted” in the section of the Registration Statement and the Prospectus entitled “Capitalization” (subject to the issuance of Additional Shares at any additional time of purchase). All of the issued and outstanding shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and non-assessable, have been issued in compliance with all applicable federal and state securities laws and were not issued in violation of any preemptive, subscription or similar right. Except as described in the Registration Statement, the Disclosure Package and the Prospectus (i) no person has a contractual or other right to cause the Company to issue or sell to it any shares of Common Stock or shares of any other capital stock or other equity interests of the Company and (ii) no person has any preemptive or similar rights to purchase any shares of Common Stock or shares of any other capital stock or other equity interests of the Company.

(j) Upon the closing of the sale of the Shares to the Underwriters, no shares of preferred stock of the Company shall be issued or outstanding, and no

holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company shall have any right to acquire any shares of preferred stock of the Company.

(k) The Company has no subsidiaries (as defined in the Act). Except as described in the Registration Statement, the Disclosure Package and the Prospectus, the Company does not own, directly or indirectly, any long-term debt or any equity interest in any firm, corporation, partnership, joint venture, association or other entity.

(l) The financial statements, together with the related schedules and notes, included in the Registration Statement, the Disclosure Package or the Prospectus present fairly the financial position of the Company as of the dates indicated and the results of operations and cash flows of the Company for the periods specified, have been prepared in compliance with the requirements of the Act and are in conformity with generally accepted accounting principles applied on a consistent basis during the periods involved. Any pro forma financial statements or data included in the Registration Statement, the Disclosure Package or the Prospectus comply as to form in all material respects with the applicable accounting requirements of the Act, and the adjustments used to prepare such pro forma financial statements or data are reasonable and have been properly applied to the historical amounts in the compilation of those statements or data. The other financial and statistical data set forth in the Registration Statement, the Disclosure Package or the Prospectus are accurately presented and prepared on a basis consistent with such financial statements and with the books and records of the Company. There are no financial statements (historical or pro forma) that are required to be included in the Registration Statement, any Preliminary Prospectus or the Prospectus that are not included as required. Grant Thornton LLP, whose report on the financial statements of the Company is filed with the Commission as part of the Registration Statement, any Preliminary Prospectus or the Prospectus, are independent public accountants as required by the Act and by Rule 3600T of the Public Company Accounting Oversight Board. Except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, the Company has no material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), and the Company, together with its "related parties," is not the "primary beneficiary" of any "variable interest entities" (as such terms are used in Financial Accounting Standards Board Interpretation No. 46). Any disclosure contained in the Registration Statement, any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus that meets the definition of "non-GAAP financial measures" set forth in the rules and regulations of the Commission comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Act.

(m) Subsequent to the date of the most recent audited balance sheet of the Company included in the Registration Statement, the Disclosure Package and the Prospectus, in each case excluding any amendments or supplements to the

foregoing made after the execution of this Agreement, except as disclosed in the Registration Statement, the Disclosure Package and the Prospectus, there has not been (i) any material adverse change, or any development involving a prospective material adverse change, in the business, operations, properties, prospects, management, condition (financial or other) or results of operations of the Company, (ii) any transaction which is material to the Company, (iii) any obligation or liability, direct or contingent, which is material to the Company, incurred by the Company, (iv) any change in the capital stock or outstanding indebtedness of the Company or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company.

(n) The Company is not in breach or violation of, or in default under (nor has any event occurred which with notice, lapse of time or both would result in any breach or violation of, or constitute a default under, or give the holder of any indebtedness the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (i) its charter, bylaws or other organizational documents, (ii) any provision of any license, permit, indenture, mortgage, deed of trust, bank loan or credit agreement or other evidence of indebtedness, or any lease, contract or other agreement or instrument to which the Company is a party or by it or any of its properties may be bound or affected, (iii) any federal, state, local or foreign law, regulation or rule or any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq), or (iv) any decree, judgment or order applicable to the Company, or any of its respective properties, except, in the case of clauses (ii) and (iii), such as would not, individually or in the aggregate, have a Material Adverse Effect.

(o) The Company has obtained and possesses all necessary licenses, permits, authorizations, consents and approvals and has made all necessary filings required under any federal, state, local or foreign law, regulation or rule (collectively, "Permits"), and has obtained all necessary authorizations, consents and approvals from other persons (collectively, "Approvals"), in order to conduct its business as described in the Registration Statement, the Disclosure Package or the Prospectus, other than such Permits and Approvals the failure of which to obtain, possess or file would not, individually or in the aggregate, have a Material Adverse Effect. The Company is not in violation of, or in default under, or has received notice of any proceedings relating to revocation or modification of, any Permit or Approval, except where such violation, default, revocation or modification would not, individually or in the aggregate, have a Material Adverse Effect.

(p) All contracts, leases, documents, properties or affiliate transactions of a character required to be described in the Registration Statement or the Prospectus or to be filed as an exhibit to the Registration Statement have been so described or filed as required. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, there are no actions, suits, claims,

investigations or proceedings pending or, to the Company's knowledge, threatened, with respect to the Company to which the Company or any of its directors or officers is a party, or of which any of their respective properties is subject, at law or in equity, before or by any federal, state, local or foreign court or governmental commission, board, body, authority or agency, before any arbitrator or mediation panel or other body, or before or by any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq).

(q) The Company has good title to all real and personal property owned, or described in the Registration Statement, the Disclosure Package or the Prospectus as being owned, by it, free and clear of all liens, encumbrances and defects except such as are described in the Registration Statement, the Disclosure Package and the Prospectus or such as would not, individually or in the aggregate, have a Material Adverse Effect. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, all real property and buildings held under lease by the Company are held by it under valid, subsisting and enforceable leases with such exceptions as do not materially interfere with the use made and proposed to be made of such property and buildings by the Company.

(r) The Company and its properties, assets and operations are in compliance with, and the Company holds all permits, authorizations and approvals required under, Environmental Laws (as defined below), except to the extent that failure to so comply or to hold such permits, authorizations or approvals would not, individually or in the aggregate, have a Material Adverse Effect. There are no past, present or, to the knowledge of the Company, reasonably anticipated future events, conditions, circumstances, activities, practices, actions, omissions or plans that could reasonably be expected to give rise to any material costs or liabilities to the Company under, or to interfere with or prevent material compliance by the Company with, Environmental Laws. Except as would not, individually or in the aggregate, have a Material Adverse Effect, the Company (i) is not the subject of any investigation, (ii) has not received any notice or claim, (iii) is not a party to or affected by any pending or threatened action, suit or proceeding, (iv) is not bound by any judgment, decree or order and (v) has not entered into any agreement, in each case relating to any actual or alleged violation of any Environmental Law or any actual or alleged release or threatened release or clean-up (at any location) of any Hazardous Materials (as defined below). As used herein, "Environmental Law" means any federal, state, local or foreign law, statute, ordinance, rule, regulation, order, decree, judgment, injunction, permit, license, authorization or other binding requirement, or common law, relating to health, safety or the protection, clean-up or restoration of the environment or natural resources, including those relating to the distribution, processing, generation, treatment, storage, disposal, transportation, other handling or release or threatened release of Hazardous Materials, and "Hazardous Material" means any material (including, without limitation, pollutants, contaminants and hazardous or toxic substances or wastes) that is regulated by or may give rise to liability under any Environmental Law. In the ordinary course of its business, the Company conducts a periodic review of the effect of the Environmental Laws on its business, operations and



properties, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for cleanup, closure of properties or compliance with the Environmental Laws, any related constraints on operating activities and any potential liabilities to third parties).

(s) Other than as set forth in the Registration Statement, the Disclosure Package and the Prospectus, the Company owns or has valid licenses to use all patents, trademarks, servicemarks, trade names, copyrights, trade secrets, information, proprietary rights and processes ("Intellectual Property") that are described in the Registration Statement, the Disclosure Package or the Prospectus as owned, licensed or otherwise controlled by the Company or are material to its business as currently conducted or as proposed to be conducted (including the commercialization of products or services described in the Registration Statement, the Disclosure Package or the Prospectus as under development), in each case as such business is described in the Registration Statement, the Disclosure Package or the Prospectus (collectively, the "Company IP"), without infringement of the rights of others, and the Company has taken all steps reasonably necessary to secure interests in the Company IP. The Company is not subject to any judgment, order, injunction or decree, or is a party to any agreement, which restricts or impairs in any material respect the Company's use of the Company IP. To the knowledge of the Company, no claims have been asserted by any third party with respect to the validity, scope or enforceability of the Company IP, or with respect to the Company's ownership of or right to use any of the Company IP, and there is no reasonable basis for any such claim. The Company has complied with the terms of any agreement pursuant to which the Company IP has been licensed to the Company, and except as would not, individually or in the aggregate, have a Material Adverse Effect, all such agreements are in full force and effect. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, the Company is not aware of any options, licenses or agreements pursuant to which third parties possess rights to the Company IP. None of the technology employed by the Company has been obtained or is used or proposed to be used by the Company in violation of any rights of a third party. Except as described in the Registration Statement, the Disclosure Package and the Prospectus, to the Company's knowledge the Company has not infringed and is not infringing and, by conducting its business as described in the Registration Statement, the Disclosure Package or the Prospectus and commercializing the products under development described therein, would not infringe the Intellectual Property of a third party, and the Company has not received notice of a claim by a third party to the contrary.

(t) The clinical, pre-clinical and other studies and tests conducted by or on behalf of or sponsored by the Company or in which the Company or its products or product candidates have participated that are described in the Registration Statement, the Disclosure Package or the Prospectus or the results of which are referred to in the Registration Statement, the Disclosure Package or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with standard medical and scientific research procedures. The descriptions in the Registration Statement, the Disclosure Package or the Prospectus of the results of

such studies and tests are accurate and complete in all material respects and fairly present the data derived from such studies and tests, and the Company has no knowledge of any other studies or tests the results of which, when considered in light of the disclosures in the Registration Statement, the Disclosure Package and the Prospectus, are inconsistent with or otherwise call into question the results described or referred to in the Registration Statement, the Disclosure Package or the Prospectus. Except to the extent described in the Registration Statement, the Disclosure Package and the Prospectus, the Company has operated and currently is in compliance in all material respects with all applicable rules, regulations and policies of the U.S. Food and Drug Administration and comparable drug regulatory agencies outside of the United States (collectively, the “Regulatory Authorities”). Except to the extent described in the Registration Statement, the Disclosure Package and the Prospectus, the Company has not received any notices or other correspondence from the Regulatory Authorities or any other governmental agency requiring the termination, suspension or material modification of any clinical or pre-clinical studies or tests that are described in the Registration Statement, the Disclosure Package or the Prospectus or the results of which are referred to in the Registration Statement, the Disclosure Package and the Prospectus.

(u) All tax returns required to be filed by the Company have been filed, other than those filings not yet due (including available extensions) or being contested in good faith, and all taxes, including withholding taxes, penalties and interest, assessments, fees and other charges due pursuant to such returns or pursuant to any assessment received by the Company have been paid, other than those being contested in good faith and for which adequate reserves have been provided.

(v) The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management’s general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and its directors and officers each are in compliance in all material respects, with respect to the Company, with all applicable effective provisions of the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) and the rules and regulations of the Commission and the Nasdaq promulgated thereunder. The Company has established and maintains and evaluates “disclosure controls and procedures” (as such term is defined in Rule 13a-15 and 15d-15 under the Exchange Act) and “internal control over financial reporting” (as such term is defined in Rule 13a-15 and 15d-15 under the Exchange Act); such disclosure controls and procedures are designed to ensure that material information relating to the Company is made known to the Company’s Chief Executive Officer and its Chief Financial Officer by others within the Company, and such disclosure controls and procedures are effective to perform the functions

for which they were established; the Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) any significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize, and report financial data; and (ii) any fraud, whether or not material, that involves management or other employees who have a role in the Company's internal controls; all material weaknesses in internal controls have been identified for the Company's auditors; since the date of the most recent evaluation of such disclosure controls and procedures, there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

(w) The Company has provided you true, correct and complete copies of all documentation pertaining to any extension of credit in the form of a personal loan made, directly or indirectly, by the Company to any director or executive officer of the Company, or to any family member or affiliate of any director or executive officer of the Company. On or after July 30, 2002, the Company has not, directly or indirectly: (i) extended credit, arranged to extend credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer of the Company, or to or for any family member or affiliate of any director or executive officer of the Company; or (ii) made any material modification, including any renewal thereof, to any term of any personal loan to any director or executive officer of the Company, or any family member or affiliate of any director or executive officer, which loan was outstanding on July 30, 2002.

(x) The Company maintains insurance of the types and in amounts reasonably adequate for their respective businesses, including, but not limited to, insurance covering real and personal property owned or leased by the Company and against theft, damage, destruction, acts of vandalism and other risks customarily insured against, all of which insurance is in full force and effect.

(y) No labor dispute with the employees of the Company or, to the knowledge of the Company, any of the customers or suppliers of the Company exists. To the knowledge of the Company, no such dispute is imminent that would, individually or in the aggregate, have a Material Adverse Effect.

(z) The Company is not engaged in any unfair labor practice. Except for matters which would not, individually or in the aggregate, have a Material Adverse Effect, (i) there is (A) no unfair labor practice complaint pending or, to the Company's knowledge, threatened against the Company before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under collective bargaining agreements is pending or threatened, (B) no strike, labor dispute, slowdown or stoppage pending or, to the Company's knowledge, threatened against the Company and (C) no union representation dispute currently existing concerning the employees of the Company, and (ii) to the Company's knowledge, (A) no union organizing activities are currently taking place concerning the employees of the Company and (B) there has been no violation of any federal,

state, local or foreign law relating to discrimination in the hiring, promotion or pay of employees, any applicable wage or hour laws or any provision of the Employee Retirement Income Security Act of 1974 (“ERISA”) or the rules and regulations promulgated thereunder concerning the employees of the Company.

(aa) The Company has not, nor, to the Company’s knowledge, has any employee or agent of the Company made any payment of funds of the Company or received or retained any funds in violation of any law, rule or regulation, which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement, any Preliminary Prospectus or the Prospectus.

(bb) The Company has obtained for the benefit of the Underwriters the agreement (a “Lock-Up Agreement”), in the form set forth as Exhibit A hereto, of each of its directors and officers and of all securities holders of the Company (assuming, for this purpose, the exercise or conversion of all outstanding securities or other rights exercisable or convertible, directly or indirectly, for shares of Common Stock).

(cc) The Company has not sent or received any notice of termination of, or intent not to renew, any of the contracts or agreements referred to or described in the Registration Statement, the Disclosure Package or the Prospectus or referred to or described in or filed as an exhibit to the Registration Statement, and no such termination has been threatened by the Company or, to the knowledge of the Company, by any other party to any such contract or agreement.

(dd) All statistical and market-related data included in the Registration Statement, the Disclosure Package or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate, and, to the extent required, the Company has obtained the written consent to the use of such data from such sources.

(ee) The Company is not, and at no time during which a prospectus is required by the Act to be delivered (whether physically or through compliance with Rule 172 under the Act or any similar rule) in connection with any sale of Shares will not be, and, after giving effect to the offering and sale of the Shares, will not be an “investment company” or an entity “controlled” by an “investment company,” as such terms are defined in the Investment Company Act of 1940, as amended (the “Investment Company Act”).

(ff) To the Company’s knowledge, there are no affiliations or associations between any member of the National Association of Securities Dealers, Inc. (“NASD”) and the Company or any of the Company’s officers, directors or 5% or greater securityholders, except as described in the Registration Statement (excluding the exhibits thereto), the Disclosure Package and the Prospectus.

In addition, any certificate signed by any officer of the Company and delivered to you or counsel for the Underwriters in connection with the offering of the Shares shall be deemed to be a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

3. Certain Covenants of the Company. The Company hereby agrees:

(a) if, at the time this Agreement is executed and delivered, it is necessary for a post-effective amendment to the Registration Statement, or a Registration Statement under Rule 462(b) under the Act, to be filed with the Commission and become effective before the offering of the Shares may commence, to use its best efforts to cause such post-effective amendment or such Registration Statement to be filed and become effective as soon as possible;

(b) to advise you promptly and (if requested by you) to confirm such advice in writing, (i) when any post-effective amendment to the Registration Statement becomes effective and (ii) when the Prospectus is filed with the Commission pursuant to Rule 424(b) under the Act (which the Company agrees to file in a timely manner in accordance with such Rules);

(c) to furnish such information as may be required and otherwise to cooperate in qualifying the Shares for offering and sale under the securities or blue sky laws of such states as you may designate and to maintain such qualifications in effect so long as required for the distribution of the Shares; provided that the Company shall not be required to qualify as a foreign corporation or to consent to the service of process under the laws of any such state (except service of process with respect to the offering and sale of the Shares); and to promptly advise you of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the initiation or threat of any proceeding for such purpose;

(d) to make available to the Underwriters in New York City, as soon as practicable after this Agreement becomes effective, and thereafter from time to time to furnish to the Underwriters, as many copies of the Prospectus (or of the Prospectus as amended or supplemented if the Company shall have made any amendments or supplements thereto after the effective date of the Registration Statement) as the Underwriters may reasonably request for the purposes contemplated by the Act; in case any Underwriter is required to deliver (whether physically or through compliance with Rule 172 under the Act or any similar rule) a prospectus after the nine-month period referred to in Section 10(a)(3) of the Act in connection with the sale of the Shares, to prepare promptly upon request such amendment or amendments to the Registration Statement and such prospectuses as may be necessary to permit compliance with the requirements of Section 10(a)(3) of the Act;

(e) to advise you promptly, confirming such advice in writing (if requested by you), of any request by the Commission for amendments or

supplements to the Registration Statement, any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus or for additional information with respect thereto, or of notice of institution of proceedings for, or the entry of, a stop order suspending the effectiveness of the Registration Statement and, if the Commission should enter a stop order suspending the effectiveness of the Registration Statement, to use its best efforts to obtain the lifting or removal of such order as soon as possible; to advise you promptly of any proposal to amend or supplement the Registration Statement, any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus and to file no such amendment or supplement to which you shall object in writing;

(f) if necessary or appropriate in connection with the offer and sale of the Shares, to file a Rule 462(b) Registration Statement in the manner prescribed by the Act so that such Rule 462(b) Registration Statement shall become effective upon filing;

(g) to furnish to you and, upon request, to each of the other Underwriters for a period of five years from the date of this Agreement (i) copies of any reports or other communications which the Company shall send to its stockholders or shall from time to time publish or publicly disseminate, (ii) copies of all annual, quarterly, current and transition reports filed with the Commission on Forms 10-K, 10-Q and 8-K, or such other similar forms, as may be designated by the Commission, (iii) copies of documents or reports filed with the Nasdaq or with any national securities exchange on which any class of securities of the Company is listed and (iv) such other information as you may reasonably request regarding the Company, in each case as soon as reasonably practicable after such reports, communications, documents or information become available;

(h) to advise the Underwriters promptly of the happening of any event known to the Company within the period during which a prospectus is required by the Act to be delivered under the Act (whether physically or through compliance with Rule 172 under the Act or any similar rule) in connection with any sale of Shares, which event could require the making of any change in the Prospectus then being used so that the Prospectus would not include an untrue statement of material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they are made, not misleading, and, during such time, to prepare and furnish, at the Company's expense, to the Underwriters promptly such amendments to the Registration Statement and supplements to the Prospectus as may be necessary to reflect any such change and to furnish you a copy of such proposed amendment or supplement before filing any such amendment or supplement with the Commission;

(i) to make generally available to its security holders, and to deliver to you, an earnings statement of the Company (which will satisfy the provisions of Section 11(a) of the Act) covering a period of twelve months beginning after the effective date of the Registration Statement (as defined in Rule 158(c) of the Act) and ending not later than March 31, 2008;

