CATALYST PHARMACEUTICAL PARTNERS, INC.
Form POS AM
May 21, 2012
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As filed with the Securities and Exchange Commission on May 21, 2012

Registration No. 333-180617

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

POST-EFFECTIVE

AMENDMENT NO. 2

To

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**2834**	**76-0837053**

(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

355 Alhambra Circle

Suite 1500

Coral Gables, Florida 33134

(305) 529-2522

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Patrick J. McEnany

Catalyst Pharmaceutical Partners, Inc.

355 Alhambra Circle, Suite 1500

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 the public: As soon as practicable after the effective date of this registration statement.

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 of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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(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 statement number of the earlier effective registration statement for the same offering. ¨

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

Large accelerated filer ¨	Accelerated Filer ¨
Non-accelerated filer ¨ (do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Shares to be Registered	**Proposed Maximum Aggregate Offering Price (1)(2)**	**Amount of Registration Fee**
Units, each consisting of:		
(i) Common stock, par value $0.001 per share		
(ii) Warrant to purchase common stock		
Common stock issuable upon exercise of the warrants		
Total	$9,997,500	$1,145.71 (3)

(1) Estimated solely for the calculating the amount of the registration fee pursuant to Section 457(o) under the Act.
(2) Pursuant to Rule 416(a) under the Act, this registration statement shall be deemed to cover any additional number of shares of common stock as may be issued from time to time upon conversion of the warrants to prevent dilution as a result of stock splits, stock dividends or similar transactions. No fee is required pursuant to Rule 457(i) under the Act.
(3) Previously paid

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 that specifically states that the registration statement shall thereafter 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 Securities and Exchange Commission, acting pursuant to said Section 8(a) may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold 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 it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 21, 2012

Preliminary Prospectus

7,500,000 Units

Each unit consisting of one share of common stock and a warrant to purchase up to one-half of one share of common stock

We are offering 7,500,000 units, with each unit consisting of one share of our common stock and a warrant to purchase up to one-half of one share of our common stock (and the shares of common stock issuable from time to time upon exercise of the offered warrants), pursuant to this prospectus. The warrants will have an exercise price of $ per share of common stock, will be exercisable immediately after issuance and will expire five years from the date of their issuance. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

Our common stock is quoted on the Nasdaq Capital Market under the symbol CPRX . On May 18, 2012 the last reported price per share of our common stock as quoted on the Nasdaq Capital Market was $0.80. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

Our business and investing in our securities involves significant risks. You should carefully read and consider the *Risk Factors* beginning on page 5 of this prospectus before investing.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Corresponding Warrant	Total
Public offering price	$	$

Underwriting discount (1)	$	$
Proceeds, before expenses, to us	$	$

(1) See *Underwriting* on page 83 of this prospectus for a description of the compensation payable to the underwriters.

The underwriters expect to deliver the shares of common stock and the warrants against payment on or about May , 2012, subject to customary closing conditions.

Cowen and Company

Sole Book-Running Manager

Roth Capital Partners

The date of this prospectus is May , 2012.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that which is contained in this prospectus. This prospectus may be used only where it is legal to sell these securities. The information in this prospectus may only be accurate on the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of securities.

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SUMMARY

This summary highlights information contained elsewhere in this prospectus; it does not contain all of the information you should consider before investing. You should carefully read the entire prospectus before making an investment decision.

This prospectus includes trademarks, service marks or trade names owned by us or other companies. All trademarks, service marks or trade names included in this prospectus are the property of their respective owners.

Throughout this prospectus, the terms we , us , our and company refer to Catalyst Pharmaceutical Partners, Inc.

Our Business

We are a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in clinical development; CPP-109 and CPP-115. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. We also hope to evaluate CPP-109 for the treatment of other addictions and other selected central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. CPP-109 and CPP-115 have both been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized, for this indication, that CPP-109 and CPP-115 are intended for the treatment of a serious or life-threatening condition and demonstrate the potential to address this unmet medical need. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

We are currently involved in the following product development activities: (i) we are jointly conducting with the National Institute on Drug Abuse (NIDA) and the Veterans Administration (VA) a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (and, based on current information, we expect to obtain top line results from this trial early in the first quarter of 2013); and (ii) we are conducting a Phase I(a) clinical study evaluating the safety of CPP-115 in healthy volunteers (and, based on current information, we expect to obtain the results from this trial during the second quarter of 2012).