(j) to furnish to you three conformed copies of the Registration Statement, as initially filed with the Commission, and of all amendments thereto (including all exhibits thereto) and sufficient additional conformed copies (other than exhibits) for distribution of a copy to each of the other Underwriters;

(k) to furnish to you as soon as reasonably practicable prior to the time of purchase and any additional time of purchase, as the case may be, but not later than two business days prior thereto, a copy of the latest available unaudited interim consolidated financial statements, if any, of the Company and the Subsidiaries which have been read by the Company's independent certified public accountants, as stated in their letter to be furnished pursuant to Section 5(e) hereof;

(l) to apply the net proceeds from the sale of the Shares in the manner set forth under the caption "Use of Proceeds" in the Prospectus;

(m) to pay all costs, expenses, fees and taxes in connection with (i) the preparation and filing of the Registration Statement, any Rule 462(b) Registration Statement, each Preliminary Prospectus, the Prospectus, each Permitted Free Writing Prospectus and any amendments or supplements thereto, and the printing and furnishing of copies of each thereof to the Underwriters and to dealers (including costs of mailing and shipment), (ii) the registration, issue, sale and delivery of the Shares, including any stock or transfer taxes and stamp or similar duties payable upon the sale, issuance or delivery of the Shares to the Underwriters, (iii) the printing of this Agreement, any Agreement Among Underwriters, any dealer agreements, any Powers of Attorney and any closing documents (including compilations thereof) and the reproduction and/or printing and furnishing of copies of each thereof to the Underwriters and (except closing documents) to dealers (including costs of mailing and shipment), (iv) the qualification of the Shares for offering and sale under state laws and the determination of their eligibility for investment under state law as aforesaid (including associated filing fees and the reasonable legal fees and disbursements of counsel for the Underwriters) and the printing and furnishing of copies of any blue sky surveys or legal investment surveys to the Underwriters and to dealers, (v) any listing of the Shares on any securities exchange or qualification of the Shares for quotation on the Nasdaq Global Market and any registration thereof under the Exchange Act, (vi) review of the public offering of the Shares by the NASD Regulation, Inc. (including associated filing fees and the reasonable legal fees and disbursements of counsel for the Underwriters), (vii) the costs and expenses of the Company relating to presentations or meetings undertaken in connection with the marketing of the offer and sale of the Shares to prospective investors and your sales forces, including, without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations, travel, lodging and other expenses incurred by the officers of the Company and any such consultants, and the cost of any aircraft chartered by or on behalf of the Company in connection with the road show, (viii) the costs and expenses of qualifying the Shares for inclusion in DTC's book-entry settlement system and (ix) the performance of the Company's other obligations hereunder;

(n) to comply with Rule 433(g) under the Act;

(o) for so long as the delivery of a prospectus (whether physically or through compliance with Rule 172 under the Act or any similar rule) is required in connection with the offer or sale of the Shares, to furnish to you a reasonable period of time before filing with the Commission a copy of any document proposed to be filed pursuant to Section 13, 14 or 15(d) of the Exchange Act and to not make any filing to which you shall reasonably object;

(p) to furnish to its stockholders as soon as practicable after the end of each fiscal year an annual report (including a consolidated balance sheet, statement of income, stockholders' equity and cash flows of the Company for such fiscal year, accompanied by a copy of the report thereon of nationally recognized independent certified public accountants duly registered with the Public Company Oversight Accounting Board);

(q) to not take, directly or indirectly, any action designed to or which may constitute or which might reasonably be expected to cause or result, under the Exchange Act or otherwise, in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Shares;

(r) not to sell, offer or agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase or otherwise dispose of, directly or indirectly, any shares of Common Stock or securities convertible into or exchangeable or exercisable for Common Stock or any warrants or other rights to purchase Common Stock or any such securities or any other securities of the Company that are substantially similar to Common Stock, or file or cause to be declared effective a registration statement under the Act relating to the offer and sale of any shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock or any warrants or other rights to purchase Common Stock or any other securities of the Company that are substantially similar to Common Stock, for a period of 180 days after the date hereof (the "Lock-Up Period"), without the prior written consent of First Albany, except for (i) the registration of the offer and sale of the Shares, and the sales of the Shares, to the Underwriters pursuant to this Agreement, (ii) issuances of Common Stock upon the exercise of options or warrants disclosed as outstanding in the Registration Statement (excluding the exhibits thereto), the Disclosure Package and the Prospectus and (iii) the issuance of employee stock options not exercisable during the Lock-Up Period pursuant to stock option plans described in the Registration Statement (excluding the exhibits thereto), the Disclosure Package and the Prospectus; provided, however, that, if (i) during the period that begins on the date that is 15 calendar days plus 3 business days before the last day of the Lock-Up Period and ends on the last day of the Lock-Up Period, the Company issues an earnings release or significant news or a significant event relating to the Company occurs; or (ii) prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Lock-Up Period, then the restrictions imposed by this Section 3(r) shall continue to apply until the expiration



of the date that is 15 calendar days plus 3 business days after the date on which such significant news, such significant event or the issuance of such earnings release occurs;

(s) to maintain a transfer agent and, if necessary under the jurisdiction of incorporation of the Company, a registrar for the Common Stock;

(t) subject to Section 3(o) hereof, to file promptly all reports and any definitive proxy or information statement required to be filed by the Company with the Commission in order to comply with the Exchange Act subsequent to the date of the Prospectus and for so long as the delivery of a prospectus (whether physically or through compliance with Rule 172 under the Act or any similar rule) is required in connection with the offering or sale of the Shares, and to promptly notify you of such filing;

(u) not to, directly or indirectly, offer or sell any Shares by means of any "prospectus" (within the meaning of the Act), or use any "prospectus" (within the meaning of the Act) in connection with the offer or sale of the Shares, in each case other than the Preliminary Prospectuses and the Permitted Free Writing Prospectuses, if any; not to, directly or indirectly, prepare, use or refer to any Permitted Free Writing Prospectus except in compliance with Rules 164 and 433 under the Act; assuming that such Permitted Free Writing Prospectus is accompanied or preceded by the most recent Preliminary Prospectus that contains a price range, and that such Permitted Free Writing Prospectus is so sent or given after the Registration Statement was filed with the Commission (and after such Permitted Free Writing Prospectus was, if required pursuant to Rule 433(d) under the Act, filed with the Commission), the sending or giving, by any Underwriter, of any Permitted Free Writing Prospectus will satisfy the provisions of Rule 164 or Rule 433 (without reliance on subsections (b), (c) and (d) of Rule 164 each of the Preliminary Prospectuses dated [insert dates of red herrings actually distributed] is a prospectus that, other than by reason of Rule 433 or Rule 431 under the Act, satisfies the requirements of Section 10 of the Act, including a price range where required by rule; and

(v) to use its best efforts to cause the Common Stock to be listed for quotation on the Nasdaq Global Market and to maintain such listing.

4. Reimbursement of Underwriters' Expenses. If the Shares are not delivered for any reason other than the termination of this Agreement pursuant to the last paragraph of Section 7 hereof or the default by one or more of the Underwriters in its or their respective obligations hereunder, the Company agrees, in addition to paying the amounts described in Section 3(m) hereof, to reimburse the Underwriters for all of their out-of-pocket expenses, including the reasonable fees and disbursements of their counsel.

5. Conditions of Underwriters' Obligations. The several obligations of the Underwriters hereunder to purchase Shares at the time of purchase or any additional time of purchase shall be subject to the accuracy of the representations and warranties of the

Company on the date hereof and at the time of purchase and, with respect to the purchase of Shares at any additional time of purchase, at such additional time of purchase, the performance by the Company of its obligations hereunder and to the following additional conditions precedent:

- (a) You shall have received, at the time of purchase and at any such additional time of purchase, as the case may be, an opinion of Akerman Senterfitt, counsel for the Company, addressed to the Underwriters and dated the time of purchase or such additional time of purchase, as the case may be, with reproduced copies for each of the other Underwriters and in form and substance satisfactory to you, in the form set forth in Exhibit B hereto.
- (b) You shall have received at the time of purchase and at any such additional time of purchase, as the case may be, the opinion of Hoffman & Baron, patent counsel to Brookhaven Science Associates, addressed to the Underwriters and dated the time of purchase or such additional time of purchase, as the case may be, with reproduced copies for each of the other Underwriters and in form and substance satisfactory to you, in the form set forth in Exhibit C hereto.
- (c) You shall have received at the time of purchase and at any such additional time of purchase, as the case may be, the opinion of Hyman, Phelps & McNamara, PC, regulatory counsel to the Company, addressed to the Underwriters and dated the time of purchase or such additional time of purchase, as the case may be, with reproduced copies for each of the other Underwriters and in form and substance satisfactory to you, in the form set forth in Exhibit D hereto.
- (d) You shall have received at the time of purchase and at any such additional time of purchase, as the case may be, the opinion of Dewey Ballantine LLP, counsel for the Underwriters, dated the time of purchase or such additional time of purchase, as the case may be, with respect to the issuance and sale of the Shares by the Company, the Registration Statement, the Disclosure Package, the Prospectus and such other related matters as the Underwriters may require.
- (e) You shall have received from Grant Thornton LLP letters dated, respectively, the date of this Agreement and the time of purchase and any such additional time of purchase, as the case may be, and addressed to the Underwriters (with reproduced copies for each of the other Underwriters) in the forms approved by you.
- (f) No amendment to the Registration Statement or supplement to any Preliminary Prospectus or to the Prospectus shall at any time have been filed to which you have objected in writing.
- (g) The Registration Statement and any registration statement required to be filed, prior to the sale of the Shares, under the Act pursuant to Rule 462(b) shall have been filed and shall have become effective under the Act; the registration statement on form 8-A under the Exchange Act shall have become effective; and, if

Rule 430A under the Act is used, the Prospectus shall have been filed with the Commission pursuant to Rule 424(b) under the Act at or before 5:30 PM New York City time on the second full business day after the date of this Agreement or such shorter period of time prescribed by such Rule 424(b).

(h) Prior to the time of purchase, and, if applicable, the additional time of purchase, (i) no stop order with respect to the effectiveness of the Registration Statement shall have been issued under the Act or proceedings initiated under Section 8(d) or 8(e) of the Act; (ii) the Registration Statement and all amendments thereto shall not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (iii) the Disclosure Package shall not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they are made, not misleading; and (iv) the Prospectus, and no amendment or supplement thereto shall include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they are made, not misleading.

(i) Between the time of execution of this Agreement and the time of purchase or any additional time of purchase, as the case may be (i) no change or any development involving a prospective change in the business, operations, properties, prospects, management, condition (financial or other) or results of operations of the Company shall occur or become known and (ii) no transaction shall have been entered into by the Company, the effect of which, in any case referred to in clause (i) or (ii) above, is, in your sole judgment, so material and adverse as to make it impractical or inadvisable to proceed with the offering or delivery of the Shares as contemplated by the Registration Statement (exclusive of any amendment thereof), the Disclosure Package or the Prospectus (exclusive of any supplement thereto).

(j) The Company will, at the time of purchase or any such additional time of purchase, as the case may be, deliver to you a certificate, dated the time of purchase or such additional time of purchase, as the case may be, signed by its chief executive officer and its chief financial officer, in the form attached hereto as Exhibit E.

(k) You shall have received each of the signed Lock-Up Agreements referred to in Section 2(bb) hereof, and each such Lock-Up Agreement shall be in full force and effect at the time of purchase and such additional time of purchase, as the case may be.

(l) The Shares shall have been approved for inclusion in the Nasdaq Global Market, subject only to notice of issuance at or prior to the time of purchase or any such additional time of purchase, as the case may be.

(m) Between the time of execution of this Agreement and the time of purchase or any such additional time of purchase, as the case may be (i) no downgrading shall have occurred in the rating accorded any securities of, or guaranteed by, the Company or any Subsidiary by any "nationally recognized statistical rating organization," as that term is defined in Rule 436(g)(2) under the Act, and (ii) no such organization shall have announced or given notice of any intended or potential downgrading in any such rating or of a possible change in any such rating that does not indicate the direction of the possible change.

(n) The Company shall have furnished to you such other documents and certificates as to the accuracy and completeness of any statement in the Registration Statement, the Disclosure Package and the Prospectus as of the time of purchase and any additional time of purchase, as the case may be, as you may reasonably request.

6. Effective Date of Agreement; Termination. This Agreement shall become effective when the parties hereto have executed and delivered this Agreement. Until such time as this Agreement has become effective, it may be terminated by you or the Company at any time and for any reason.

The obligations of the several Underwriters hereunder shall be subject to termination in your absolute discretion if subsequent to the execution and delivery of this Agreement, there shall have occurred: (i) any change in U.S. or international financial, political or economic conditions or currency exchange rates or exchange controls as would, in your sole judgment, be likely to prejudice materially the success of the proposed issue, sale or distribution of the Shares, whether in the primary market or in respect of dealings in the secondary market; (ii) any suspension or material limitation of trading in securities generally on the New York Stock Exchange or the Nasdaq National Market, or any setting of minimum prices for trading on the New York Stock Exchange or the Nasdaq National Market, or any suspension or material limitation of trading of any securities of the Company on the Nasdaq or on any exchange or in the over-the-counter market; (iii) any banking moratorium declared by U.S. Federal or New York authorities; (iv) any major disruption in commercial banking or settlements of securities or clearance services in the United States; or (v) any attack on, or outbreak or escalation of hostilities or act of terrorism involving, the United States, any declaration of war by Congress or any other national or international calamity or emergency if, in your sole judgment, the effect of any such attack, outbreak, escalation, act, declaration, calamity or emergency makes it impracticable or inadvisable to proceed with completion of the offering or the sale of and payment for the Shares on the terms and in the manner contemplated by the Registration Statement, the Disclosure Package or the Prospectus.

If you elect to terminate this Agreement as provided in this Section 6, you shall notify the Company and each other Underwriter promptly by letter or telegram.

If the sale to the Underwriters of the Shares, as contemplated by this Agreement, is not carried out by the Underwriters for any reason permitted under this Agreement, or if such sale is not carried out because the Company shall be unwilling or

unable to comply with any of the terms of this Agreement, the Company shall not be under any obligation or liability under this Agreement (except to the extent provided in Sections 3(m), 4 and 8 hereof), and the Underwriters shall be under no obligation or liability to the Company under this Agreement (except to the extent provided in Section 8 hereof) or to one another hereunder.

7. **Increase in Underwriters' Commitments.** Subject to Sections 5 and 6 hereof, if any Underwriter shall default in its obligation to purchase and pay for the Firm Shares to be purchased by it hereunder, and if the number of Firm Shares which all Underwriters so defaulting shall have agreed but failed to purchase and pay for does not exceed 10% of the total number of Firm Shares, then the non-defaulting Underwriters shall purchase and pay for (in addition to the aggregate number of Firm Shares they are obligated to purchase pursuant to Section 1 hereof) the number of Firm Shares agreed to be purchased by all such defaulting Underwriters, as hereinafter provided. Such Firm Shares shall be purchased and paid for by such non-defaulting Underwriter or Underwriters in such amount or amounts as you may designate with the consent of each Underwriter so designated or, in the event no such designation is made, such Firm Shares shall be purchased and paid for by all non-defaulting Underwriters pro rata in proportion to the aggregate number of Firm Shares set opposite the names of such non-defaulting Underwriters in Schedule A hereto.

Without relieving any defaulting Underwriter from its obligations hereunder, the Company agrees with the non-defaulting Underwriters that it will not sell any Firm Shares hereunder unless all of the Firm Shares are purchased by the Underwriters (or by substituted Underwriters selected by you with the approval of the Company or selected by the Company with your approval).

If a new Underwriter or Underwriters are substituted by the Underwriters or by the Company for a defaulting Underwriter or Underwriters in accordance with this Section 7, the Company or you shall have the right to postpone the time of purchase for a period not exceeding five business days in order that any necessary changes in the Registration Statement, the Disclosure Package or the Prospectus or other documents may be effected.

The term "Underwriter" as used in this Agreement shall refer to and include any Underwriter substituted under this Section 7 with like effect as if such substituted Underwriter had originally been named in Schedule A hereto.

If the aggregate number of Shares which the defaulting Underwriter or Underwriters agreed to purchase exceeds 10% of the total number of Shares which all Underwriters agreed to purchase hereunder, and if neither the non-defaulting Underwriters nor the Company shall make arrangements within the five business day period stated above for the purchase of all the Shares which the defaulting Underwriter or Underwriters agreed to purchase hereunder, this Agreement shall terminate without further act or deed and without any liability on the part of the Company to any non-defaulting Underwriter and without any liability on the part of any non-defaulting Underwriter to the Company. Nothing in this paragraph, and no action taken hereunder, shall relieve any defaulting

Underwriter from liability in respect of any default of such Underwriter under this Agreement.

8. Indemnity and Contribution.

(a) The Company agrees to indemnify, defend and hold harmless each Underwriter, its partners, directors and officers, and any person who controls any Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, and the successors and assigns of all of the foregoing persons, from and against any loss, damage, expense, liability or claim (including the reasonable cost of investigation) which, jointly or severally, any such Underwriter or any such person may incur under the Act, the Exchange Act, the common law or otherwise, insofar as such loss, damage, expense, liability or claim arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or in the Registration Statement as amended by any post-effective amendment thereof by the Company) or arises out of or is based upon any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as any such loss, damage, expense, liability or claim arises out of or is based upon any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning such Underwriter furnished in writing by or on behalf of such Underwriter through you to the Company expressly for use in, the Registration Statement or arises out of or is based upon any omission or alleged omission to state a material fact in the Registration Statement in connection with such information, which material fact was not contained in such information and which material fact was required to be stated in such Registration Statement or was necessary to make such information not misleading, (ii) any untrue statement or alleged untrue statement of a material fact included in any Prospectus (the term Prospectus for the purpose of this Section 8 being deemed to include any Preliminary Prospectus, the Prospectus and any amendments or supplements to the foregoing), in any Issuer Free Writing Prospectus, in any "issuer information" (as defined in Rule 433 under the Act) of the Company or arises out of or is based upon any omission or alleged omission to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, except, with respect to such Prospectus or Permitted Free Writing Prospectus, insofar as any such loss, damage, expense, liability or claim arises out of or is based upon any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning such Underwriter furnished in writing by or on behalf of such Underwriter through you to the Company expressly for use in, such Prospectus or Permitted Free Writing Prospectus or arises out of or is based upon any omission or alleged omission to state a material fact in such Prospectus or Permitted Free Writing Prospectus in connection with such information, which material fact was not contained in such information and which material fact was necessary in order to make the statements in such information, in the light of the circumstances under which they were made, not misleading, (iii) any untrue statement or alleged untrue statement made by the Company in Section 2 hereof or the failure by the Company to perform, when and as required, any agreement or covenant contained herein; or (iv) any untrue statement or alleged untrue statement of any material fact contained in any audio or visual materials provided by the Company or based upon written information furnished by or on behalf of

the Company including, without limitation, slides, videos, films or tape recordings used in connection with the marketing of the Shares.

If any action, suit or proceeding (each, a "Proceeding") is brought against an Underwriter or any such person in respect of which indemnity may be sought against the Company pursuant to the foregoing paragraph, such Underwriter or such person shall promptly notify the Company in writing of the institution of such Proceeding and the Company shall assume the defense of such Proceeding, including the employment of counsel reasonably satisfactory to such indemnified party and payment of all fees and expenses; provided, however, that the omission to so notify the Company shall not relieve the Company from any liability which the Company may have to any Underwriter or any such person or otherwise. Such Underwriter or such person shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter or of such person unless the employment of such counsel shall have been authorized in writing by the Company in connection with the defense of such Proceeding or the Company shall not have, within a reasonable period of time in light of the circumstances, employed counsel to have charge of the defense of such Proceeding or such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from, additional to or in conflict with those available to the Company (in which case the Company shall not have the right to direct the defense of such Proceeding on behalf of the indemnified party or parties), in any of which events such fees and expenses shall be borne by the Company and paid as incurred (it being understood, however, that the Company shall not be liable for the expenses of more than one separate counsel (in addition to any local counsel) in any one Proceeding or series of related Proceedings in the same jurisdiction representing the indemnified parties who are parties to such Proceeding). The Company shall not be liable for any settlement of any Proceeding effected without the written consent of the Company, but if settled with the written consent of the Company, the Company agrees to indemnify and hold harmless any Underwriter and any such person from and against any loss or liability by reason of such settlement. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested the Company to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second sentence of this paragraph, then the Company agrees that it shall be liable for any settlement of any Proceeding effected without the Company's written consent if (i) such settlement is entered into more than 60 business days after receipt by the Company of the aforesaid request, (ii) the Company shall not have fully reimbursed the indemnified party in accordance with such request prior to the date of such settlement and (iii) the indemnified party shall have given the Company at least 30 days' prior notice of its intention to settle. The Company shall not, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened Proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such Proceeding and does not include an admission of fault, culpability or a failure to act, by or on behalf of such indemnified party.

(b) Each Underwriter severally agrees to indemnify, defend and hold harmless the Company, its directors and officers, and any person who controls the Company within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, and the successors and assigns of all of the foregoing persons, from and against any loss, damage, expense, liability or claim (including the reasonable cost of investigation) which the Company or any such person may incur under the Act, the Exchange Act, the common law or otherwise, insofar as such loss, damage, expense, liability or claim arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning such Underwriter furnished in writing by or on behalf of such Underwriter through you to the Company expressly for use in, the Registration Statement (or in the Registration Statement as amended by any post-effective amendment thereof by the Company), or arises out of or is based upon any omission or alleged omission to state a material fact in such Registration Statement in connection with such information, which material fact was not contained in such information and which material fact was required to be stated in such Registration Statement or was necessary to make such information not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in, and in conformity with information concerning such Underwriter furnished in writing by or on behalf of such Underwriter through you to the Company expressly for use in, a Prospectus or a Permitted Free Writing Prospectus, or arises out of or is based upon any omission or alleged omission to state a material fact in such Prospectus or Permitted Free Writing Prospectus in connection with such information, which material fact was not contained in such information and which material fact was necessary in order to make the statements in such information, in the light of the circumstances under which they were made, not misleading.

If any Proceeding is brought against the Company or any such person in respect of which indemnity may be sought against any Underwriter pursuant to the foregoing paragraph, the Company or such person shall promptly notify such Underwriter in writing of the institution of such Proceeding and such Underwriter shall assume the defense of such Proceeding, including the employment of counsel reasonably satisfactory to such indemnified party and payment of all fees and expenses; provided, however, that the omission to so notify such Underwriter shall not relieve such Underwriter from any liability which such Underwriter may have to the Company or any such person or otherwise. The Company or such person shall have the right to employ their or its own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of the Company or such person unless the employment of such counsel shall have been authorized in writing by such Underwriter in connection with the defense of such Proceeding or such Underwriter shall not have, within a reasonable period of time in light of the circumstances, employed counsel to defend such Proceeding or such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to or in conflict with those available to such Underwriter (in which case such Underwriter shall not have the right to direct the defense of such Proceeding on behalf of the indemnified party or parties, but such Underwriter may employ counsel and participate in the defense thereof but the fees and expenses of such counsel shall be at the expense of such Underwriter), in any of which events such fees and expenses shall be borne by such Underwriter and paid as incurred (it being understood, however, that such Underwriter shall not be liable for the expenses of more than one



separate counsel (in addition to any local counsel) in any one Proceeding or series of related Proceedings in the same jurisdiction representing the indemnified parties who are parties to such Proceeding). No Underwriter shall be liable for any settlement of any such Proceeding effected without the written consent of such Underwriter but if settled with the written consent of such Underwriter, such Underwriter agrees to indemnify and hold harmless the Company and any such person from and against any loss or liability by reason of such settlement. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second sentence of this paragraph, then the indemnifying party agrees that it shall be liable for any settlement of any Proceeding effected without its written consent if (i) such settlement is entered into more than 60 business days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement and (iii) such indemnified party shall have given the indemnifying party at least 30 days' prior notice of its intention to settle. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened Proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such Proceeding.

(c) If the indemnification provided for in this Section 8 is unavailable to an indemnified party under subsections (a) or (b), as applicable, of this Section 8 in respect of any losses, damages, expenses, liabilities or claims referred to therein, then each applicable indemnifying party, in lieu of indemnifying such indemnified party, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, damages, expenses, liabilities or claims (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Shares or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and of the Underwriters on the other in connection with the statements or omissions which resulted in such losses, damages, expenses, liabilities or claims, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same respective proportions as the total proceeds from the offering (net of underwriting discounts and commissions but before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, bear to the aggregate public offering price of the Shares. The relative fault of the Company on the one hand and of the Underwriters on the other shall be determined by reference to, among other things, whether the untrue statement or alleged untrue statement of a material fact or omission or alleged omission relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The amount paid or payable by a party as a result of the losses, damages, expenses, liabilities and claims referred to in this subsection shall be deemed to include any legal or other fees

or expenses reasonably incurred by such party in connection with investigating, preparing to defend or defending any Proceeding.

(d) The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 8 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in subsection (c) above. Notwithstanding the provisions of this Section 8, in no case shall any Underwriter be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by such Underwriter and distributed to the public were offered to the public exceeds the amount of any damage which such Underwriter has otherwise been required to pay by reason of such untrue statement or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to this Section 8 are several in proportion to their respective underwriting commitments and not joint.

(e) The indemnity and contribution agreements contained in this Section 8 and the covenants, warranties and representations of the Company contained in this Agreement shall remain in full force and effect regardless of any investigation made by or on behalf of any Underwriter, its partners, directors or officers or any person (including each partner, officer or director of such person) who controls any Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, or by or on behalf of the Company, its directors or officers or any person who controls any of the foregoing within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, and shall survive any termination of this Agreement or the issuance and delivery of the Shares. The Company and each Underwriter agree promptly to notify each other of the commencement of any Proceeding against it and, in the case of the Company, against any of the officers or directors of the Company in connection with the issuance and sale of the Shares, or in connection with the Registration Statement, any Preliminary Prospectus, the Prospectus, any Permitted Free Writing Prospectus or any Issuer Free Writing Prospectus.

9. Notices. Except as otherwise herein provided, all statements, requests, notices and agreements shall be in writing or by telegram and, if to the Underwriters, shall be sufficient in all respects if delivered or sent to First Albany Capital Inc., One Penn Plaza, 42nd Floor, New York, NY 10119, Attention: Syndicate Department; and if to the Company, shall be sufficient in all respects if delivered or sent to the Company at the offices of the Company at 220 Miracle Mile, Suite 234, Coral Gables, FL 33134, Attention: Chief Executive Officer.

10. No Fiduciary Duty. The Company hereby acknowledges that (a) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters and any affiliate through which they may be acting, on the other, (b) the Underwriters are acting as principal and not as an agent or fiduciary of the Company and (c) the Company's engagement of the Underwriters in connection with the offering and the process leading up

to the offering is as independent contractors and not in any other capacity. Furthermore, the Company agrees that it is solely responsible for making its own judgments in connection with the offering (irrespective of whether any of the Underwriters has advised or is currently advising the Company on related or other matters). The Company agrees that it will not claim that the Underwriters have rendered advisory services of any nature or respect, or owe an agency, fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

11. Information Furnished by the Underwriters. The statements set forth in the eighth paragraph, and in the section "Stabilization and Short Positions," under the caption "Underwriting" in the Prospectus, only insofar as such statements relate to the amount of selling concession and reallocation or to over-allotment and stabilization activities that may be undertaken by the Underwriters, constitute the only information furnished by or on behalf of the Underwriters as such information is referred to in Sections 2 and 8 hereof.

12. Governing Law; Construction. This Agreement and any claim, counterclaim or dispute of any kind or nature whatsoever arising out of or in any way relating to this Agreement ("Claim"), directly or indirectly, shall be governed by, and construed in accordance with, the laws of the State of New York. The section headings in this Agreement have been inserted as a matter of convenience of reference and are not a part of this Agreement.

13. Submission to Jurisdiction. Except as set forth below, no Claim may be commenced, prosecuted or continued in any court other than the courts of the State of New York located in the City and County of New York or in the United States District Court for the Southern District of New York, which courts shall have jurisdiction over the adjudication of such matters, and you and the Company consent to the jurisdiction of such courts and personal service with respect thereto. The Company hereby consents to personal jurisdiction, service and venue in any court in which any Claim arising out of or in any way relating to this Agreement is brought by any third party against an Underwriter or any indemnified party. Each Underwriter and the Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) waives all right to trial by jury in any action, proceeding or counterclaim (whether based upon contract, tort or otherwise) in any way arising out of or relating to this Agreement. The Company agrees that a final judgment in any such action, proceeding or counterclaim brought in any such court shall be conclusive and binding thereupon, and may be enforced in any other courts in the jurisdiction to which the Company is or may be subject, by suit upon such judgment.

14. Parties at Interest. The Agreement herein set forth has been and is made solely for the benefit of the Underwriters, the Company and, to the extent provided in Section 8 hereof, the controlling persons, directors and officers referred to in such section, and their respective successors, assigns, heirs, personal representatives and executors and administrators. No other person, partnership, association or corporation (including a purchaser, as such purchaser, from any of the Underwriters) shall acquire or have any right under or by virtue of this Agreement.

15. Counterparts. This Agreement may be signed by the parties in one or more counterparts which together shall constitute one and the same agreement among the parties.

16. Successors and Assigns. This Agreement shall be binding upon the Underwriters and the Company and their successors and assigns and any successor or assign of any substantial portion of the Company's and any of the Underwriters' respective businesses and/or assets.

*[The Remainder of This Page Intentionally Left Blank; Signature Page Follows]*

If the foregoing correctly sets forth the understanding among the Company and the Underwriters, please so indicate in the space provided below for such purpose, whereupon this letter and your acceptance shall constitute a binding agreement among the Company and the several Underwriters.

Very truly yours,

CATALYST PHARMACEUTICAL PARTNERS, INC.

By: \_\_\_\_\_  
Name:  
Title:

Accepted and agreed to as of the date  
first above written:

FIRST ALBANY CAPITAL INC.  
STIFEL, NICOLAUS & COMPANY, INCORPORATED  
*As Representatives of the several Underwriters*

By: FIRST ALBANY CAPITAL INC.

By: \_\_\_\_\_  
Name:  
Title:

**SCHEDULE A**

<u>Underwriter</u>	<u>Number of Firm Shares</u>
First Albany Capital Inc.	<input type="text"/>
Stifel, Nicolaus & Company, Incorporated	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
Total	<u><input type="text"/></u>

**SCHEDULE B**

PERMITTED FREE WRITING PROSPECTUSES

[(Excluding Electronic Roadshows)]

[ ]

**EXHIBIT A**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

Common Stock

\_\_\_\_\_, 2006

First Albany Capital Inc.  
Stifel, Nicolaus & Company, Incorporated  
*As Representatives of the several Underwriters*

c/o First Albany Capital Inc.  
One Penn Plaza, 42nd Floor  
New York, New York 10119

Ladies and Gentlemen:

This Lock-Up Letter Agreement is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement") to be entered into by and among Catalyst Pharmaceutical Partners, Inc., a Delaware corporation (the "Company"), and you, as representatives of the several Underwriters named therein, with respect to the public offering (the "Offering") of common stock, par value \$0.001 per share, of the Company (the "Common Stock").

In order to induce you to enter into the Underwriting Agreement, the undersigned agrees that, during the period (the "Lock-Up Period") that begins on the date hereof and ends as of the close of business, New York time, on the 181st day after the date of the final prospectus relating to the Offering, the undersigned will not, directly or indirectly, without the prior written consent of First Albany Capital Inc., (i) sell, offer to sell, contract to sell, hypothecate, pledge, grant any option to purchase or otherwise dispose of or agree to dispose of, or file or participate in the filing of a registration statement with the Securities and Exchange Commission (the "Commission") with respect to, or establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Securities Exchange Act of 1934, as amended, and the rules and regulations of the Commission promulgated thereunder with respect to, any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, or any warrants or other rights to purchase Common Stock or any such security, except for the exercise of any stock option by the undersigned, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock, or any warrants or other rights to purchase Common Stock or any such security, whether any such transaction is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, or (iii) publicly announce an intention to effect any transaction specified in clause (i) or (ii). The foregoing sentence shall not



apply to (a) the registration of, or sale to the Underwriters of, any Common Stock pursuant to the Offering and the Underwriting Agreement, (b) bona fide gifts, provided the recipient or recipients thereof agree in writing to be bound by the terms of this Lock-Up Letter Agreement or (c) dispositions to any trust for the direct or indirect benefit of the undersigned and/or the immediate family of the undersigned, provided that such trust agrees in writing to be bound by the terms of this Lock-Up Letter Agreement. For purposes of this paragraph, "immediate family" shall mean the undersigned and the spouse, any lineal descendant, father, mother, brother or sister of the undersigned.

In addition, the undersigned hereby waives any rights the undersigned may have to require registration of Common Stock in connection with the filing of a registration statement relating to the Offering. The undersigned further agrees that, during the Lock-Up Period, the undersigned will not, directly or indirectly, without the prior written consent of First Albany Capital Inc., make any demand for, or exercise any right with respect to, the registration of Common Stock of the Company or any securities convertible into or exercisable or exchangeable for Common Stock.

In addition, if (i) during the period that begins on the date that is 15 calendar days plus 3 business days before the last day of the Lock-Up Period and ends on the last day of the Lock-Up Period, the Company issues an earnings release or significant news or a significant event relating to the Company occurs; or (ii) prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the Lock-Up Period, then the restrictions imposed by this Lock-Up Letter Agreement shall continue to apply until the expiration of the date that is 15 calendar days plus 3 business days after the date on which such significant news, such significant event or the issuance of such earnings release occurs.

This Lock-Up Letter Agreement shall be terminated and the undersigned shall be released from the undersigned's obligations hereunder (i) upon the date the Company notifies you in writing that it does not intend to proceed with the Offering, (ii) upon the date the registration statement filed with the Securities and Exchange Commission with respect to the Offering is withdrawn or (iii) upon the date the Underwriting Agreement is terminated, for any reason, prior to the "time of purchase" (as defined in the Underwriting Agreement).

Yours very truly,

\_\_\_\_\_  
Name:

**EXHIBIT B**

OPINION OF AKERMAN SENTERFITT

1. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of Delaware, with the requisite corporate power and authority to own, lease and operate its properties and conduct its business as described in the Registration Statement, the Disclosure Package or the Prospectus, to execute and deliver the Underwriting Agreement and to issue, sell and deliver the Shares as contemplated by the Underwriting Agreement.
2. The Company and is duly qualified to do business as a foreign corporation and is in good standing in each jurisdiction in which such qualification is necessary, except where the failure to so qualify would not, individually or in the aggregate, have a Material Adverse Effect.
3. The Underwriting Agreement has been duly authorized, executed and delivered by the Company.
4. The Shares have been duly authorized and, when issued and delivered to and paid for by the Underwriters, will be validly issued, fully paid and non-assessable.
5. The Company has authorized and outstanding shares of capital stock as set forth in the Registration Statement, the Disclosure Package or the Prospectus; the outstanding shares of capital stock of the Company (A) have been duly authorized and validly issued and are fully paid and non-assessable, (B) are free of preemptive, subscription or similar rights under the

Delaware General Corporation Law, including all applicable provisions of the Delaware Constitution and reported judicial decisions interpreting these laws (collectively, the "DGCL") or the charter or bylaws or other organizational documents of the Company or any contract, commitment or instrument described in the Registration Statement or the Prospectus or filed as an exhibit to the Registration Statement or otherwise known to us and (C) to our knowledge, were issued in compliance with all applicable federal and state securities laws; the Shares, when issued, will be free of preemptive, subscription or similar rights under the DGCL or the charter or bylaws or other organizational documents of the Company or any contract, commitment or instrument described in the Registration Statement or the Prospectus or filed as an exhibit to the Registration Statement or otherwise known to us; the holders of the Shares will not be subject to personal liability by reason of being such holders; and the certificates for the Shares are in due and proper form and conform to the requirements of the DGCL and the Nasdaq.

6. The capital stock of the Company, including the Shares, conforms in all material respects to the description thereof contained in the Registration Statement, the Disclosure Package or the Prospectus.

7. The Registration Statement, each Preliminary Prospectus and the Prospectus (except as to the financial statements and schedules and the financial data derived therefrom, as to which we express no opinion) comply as to form in all material respects with the requirements of the Act.

8. To our knowledge, the Company is not an "ineligible issuer" (as defined in Rule 405 under the Act) as of the eligibility determination date for purposes of Rule 164 and Rule 433 under the Act with respect to the offering of the Shares contemplated by the Registration Statement.

9. The Registration Statement has become effective under the Act, and to our knowledge no stop order with respect to the effectiveness thereof has been issued and no stop order proceedings with respect thereto are pending or threatened under the Act; and any required filing of the Prospectus and any supplement thereto pursuant to Rule 424 under the Act has been made in the manner and within the time period required by such Rule 424 and in the manner and within the time period required by Rule 430A under the Act.

10. No approval, authorization, consent or order of or filing with any federal or state governmental commission, board, body, authority or agency, or under any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq), or of or with the stockholders of the Company, is required in connection with the execution and delivery of the Underwriting Agreement and the issuance, sale

and delivery of the Shares and consummation of the other transactions contemplated by the Underwriting Agreement other than those that have been obtained under the Act and the rules of the Nasdaq and other than any necessary qualification under the state securities or blue sky laws of the various jurisdictions in which the Shares are being offered by the Underwriters or any necessary approval of the Corporate Financing Department of the NASD, as to which qualification and approval we express no opinion.

11. The execution and delivery by the Company of the Underwriting Agreement and the performance by the Company of its obligations hereunder, including the consummation of the transactions contemplated by the Underwriting Agreement and by the Registration Statement and the Prospectus, do not constitute, and will not result in, a breach or violation of, or a default under (nor an event which, with notice, lapse of time or both would result in a breach or violation of, or constitute a default under or give the holder of any indebtedness the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under), nor result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to (A) any provision of the charter or bylaws or other organizational documents of the Company, (B) any provision of any license, permit, franchise or authorization issued to the Company, or of any indenture, mortgage, deed of trust, note, bank loan or credit agreement or other evidence of indebtedness, or any lease, contract or other agreement or instrument to which the Company is a party or by which it may be bound or affected, or to which any of the property or assets of the Company is subject or may be bound or affected, in each case that is described in the Registration Statement or the Prospectus or filed as an exhibit to the Registration Statement or otherwise known to us, (C) any federal or state law, regulation or rule or any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq) or (D) any decree, judgment or order known by us to be applicable to the Company.