Lundbeck Inc. s (Lundbeck) exclusivity for Sabril® tablets (its version of vigabatrin) as an adjunctive therapy to treat refractory complex partial seizures in adults will expire on August 21, 2014. At the present time, we expect to submit a new drug application (NDA) under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (the FDCA) for CPP-109. A 505(b)(2) application is one that relies, at least partially, upon data that a company does not own or have right of reference to, including published literature. A 505(b)(2) application can also rely upon the FDA s previous findings of safety and efficacy for previously approved products. Additional information in a 505(b)(2) application includes data on manufacturing, bioequivalence and bioavailability; studies to support any change relative to the previously approved product; information with respect to any patents that claim the drug or use of the drug for which approval is sought; and an appropriate certification with respect to any patents listed for the previously approved drug on which investigations relied upon for NDA approval were conducted, or that claim a use of the listed drug. There can be no assurance whether, or to what extent, the FDA will file any 505(b)(2) NDA that we may submit for CPP-109. Further, we believe that we will be prevented from submitting a 505(b)(2) NDA for CPP-109 until August 21, 2014.

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Generally, the process of seeking approval of an NDA requires multiple clinical trials, including two pivotal U.S. Phase III clinical trials. In our case, because CPP-109 is intended to treat a serious condition for which there is no approved therapy, there is a possibility that if the data from the Phase II(b) trial are sufficiently compelling, the FDA will file an NDA submitted by us for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat addiction. However, it is more likely that the FDA will require at least one Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will file an NDA for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA files an NDA for CPP-109 based on the results of our current Phase II(b) trial, we expect that we will not be in a position to submit an NDA for CPP-109 until August 21, 2014. Finally, if the FDA requires more than one Phase III clinical trial, our NDA submission could be delayed even further. There can be no assurance that the data from our ongoing Phase II(b) trial will be sufficiently compelling or that even if such data are sufficiently compelling, that the FDA will file an NDA submitted for CPP-109 based on the results of that trial.

Our Strategy

Our strategy is to become a leading specialty pharmaceutical company focused on the in-licensing and development of proprietary drug candidates for the treatment of selected diseases of the central nervous system. Our near-term strategy is to focus on the regulatory approval of CPP-109 for the treatment of cocaine addiction and to initially demonstrate the safety and efficacy of CPP-115 for the treatment of addiction and epilepsy. Our long-term strategy is to gain approvals for additional indications for CPP-109, including methamphetamine addiction, and to initially gain approval for CPP-115 to treat addiction and epilepsy. Specifically, we intend to:

Focus on CPP-109 for cocaine addiction. A treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status from the FDA for CPP-109 for cocaine addiction may facilitate the regulatory approval process. Enrollment for our U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction that we are conducting with NIDA and the VA began in the first quarter of 2011. This trial is currently ongoing and we expect to receive top-line results from this trial early in the first quarter of 2013. Assuming success, we expect that this trial will serve as one of the adequate and well-controlled trials required to support approval of an NDA.

Develop additional indications for CPP-109. The mechanism of action of CPP-109 and pre-clinical data indicate it may be suitable as a potential treatment for addictions to methamphetamine, nicotine, prescription pain medications, alcohol and marijuana, as well as for obsessive-compulsive disorders including binge eating patterns and compulsive gambling. We hope to develop CPP-109 for one or more of these additional indications, subject to the availability of funding.

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

Identify and initiate strategic partnering discussions for specific indications in the U.S. and Europe. We believe that there may be several potential pharmaceutical partners interested in jointly developing and marketing CPP-109 and CPP-115 in the U.S. and/or Europe. We have held preliminary discussions with several parties regarding potential transactions, but no agreements have been entered into to date.

Company Information

Our principal executive offices are located at 355 Alhambra Circle, Suite 1500, Coral Gables, Florida 33134, and our telephone number at that address is (305) 529-2522.

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The Offering

Units being offered by us	7,500,000 units, each unit consisting of one share of common stock and one warrant to purchase up to one-half of one share of common stock (and the shares of common stock issuable from time to time upon exercise of the offered warrants).
Common stock to be outstanding after this offering	32,241,520 shares
Warrants being offered by us	Warrants to purchase up to an aggregate of 3,750,000 shares of common stock will be offered in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. The exercise price of the warrants is $ per share of common stock, subject to adjustment. The warrants will be exercisable during the period commencing on the date of original issuance and ending five years from such date.
Use of Proceeds	We intend to use the net proceeds of this offering: (i) to fund the activities necessary to support the submission of an NDA for CPP-109 for FDA approval and to begin to prepare for the commercial launch of CPP-109, assuming that the data from the currently ongoing Phase II(b) trial are compelling and the FDA files an NDA submitted by us for CPP-109 based on the data from the Phase II(b) trial, (ii) to manufacture sufficient CPP-115 for use in one or more future safety and/or proof-of-concept studies of CPP-115, and (iii) for general corporate purposes. See *Use of Proceeds* for further information.
Risk Factors	See *Risk Factors* , as well as other information included in this prospectus, for a discussion of factors you should read and consider carefully before investing in our securities.
Trading Market	Our common stock is traded on the Nasdaq Capital Market under the symbol CPRX. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