12. To our knowledge, the Company is not in breach or violation of, or in default under (nor has any event occurred which with notice, lapse of time or both would result in any breach or violation of, or constitute a default under, or give the holder of any indebtedness the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (i) its charter, bylaws or other organizational documents; (ii) any provision of any license, permit, franchise or authorization issued to the Company, or of any indenture, mortgage, deed of trust, note, bank loan or credit agreement or other evidence of indebtedness, or any lease, contract or other agreement or instrument to which the Company is a party or by which it may be bound or affected, or to which any of the property or assets of the Company is subject or may be bound or affected, in each case that is described in the Registration Statement or the Prospectus or filed as an exhibit to the Registration Statement or otherwise know to us; (iii) any federal or state law, regulation or rule or any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including, but not limited to, the Nasdaq); or (iv) any decree, judgment or order applicable to the Company, or any of its properties.

13. To our knowledge, there are no contracts, licenses, agreements, leases, documents or affiliate transactions of a character which are required to be described in the

Registration Statement, any Preliminary Prospectus or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described or filed as required.

14. To our knowledge, there are no actions, suits, claims, investigations or proceedings pending or threatened to which the Company or any of the Subsidiaries is subject or of which any of their respective properties is subject, whether at law or in equity or before or by any federal, state, local or foreign governmental or regulatory commission, court, board, body, authority or agency, which are required to be described in the Registration Statement or the Prospectus but are not so described as required.

15. The Company is not and, after giving effect to the offer and sale of the Shares, will not be an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act.

16. Those statements in the Registration Statement, the Preliminary Prospectus or the Prospectus that are descriptions of contracts, agreements or other legal documents or of legal proceedings, or refer to statements of law or legal conclusions, are accurate and complete in all material respects and present fairly the information purported to be shown.

17. No person has the right, pursuant to the terms of any contract, agreement or other instrument described in the Registration Statement or the Prospectus or filed as an exhibit to the Registration Statement, or otherwise known to us, to have any securities issued by the Company registered pursuant to the Act, included in the Registration Statement or sold in the offering contemplated thereby.

We have participated in conferences with officers and other representatives of the Company, representatives of the independent public accountants of the Company and representatives of the Underwriters at which the contents of the Registration Statement, the Disclosure Package and the Prospectus were discussed and, although we are not passing upon and do not assume responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement, the Disclosure Package or the Prospectus (except as and to the extent stated in subparagraphs 5, 6, and 16 above), on the basis of the foregoing, nothing has come to our attention that causes us to believe that (i) the Registration Statement, at the Effective Time, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Prospectus, as of its date, or as of the date hereof, included or includes an untrue statement of a material fact or omitted or omits to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iii) the Disclosure Package, as of the time of the determination of the price of the Shares or the date hereof, included or includes an untrue statement of a material fact or omitted or omits to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (it being understood that we express no opinion with respect to the financial statements and schedules, and other financial, or statistical data derived therefrom, included in the Registration Statement, the Disclosure Package or the Prospectus.

EXHIBIT C

OPINION OF HOFFMAN & BARON

1. Based on information provided by Brookhaven Science Associates ("BSA") and to our knowledge, BSA is listed in the records of the appropriate patent offices as the owner of the Patents.
2. Based on information provided by BSA and to our knowledge, BSA has complied with the United States Patent and Trademark Office's duty of candor and good faith as set forth in 37 C.F.R. Section 1.56 for all of the Patents.
3. We have no knowledge of any facts that form a basis for finding of unenforceability or invalidity of any of the patent rights owned by BSA, and we are unaware of any facts that would preclude the grant of a patent from each of the patent applications set forth in Exhibit A hereto.
4. Based on information provided by BSA and to our knowledge, there is no infringement by any third party of any of the Patents of BSA.
5. Other than those rights retained by the U.S. Government and its sublicensees, to our knowledge, there is no pending or threatened action, suit, proceeding or legal claim by others challenging the Company's or its licensor's right in and/or to any rights in the Patents and we are unaware of any facts that would form a reasonable basis for such claim.
6. Based on information provided by BSA and to our knowledge, there is no pending or threatened action, suit, proceeding or legal claim by others challenging the validity or scope of any Intellectual Property, and we are unaware of any facts that would form a reasonable basis for any such claim.
7. Based on information provided by BSA and to our knowledge, there is no pending or threatened action, suit, proceeding or legal claim by others that the technology covered by the Patents infringe any patent. We advise that as to "method of treatment" or "method of use" claims, a license may be required from the owner of any patent for an action substance(s) used in such method(s).
8. To our knowledge, including our comments set forth in Exhibit C hereto, we know of no prior art that would render subject matter claimed in the Patents unpatentable.
9. Based on information provided by BSA and to our knowledge, there are no inventorship challenges, any interference which has been declared or provoked, or any other material fact with respect to the Patents that would either (A) preclude the issuance of patents with respect to pending applications; (B) lead us to conclude that patents issuing from such patent applications would not be valid and enforceable; or (C) subject to rights retained by the U.S. Government and its sublicensees, result in a third party having any rights in any patents issuing from such patent applications.

10. The statements included in the Registration Statement, the Preliminary Prospectus or the Prospectus referencing Intellectual Property matters, insofar as such statements constitute summaries of legal matters, contracts, agreements, documents or proceedings referred to therein, or refer to statements of law or legal conclusions, are in all material respects accurate and complete statements or summaries of the matters therein set forth and present fairly the information therein set forth.

11. Nothing has come to our attention that causes us to believe that such above-described portions of the Registration Statement, at the time such Registration Statement became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, or that such above described portions of the Disclosure Package and Prospectus, at the time of the determination of the price of the Shares and on the date hereof contained or contains an untrue statement of material fact or omitted or omits to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

**EXHIBIT D**

OPINION OF HYMAN, PHELPS & MCNAMARA, PC

1. Insofar as the statements in the Registration Statement, the Disclosure Package or the Prospectus relating to FDA regulatory matters (the "Designated Regulatory Provisions") purport to describe or summarize applicable provisions of the FDA Laws, at the time the Registration Statement became effective, as of the date of the date of the Prospectus, and on the date hereof, such statements were and are accurate in all material respects, subject to any qualifications set forth therein; and
2. Nothing has come to our attention which causes us to believe that the Designated Regulatory Provisions, at the time the Registration Statement became effective and at all times subsequent thereto up to and on the Closing Date, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.



**EXHIBIT E**

OFFICERS' CERTIFICATE

Each of the undersigned, Patrick J. McEnany, Chief Executive Officer of Catalyst Pharmaceutical Partners, Inc., a [Delaware] corporation (the "Company"), and Jack Weinstein, Chief Financial Officer of the Company, on behalf of the Company, does hereby certify pursuant to Section 5(j) of that certain Underwriting Agreement dated [trade date] (the "Underwriting Agreement") between the Company and, on behalf of the several Underwriters named therein (the "Underwriters"), First Albany Capital Inc., Stifel, Nicolaus & Company, Incorporated [other co-managers], that as of [closing date]:

1. He has reviewed the Registration Statement, the Disclosure Package and the Prospectus and each Permitted Free Writing Prospectus.
2. The representations and warranties of the Company as set forth in the Underwriting Agreement are true and correct as of the date hereof and as if made on the date hereof.
3. The Company has performed and complied with all of its obligations and agreements and satisfied all conditions on its part to be performed, complied with or satisfied under the Underwriting Agreement at or prior to the date hereof.
4. No stop order suspending the effectiveness of the Registration Statement has been issued, and no proceedings for that purpose have been instituted or are contemplated by the Commission.
5. The Registration Statement and all amendments thereto do not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Prospectus and all amendments or supplements thereto do not contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they are made, not misleading.
6. [Any required 462(b) Registration Statement, satisfying the requirements of subparagraphs (1) and (3) of Rule 462(b) under the Act, was filed pursuant to Rule 462(b), including payment of the applicable filing fee in accordance with Rule 111(a) or (b) under the Act, prior to the time the Prospectus was printed and distributed to any Underwriter.]
7. The financial statements and other financial information included in the Registration Statement or the Prospectus fairly present the financial condition, results of operations and cash flows of the Company and the Subsidiaries as of, and for, the periods therein presented.

Capitalized terms used herein without definition shall have the respective meanings ascribed to them in the Underwriting Agreement.

IN WITNESS WHEREOF, the undersigned have hereunto set their hands on this [closing date].

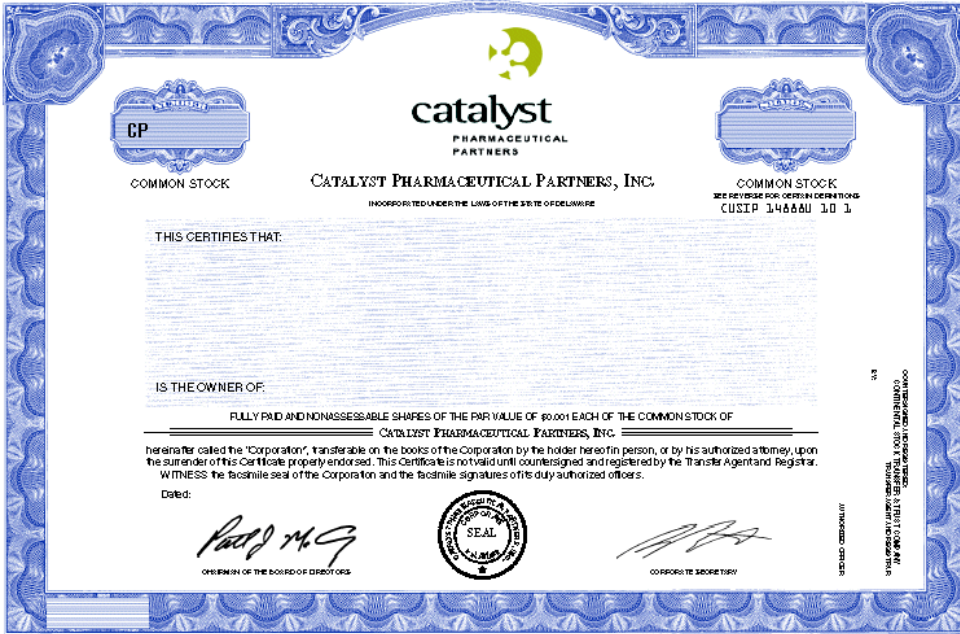
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Name: Patrick J. McEnany  
Title: Chief Executive Officer

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Name: Jack Weinstein  
Title: Chief Financial Officer

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COMMON STOCK

COMMON STOCK  
SEE REVERSE FOR CERTAIN OPERATIONS  
CUSIP 14888U 10 1

CATALYST PHARMACEUTICAL PARTNERS, INC.  
INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

THIS CERTIFIES THAT:  
  
IS THE OWNER OF:

FULLY PAID AND NONASSESSABLE SHARES OF THE PAR VALUE OF \$0.001 EACH OF THE COMMON STOCK OF  
CATALYST PHARMACEUTICAL PARTNERS, INC.

hereinafter called the "Corporation", transferable on the books of the Corporation by the holder hereof in person, or by his authorized attorney, upon the surrender of this Certificate properly endorsed. This certificate is not valid until countersigned and registered by the Transfer Agent and Registrar.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

Dated:  
  
CHAIRMAN OF THE BOARD OF DIRECTORS



CORPORATE SECRETARY

SECURED CREDENTIALS  
THIS DOCUMENT IS UNCLASSIFIED  
DATE 05/03/2011 BY 60322 UCBAW/STP  
UNCLASSIFIED//FOR OFFICIAL USE ONLY

THE CORPORATION HAS MORE THAN ONE CLASS OF STOCK AUTHORIZED TO BE ISSUED. THE CORPORATION WILL FURNISH WITHOUT CHARGE TO EACH STOCKHOLDER UPON WRITTEN REQUEST A COPY OF THE FULL TEXT OF THE PREFERENCES, VOTING POWERS, QUALIFICATIONS AND SPECIAL AND RELATIVE RIGHTS OF THE SHARES OF EACH CLASS OF STOCK (AND ANY SERIES THEREOF) AUTHORIZED TO BE ISSUED BY THE CORPORATION AS SET FORTH IN THE CERTIFICATE OF INCORPORATION OF THE CORPORATION AND AMENDMENTS THERETO FILED WITH THE SECRETARY OF THE STATE OF DELAWARE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT-	_____ Custodian _____	UNIF TRANS MIN ACT-	_____ Custodian _____
TEN ENT	- as tenants by the entireties		(Cust) (Minor)		(Cust) (Minor)
JT TEN	- as joint tenants with right of survivorship and not as tenants in common		under Uniform Gifts to Minors Act _____ (State)		under Uniform Transfers to Minors Act _____ (State)

Additional abbreviations may also be used though not in the above list.

FOR VALUE RECEIVED \_\_\_\_\_ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING ZIP CODE OF ASSIGNEE)

Shares of the Common Stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

\_\_\_\_\_ Attorney to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated \_\_\_\_\_ **X** \_\_\_\_\_

**X** \_\_\_\_\_  
NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

SIGNATURE(S) GUARANTEED: \_\_\_\_\_  
THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS, AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

KEEP THIS CERTIFICATE IN A SAFE PLACE. IF IT IS LOST, STOLEN, MUTILATED OR DESTROYED, THE CORPORATION WILL REQUIRE A BOND OF INDEMNITY AS A CONDITION TO THE ISSUANCE OF A REPLACEMENT CERTIFICATE.

## EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this "Agreement") is made as of the \_\_\_ day of September, 2006 by and between Patrick J. McEnany (the "Employee"), and Catalyst Pharmaceutical Partners, Inc., a Delaware corporation (the "Company").

WHEREAS, the Company desires to continue to employ the Employee and the Employee wishes to perform services for the Company pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations contained, herein, and intending to be legally bound, the parties, subject to the terms and conditions set forth herein, agree as follows:

1. Employment and Term; Service as a Board Member. The Company hereby employs the Employee, and the Employee hereby accepts employment with the Company, as the President and Chief Executive Officer (such position, referred to herein as the Employee's "Position") for a period commencing on the closing date of the Company's initial public offering, as contemplated by the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission (File No. 333-136039) (the "Effective Date") and continuing until the earlier of: (a) the third anniversary of the Effective Date, or (b) termination of the Employee in accordance with Section 7 of this Agreement (the "Term"). On the third Anniversary of the Effective Date, unless this Agreement is renewed by written agreement between the Company and the Employee, the Employee will become an "at will" employee and his employment may be terminated at any time, for any reason or no reason, with or without Cause, by him or by the Company; provided, however, that if the Employee's employment is terminated without Cause or for Good Reason following such non-renewal, then, subject to the provisions of Section 7.5 or Section 7.6 of this Agreement (as applicable), the Company will continue to pay to the Employee his then current Base Salary for the twelve (12) month period following such date of termination. In addition and for no additional consideration, Employee hereby agrees to serve as a member of the Company's Board of Directors (the "Board") to the extent elected by the shareholders of the Company and consistent with the by-laws of the Company as they may be amended from time-to-time. This Agreement supercedes the Employment Agreement between the parties hereto dated January 1, 2005, which shall be of no further force or effect as of the Effective Date.
2. Duties and Responsibilities.
  - 2.1. Generally. During the Term, Employee hereby agrees to serve the Company faithfully and to the best of his ability and shall devote his full time, attention, skill and efforts to the performance of the duties: (i) as shall be specified and designated from time-to-time by the Board; and (ii) customarily performed by the Chief Executive Officer of a business of the size and nature similar to that of the Company. During the Term, Employee shall report directly to the Board. Without limiting the generality of the foregoing, the Employee will be responsible for the overall well being of the Company.

- 2.2. Travel Obligations. Employee acknowledges that his Position will require travel from time-to-time for Company business.
- 2.3. Primary Location. On the Effective Date, Employee's business location of record will be Coral Gables, Florida.
3. Other Business Activities. During the Term, the Employee will not, without the prior written consent of the Company, which consent shall not be unreasonably withheld, directly or indirectly engage in any other business activity or pursuit whatsoever, except such activities in connection with any charitable or civic activities or serving as an executor, trustee or in other similar fiduciary capacity as do not interfere with his performance of his responsibilities and obligations pursuant to this Agreement. Further, Employee may also serve as an outside director on the Board of Directors up to three (3) public companies, so long as it does not interfere with his performance for and obligations to the Company.
4. Compensation
- 4.1. Base Salary. The Company shall pay the Employee, and the Employee hereby agrees to accept, as compensation for all services rendered by Employee in any capacity under this Agreement or otherwise in consideration for the covenants referenced in Section 5 of this Agreement, base salary at the annual rate of Three Hundred Fifteen Thousand Dollars (\$315,000) less applicable withholding (as the same may hereafter be adjusted, the "Base Salary"). Base Salary shall be paid in accordance with the Company's payroll practices in effect from time-to-time. The Board (excluding Employee in his capacity as a member of the Board), or any committee of the Board charged with that responsibility shall review the performance of Employee annually, on or about the anniversary of the Effective Date and make such appropriate adjustments to the Employee's Base Salary in their discretion, as they may determine.
- 4.2. Annual Bonus Program. For each calendar year of the Agreement, Employee will be eligible to participate in any annual bonus programs (the "Annual Bonus") established by the Board (excluding Employee in his capacity as a member of the Board) from time-to-time for the benefit of Company management, in each case to the extent Employee is eligible under the terms of such annual bonus program.
- 4.3. Benefits and Expenses. The Employee shall be eligible to participate in the benefit plans and programs (including without limitation, the sick leave, holidays and retirement plans or programs) that are available to other employees of the Company generally on the same terms as such other employees (excluding any equity-based compensation plan, program or policy), in each case to the extent that the Employee is eligible under the terms of such plans or programs. Employee shall be eligible for expense allowances and/or reimbursements for reasonable expenses incurred in connection with the performance of his duties hereunder as are consistent with the Company's usual practice and policies with respect to such allowances and reimbursements.
- 4.4. Vacation. In addition to paid holidays recognized by the Company from time-to-time, Employee shall be entitled to three calendar weeks of paid vacation during any calendar

year of the Term of this Agreement. Vacation accrued with respect to any calendar year will be forfeited if Employee does not take such vacation prior to the last day of such calendar year unless Employee receives, prior to such last day, written confirmation from the Board that such vacation will not be forfeited.

4.5. Withholding. The Base Salary and all other payments made under this Agreement are inclusive of all applicable income, social security and other taxes and charges which are required by law to be withheld from Employee's wages by the Company, and which will be withheld and paid in accordance with applicable law and the Company's normal payroll practices.

5. Confidentiality. Employee agrees that at all times during the term of this Agreement and after the termination of employment for as long as such information remains non-public information, Employee shall (i) hold in confidence and refrain from disclosing to any other party all information, whether written or oral, tangible or intangible, of a private, secret, proprietary or confidential nature, of or concerning the Company or any of its affiliates and their business and operations, and all files, letters, memoranda, reports, records, computer disks or other computer storage medium, data, models or any photographic or other tangible materials containing such information ("Confidential Information"), including without limitation, any sales, promotional or marketing plans, clinical data or information about the Company's product development efforts, programs, techniques, practices or strategies, or future development plans (including existing and entry into new geographic and/or product markets), and any customer lists, (ii) use the Confidential Information solely in connection with his employment with the Company or any of its affiliates and for no other purpose, (iii) take all precautions necessary to ensure that the Confidential Information shall not be, or be permitted to be, shown, copied or disclosed to third parties, without the prior written consent of the Company or any of its affiliates, and (iv) observe all security policies implemented by the Company or any of its subsidiaries or affiliates from time to time with respect to the Confidential Information. In the event that Employee is ordered to disclose any Confidential Information, whether in a legal or regulatory proceeding or otherwise, Employee shall provide the Company or any of its affiliates with prompt notice of such request or order so that the Company or any of its subsidiaries or affiliates may seek to prevent disclosure. In addition to the foregoing Employee shall not at any time libel, defame, ridicule or otherwise disparage the Company.

Employee agrees that all work done in the name of or on behalf of the Company is deemed the property of the Company pursuant to this Agreement.

6. Restrictive Covenants. In consideration of his employment and the other benefits arising under this Agreement, the Employee agrees that during the Term and for a period of one (1) year following the termination of this Agreement in accordance with section 7 hereof, Employee shall not, directly or indirectly,

6.1. alone or as a partner, joint venturer, officer, director, member, employee, consultant, agent, independent contractor or stockholder of, or lender to, any company or business, engage in any business which competes, directly or indirectly, with any business of the Company; provided, however, that the beneficial ownership of less than one percent

(1%) of the shares of stock of any corporation having a class of equity securities actively traded on a national securities exchange or over-the-counter market shall not be deemed, in and of itself, to violate the prohibitions of this section;

- 6.2. for any reason, (i) induce any customer of the Company or any of its affiliates to patronize any business directly or indirectly in competition with the businesses conducted by the Company or any of its subsidiaries or affiliates in any market in which the Company or any of its affiliates does business; (ii) canvass, solicit or accept from any customer of the Company or any of its affiliates any such competitive business; or (iii) request or advise any customer or vendor of the Company or any of its affiliates to withdraw, curtail or cancel any such customer's or vendor's business with the Company or any of its affiliates; or
- 6.3. for any reason, employ, or knowingly permit any company or business entity directly or indirectly controlled by him to employ, any person who was employed by the Company or its affiliates at or within the prior six months, or in any manner seek to induce any such person to leave his or her employment.

The provisions of this Section shall apply to Employee whether or not Employee's employment with the Company has been terminated for Cause or without Cause and whether or not the Company is required to pay Employee severance benefits. Notwithstanding the foregoing, if this Agreement expires by its terms at the end of the Term or if Employee is terminated without Cause, the provisions of this Section 6 shall apply to Employee only if the Company provides Employee with all of the severance benefits which it would be obligated to provide him as if the Employee had been terminated from his employment with the Company without Cause.

7. Termination. The Employee's employment hereunder may be terminated during the Term upon the occurrence of any one of the events described in this Section 6. Upon termination, the Employee shall be entitled only to such compensation and benefits as described in this Section 7.

7.1. Termination for Disability.

- 7.1.1. In the event of the Disability (as hereinafter defined) of the Employee, the Employee's employment and/or his performance of service as a member of the Board may be terminated by the Company by notice to the Employee.
- 7.1.2. In the event of a termination of the Employee's employment pursuant to Section 7.1.1: (i) the Employee will be entitled to receive any accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the termination of employment), including without limitation, payment prescribed under any disability plan or arrangement in which he is a participant or to which he is a party in his capacity as an employee of the Company; (ii) the Company shall continue to pay Employee his Base Salary at the time of the Disability for a period of one (1) year following such disability, such payments to be made in accordance with normal



payroll practices, except that such payments may be reduced or eliminated by the amount paid with respect to such disability by any disability insurance policy that the Company may purchase for the benefit of the Employee; and (iii) if the Employee and/or his spouse or eligible dependents elect continuation of medical and/or dental benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company will pay the full premium cost of such participation for a period of twenty-nine (29) months following the date of such termination or until the Employee or his spouse or dependents cease to be eligible for participation under COBRA, whichever is shorter. Except as specifically set forth in this Section 7.1, or to the extent provided under any Company-provided disability benefits policy, the Company shall have no other liability or obligation to the Employee for compensation or benefits by reason of such termination.

- 7.1.3. For purposes of this Section 7.1, "Disability" shall mean a physical or mental condition that entitles the Employee to benefits under the Company's long-term disability policy which covers the Employee, if any, or, in the absence of coverage under any such policy, a disability which prevents the Employee from performing his duties, with or without a reasonable accommodation, under this Agreement for forty-five (45) calendar days during any period of 180 calendar days. The Company will notify the Employee of commencement of the disability period, which period cannot commence more than fourteen (14) calendar days prior to the date of the notice. The determination of whether the Employee has a Disability will be made by the Board (excluding Employee in his capacity if a member of the Board). Any dispute as to whether the Employee is or was prevented from performing his duties under this Agreement because of a physical or mental disability or incapacitation, whether his disability or incapacity has ceased or whether he is able to resume his duties under this Agreement shall be finally and conclusively decided by a licensed physician chosen by the Company, and any such determination by the physician shall be conclusive and binding on the parties hereto. The Employee must submit to all tests and examinations and provide all information as requested by the physician.
- 7.2. Termination by Death. Employee's employment shall automatically be terminated on his death. Employee's executors, legal representatives or administrators shall receive any accrued and unpaid Base Salary and Annual Bonus through the date of the Employee's death (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the Employee's death). Employee's estate shall also be paid, for a period of one (1) year following the date of the Employee's death, the Employee's Base Salary at the time of his death, in accordance with normal payroll practices. The Company may reduce or eliminate such payments to the extent that Employee's estate (or a beneficiary designated by the Employee) is paid such amounts from a life insurance policy purchased for the benefit of the Employee by the Company. In addition, if the Employee's spouse and/or eligible dependents elect continuation of medical and/or dental benefits under COBRA, the Company will pay the full premium cost of such participation for a period of twenty-four (24) months following the date of the Employee's death or until the Employee's spouse or dependents cease to be eligible for participation under COBRA, whichever is shorter. Except as specifically set forth in this Section 7.2, or to the extent provided under any Company-provided life insurance

policy, the Company shall have no other liability or obligation hereunder to the Employee's executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through him by reason of the Employee's death.

- 7.3. Termination by the Employee Without Good Reason. Upon thirty (30) days' prior written notice to the Board, the Employee may terminate his employment and his performance of service as a member of the Board with the Company without Good Reason (as defined below) and for a reason other than those identified in Section 7.1 or Section 7.2 of this Agreement. In the event of a termination of the Employee's employment and his performance of service as a member of the Board pursuant to this Section 7.3, the Employee shall be entitled to receive any accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to such date). All other Base Salary and Annual Bonus shall cease at the effective date of such termination. Except as specifically set forth in this Section 7.3, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.4. Termination By the Company for Cause.
- 7.4.1. Upon written notice to the Employee from the Board or an appropriate officer of the Company designated by the Board, the Company may terminate the Employee's employment at any time for Cause as defined in Section 7.4.3 of this Agreement.
- 7.4.2. In the event of a termination of the Employee's employment pursuant to Section 7.4.1, the Employee shall be entitled to receive accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the termination of employment). All other Base Salary and Annual Bonus shall cease at the effective date of such termination. Except as specifically set forth in this Section 7.4, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.4.3. For purposes of this Agreement, "Cause" shall mean, without limitation, as determined by the Board in good faith (excluding Employee in his capacity if a member of the Board): (i) commission by Employee of any act of fraud or any act of misappropriation or personal dishonesty relating to or involving the Company in any way; (ii) the Employee's willful failure, neglect or refusal to perform, or gross negligence in the performance of, his material duties and responsibilities or any express direction of the Company (other than the failure, neglect or refusal to perform an unlawful act), or any violation of any rule, regulation, policy or plan established by the Company from time-to-time regarding the conduct of its employees and/or its business, if such violation is not remedied by the Employee within ten (10) days of receiving notice of such violation from the Company; (iii) Employee's violation of any obligation of this Agreement that is not remedied by the Employee within ten (10) days after receiving notice of such violation from the Company; or (iv) Employee's arrest for, conviction of or plea of nolo contendere to a crime constituting a felony.

7.4.4. The Employee shall not, under any circumstances, be deemed to have been terminated for Cause unless and until there shall have been delivered to him a copy of a Board resolution (the "Board Resolution") duly adopted by the affirmative vote of not less than fifty one percent (51%) of the Board (with Employee not being permitted to vote on this matter) at a meeting of the Board held for that purpose. Any such Board Resolution, which in the event of an alleged termination for Cause under Sections 7.4.3 (ii) and (iii) hereof shall be dated no sooner than ten (10) days after such notice has been deemed to have been given to the Employee and the Employee shall have had an opportunity, together with counsel, to be heard before the Board, shall find that in the good faith opinion of the Board, the Employee was guilty of conduct constituting Cause and specifying the particulars thereof in detail.

7.5. Termination by the Company Without Cause.

7.5.1. Upon written notice to the Employee from the Board or an appropriate officer of the Company designated by the Board, the Company may terminate the Employee's employment at any time without Cause.

7.5.2. In the event of a termination of the Employee's employment pursuant to Section 7.5.1: (i) the Company will pay to Employee any earned but unpaid Base Salary through the date of such termination; (ii) the Company will reimburse the Employee's unreimbursed business expenses pursuant to Section 4.3 for all expenses incurred in the performance of his duties prior to the date of such termination; (iii) the Company will pay to Employee any earned and accrued but unpaid Annual Bonus as of the date of such termination; (iv) commencing on the day immediately following "the date of such termination, the Company will continue to pay to the Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twelve (12) month period following such date of termination without Cause; provided, however, that if Employee is terminated without Cause following a Change in Control (as defined below), the Company will continue to pay to Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twenty-four (24) month period following such date of termination, which amount shall be paid as a lump sum within thirty (30) days after the date of termination, or, at the Company's election, in accordance with the Company's payroll practices in effect from time-to-time. Except as specifically set forth in this Section 7.5, the Company shall have no other liability or obligation hereunder by reason of such termination.

7.5.3. Notwithstanding any other provision in this Agreement to the contrary, Employee hereby agrees and acknowledges that he will not be entitled to and the Company shall have no obligation to pay or provide any amount or benefit provided under Section 1 or Section 7.5 of this Agreement unless Employee executes and delivers to the Company and does not revoke a release satisfactory to the Company in a manner consistent with the requirements of the Age Discrimination in Employment Act.

7.6. Termination by the Employee for Good Reason.

- 7.6.1. The Employee may terminate the Employee's employment and his performance of service as a member of the Board at any time for Good Reason (as hereinafter defined), upon written notice from the Employee to the Company in connection with his resignation for Good Reason setting forth the effective date of termination (which shall not be less than thirty (30) business days from the date such notice is given).
- 7.6.2. In the event of a termination of the Employee's employment for Good Reason pursuant to Section 7.6.1: (i) the Company will pay to Employee any earned but unpaid Base Salary through the date of such termination; (ii) the Company will reimburse the Employee's unreimbursed business expenses pursuant to Section 4.3 for all expenses incurred in the performance of his duties prior to the date of such termination; (iii) the Company will pay to Employee any earned and accrued but unpaid Annual Bonus as of the date of such termination; (iv) commencing on the day immediately following the date of such termination, the Company will continue to pay to the Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twelve (12) month period following such date of termination for Good Reason; provided, however, that if Employee terminates his employment and performance of service as a member of the Board for Good Reason following a Change in Control, the Company will pay to Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the eighteen (18) month period following such date of termination, which amount shall be paid as a lump sum within thirty (30) days after the date of termination, or, at the Company's election, in accordance with the Company's payroll practices in effect from time-to-time. Except as specifically set forth in this Section 7.6, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.6.3. Notwithstanding any other provision in this Agreement to the contrary, Employee hereby agrees and acknowledges that he will not be entitled to and the Company shall have no obligation to pay or provide any amount or benefit provided under Section 1 or Section 7.6 of this Agreement unless Employee executes and delivers to the Company and does not revoke a release satisfactory to the Company in a manner consistent with the requirements of the Age Discrimination in Employment Act.
- 7.6.4. For purposes of this Agreement, "Good Reason" shall mean, as determined by the Company, the first occurrence of either: (i) any material alteration by the Company of Employee's positions, functions, duties or responsibilities that is not remedied by the Company within ten (10) days after receiving notice of such material alteration from Employee, including any change that (a) alters Employee's reporting responsibility or (b) causes Employee's Position with the Company to become of less importance than the applicable positions; (ii) a material decrease in Employee's Base Salary that has not been agreed to by the Employee; (iii) failure of the Company to perform any of its obligations under this Agreement that are not

remedied by the Company within ten (10) days after receiving notice of such failure to perform from Employee; or (iv) relocation of the principal office of the Company outside fifty (50) miles of the greater Miami, Florida area; provided, however, that Employee's consent to any event which would otherwise constitute "Good Reason" shall be conclusively presumed if Employee does not exercise his rights hereunder within ninety (90) days of the event.

7.6.5. For purposes of this Agreement, "Change in Control" means: (i) the sale, transfer, assignment or other disposition (including by merger or consolidation, but excluding any sales by stockholders made as part of an underwritten public offering of the common stock of the Company) by stockholders of the Company, in one transaction or a series of related transactions, of more than fifty percent (50%) of the voting power represented by the then outstanding capital stock of the Company to one or more Persons (other than to Employee or a "group" (as that term is defined under the Securities Exchange Act of 1934) in which Employee is a member); (ii) the sale of substantially all the assets of the Company (other than a transfer of financial assets made in the ordinary course of business for the purpose of securitization); or (iii) the liquidation or dissolution of the Company.

8. Parachute Payments. Payments under this Agreement shall be made without regard to whether the deductibility of such payments (or any other payments) would be limited or precluded by Section 280G of the Internal Revenue Code of 1986 (the "Code") and without regard to whether such payments would subject the Employee to the federal excise tax levied on certain "excess parachute payments" under Section 4999 of the Code; provided, however, that if the Total After-Tax Payments (as defined below) would be increased by the limitation or elimination of any amount payable under this Agreement, then the amount payable under this Agreement will be reduced to the extent necessary to maximize the Total After-Tax Payments. The determination of whether and to what extent payments under this Agreement are required to be reduced in accordance with the preceding sentence will be made at the Company's expense by an independent, certified public accountant selected by the Employee and reasonably acceptable to the Company. In the event of any underpayment or overpayment under this Agreement (as determined after the application of this Section 8), the amount of such underpayment or overpayment will be immediately paid by the Company to the Employee or refunded by the Employee to the Company, as the case may be, with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code. For purposes of this Agreement, "Total After-Tax Payments" means the total of all "parachute payments" (as that term is defined in Section 280G(b)(2) of the Code) made to or for the benefit of Employee (whether made hereunder or otherwise), after reduction for all applicable federal taxes (including, without limitation, the tax described in Section 4999 of the Code).

9. Representations. The Employee represents and warrants to the Company that:

9.1. there are no restrictions, agreements or understandings whatsoever to which the Employee is a party which would prevent or make unlawful the Employee's execution of this Agreement or the Employee's employment hereunder, or which is or would be inconsistent or in conflict with this Agreement or the Employee's employment

hereunder, or would prevent, limit or impair in any way the performance by the Employee of his obligations hereunder;

9.2. the Employee's execution of this Agreement and the Employee's employment hereunder shall not constitute a breach of any contract, agreement or understanding, oral or written, to which the Employee is a party or by which the Employee is bound; and

10. Survival of Provisions. The provisions of this Agreement set forth in Sections 5 through 8 and 10 through 18 hereof shall survive the termination of the Employee's employment hereunder.
11. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Employee and their respective successors, executors, administrators, heirs and/or permitted assigns; provided, however, that neither the Employee nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party hereto, except that, without such consent, the Company may assign this Agreement to an Affiliate or any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise, provided that such successor assumes in writing all of the obligations of the Company under this Agreement, subject, however, to the Employee's rights as to termination as provided in Section 7 hereof.

12. Notice. Any notice or communication required or permitted under this Agreement shall be made in writing and sent by certified or registered mail, return receipt requested, addressed as follows:

If to Employee:

Patrick J. McEnany

\_\_\_\_\_  
\_\_\_\_\_

If to the Company:

Catalyst Pharmaceutical Partners, Inc.  
220 Miracle Mile, Suite 234  
Coral Gables, Florida 33134  
Attn: Chief Financial Officer

With a copy to:

Philip B. Schwartz, Esq.  
Akerman Senterfitt  
One Southeast Third Avenue  
Miami, Florida 33131

or to such other address as either party may from time-to-time duly specify by notice given to the other party in the manner specified above.

13. Waiver of Personal Liability. To the extent permitted by applicable law. Employee hereby acknowledges and agrees that he shall have recourse only to the Company (and its successors-in-interest) with respect to any claims he may have for compensation or benefits arising in connection with his employment, whether or not under this Agreement or under any other plan, program, or arrangement, including, but not limited to, any agreements related to the grant or exercise of equity options or other equity rights in the Company. To the extent permitted by applicable law, the Employee hereby waives any such claims for compensation, benefits and equity rights against officers, directors, managers, members, stockholders, or other representatives in their personal or separate capacities.
14. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature between the parties hereto relating to the employment of the Employee with the Company. This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.
15. Waiver. The waiver of the breach of any term or provision of this Agreement shall not operate as or be construed to be a waiver of any other or subsequent breach of this Agreement.
16. Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Florida, without regard to its rules on conflict of laws.
17. Invalidity. In case any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the validity of any other provision of this Agreement, and such provision(s) shall be deemed modified to the extent necessary to make it enforceable.
18. Section Headings. The section headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.
19. Legal Fees; Limitations. If an action at law or in equity is necessary to enforce or interpret the terms of this Agreement and the Employee is the prevailing party, he shall be entitled to recover, in addition to any other relief, all reasonable attorney's fees, costs and

disbursements. In the event that the provisions of Sections 5 or 6 hereof should ever be adjudicated to exceed the time, geographic, or other limitations permitted by applicable law in any applicable jurisdiction, then such provisions shall be deemed reformed in such jurisdiction to the maximum time, geographic, or other limitations permitted by applicable law.

20. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

**[Signatures on Following Page]**



IN WITNESS WHEREOF, the parties hereto have caused this agreement to be made this \_\_\_ day of \_\_\_, 2006.

**EMPLOYEE**

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

**CATALYST PHARMACEUTICAL  
PARTNERS, INC.**

By: /s/ \_\_\_\_\_  
Jack Weinstein  
Vice President and Chief Financial Officer

## EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (this "Agreement") is made as of the \_\_\_ day of September, 2006 by and between Jack Weinstein (the "Employee"), and Catalyst Pharmaceutical Partners, Inc., a Delaware corporation (the "Company").

WHEREAS, the Company desires to continue to employ the Employee and the Employee wishes to perform services for the Company pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants and obligations contained, herein, and intending to be legally bound, the parties, subject to the terms and conditions set forth herein, agree as follows:

1. Employment and Term. The Company hereby employs the Employee, and the Employee hereby accepts employment with the Company, as the Vice President, Treasurer and Chief Financial Officer (such position, referred to herein as the Employee's "Position") for a period commencing on the closing date of the Company's initial public offering, as contemplated by the Company's Registration Statement on Form S-1 (File No. 333-136039) (the "Effective Date") and continuing until the earlier of: (a) the second anniversary of the Effective Date, or (b) termination of the Employee in accordance with Section 7 of this Agreement (the "Term"). On the second Anniversary of the Effective Date, unless this Agreement is renewed by written agreement between the Company and the Employee, the Employee will become an "at will" employee and his employment may be terminated at any time, for any reason or no reason, with or without Cause, by him or by the Company; provided, however, that if the Employee's employment is terminated without Cause or for Good Reason following such non-renewal, then, subject to the provisions of Section 7.5 or Section 7.6 of this Agreement (as applicable), the Company will continue to pay to the Employee his then current Base Salary for the twelve (12) month period following such date of termination. This Agreement supercedes the Consulting Agreement between the parties hereto dated effective October 1, 2004, as amended. Such agreement shall be of no further force or effect as of the Effective Date.
2. Duties and Responsibilities.
  - 2.1. Generally. During the Term, Employee hereby agrees to serve the Company faithfully and to the best of his ability and shall devote his full time, attention, skill and efforts to the performance of the duties: (i) as shall be specified and designated from time-to-time by the Board; and (ii) customarily performed by the Chief Financial Officer of a business of the size and nature similar to that of the Company. During the Term, Employee shall report directly to the Chief Executive Officer of the Company.
  - 2.2. Travel Obligations. Employee acknowledges that his Position will require travel from time-to-time for Company business.