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The number of shares of our common stock to be outstanding after this offering as shown above is based on 24,741,520 shares outstanding as of May 21, 2012 and excludes:

- 2,019,888 shares of our common stock subject to outstanding options under our 2006 Stock Incentive Plan having a weighted average exercise price of $1.19 per share;
- 1,459,220 shares of our common stock subject to outstanding options outside of our 2006 Stock Incentive Plan having a weighted average exercise price of $0.69 per share;
- 239,270 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan; and
- 1,523,370 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of $1.30 per share.

Except as otherwise indicated, all information in this prospectus assumes no exercise of the warrants offered hereby.

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RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below as well as the other information in this prospectus before deciding to invest in or maintain your investment in our company. The risks described below are not intended to be an all-inclusive list of the potential risks relating to an investment in our securities. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business. As a result, the trading price or value of our securities could be materially adversely affected and you may lose all or part 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. We are the successor by merger to a company that began operations in 2002. As such, we have a limited operating history upon which you can evaluate our current business and our prospects. The likelihood of our future success must be viewed in light of the problems, expenses, difficulties, delays and complications often encountered in the operation of a new business, especially in the pharmaceutical industry, where failures of new companies are common. We are subject to the risks inherent in the ownership and operation of a development stage company, including availability of capital, regulatory setbacks and delays, fluctuations in expenses, competition and government regulation. If we fail to address these risks and uncertainties, our business, results of operations, financial condition and prospects would be adversely affected.

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

We have had no revenues from product sales to date, currently have no products available for commercial sale, and have never had any products available for commercial sale. We expect to incur losses at least until we can commercialize CPP-109. Our net loss was $6,391,062 for the year ended December 31, 2011 and $1,089,186 for the three months ended March 31, 2012, and as of March 31, 2012 we had a deficit accumulated during the development stage of $39,191,803. We may never obtain approval of an NDA for CPP-109 or CPP-115 and may never achieve profitability.

Our business will require additional capital.

Our business will require additional capital to meet our product development objectives. We presently have funds that will allow us to complete: (i) the U.S. Phase II(b) clinical trial of CPP-109 that we are jointly conducting with NIDA and the VA; and (ii) the Phase I(a) clinical trial of CPP-115 evaluating the safety of CPP-115 in humans. We currently expect to receive the results from the U.S. Phase I(a) trial of CPP-115 in the second quarter of 2012 and the Phase II(b) trial of CPP-109 early in the first quarter of 2013. Based on currently available information and without considering the net proceeds of this offering, we estimate that we have sufficient working capital to support our operations through the end of the first quarter of 2013. The expectations described above are based on current information available to us. If the cost of these studies is greater than we expect, or it takes longer to complete and obtain the results of these studies, our assumptions may not prove to be accurate.

At the present time, we will require additional funding to complete studies or trials other than those described above, including any Phase III clinical trial that we may be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction and any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and epilepsy. Since these studies and trials have not yet been developed, we cannot estimate what our funding requirements will be with respect to such additional

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studies and trials. We will also require additional working capital to support our operations beyond the first quarter of 2013 (without considering the proceeds of this offering). There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

We expect to raise any required additional funds through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations, governmental research grants or cost sharing arrangements with NIDA, the National Institute of Neurological Disorders and Stroke (NINDS) or other appropriate agencies that operate under the NIH umbrella, and/or other means. However, there is no assurance that any such grants will be made available, and if available, that we will qualify to receive any such grants. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations.

Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

Our business is subject to substantial competition.

The biotechnology and pharmaceutical industries are highly competitive. In particular, competition for the development and marketing of therapies to treat addictive substances such as cocaine and methamphetamine and epilepsy is intense and expected to increase. Many of our competitors have substantially greater financial and other resources, larger research and development staffs and more experience developing products, obtaining FDA and other regulatory approval of products and manufacturing and marketing products. We compete against pharmaceutical companies that are developing or currently marketing therapies for epilepsy and addictive substances. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of treatments for substance abuse and epilepsy, technologies and processes that are, or in the future may be, the basis for competitive commercial products. While we believe that our product candidates will offer advantages over many of the currently available competing therapies, our business could be negatively impacted if our competitors present or future treatments are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payers.

Many of our competitors have substantially greater financial, technical, and human resources than we do. In addition, many of our competitors have significantly greater experience than we do in conducting clinical studies and obtaining regulatory approvals of prescription drugs. Accordingly, our competitors may succeed in obtaining FDA approval for products more rapidly than we can. Furthermore, if we are permitted to commence commercial sales of our product candidates, we may also compete with respect to manufacturing efficiency and marketing capabilities. For all of these reasons, we may not be able to compete successfully.

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

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and/or sale of CPP-109 or CPP-115. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance with an aggregate annual coverage limit of $15,000,000 per claim and $15,000,000 in the aggregate, with a deductible of $10,000 per occurrence. Our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of CPP-109, CPP-115 or any potential future products we may acquire and use in clinical trials or after FDA approval and,

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therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

The obligations incident to being a public company place significant demands on our management.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including periodic reports, disclosures and more complex accounting rules. As directed by Section 404 of Sarbanes-Oxley, the SEC adopted rules requiring public companies to include a report of management on a company s internal control over financial reporting in their Annual Report on Form 10-K. Based on current rules, we are required to annually report under Section 404(a) of Sarbanes-Oxley regarding our management s assessment as to the effectiveness of our internal control over financial reporting. If we are unable to conclude that we have effective internal control over our financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

Risks Related to the Development of Our Drug Candidates

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

There is limited clinical evidence currently indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, one double-blind, placebo controlled trial and two open-label clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine addiction and methamphetamine addiction. Only 76 persons receiving vigabatrin completed these trials in the aggregate. Further, these studies were conducted in Mexico at a single substance abuse center and were not subject to FDA oversight in any respect, including study design and protocol. In the U.S., one double-blind, placebo controlled trial and one double-blind, placebo controlled proof-of-concept study have been completed. Only 121 persons in the aggregate received CPP-109 (vigabatrin) in these trials. None of these studies, individually or in the aggregate, provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA. Further, less than 200 persons have received vigabatrin in clinical trials assessing its efficacy to treat addiction, which is a limited number of subjects.

Our product development efforts may fail.

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

- CPP-109 or CPP-115 may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;
- CPP-109 or CPP-115 may not be economical to market or take substantially longer to obtain necessary regulatory approvals than anticipated; or
- Competitors may market equivalent or superior products.

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

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

We will only obtain regulatory approval to commercialize CPP-109 or CPP-115 if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well-controlled clinical studies and trials that the drug is safe and effective for its intended use and that it otherwise meets

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approval requirements. A failure of one or more pre-clinical or clinical studies can occur at any stage of product development. We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for, or commercializing our product candidates, including but not limited to:

- regulators or institutional review boards (IRBs) may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions may be imposed upon us by the FDA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for reinspection due to changes in the regulatory environment;
- the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;
- we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;
- our third-party contractors, clinical investigators or contractual collaborators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and
- the costs of our pre-clinical and/or clinical trials may be greater than we anticipate.

Vigabatrin has known side effects that may hinder our ability to produce safe and commercially viable products.

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

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

These known side effects, as well as other side effects that may be discovered during our clinical trials, may cause the FDA or other governmental agencies to halt clinical trials prior to their completion, prevent the initiation of further clinical trials, or deny the approval of CPP-109 as a treatment for addiction. These known side effects will most likely cause the FDA to require as a condition of approval, implementation of a risk evaluation and mitigation strategy (REMS), as was required for the recent approvals of Sabril® for refractory complex partial seizures and infantile spasms. Such strategy will likely include Black Box warnings, restrictions on promotion and distribution, a communication plan for healthcare professionals, certification of prescribers and pharmacies, and testing of patients on the drug to monitor whether the administration of the drug continues to be safe and effective for the patient. Should CPP-115 prove to have VFDs (even at levels lower than CPP-109), the above risks will apply to it as well.

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We rely on third parties to conduct our pre-clinical studies and clinical studies and trials, and if they do not perform their obligations to us we may not be able to obtain approval for CPP-109 or CPP-115.

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

If we conduct studies with other parties, such as NIDA, we may not have control over all decisions associated with that trial. To the extent that we disagree with the other party on such issues as study design, study timing and the like, it could adversely affect our drug development plans. Although we intend to rely on third parties to manage the data from these studies and trials, we are responsible for confirming that each of our studies and trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies will require us to comply with applicable regulations and standards, commonly referred to as good laboratory practice and good clinical practice, for conducting, recording and reporting the results of such studies and trials to assure that the data and the results are credible and accurate and that the human study and trial participants are adequately protected. Our reliance on third parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for our product candidates if these requirements are not met.