- 2.3. Primary Location. On the Effective Date, Employee's business location of record will be at a Company office to be located in Bergen County, New Jersey.
3. Other Business Activities. During the Term, the Employee will not, without the prior written consent of the Company, which consent shall not be unreasonably withheld, directly or indirectly engage in any other business activity or pursuit whatsoever, except such activities in connection with any charitable or civic activities or serving as an executor, trustee or in other similar fiduciary capacity as do not interfere with his performance of his responsibilities and obligations pursuant to this Agreement.
4. Compensation
- 4.1. Base Salary. The Company shall pay the Employee, and the Employee hereby agrees to accept, as compensation for all services rendered by Employee in any capacity under this Agreement or otherwise in consideration for the covenants referenced in Section 5 of this Agreement, base salary at the annual rate of Two Hundred Thousand Dollars (\$200,000) less applicable withholding (as the same may hereafter be adjusted, the "Base Salary"). Base Salary shall be paid in accordance with the Company's payroll practices in effect from time-to-time. The Board (or any committee of the Board charged with that responsibility) shall review the performance of Employee annually, on or about the anniversary of the Effective Date and make such appropriate adjustments to the Employee's Base Salary in their discretion, as they may determine.
- 4.2. Annual Bonus Program. For each calendar year of the Agreement, Employee will be eligible to participate in any annual bonus programs (the "Annual Bonus") established by the Board from time-to-time for the benefit of Company management, in each case to the extent Employee is eligible under the terms of such annual bonus program.
- 4.3. Benefits and Expenses. The Employee shall be eligible to participate in the benefit plans and programs (including without limitation, the sick leave, holidays and retirement plans or programs) that are available to other employees of the Company generally on the same terms as such other employees (excluding any equity-based compensation plan, program or policy), in each case to the extent that the Employee is eligible under the terms of such plans or programs. Employee shall be eligible for expense allowances and/or reimbursements for reasonable expenses incurred in connection with the performance of his duties hereunder as are consistent with the Company's usual practice and policies with respect to such allowances and reimbursements.
- 4.4. Vacation. In addition to paid holidays recognized by the Company from time-to-time, Employee shall be entitled to three calendar weeks of paid vacation during any calendar year of the Term of this Agreement. Vacation accrued with respect to any calendar year will be forfeited if Employee does not take such vacation prior to the last day of such calendar year unless Employee receives, prior to such last day, written confirmation from the Board that such vacation will not be forfeited.

4.5. Withholding. The Base Salary and all other payments made under this Agreement are inclusive of all applicable income, social security and other taxes and charges which are required by law to be withheld from Employee's wages by the Company, and which will be withheld and paid in accordance with applicable law and the Company's normal payroll practices.

5. Confidentiality. Employee agrees that at all times during the term of this Agreement and after the termination of employment for as long as such information remains non-public information, Employee shall (i) hold in confidence and refrain from disclosing to any other party all information, whether written or oral, tangible or intangible, of a private, secret, proprietary or confidential nature, of or concerning the Company or any of its affiliates and their business and operations, and all files, letters, memoranda, reports, records, computer disks or other computer storage medium, data, models or any photographic or other tangible materials containing such information ("Confidential Information"), including without limitation, any sales, promotional or marketing plans, clinical data or information about the Company's product development efforts, programs, techniques, practices or strategies, or future development plans (including existing and entry into new geographic and/or product markets), and any customer lists, (ii) use the Confidential Information solely in connection with his employment with the Company or any of its affiliates and for no other purpose, (iii) take all precautions necessary to ensure that the Confidential Information shall not be, or be permitted to be, shown, copied or disclosed to third parties, without the prior written consent of the Company or any of its affiliates, and (iv) observe all security policies implemented by the Company or any of its subsidiaries or affiliates from time to time with respect to the Confidential Information. In the event that Employee is ordered to disclose any Confidential Information, whether in a legal or regulatory proceeding or otherwise, Employee shall provide the Company or any of its affiliates with prompt notice of such request or order so that the Company or any of its subsidiaries or affiliates may seek to prevent disclosure. In addition to the foregoing Employee shall not at any time libel, defame, ridicule or otherwise disparage the Company.

Employee agrees that all work done in the name of or on behalf of the Company is deemed the property of the Company pursuant to this Agreement.

6. Restrictive Covenants. In consideration of his employment and the other benefits arising under this Agreement, the Employee agrees that during the Term and for a period of one (1) year following the termination of this Agreement in accordance with section 7 hereof, Employee shall not, directly or indirectly,

6.1. alone or as a partner, joint venturer, officer, director, member, employee, consultant, agent, independent contractor or stockholder of, or lender to, any company or business, engage in any business which competes, directly or indirectly, with any business of the Company; provided, however, that the beneficial ownership of less than one percent (1%) of the shares of stock of any corporation having a class of equity securities actively traded on a national securities exchange or over-the-counter market shall not be deemed, in and of itself, to violate the prohibitions of this section;

- 6.2. for any reason, (i) induce any customer of the Company or any of its affiliates to patronize any business directly or indirectly in competition with the businesses conducted by the Company or any of its subsidiaries or affiliates in any market in which the Company or any of its affiliates does business; (ii) canvass, solicit or accept from any customer of the Company or any of its affiliates any such competitive business; or (iii) request or advise any customer or vendor of the Company or any of its affiliates to withdraw, curtail or cancel any such customer's or vendor's business with the Company or any of its affiliates; or
- 6.3. for any reason, employ, or knowingly permit any company or business entity directly or indirectly controlled by him to employ, any person who was employed by the Company or its affiliates at or within the prior six months, or in any manner seek to induce any such person to leave his or her employment.

The provisions of this Section shall apply to Employee whether or not Employee's employment with the Company has been terminated for Cause or without Cause and whether or not the Company is required to pay Employee severance benefits. Notwithstanding the foregoing, if this Agreement expires by its terms at the end of the Term or if Employee is terminated without Cause, the provisions of this Section 6 shall apply to Employee only if the Company provides Employee with all of the severance benefits which it would be obligated to provide him as if the Employee had been terminated from his employment with the Company without Cause.

7. Termination. The Employee's employment hereunder may be terminated during the Term upon the occurrence of any one of the events described in this Section 6. Upon termination, the Employee shall be entitled only to such compensation and benefits as described in this Section 7.

7.1. Termination for Disability.

- 7.1.1. In the event of the Disability (as hereinafter defined) of the Employee, the Employee's employment and/or his performance of service as a member of the Board may be terminated by the Company by notice to the Employee.
- 7.1.2. In the event of a termination of the Employee's employment pursuant to Section 7.1.1: (i) the Employee will be entitled to receive any accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the termination of employment), including without limitation, payment prescribed under any disability plan or arrangement in which he is a participant or to which he is a party in his capacity as an employee of the Company; (ii) the Company shall continue to pay Employee his Base Salary at the time of the Disability for a period of one (1) year following such disability, such payments to be made in accordance with normal payroll practices, except that such payments may be reduced or eliminated by the amount paid with respect to such disability by any disability insurance policy that the Company may purchase for the benefit of the Employee; and (iii) if the Employee and/or his spouse or eligible dependents elect continuation of medical

and/or dental benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (“COBRA”), the Company will pay the full premium cost of such participation for a period of twenty-nine (29) months following the date of such termination or until the Employee or his spouse or dependents cease to be eligible for participation under COBRA, whichever is shorter. Except as specifically set forth in this Section 7.1, or to the extent provided under any Company-provided disability benefits policy, the Company shall have no other liability or obligation to the Employee for compensation or benefits by reason of such termination.

- 7.1.3. For purposes of this Section 7.1, “Disability” shall mean a physical or mental condition that entitles the Employee to benefits under the Company’s long-term disability policy which covers the Employee, if any, or, in the absence of coverage under any such policy, a disability which prevents the Employee from performing his duties, with or without a reasonable accommodation, under this Agreement for forty-five (45) calendar days during any period of 180 calendar days. The Company will notify the Employee of commencement of the disability period, which period cannot commence more than fourteen (14) calendar days prior to the date of the notice. The determination of whether the Employee has a Disability will be made by the Board. Any dispute as to whether the Employee is or was prevented from performing his duties under this Agreement because of a physical or mental disability or incapacitation, whether his disability or incapacity has ceased or whether he is able to resume his duties under this Agreement shall be finally and conclusively decided by a licensed physician chosen by the Company, and any such determination by the physician shall be conclusive and binding on the parties hereto. The Employee must submit to all tests and examinations and provide all information as requested by the physician.
- 7.2. Termination by Death. Employee’s employment shall automatically be terminated on his death. Employee’s executors, legal representatives or administrators shall receive any accrued and unpaid Base Salary and Annual Bonus through the date of the Employee’s death (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the Employee’s death). Employee’s estate shall also be paid, for a period of one (1) year following the date of the Employee’s death, Employee’s Base Salary at of his death, in accordance with normal payroll practices. The Company may reduce or eliminate such payments to the extent that the Employee’s estate (or a beneficiary designated by the Employee) is paid such amounts due from a life insurance policy purchased for the benefit of the Employee by the Company . In addition, if the Employee’s spouse and/or eligible dependents elect continuation of medical and/or dental benefits under COBRA, the Company will pay the full premium cost of such participation for a period of twenty-four (24) months following the date of the Employee’s death or until the Employee’s spouse or dependents cease to be eligible for participation under COBRA, whichever is shorter. Except as specifically set forth in this Section 7.2, or to the extent provided under any Company-provided life insurance policy, the Company shall have no other liability or obligation hereunder to the Employee’s executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through him by reason of the Employee’s death.

- 7.3. Termination by the Employee Without Good Reason. Upon thirty (30) days' prior written notice to the Board, the Employee may terminate his employment with the Company without Good Reason (as defined below) and for a reason other than those identified in Section 7.1 or Section 7.2 of this Agreement. In the event of a termination of the Employee's employment pursuant to this Section 7.3, the Employee shall be entitled to receive any accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to such date). All other Base Salary and Annual Bonus shall cease at the effective date of such termination. Except as specifically set forth in this Section 7.3, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.4. Termination by the Company for Cause.
- 7.4.1. Upon written notice to the Employee from the Board or an appropriate officer of the Company designated by the Board, the Company may terminate the Employee's employment at any time for Cause as defined in Section 7.4.3 of this Agreement.
- 7.4.2. In the event of a termination of the Employee's employment pursuant to Section 7.4.1, the Employee shall be entitled to receive accrued and unpaid Base Salary and Annual Bonus through the date of such termination (and reimbursement for expenses, in accordance with Section 4.3, incurred prior to the termination of employment). All other Base Salary and Annual Bonus shall cease at the effective date of such termination. Except as specifically set forth in this Section 7.4, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.4.3. For purposes of this Agreement, "Cause" shall mean, without limitation, as determined by the Board in good faith: (i) commission by Employee of any act of fraud or any act of misappropriation or personal dishonesty relating to or involving the Company in any way; (ii) the Employee's willful failure, neglect or refusal to perform, or gross negligence in the performance of, his material duties and responsibilities or any express direction of the Company (other than the failure, neglect or refusal to perform an unlawful act), or any violation of any rule, regulation, policy or plan established by the Company from time-to-time regarding the conduct of its employees and/or its business, if such violation is not remedied by the Employee within ten (10) days of receiving notice of such violation from the Company; (iii) Employee's violation of any obligation of this Agreement that is not remedied by the Employee within ten (10) days after receiving notice of such violation from the Company; or (iv) Employee's arrest for, conviction of or plea of nolo contendere to a crime constituting a felony.
- 7.4.4. The Employee shall not, under any circumstances, be deemed to have been terminated for Cause unless and until there shall have been delivered to him a copy of a Board resolution (the "Board Resolution") duly adopted by the affirmative vote of not less than fifty one percent (51%) of the Board at a meeting of the Board held for that purpose. Any such Board Resolution, which in the event of an alleged

termination for Cause under Sections 7.4.3 (ii) and (iii) hereof shall be dated no sooner than ten (10) days after such notice has been deemed to have been given to the Employee and the Employee shall have had an opportunity, together with counsel, to be heard before the Board, shall find that in the good faith opinion of the Board, the Employee was guilty of conduct constituting Cause and specifying the particulars thereof in detail.

7.5. Termination by the Company Without Cause.

- 7.5.1. Upon written notice to the Employee from the Board or an appropriate officer of the Company designated by the Board, the Company may terminate the Employee's employment at any time without Cause.
- 7.5.2. In the event of a termination of the Employee's employment pursuant to Section 7.5.1: (i) the Company will pay to Employee any earned but unpaid Base Salary through the date of such termination; (ii) the Company will reimburse the Employee's unreimbursed business expenses pursuant to Section 4.3 for all expenses incurred in the performance of his duties prior to the date of such termination; (iii) the Company will pay to Employee any earned and accrued but unpaid Annual Bonus as of the date of such termination; (iv) commencing on the day immediately following "the date of such termination, the Company will continue to pay to the Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twelve (12) month period following such date of termination without Cause; provided, however, that if Employee is terminated without Cause following a Change in Control (as defined below), the Company will continue to pay to Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twenty-four (24) month period following such date of termination, which amount shall be paid as a lump sum within thirty (30) days after the date of termination, or, at the Company's election, in accordance with the Company's payroll practices in effect from time-to-time. Except as specifically set forth in this Section 7.5, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.5.3. Notwithstanding any other provision in this Agreement to the contrary, Employee hereby agrees and acknowledges that he will not be entitled to and the Company shall have no obligation to pay or provide any amount or benefit provided under Section 1 or Section 7.5 of this Agreement unless Employee executes and delivers to the Company and does not revoke a release satisfactory to the Company in a manner consistent with the requirements of the Age Discrimination in Employment Act.

7.6. Termination by the Employee for Good Reason.

- 7.6.1. The Employee may terminate the Employee's employment at any time for Good Reason (as hereinafter defined), upon written notice from the Employee to the Company in connection with his resignation for Good Reason setting forth the



effective date of termination (which shall not be less than thirty (30) business days from the date such notice is given).

- 7.6.2. In the event of a termination of the Employee's employment for Good Reason pursuant to Section 7.6.1: (i) the Company will pay to Employee any earned but unpaid Base Salary through the date of such termination; (ii) the Company will reimburse the Employee's unreimbursed business expenses pursuant to Section 4.3 for all expenses incurred in the performance of his duties prior to the date of such termination; (iii) the Company will pay to Employee any earned and accrued but unpaid Annual Bonus as of the date of such termination; (iv) commencing on the day immediately following the date of such termination, the Company will continue to pay to the Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the twelve (12) month period following such date of termination for Good Reason; provided, however, that if Employee terminates his employment for Good Reason following a Change in Control, the Company will pay to Employee his then current Base Salary until the expiration of the later of: (a) the third anniversary of the Effective Date, or (b) the eighteen (18) month period following such date of termination, which amount shall be paid as a lump sum within thirty (30) days after the date of termination, or, at the Company's election, in accordance with the Company's payroll practices in effect from time-to-time. Except as specifically set forth in this Section 7.6, the Company shall have no other liability or obligation hereunder by reason of such termination.
- 7.6.3. Notwithstanding any other provision in this Agreement to the contrary, Employee hereby agrees and acknowledges that he will not be entitled to and the Company shall have no obligation to pay or provide any amount or benefit provided under Section 1 or Section 7.6 of this Agreement unless Employee executes and delivers to the Company and does not revoke a release satisfactory to the Company in a manner consistent with the requirements of the Age Discrimination in Employment Act.
- 7.6.4. For purposes of this Agreement, "Good Reason" shall mean, as determined by the Company, the first occurrence of either: (i) any material alteration by the Company of Employee's positions, functions, duties or responsibilities that is not remedied by the Company within ten (10) days after receiving notice of such material alteration from Employee, including any change that (a) alters Employee's reporting responsibility or (b) causes Employee's Position with the Company to become of less importance than the applicable positions; (ii) a material decrease in Employee's Base Salary that has not been agreed to by the Employee; or (iii) failure of the Company to perform any of its obligations under this Agreement that are not remedied by the Company within ten (10) days after receiving notice of such failure to perform from Employee; provided, however, that Employee's consent to any event which would otherwise constitute "Good Reason" shall be conclusively presumed if Employee does not exercise his rights hereunder within ninety (90) days of the event.

7.6.5. For purposes of this Agreement, "Change in Control" means: (i) the sale, transfer, assignment or other disposition (including by merger or consolidation, but excluding any sales by stockholders made as part of an underwritten public offering of the common stock of the Company) by stockholders of the Company, in one transaction or a series of related transactions, of more than fifty percent (50%) of the voting power represented by the then outstanding capital stock of the Company to one or more Persons (other than to Employee or a "group" (as that term is defined under the Securities Exchange Act of 1934) in which Employee is a member); (ii) the sale of substantially all the assets of the Company (other than a transfer of financial assets made in the ordinary course of business for the purpose of securitization); or (iii) the liquidation or dissolution of the Company.

8. Parachute Payments. Payments under this Agreement shall be made without regard to whether the deductibility of such payments (or any other payments) would be limited or precluded by Section 280G of the Internal Revenue Code of 1986 (the "Code") and without regard to whether such payments would subject the Employee to the federal excise tax levied on certain "excess parachute payments" under Section 4999 of the Code; provided, however, that if the Total After-Tax Payments (as defined below) would be increased by the limitation or elimination of any amount payable under this Agreement, then the amount payable under this Agreement will be reduced to the extent necessary to maximize the Total After-Tax Payments. The determination of whether and to what extent payments under this Agreement are required to be reduced in accordance with the preceding sentence will be made at the Company's expense by an independent, certified public accountant selected by the Employee and reasonably acceptable to the Company. In the event of any underpayment or overpayment under this Agreement (as determined after the application of this Section 8), the amount of such underpayment or overpayment will be immediately paid by the Company to the Employee or refunded by the Employee to the Company, as the case may be, with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code. For purposes of this Agreement, "Total After-Tax Payments" means the total of all "parachute payments" (as that term is defined in Section 280G(b)(2) of the Code) made to or for the benefit of Employee (whether made hereunder or otherwise), after reduction for all applicable federal taxes (including, without limitation, the tax described in Section 4999 of the Code).

9. Representations. The Employee represents and warrants to the Company that:

- 9.1. there are no restrictions, agreements or understandings whatsoever to which the Employee is a party which would prevent or make unlawful the Employee's execution of this Agreement or the Employee's employment hereunder, or which is or would be inconsistent or in conflict with this Agreement or the Employee's employment hereunder, or would prevent, limit or impair in any way the performance by the Employee of his obligations hereunder;
- 9.2. the Employee's execution of this Agreement and the Employee's employment hereunder shall not constitute a breach of any contract, agreement or understanding, oral or written, to which the Employee is a party or by which the Employee is bound; and

10. Survival of Provisions. The provisions of this Agreement set forth in Sections 5 through 8 and 10 through 18 hereof shall survive the termination of the Employee's employment hereunder.
11. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Employee and their respective successors, executors, administrators, heirs and/or permitted assigns; provided, however, that neither the Employee nor the Company may make any assignments of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party hereto, except that, without such consent, the Company may assign this Agreement to an Affiliate or any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise, provided that such successor assumes in writing all of the obligations of the Company under this Agreement, subject, however, to the Employee's rights as to termination as provided in Section 7 hereof.
12. Notice. Any notice or communication required or permitted under this Agreement shall be made in writing and sent by certified or registered mail, return receipt requested, addressed as follows:

If to Employee:

Jack Weinstein

\_\_\_\_\_

\_\_\_\_\_

If to the Company:

Catalyst Pharmaceutical Partners, Inc.  
220 Miracle Mile, Suite 234  
Coral Gables, Florida 33134  
Attn: Chief Executive Officer

With a copy to:

Philip B. Schwartz, Esq.  
Akerman Senterfitt  
One Southeast Third Avenue  
Miami, Florida 33131

or to such other address as either party may from time-to-time duly specify by notice given to the other party in the manner specified above.

13. Waiver of Personal Liability. To the extent permitted by applicable law. Employee hereby acknowledges and agrees that he shall have recourse only to the Company (and its successors-in-interest) with respect to any claims he may have for compensation or benefits arising in connection with his employment, whether or not under this Agreement or under any other plan, program, or arrangement, including, but not limited to, any agreements related to the grant or exercise of equity options or other equity rights in the Company. To the extent permitted by applicable law, the Employee hereby waives any such claims for compensation, benefits and equity rights against officers, directors, managers, members, stockholders, or other representatives in their personal or separate capacities.
14. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature between the parties hereto relating to the employment of the Employee with the Company. This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.
15. Waiver. The waiver of the breach of any term or provision of this Agreement shall not operate as or be construed to be a waiver of any other or subsequent breach of this Agreement.
16. Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Florida, without regard to its rules on conflict of laws.
17. Invalidity. In case any one or more of the provisions contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the validity of any other provision of this Agreement, and such provision(s) shall be deemed modified to the extent necessary to make it enforceable.
18. Section Headings. The section headings in this Agreement are for convenience only; they form no part of this Agreement and shall not affect its interpretation.
19. Legal Fees; Limitations. If an action at law or in equity is necessary to enforce or interpret the terms of this Agreement and the Employee is the prevailing party, he shall be entitled to recover, in addition to any other relief, all reasonable attorney's fees, costs and disbursements. In the event that the provisions of Sections 5 or 6 hereof should ever be adjudicated to exceed the time, geographic, or other limitations permitted by applicable law in any applicable jurisdiction, then such provisions shall be deemed reformed in such jurisdiction to the maximum time, geographic, or other limitations permitted by applicable law.
20. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.

**[Signatures on Following Page]**

IN WITNESS WHEREOF, the parties hereto have caused this agreement to be made this \_\_\_ day of \_\_\_, 2006.

**EMPLOYEE**

/s/ \_\_\_\_\_  
Jack Weinstein

**CATALYST PHARMACEUTICAL  
PARTNERS, INC.**

By: /s/ \_\_\_\_\_  
Patrick J. McEnany  
President and Chief Executive Officer

CONSENT OF INDEPENDENT  
REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated July 24, 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  
September 25, 2006

Fort Lauderdale  
Jacksonville  
Los Angeles  
Madison  
Miami  
New York  
Orlando  
Tallahassee  
Tampa  
Tysons Corner  
Washington, DC  
West Palm Beach



One Southeast Third Avenue  
28th Floor  
Miami, Florida 33131-1714  
www.akerman.com  
305 374 5600 tel 305 374 5095 fax

September 25, 2006

**VIA FEDERAL EXPRESS AND EDGAR SUBMISSION**

Securities and Exchange Commission  
Division of Corporation Finance  
100 F Street, N.E., Mail Stop 6010  
Washington, DC 20549  
Attention: Jeffrey Reidler, Assistant Director

**Re: Catalyst Pharmaceutical Partners, Inc.  
Registration Statement on Form S-1  
Commission File No. 333-136039**

Dear Mr. Reidler:

We are responding to the comments in your letter to Patrick J. McEnany, Chief Executive Officer of Catalyst Pharmaceutical Partners, Inc. dated September 14, 2006. The comments should be read in connection with the enclosed copy of Amendment No. 2 filed on the date hereof (Amendment No. 2), which has been marked to show changes to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 filed on September 1, 2006. We refer to Catalyst Pharmaceutical Partners, Inc. as the "Issuer" or the "Registrant." The following responses are made on the Registrant's behalf.

**FORM S-1**

**Prospectus Summary, Page 3**

- 1. We note your response to comment 12 and your revised disclosure on pages 4 and 5 of the Prospectus Summary and reissue the comment. As presently drafted, we believe your discussion on your clinical trials is too detailed for proper inclusion in the summary. Instead, your clinical testing disclosure in the Summary should be**

limited to a discussion of the extent of testing, such as the drugs, indication(s) and current phase of testing. Please revise your summary section accordingly.

Issuer's Response

As requested, we have simplified the discussion of our clinical trials in the Summary. We have also updated the data in the second paragraph on page 3 and on pages 43 and 44 based on the 2005 SAMHSA Survey that was issued in early September 2006.

Our Business Strategy, page 6

2. **We note your response to comment 13 and reissue the comment in part. Please balance the discussion of your strategy in the summary with a discussion of obstacles implementing the following stated goals: (i) your plan to acquire or license additional addiction therapies; (ii) your plan to develop a new form of CPP-109; and (iii) your plan to utilize the knowledge, services and relationships of members of your Scientific Advisory Board.**

Issuer's Response

We have added additional bullets to the "Risks Affecting Our Business" on page 6 of the Summary in response to your comment.

"We are a developmental stage company whose limited operating history..." page 10

3. **We note your response to comment 21 and reissue the comment. Please revise the heading of your risk factor to indicate that your company has no products available nor have you ever had any products available for commercial sale.**

Issuer's Response

We have separated this risk factor into two separate risk factors, one of which includes the requested heading.

"We are dependent on a single chemical compound, vigabatrin." page 11

4. **We note your response to comment 29 and your supplemental response that you do not believe you will lose any proprietary position as a result of publication by academic collaborators of data obtained from clinical studies, and that accordingly you have removed the language to that effect. Please explain to us why you believe you would not lose any proprietary position as a result of publication by academic collaborators of data obtained from clinical studies.**
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Issuer's Response

In the case of vigabatrin, the Registrant's proposed use of this chemical entity is a new use of an existing product. Because vigabatrin has not been approved for use in the United States, the Registrant is obligated to make filings with the FDA with respect to the product as if it were a new chemical entity. Notwithstanding, the product has been approved for use, marketed and used in over 30 countries over the past decade, and vigabatrin and its risk profile has been well documented in the scientific community. Unlike other situations in which academic publication might cause a product to lose potential patent protection, since the primary patents upon which the Registrant relies are already issued, the Registrant does not believe that it will lose any intellectual property rights if academics publish information about the use of vigabatrin in the treatment of addiction.

The Registrant believes that the continued interest in this product by the scientific community will positively impact its product development efforts and the possibility that its product will be approved in the United States for treating cocaine and methamphetamine addiction, which the FDA considers a life-threatening condition for which there is currently no pharmacologic products approved for treatment. As such, the Registrant supports efforts in the scientific community to study vigabatrin's use in treating addiction.

"We will need to develop marketing, distribution and production capabilities . . ." page 13

5. **We note your response to comment 25 and reissue the comment. Please identify the manufacturer in this risk factor.**

Issuer's Response

As requested, we have identified the contract manufacturer in the risk factor on page 13.

"We have no experience as a public company, and the obligations incident . . ." page 15

6. **We note the disclosure relating to the material weakness identified by your independent auditors following completion of your 2005, 2004 and 2003 financial statements. You indicate that the deficiency noted related to your accounting for equity instruments. Please expand your disclosure by indicating what about your accounting for equity instruments was found to be deficient.**

Issuer's Response

We have expanded the risk factor disclosure on page 15 to indicate in what regard the Registrant's accounting for equity instruments was found to be deficient.

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"We may incur substantial costs as a result of litigation or other proceedings . . . ." page 17

7. **You indicate that Ovation announced in April 2006 that they intend to commercialize Sabril for cocaine addiction, which you believe would infringe upon your patent rights. Please expand your disclosure to provide for any conversations or other communications you have held or received from Ovation regarding their April 2006 announcement. If no conversations or other communications have been held or received, please indicate that fact. Additionally, please indicate why you have not yet approached Ovation regarding the April 2006 announcement.**

Issuer's Response

The following sets forth a summary of the Registrant's discussions with Ovation and knowledge of their product development efforts:

- In 2004, the Registrant contacted Ovation to discuss the possibility of cross-referencing the safety data for Sabril. While discussions were held, no agreements were reached. At the time, Ovation advised the Registrant that it was focused on seeking approval of an NDA for Sabril for use in treating epilepsy and West Syndrome.
  - In May 2005, the National Institute on Drug Abuse ("NIDA") announced through publication in the Federal Register (Vo. 70, No. 97, Friday, May 20, 2005) that it was seeking a cooperative research and development agreement ("CRADA") with a pharmaceutical or biotechnology company to test the hypothesis that vigabatrin may be a safe and effective medication for the treatment of cocaine and methamphetamine dependence. The proposed CRADA was for a Phase I and a Phase II clinical trial to be conducted over a three to five year period. By way of background, a CRADA is not for funding of clinical studies, but rather contemplates the delivery by NIDA of in-kind services with respect to the CRADA partner's clinical trials.
  - The Registrant filed an application for the CRADA. During the CRADA process, the Registrant became aware (based on discussions with NIDA) that two other parties, Ovation and Reckitt Benckiser Pharmaceuticals, Inc., ("Reckitt"), had filed applications for the CRADA. Reckitt had previously obtained approvals from the FDA for two pharmaceutical products used to treat opioid dependence (Suboxone and Subtex) and already had a sales force marketing to the addiction community. They had developed both drugs under a CRADA. One of the Registrant's directors and advisors, Charles O'Keeffe, was the former President and CEO of Reckitt.
  - In the summer of 2005, the Registrant and Reckitt had discussions about joining forces with respect to the CRADA. Thereafter, in August 2005, Reckitt and the
-

Registrant advised NIDA that they intended to join forces to pursue the CRADA. In connection with those discussions, representatives of Reckitt and Mr. O'Keeffe, met with Ovation to discuss the possibility of gaining access to pre-clinical data relating to Sabril. However, Ovation was unwilling to agree to any such cross-referencing.

- Following these discussions with Ovation, the Registrant requested that NIDA consider not entering into a CRADA with an entity that does not have rights to commercialize vigabatrin as a treatment for cocaine and methamphetamine addiction. Based on discussions with Brookhaven and its patent counsel, the Registrant believes that its licensed patents would preclude third parties (including Ovation) from commercializing vigabatrin in the U.S. as a treatment for cocaine and methamphetamine addiction. The Registrant also advised Ovation of this fact. However, in December 2005, NIDA advised Catalyst that the rights to commercialize the product were not a factor that would be considered in the selection of a CRADA collaborator. Further, Ovation advised the Registrant that its clinical testing of vigabatrin to treat cocaine and methamphetamine addiction would not violate Registrant's patents.
  - The Registrant has been advised that NIDA selected Ovation for the CRADA. However, at this date, almost nine months after these events, the Registrant believes that the CRADA has not yet been entered into based on the fact that: (i) neither NIDA nor Ovation has announced that a CRADA has been signed, and (ii) Ovation's website continues to make reference, with respect to Sabril, only to Ovation's plans to seek an NDA approval for Sabril for the treatment of Infantile Spasms (West Syndrome). The Registrant was also advised by a third party who attended the UBS Global Special Pharmaceutical Conference in April 2006 that Ovation publicly stated at the conference that it intended to work with NIDA to develop vigabatrin for the treatment of cocaine addiction. Further, several members of the Registrant's Scientific Advisory Board are very involved with representatives of NIDA on various projects, and at this time neither the Registrant's management nor, to the Registrant's knowledge, the members of the Registrant's Scientific Advisory Board, have been advised that the CRADA has been signed or that Ovation has taken any steps to pursue clinical trials with respect to the use of vigabatrin to treat cocaine or methamphetamine addiction.
  - The Registrant believes that Ovation's involvement in clinical trials testing the use of vigabatrin in treating cocaine would not violate Registrant's licensed patents. However, the Registrant believes that if Ovation were to obtain approval of an NDA for vigabatrin to treat cocaine and/or methamphetamine and seek to commercialize the product for such purposes, it would violate the Registrant's licensed patents.
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The Registrant has reported in its Registration Statement on pages 17 and 24 what it believes to be the material information regarding Ovation:

- Ovation has indicated an intent to seek to develop Sabril for the treatment of cocaine addiction;
- The Registrant believes that Ovation's commercialization of vigabatrin to treat cocaine and methamphetamine addiction would violate its licensed patents and that the Registrant would pursue an infringement claim against Ovation if it seeks to commercialize Sabril for this indication; and
- The Registrant has notified Ovation of its position regarding the potential infringement.

"If our non-clinical or clinical trials are unsuccessful or significantly delayed . . . ." page 18

8. We note your response to comment 23 and revisions to several of the risk factors we referenced in our previous comment letter including the risk factor referenced above, and reissue the comment. We believe this risk factor still contains overlapping disclosure and also contains a couple of risks that warrant separate discussion. With respect to overlapping disclosure we note the disclosure contained in the risk factor entitled "There is currently little scientific evidence supporting the use of vigabatrin to treat addiction" on page 10 overlaps with this risk factor as both appear to contain redundant disclosure related to the possibility that CPP-109 may not be found to be safe and effective as well as the fact that you will need to conduct extensive additional studies with respect to the CPP-109 product. Please revise this risk factor to eliminate redundant discussions related to those areas.

With respect to the risks that warrant separate discussion, we note the discussion in the fourth paragraph of this risk factor discussing the risks and consequences related to the possibility that you may be unable to demonstrate that CPP-109 is bioequivalent to Sabril. Please present your discussion regarding that risk as a new separate risk factor discussion. Similarly, your discussion in the fifth paragraph relating to difficulties in conducting your clinical trials due to the nature of the addiction mechanism and the resulting target patient population warrants discussion in a new separate risk factor. Please revise your risk factor section accordingly.

Issuer's Response

We have made the changes that you requested on pages 10 and 19.

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"If the FDA does not accept an NDA from us based on the results of our Phase II . . . ." page 19

9. **You indicate in this risk factor that "if the results of our Phase II clinical trial in the United States are compelling, we may elect to file an NDA on the basis of this study and seek FDA review under its accelerated approval process." This disclosure is confusing because later in the risk factor you indicate that [e]ven if your Phase II trial is successfully completed, "the FDA will not likely accept an NDA on the basis of a single study or review the NDA under the accelerated approval process." Why would you submit an NDA based on a single study if it is likely to be rejected by the FDA? Please explain or revise your disclosure accordingly.**

Issuer's Response

The Registrant believes, based on the advice of its regulatory counsel, that in light of the unmet medical need associated with the treatment of cocaine and methamphetamine addiction, that if the data from the Registrant's U.S. Phase II clinical trial are sufficiently compelling, it may be possible for the Registrant to submit an NDA for CPP-109, and that such NDA may be accepted for filing and approved. This may particularly be the case if the results from Phase II study being conducted in Mexico are also compelling. See response to Comment 16. Such approval may involve referral of the matter to an FDA advisory panel, or it may be an approval with required follow-up post-NDA approval clinical testing. As a result, the Registrant intends, if the data from its Phase II U.S. clinical trial are sufficiently compelling, to submit an NDA for CPP-109 based upon this single study. In that regard, the Registrant believes, after discussion with its regulatory counsel, that other NDA's relating to pharmaceutical products developed to meet unmet medical needs have been approved in this manner.

Notwithstanding, even if the data from the U.S. Phase II clinical trial are compelling, the FDA may not accept for filing an NDA submitted by the Registrant based on the Phase II data, or even if such NDA is accepted for filing it may not be approved. As a result, the Registrant makes clear in its disclosure that even though it intends to seek to file an NDA if the data from its U.S. Phase II clinical trial are compelling, it is most likely that a Phase III clinical trial will be required to be completed before an NDA for CPP-109 will be considered for approval by the FDA.

"We are effectively controlled by our Chairman and Chief Executive Officer . . . ." page 22

10. **Please revise your risk factor heading to reflect the potential adverse effect of control by your Chairman and Chief Executive Officer, such as his ability to significantly influence or exert control over the outcome of most stockholder actions, including the entrenchment of management and the election of all directors.**
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*Issuer's Response*

We have added the requested language to the risk factor heading on page 22.

"You will experience immediate and substantial dilution as a result of this . . . ." page 23

11. We note your response to comment 36 and the inclusion of a cross-reference directing your readers to the Dilution section to obtain more information on how they will experience immediate and substantial dilution as a result of your current proposed offering and reissue the comment. Cross-references to other sections of the document should be avoided because your reader should be able to obtain descriptions of a particular risk and the specific and immediate effects by reading the disclosure contained in the risk factor section. Please revise this risk factor to explain that investors who purchase shares will:

- a. Pay a price that substantially exceeds the value of your assets after subtracting its liabilities; and
- b. Contribute \_\_\_% of the total amount to fund the company but will only own \_\_\_% of the outstanding share capital and \_\_\_% of the voting rights.

*Issuer's Response*

We have added the requested language to the risk factor on page 23.

"Our business may require additional capital," page 23

12. We note your response to comment 19 and your revised disclosure, including the new risk factor entitled "Our business may require additional capital" on page 23. Previously we sought for you to add a risk factor concerning your need for additional capital and to have that risk factor placed in close proximity to the risk factor discussion regarding the dilution consequences of you raising additional capital. Based on the revisions you have provided, however, it appears that your new risk factor regarding your need to raise additional capital is more appropriate for placement after the first risk factor entitled "We are a developmental stage company whose limited operating history makes it difficult to evaluate our future performances" on page 10 of your risk factor. Please revise your risk factor section accordingly.

*Issuer's Response*

As requested, we have moved the risk factor to page 10.

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Use of Proceeds, page 26

13. **We note your response to comment 43 and reissue the comment in part. Please state the approximate dollar amount for each of general corporate purposes you list in this section.**

Issuer's Response

We continue to believe that the disclosure contained in Amendment No. 1 regarding Use of Proceeds was the material information required to be included therein. As a starting point, we are only allocating to general corporate purposes approximately \$1.5 million, which is less than 5% of the anticipated net proceeds of the offering. Further, we believe that the material disclosure required to be contained in Use of Proceeds relates to the funds that are being allocated for clinical studies and how far the Registrant believes such proceeds will allow it to go in its product development efforts. In that regard, we believe that the Use of Proceeds section in Amendment No. 1 as filed sets forth the information required to be included in Use of Proceeds.

As a result, we request that the Staff reconsider Comment No. 13.

Dilution, page 29

14. **We note your response to prior comment 45 but continue to believe that you need to disclose the historical net tangible book value and related per share amount as of the most recent historical balance sheet date with separate lines for the effects of all conversions of preferred stock subsequent to the balance sheet date. Refer to Item 506 of Regulation S-K.**

Issuer's Response

Based upon my discussions of September 18, 2006 with Todd Sherman of your office, we have added on page 30 the historical net tangible book value and related amounts as of the most recent historical balance sheet date with a bridge to the pro forma effect of the private placement completed in July 2006, the issuance of shares in July 2006 to the Registrant's scientific advisors and the conversion of outstanding preferred stock into common stock upon the completion of the offering.

Management's Discussion and Analysis, page 33

15. **We note your response to comment 25 and your supplemental response indicating that the material terms of your agreement with your contract manufacturer has been added to the Management's Discussion and Analysis section and further that a cross reference has been added to the text on page 53 of your Business section. First, please note that description of material agreements should be provided for in**
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the text of the Business section as opposed to the Management's Discussion and Analysis section or in a footnote. Second, we do not believe your description of the contract manufacturing agreement as currently drafted adequately provides the material terms of the agreement. For example, you do not disclose the identity of the contractor or when the agreement expires. Additionally, you do not indicate if there are any renewal, indemnification or termination provisions. You should also add disclosure regarding your rights and obligations under the agreement. In that regard, please revise your Business section to provide all the material terms of the manufacturing agreement.