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

Our current plans for the development of CPP-109 include efforts to generate the data we believe will be necessary in order to obtain marketing approval of CPP-109 for other additional indications including, but not limited to, methamphetamine addiction. If we are successful in obtaining approval of an NDA for CPP-109 as a treatment for cocaine addiction, of which there can be no assurance, we plan to subsequently conduct trials in support of, and submit supplemental NDAs for additional indications. Depending on the data we rely upon, approval for additional indications for CPP-109 may be delayed. In addition, even if we receive supplemental NDA approval, the FDA has broad discretion to require us to generate additional data related to safety and efficacy to supplement the data included in the supplemental NDA. We could be required, before obtaining marketing approval for CPP-109 for additional indications, to conduct substantial new research and development activities, which could be more costly and time-consuming than we currently anticipate. The FDA may not agree that we can market CPP-109 for additional indications. If we are required to generate substantial additional data beyond what we have planned to support approval, our product development and commercialization efforts will be delayed and we may suffer significant harm to our future financial performance. In addition, submission of supplemental NDAs for additional indications, conducting new research and development and generating additional data to support FDA approval will require that we obtain additional financing, and we can provide no assurance that we will be able to obtain such financing on acceptable terms, or at all.

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

We may encounter difficulties in our future clinical studies and trials recruiting patients due to the nature of the addiction mechanism and our resulting target patient population. Because addicts are typically addicted to multiple substances, we may not be able to recruit a sufficient number of eligible participants within our

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anticipated timeframe or at all. In addition, due to the neurological and physiological mechanisms and implications of substance addiction, it is likely that many of our clinical study and trial participants will either not comply with trial protocols, or not complete the study or trial. An unusually low rate of compliance or completion will present challenges, such as determining the statistical significance of study or trial results. Additionally, we compete for study and trial subjects with others conducting clinical trials testing other treatments for addictions. Finally, unrelated third parties and investigators in the academic community have expressed interest in testing vigabatrin for the treatment of drug abuse. If these third-party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected.

Risks Related to Commercialization of our Drug Candidates

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

In order to generate sales of CPP-109, CPP-115 or any other products we may develop, we must either acquire or develop an internal marketing force with technical expertise and with supporting documentation capabilities, or make arrangements with third parties to perform these services for us. The acquisition and development of a marketing and distribution infrastructure will require substantial resources and compete for available resources with our drug development efforts. To the extent that we enter into marketing and distribution arrangements with third parties, our revenues will depend on the efforts of others. If we fail to enter into such agreements, or if we fail to develop our own marketing and distribution channels, we would experience delays in product sales and incur increased costs.

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

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

In the past and currently, we purchase all supplies of our product candidates from single suppliers. While we have contractual freedom to source this ingredient elsewhere, there is no guarantee we will either be successful in identifying alternative supplier(s) or that these manufacturers will be qualified to manufacture the product to our specifications or that such future supplier(s) will have the manufacturing capacity to meet future requirements. All such suppliers are subject to regulatory approval. We cannot assure you that any alternative supplier will have the necessary capacity to meet our requirements or that we can contract with any such manufacturer on acceptable terms or that any such alternative supplier will not require capital investment from us in order for them to meet our requirements.

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We may encounter difficulties in managing our growth, which would adversely affect our results of operations.

If we are successful in obtaining approval to commercialize CPP-109 or CPP-115, we will need to significantly expand our operations, which could put significant strain on our management and our operational and financial resources. We currently have six employees and conduct much of our operations through outsourcing arrangements. To manage future growth, we will need to hire, train, and manage additional employees. Concurrent with expanding our operational and marketing capabilities, we will also need to increase our product development activities. We may not be able to support, financially or otherwise, future growth, or hire, train, motivate, and manage the required personnel. Our failure to manage growth effectively could limit our ability to achieve our goals.

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

Our commercial success will depend on reimbursement from third-party and governmental insurers.

Sales of pharmaceutical products in the United States depend largely on reimbursement of patients costs by private insurers, government health care programs including Medicare and Medicaid, and other organizations. These third-party payers control healthcare costs by limiting both coverage and the level of reimbursement for healthcare products. In particular, the rising costs of pharmaceutical products are a subject of considerable attention and debate. Third-party payers are increasingly altering reimbursement levels and challenging the price and cost-effectiveness of pharmaceutical products. The reimbursement status of newly approved pharmaceutical products in particular is generally uncertain. The levels at which government authorities and private health insurers reimburse physicians or patients for the price they pay for CPP-109, CPP-115 and other products we may develop could affect the extent to which we are able to commercialize our products successfully.