Issuer's Response

We have added the terms of the Registrant's agreement with its contract manufacturer to the Business section at pages 55 and 56, including the additional terms that you requested.

Our Business, page 40

Overview, page 40

16. We note your response to comment 37 and your supplemental response that you have been advised by the FDA in writing that the FDA may consider the Mexican study as a clinical support for an NDA filing by you. Please revise your document to provide the information you provide in your supplemental response to us. Please also provide disclosure indicating under conditions the FDA may consider the Mexican study in support of an NDA. Please also revise your document to add appropriate caveats, such as (i) the FDA still requiring you to conduct further testing in the U.S. in support of the NDA; and (ii) the FDA may not consider the Mexican study as a clinical support for an NDA and as a result you may have to conduct all new testing in the U.S. prior to submitting an NDA. Please also provide us with a copy of the NDA letter advising you that the FDA may consider the Mexican study as a clinical support for an NDA filing by you.

Issuer's Response

The Registrant was advised by the FDA in the official minutes of a meeting between the Registrant and the FDA held on March 2, 2006 that the FDA would accept the proposed Mexican study as pivotal support for an NDA if such study is conducted under Good Clinical Practice Guidelines. We have clarified the text on page 49 to clarify risks associated with whether the FDA will consider the Mexico study in its review of any NDA that the Registrant may be permitted to file. We have also clarified in the text that it is the Registrant's understanding that its U.S. clinical trials will primarily form the basis of any NDA it might be permitted to file.

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A copy of the minutes of the March 2, 2006 meeting between the Registrant and the FDA is being provided to the Staff supplementally under separate cover.

17. **We note your response to comment 50 and reissue the comment in part. Please indicate how the Fast Track status facilitates the drug development and regulatory review process.**

Issuer's Response

We have added language to pages 4 and 42 that indicates how Fast Track status facilitates drug development and the regulatory review process.

Our Clinical Research, page 45

18. **We note your response to comment 51 and your supplemental response regarding the reasons you believe no Phase I study is required. Please provide similar disclosure in your document. Additionally, please indicate how you plan to provide the FDA with evidence sufficient to demonstrate that CPP-109 is safe if you do not conduct a Phase I clinical trial.**

Issuer's Response

As stated in my letter dated September 1, 2006, the Registrant believes that it may not be required to conduct a traditional Phase I trial with respect to safety or the VFD issue because Sabril has been on the market for many years outside the United States, has been well tolerated in its use, and, except for the issues of VFD's, which have been widely reported on by the scientific community, has shown no significant adverse side effects. The Registrant expects that as part of its clinical and non-clinical development of CPP-109, it will need to conduct one or more Phase I-type studies. While the scope of the required trials are uncertain, studies will likely be required regarding pharmacokinetics, cardiac function, drug-drug interaction and the effect of the drug in certain special populations.

These studies will be conducted during the pendency of the Registrant's Phase II clinical trial and/or thereafter. The Registrant does not believe that the FDA will delay its U.S. Phase II trial due to the fact that a Phase I trial has not yet been conducted. In fact, the Registrant is aware that the FDA has previously approved a Phase II clinical trial without a preceding Phase I trial for an investigator (Dr. Eugene Somoza, a Professor at the University of Cincinnati) seeking to test the use of vigabatrin in treating cocaine addiction. However, such study did not move forward because of NIDA funding issues.

The Registrant has added language on pages 19, 27 and 48 regarding these matters. It has also made clear that the funds required to complete any required Phase I studies are included within the use of proceeds from this offering.

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19. **Please add disclosure that you have also allocated funds from the proceeds of this offering for other clinical and non-clinical studies that may be required, including, if needed, a Phase I trial for your CPP-109 product.**

Issuer's Response

Please see the response to comment 18.

Clinical Studies That We Support, page 46

20. **We note your disclosure that you believe that the clinical trial that you 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. Please revise your disclosure to provide appropriate disclaimers that the FDA may still require you to conduct a Phase II study in the U.S. as your Mexico study is being conducted in a foreign country under different regulations and standards and without FDA oversight in any respect.**

Issuer's Response

We have added the requested language at page 49.

Pilot Studies, page 47

21. **We note your discussion under the subheading "Results" on page 47 where you discuss the sample sizes for calculating your P values for your pilot studies. Given the small sample sizes and large number of patients who dropped out of the studies, please explain to us how the small sample sizes could effect the reliability of the P values. To the extent you believe the P values are unreliable due to the small sample sizes, please provide additional disclosure to that fact and how and why such numbers could be unreliable in this section as well elsewhere in the document where you provide P value disclosure.**

Issuer's Response

Language has been added on pages 51 and 52 setting forth the Registrant's belief that because of the small size of the pilot studies and the number of patients who dropped out, the P-values derived from the pilot studies may not be duplicated in larger studies.

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Manufacturing, Marketing and Reimbursement, page 53

22. **We note your response to comment 54 and your supplemental response that in order to manufacture CPP-109, you will need to obtain approval of an NDA for CPP-109 and that your contract manufacturer will need to show compliance with cGMP in manufacturing operation. You also indicate that such matters have been disclosed in numerous places in the registration statement. We believe inclusion of the approval requirements in this section will be helpful to investors rather than having them refer to other sections of the document. Please revise your disclosure accordingly.**

Issuer's Response

Disclosure has been added on pages 55 and 56 to address the Staff's comment.

9. Stock Options Granted, page F-11

23. **We are deferring a final evaluation of stock compensation and other costs recognized until the estimated offering price is specified and may have further comment in this regard when the amendment containing that information is filed.**

Issuer's Response

In accordance with my telephone conversations of this date with Mr. Sherman, the Registrant is hereby providing the Staff with an updated response to Comment No. 23. Based on currently available information, the Registrant believes that if the proposed public offering is completed at the currently anticipated public offering price, of which there can be no assurance, the price range will be between \$11 per share and \$13.00 per share, and the pre-money valuation of the Registrant will be between \$100 million and \$120 million. However, because this price range anticipates a forward stock split of the outstanding common stock prior to the offering (and our share issuances to date are stated in this letter at their pre-forward stock split values), for comparative purposes, please be advised that the anticipated pre-forward stock split range for the proposed public offering is currently estimated to be between \$15.92 per share and \$19.10 per share, with the midpoint of the range being \$17.51 per share.

To help the Staff in its analysis of the Registrant's recording of charges relating to its stock-based compensation issued in or relating to fiscal 2005 and for the six months ended June 30, 2006, the Registrant provides the following information:

Securities issued in Fiscal 2005

- In October 2004, the Registrant entered into a consulting agreement with Jack Weinstein, who is currently the Registrant's Chief Financial Officer, under which the Registrant agreed to grant Mr. Weinstein a stock option to purchase 150,000 shares of the Registrant's common stock, vesting 50,000 shares immediately, 50,000 shares in October 2005 and 50,000 shares upon completion of a financing of at least \$3 million. The option exercise price of the first two tranches of options was \$2.00 per share (which the Registrant believed to be the fair market value of its common and common-equivalent shares on the grant date). The option exercise price of the last tranche of options was to be the price per share at which the \$3 million financing was completed (which, as described below, was closed in July 2006 at a common-equivalent stock value of \$4.35 per share). At the time that the consulting agreement was entered into, Mr. Weinstein was not a related party.
  - In January 2005, the Registrant entered into a consulting agreement with Charles O'Keeffe, who is currently a senior advisor to and a director of the Registrant, in which the Registrant agreed to issue to Mr. O'Keeffe \$2,500 per month in shares of its common stock at a value of \$2.00 per share (aggregating 22,500 shares for services through June 30, 2006). On the same date, Mr. O'Keeffe was also granted a stock option to purchase 200,000 shares of the Registrant's common stock at an exercise price of \$2.00 per share. On the date of the consulting agreement, which was also the grant date of the stock options, the Registrant believed that \$2.00 per share was the fair market value of its common stock. All of the options granted to Mr. O'Keeffe were fully vested upon grant. At the time that the consulting agreement was entered into, Mr. O'Keeffe was not a related party.
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- In January 2005, the Registrant needed to raise funds for a clinical trial that it wanted to undertake and for working capital. At the time, the Registrant was in discussions with several institutional funding sources with respect to a possible institutional placement. In its proposed placement, the Registrant was seeking to raise approximately \$5 million at a \$15 to \$20 million pre-money valuation. While this process was ongoing, the Registrant elected to complete a small rights offering to fund its general corporate working capital requirements. The rights offering, which closed on March 4, 2005, raised gross proceeds of \$1,084,000 and doubled the number of common and common-equivalent shares outstanding at that date. In order to avoid impacting the proposed valuation of the institutional round, the rights offering was priced at \$0.40 per share, which the Registrant believed to be a price having no relation to the then fair value of the Registrant's equity. As part of the rights offering, the Registrant also doubled the number of options granted to its co-founders, Patrick J. McEnany and Hubert Huckel, M.D., in July 2002, and to Mr. Weinstein, on identical terms to the options previously granted. For your information, the Registrant continued its efforts seeking institutional funding until early in the third quarter of 2005, at which time it abandoned its efforts and determined to move its product development efforts in a direction that would not require this level of funding. The Registrant did not receive any offers for financing as a result of its institutional fundraising efforts.
  - Early in the third quarter of 2005, the Registrant agreed to issue shares of common stock to several members of its Scientific Advisory Board, for services to be rendered by each such person during the second half of 2005 and the first half of 2006. Each of these persons was independent of the Registrant, as they were and still are employed by other parties and could have required payments to be made for their services in cash. While the Registrant committed to issue these shares in mid-2005, the shares were not formally issued until July 2006. The Registrant and the scientific advisors agreed in the contemporaneous correspondence relating to the issuance of these shares that the value of the shares was \$2.00 per share, and the following shares were issued:
    - Dr. Stephen Dewey — 3,750 shares per quarter, or 15,000 shares in the aggregate;
    - Dr. Jonathan Brodie — 3,750 shares per quarter, or 15,000 shares in the aggregate;
    - Dr. Robert Fechtner — 5,000 shares per quarter, or 20,000 shares in the aggregate; and
    - Dr. Eugene Laska — 6,250 shares per quarter, or 25,000 shares in the aggregate.
  - In the fall of 2005, the Registrant applied for a cooperative research and development agreement ("CRADA") with the National Institute on Drug Abuse ("NIDA"). The proposed CRADA would have provided for the delivery by NIDA of in-kind services with respect to the Registrant's clinical studies, thereby lowering the costs that the Registrant would have to fund for its clinical studies. In the fall of 2005, the Registrant was advised that it had not been awarded the CRADA.
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Fair value of share-based compensation for fiscal 2005

For fiscal 2005, the Registrant recorded the following stock-based compensation expense:

- \$1,067,750 relating to options granted to non-employees, significantly all of which was recorded in the first quarter of fiscal 2005; and
- \$105,000 relating to shares of common stock due at December 31, 2005 to the Registrant's scientific advisors and Mr. O'Keefe.

For accounting purposes, all of this stock-based compensation was valued at \$2.00 per share, which the Registrant believes to have been the fair value of its common stock throughout fiscal 2005 and until sometime in the second quarter of fiscal 2006. This would equate for comparative purposes to a value of the Registrant of approximately \$10.8 million in the aggregate based on 5.4 million common and common-equivalent shares outstanding at December 31, 2005. The Registrant accounted for all the equity instruments, other than the options issued to its Chief Executive Officer, using variable accounting under EITF 96-18 and accordingly has reflected these instruments at their fair value. The Chief Executive Officer's options were accounted for using the intrinsic value method in accordance with APB No. 25.

The Registrant's belief as to the fair value of its securities during fiscal 2005 and at December 31, 2005 was based on its analysis of the fair value of similar entities, its perception as to the investment community's then view regarding companies seeking to develop pharmacologic treatments for substance abuse and the then early stage of the Registrant's product development efforts. The Registrant's view on this issue was also based on its experience (described above) seeking institutional funding and the fact that it was not awarded the CRADA.

Securities issued during the six months ended June 30, 2006

- In March 2006, the Registrant committed to issue options to purchase 3,000 shares of its common stock at an exercise price of \$2.00 per share (which the Registrant believed to be the fair value of its common stock on the date of grant) to Donald Jasinski, M.D., Ph.D., who is now a member of its Scientific Advisory Board, for services. Dr. Jasinski was not a related party when the agreement was reached.
  - In March 2006, the Registrant was granted "Fast Track" status by the FDA with respect to its product candidate, CPP-109. Fast Track status means that, among other matters, the FDA recognizes that cocaine addiction is an unmet medical need for which no pharmacological products are currently available. The receipt of Fast Track status was considered a significant positive step in the Registrant's product
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development efforts by the investment community and is an important part of the reason for the increase in the fair value of the Registrant's common shares between December 31, 2005 and June 30, 2006.

- Following the receipt of Fast Track status, the Registrant determined that the appropriate next step in its product development efforts would be to undertake a Phase II clinical trial of CPP-109. In order to obtain the funding for this trial, early in the second quarter of 2006 the Registrant began discussions with several investment banking firms, which indicated an interest in assisting the Registrant in obtaining the necessary financing. The Registrant believes that the investment community's interest in the Registrant had changed since its fiscal 2005 experience due to the following factors:
    - The Registrant's receipt of Fast Track status for CPP-109 in March 2006;
    - Recent changes in the market's perception of pharmaceutical companies engaged in the development of products for treating addiction, which have been fueled by several events that occurred in late 2005 the effect of which had filtered into the investment community by the time the Registrant renewed its search for capital early in the second quarter of fiscal 2006. These events were the announcement of the Alkermes, Inc. — Cephalon, Inc. joint venture regarding Vivitrol in June 2005, the follow-on offering in November 2005 by Hythiam, Inc. and the December 2005 initial public offering by Somaxon Pharmaceuticals, Inc.; and
    - The recent substantial interest in scientific circles and in the press about the development of pharmaceutical products to treat addiction (see for example the article from the June 25, 2006 magazine section of the *New York Times* that was previously provided to the Staff on a supplemental basis).
  - During May 2006, based on its discussions with several investment banks, the Registrant concluded that while there was interest in the investment community regarding a potential private or public financing to raise the funds needed for the Registrant's product development efforts, such financing was likely to take six to nine months to complete and there was no assurance it would be successful. The Registrant was also aware that it would have to pay the costs of any such financing whether or not it was successful. Further, the Registrant needed working capital to continue the steps preparatory to its proposed Phase II clinical trial.
  - In order to fund these requirements, the Registrant decided to raise short-term working capital, and on June 9, 2006, the Registrant launched a private placement of its securities to raise a minimum of \$3 million and a maximum of \$5 million for these purposes. This private offering valued the Registrant's equity (on a pre-money basis) at \$30 million. The Registrant sold shares of its Series B Preferred Stock in this offering at a common share equivalent price of \$4.35 per share, which the Registrant believed to be the fair market value of the common and common equivalent shares at
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that date. This private placement was sold directly by the Registrant to its shareholders and to other accredited investors introduced to the Registrant by several of its shareholders, and no commissions or other remuneration was paid in connection with this private placement.

- The valuation of this private offering was based on the Registrant's discussions with several of its potential investors and financial intermediaries, as well as on discussions between the Registrant and several of its shareholders who were being asked to consider an additional investment in the Registrant. The valuation also reflected the Registrant's need to complete this financing quickly. It further reflected the fact that investors in the private placement were being asked to take on significant risk due to the fact that the Registrant would need to complete another significantly larger financing following the private placement in order to achieve its objectives. The placement ultimately closed on July 24, 2006, with the Registrant ultimately raising gross proceeds of \$3.3 million from 48 accredited investors, about half of whom were existing holders of the Registrant's securities. The placement took almost six weeks to complete and required an investment of \$500,000 by the Registrant's Chief Executive Officer to reach the minimum offering.
  - In the spring of 2006, the Registrant was engaged in a search for a Vice President of Regulatory Operations. During that search, the Registrant was introduced to Douglas Winship, who was introduced to the Registrant by a search firm and was not affiliated with the Registrant. In late June 2006, Mr. Winship agreed to join the Registrant. As part of his compensation package, the Registrant agreed to grant Mr. Winship a five-year stock option to purchase 100,000 shares of the Registrant's common stock at an exercise price of \$4.35 per share, which the Registrant believed to be the fair market value of its common stock on the date of grant. These options will vest over several years, with the first tranche of options vesting in July 2007.
  - In early July 2006, the Registrant selected First Albany Capital, Inc. and Stifel Nicolaus & Company, Incorporated as the managers of a proposed initial public offering of the Registrant's common stock. Based on recent discussions between the Registrant and First Albany, which is acting as the managing underwriter, the Registrant believes that the underwriters are considering valuing the Registrant in the offering at a pre-money valuation of between \$100 million and \$120 million. However, such pricing has not yet been finalized and reflects their thoughts on valuation prior to the marketing of the securities.
  - The Registrant believes that its proposed pre-money valuation range for its proposed initial public offering is consistent with the valuations of other biopharmaceutical companies at similar points of product development in the public securities market.
  - In September 2006, the Registrant retained Charles W. Gorodetzky, M.D., Ph.D. to act as the Registrant's Chief Medical Officer. As part of its arrangement with Dr. Gorodetzky, the Registrant agreed to issue to Dr. Gorodetzky five-year stock options
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to purchase 15,000 shares of the Registrant's common stock at an exercise price equal to the IPO price.

Fair value of share-based compensation for the first six months of fiscal 2006

The Registrant recorded the following stock-based compensation expense for the six months ended June 30, 2006:

- \$27,750 relating to options granted to non-employees;
- \$90,000 relating to shares of common stock relating to services rendered during the first six months of fiscal 2006; and
- \$123,385 relating to the 52,000 shares of common stock accrued as of December 31, 2005 at \$2.00 per share, which has been marked to the then-estimated June 30, 2006 fair value of \$4.35 per share.

For accounting purposes, all of this stock-based compensation was valued at \$4.35 per share, which the Registrant believes to have been the fair value of its common stock as of June 30, 2006. The Registrant believes that \$4.35 was the fair value of its shares based on the following:

- The arms length, willing buyer — willing seller price paid by third party investors in the Registrant's private offering;
- While there is a substantial discount between the potential IPO price of range of \$15.92 and \$19.10 (with a midpoint of \$17.51) and the value used by the Registrant in recording stock based compensation for the six months ended June 30, 2006 of \$4.35, such difference is warranted because of the following:
  - the fair value at June 30, 2006 reflects an appropriate discount in value based on the fact that completion of the public offering could not be assured (in that regard, investors in the private placement were taking on substantial risk that a large financing would not be completed, since the Registrant's product development efforts would require far more capital than the \$3.3 million raised in the private placement); and
  - there is always a substantial discount between public company and private company valuations, and the spread in this case is within the range of what the Registrant and we believe is normal under these types of circumstances.

Based on my discussions with Mr. Sherman, the Registrant has added additional language regarding Stock-based Compensation to its MDA at pages 38 and 39.

Interim Financial Statements

Notes to Financial Statements, page F-18

24. **We note your response to prior comment 65 but it does not appear to us that you have provided the disclosures required by SPAS 123R. Please provide the disclosures required by paragraphs 64, 84 and A240 of SFAS 123(R), Share-Based Payment or demonstrate to us how you currently have the required disclosures included in your interim financial statements.**
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Issuer's Response

The missing information has been added on page F-20.

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We look forward to hearing back from you regarding Amendment No. 2 to the Registration Statement. If you have any questions, please feel free to give me a call.

Sincerely,

  
Philip B. Schwartz