Risks Related to Government Regulation

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

We do not currently have any products that have been approved for commercialization. We will not be able to commercialize our products until we have obtained the requisite regulatory approvals from applicable governmental authorities. To obtain regulatory approval of a product candidate, we must demonstrate to the satisfaction of the applicable regulatory agency that such product candidate is safe and effective for its intended uses. The type and magnitude of the testing required for regulatory approval varies depending on the product candidate and the disease or condition for which it is being developed. In addition, in the U.S. we must show that the facilities used to manufacture our product candidate are in compliance with current good manufacturing practices (cGMP). We will also have to meet similar regulations in any foreign country where we may seek to commercialize CPP-109 or CPP-115. In general, these requirements mandate that manufacturers follow elaborate procedures for manufacturing, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing and distribution process. The process of obtaining regulatory approvals typically takes several years and requires the expenditure of substantial capital and other resources. Despite the time, expense and resources invested by us in the approval process, we may not be able to demonstrate that our product candidates are safe and effective, in which event we would not receive the regulatory approvals required to market them.

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The FDA and other regulatory authorities generally approve products for particular indications. Our current focus for CPP-109 and CPP-115 is to develop treatments for addiction and, with respect to CPP-115, to also develop treatments for epilepsy. CPP-109 and/or CPP-115 may not be approved for any or all of the indications that we request, which would limit the indications for which we can promote it and adversely impact our ability to generate revenues. We may be required to conduct costly, post-marketing follow-up studies if FDA requests additional information.

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

The FDA has granted Fast Track designation to CPP-109 and to CPP-115 for the treatment of cocaine addiction. Fast Track designation means that the FDA recognizes cocaine addiction as a serious or life threatening condition for which there is an unmet medical need and consequently may initiate review of sections of an NDA before the application is complete. However, Fast Track designation does not accelerate the time needed to conduct clinical trials, nor does it mean that the regulatory requirements necessary to obtain an approval are less stringent. Our Fast Track designation does not guarantee that we will qualify for, or be able to take advantage of, priority review procedures following a submission of an NDA. Additionally, our Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data from our clinical development program, or if a competitor s product is approved for the indication we are seeking.

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

Before we can obtain regulatory approval for the sale of any of our product candidates, we may have to conduct, at our own expense, pre-clinical tests in animals in order to support the safety of CPP-109 and CPP-115. Pre-clinical testing is expensive, difficult to design and implement, can take several years to complete and is uncertain as to outcome. Our pre-clinical tests may produce negative or inconclusive results, and on the basis of such results, we may decide, or regulators may require us, to halt ongoing clinical trials or conduct additional pre-clinical testing.

We may also need to conduct additional clinical studies and trials demonstrating the efficacy and/or safety of CPP-109 in humans. In the United States, in 2009 we completed both a Phase II(a) clinical trial to assess the efficacy of using CPP-109 as a treatment for cocaine addiction and a clinical proof-of-concept study to assess its efficacy as a treatment for methamphetamine addiction. Neither of these completed studies/trials provided efficacy data which would allow us to obtain approval to commercialize CPP-109 in the U.S. We may also have to conduct additional human trials (in addition to the current Phase II(b) human clinical trial) in order to seek approval to commercialize CPP-109 for the treatment of cocaine addiction. However, even if the results of our clinical trials are promising, CPP-109 may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Future clinical trials for CPP-109 may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, an inability to recruit clinical trial participants at the expected rate, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays. The risks described above also apply to our development of CPP-115.

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

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In other countries where CPP-109, CPP-115 or any other product we develop may be marketed, we will also be subject to regulatory requirements governing human clinical studies, trials and marketing approval for drugs. The requirements governing the conduct of clinical studies, trials, product licensing, pricing and reimbursement varies widely from country to country.

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

Generally, the process of seeking approval of an NDA requires multiple clinical trials, including two pivotal U.S. Phase III clinical trials. In our case, because CPP-109 is intended to treat a serious condition for which there is no approved therapy, there is a possibility that if the data from the Phase II(b) trial are sufficiently compelling, the FDA will file an NDA submitted by us for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat addiction. However, the FDA could require a Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will file an NDA submitted by us for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA files an NDA based on our current Phase II(b) trial, it is unlikely that we will submit an NDA for CPP-109 until August 21, 2014. Finally, if the FDA requires one or more Phase III clinical trials, our NDA submission could be delayed even further. There can be no assurance that the data will be compelling from our currently ongoing Phase II(b) clinical trial or that even if such data are compelling, that the FDA will file an NDA submitted by us for CPP-109 based on the results of that trial.

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

Our development of CPP-115 is at an early stage, and it is likely going to be several years before we are in a position to file an NDA for CPP-115. Further, our ability to develop CPP-115 will be dependent on our having the resources to conduct the studies and trials that would be required. There can be no assurance that we will ever file an NDA for CPP-115.

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

We rely, and intend to continue to rely, on third-party suppliers and contract manufacturers to provide us with materials for our clinical trials and commercial-scale production of our products. These suppliers and manufacturers must continuously adhere to cGMP as well as any applicable corresponding manufacturing regulations outside of the U.S. In complying with these regulations, we and our third-party suppliers and contract manufacturers must expend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that our products meet applicable specifications and other regulatory requirements. Failure to comply with these requirements could result in the FDA s refusal to approve our product even if the product is proven to be safe and effective, or an enforcement action against us, including warning letters, the seizure of products, suspension or withdrawal of approvals, shutting down of production and criminal prosecution. Any of these third-party suppliers or contract manufacturers will also be subject to inspections 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;
- reliance on the continued financial viability of the third parties;
- limitations on supply availability resulting from capacity and scheduling constraints of the third parties;

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impact on our reputation in the marketplace if manufacturers of our products, once commercialized, fail to meet the demands of our customers;

the possible breach of the manufacturing agreement by the third party because of factors beyond our control; and

the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

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

If we rely on a sole source of supply to manufacture our products we could be adversely impacted by disruptions in the manufacturing processes or capabilities of our sole supplier.

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

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

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

Our product promotion and advertising is also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA approved labeling. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety related information, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue an untitled letter or warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

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

Healthcare organizations, both public and private, continue to change the manner in which they operate and pay for services. These organizations have had to adapt to extensive and complex laws and regulations and judicial decisions governing activities including drug manufacturing and marketing. Additionally, the healthcare industry in recent years has been subject to increasing levels of government regulation of reimbursement rates and capital expenditures. We believe that the industry will continue to be subject to increasing regulation, as well as political and legal action, as additional proposals to reform the healthcare system continue to be discussed by Congress and state legislatures. This is particularly so in light of the legislative healthcare reform approved by Congress in 2010. Any new legislative initiatives, if enacted, may further increase government regulation of or other involvement in healthcare, lower reimbursement rates and otherwise change the operating environment for healthcare companies. We cannot predict the likelihood of all future changes in the healthcare industry in general, or the addiction treatment industry in particular, or what impact they may have on our results of operations, financial condition or business. Government regulations applicable to our proposed products or the interpretation thereof might change and thereby prevent us from marketing some or all of our products and services for a period of time or indefinitely.

Risks Related to Our Dependence on Third Parties

We are dependent on our relationship and license agreements with Brookhaven and Northwestern University, and we rely upon the patent rights granted to us for vigabatrin and CPP-115 pursuant to the license agreements.

All of our patent rights for CPP-109 are derived from our license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven). Pursuant to this license agreement, we have licensed rights under nine patents in the United States, and have broad foreign filings in major international markets, that were filed and obtained by Brookhaven relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions. The eight issued patents expire between 2018 and 2022, with the principal patents expiring in 2018. We also have the right to future foreign patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. See *Business Licensing and Patents* for more information about our license with Brookhaven and our licensed patents and patent applications. These rights are subject to the right of the U.S. government, under limited circumstances, to practice the covered inventions for or on its own behalf. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations to Brookhaven. If we violate or fail to perform any term or covenant of the license agreement, Brookhaven may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Brookhaven, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-109, and our business, results of operations, financial condition and prospects would be materially adversely affected.

All of our patent rights for CPP-115 are derived from our license agreement with Northwestern University (Northwestern). Pursuant to this license agreement, we have exclusive worldwide rights to two patents in the United States. These were filed and obtained by Northwestern relating to compositions of matter for a class of molecules, including CPP-115. Both patents expire in 2023. Additionally, we have licensed rights from Northwestern to a pending patent for derivatives of vigabatrin that are unrelated to CPP-115. See *Business Licensing and Patents* for more information about our license with Northwestern and our licensed patents and patent applications. These rights are subject to the right of Northwestern, under limited circumstances, to practice the covered inventions for or on its own behalf for research. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations, including milestone payments, to Northwestern. If we violate or fail to perform any term or covenant of the license agreement, Northwestern may terminate the license agreement upon satisfaction of any applicable

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notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Northwestern, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-115, and our business, results of operations, financial condition and prospects would be materially adversely affected.

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

If we obtain approval to market CPP-109 or CPP-115, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by Brookhaven and Northwestern, respectively, to exclude others from competing with us. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims sufficiently broad to prevent others from practicing our technologies or marketing competing products. Third parties may intentionally design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others. Third parties may intentionally attempt to design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others.

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

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

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

Risks Related to Our Intellectual Property

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

While we are not currently aware of any third-party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our technologies infringe or violate the patent or other

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proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our products or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we are aware that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the U.S., patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

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

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

- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and

- we may have to redesign our product so that it does not infringe others patent rights, which may not be possible or could require substantial funds or time and require additional studies.

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

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

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

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

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

Our involvement in intellectual property litigation could result in significant expense to us. Some of our competitors have considerable resources available to them and a strong economic incentive to undertake substantial efforts to stop or delay us from commercializing products. For example, Ovation Pharmaceuticals, which held the rights in North America to Sabril® for the treatment of epilepsy (prior to the acquisition of Ovation by Lundbeck), had, in the past, indicated its intent to develop Sabril® for the treatment of cocaine addiction and methamphetamine addiction. However, we have no current evidence that Lundbeck, which now

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owns Ovation, is pursuing clinical trials intended to support approval for either of these indications. We believe that Lundbeck would infringe our patent rights if they seek to commercialize Sabril® to treat cocaine addiction and/or methamphetamine addiction, and we have advised Lundbeck of our belief in that regard. We intend to vigorously pursue infringement claims against Lundbeck if it seeks to commercialize Sabril® for these indications. However, we, unlike Lundbeck and many of our other competitors, are a relatively small company with comparatively few resources available to us to engage in costly and protracted litigation. Moreover, regardless of the outcome, intellectual property litigation against or by us could significantly disrupt our development and commercialization efforts, divert our management s attention and quickly consume our financial resources.

In addition, if third parties file patent applications or issue patents claiming technology that is also claimed by us in pending applications, we may be required to participate in interference proceedings with the U.S. Patent Office or in other proceedings outside the U.S., including oppositions, to determine priority of invention or patentability. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel will be diverted from product development or other more productive matters.

Risks Related to Our Common Stock and this Offering

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

We are highly dependent on our officers, on our Board of Directors and on our scientific advisors. The loss of the services of any of these individuals could significantly impede the achievement of our scientific and business objectives. Other than an employment agreement with Patrick J. McEnany, our Chairman, President and Chief Executive Officer with respect to his services, and the consulting agreements we have with our medical director and with several of our scientific advisors, we have no employment or retention agreements with our officers, directors or scientific advisors. If we lose the services of any of our existing officers, directors or scientific advisors, or if we were unable to recruit qualified replacements on a timely basis for persons who leave our employ, our efforts to develop CPP-109, CPP-115 or other products might be significantly delayed. We do not carry key-man insurance on any of our personnel.

We have relationships with our scientific advisers and collaborators at academic and other institutions. Such individuals are employed by entities other than us and may have commitments to, or consulting advisory contracts with, such entities that may limit their availability to us. Although each scientific advisor and collaborator has agreed not to perform services for another person or entity that would create an appearance of a conflict of interest, the Chairman of our Scientific Advisory Board, Stephen L. Dewey, Ph.D., is actively involved in the investigation of neurological mechanisms involved in the addiction process. His research might result in pharmaceutical products that are competitive with, or superior to, CPP-109 or CPP-115. Similarly, other similar conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

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;

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requirements that special meetings of our stockholders may only be called by the Board of Directors; and

advance notice procedures our stockholders must comply with in order to nominate candidates for election to our Board of Directors or to place stockholders proposals on the agenda for consideration at meetings of stockholders.

On September 20, 2011, our Board of Directors approved the adoption of a stockholder rights plan. The rights plan was implemented through our entry into a rights agreement with Continental Stock Transfer & Trust Company, as rights agent, and the declaration of a non-taxable dividend distribution of one preferred stock purchase right (each, a Right) for each outstanding share of our common stock. The dividend was paid on October 7, 2011 to holders of record as of that date. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if a person acquires beneficial ownership of 17.5% or more of our common stock (or, in the case of a person who beneficially owned 17.5% or more of our common stock on the date the rights plan was adopted, such person acquires beneficial ownership of any additional shares of our common stock) or after the date of the Rights Agreement, commences a tender offer that, if consummated, would result in beneficial ownership by a person of 17.5% or more of our common stock. The rights will expire on September 20, 2016, unless the rights are earlier redeemed or exchanged.

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

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

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.

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

As of the date of this prospectus, we had 24,741,520 shares of our common stock outstanding. We also had outstanding an aggregate of 3,479,108 options to purchase shares of common stock, of which 3,059,108 shares were exercisable, and common stock purchase warrants to purchase 1,523,370 shares of common stock. We have registered for future sale: (i) 2,688,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and (ii) 1,459,220 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. The outstanding options make a part of the shares registered both under and outside of our 2006 Stock Incentive Plan. Sales of restricted shares or shares underlying stock options, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

developments concerning our clinical studies and trials and our pre-clinical studies;

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announcements of product development successes and failures by us or our competitors;

new products introduced or announced by us or our competitors;

adverse changes in the abilities of our third-party manufacturers to provide drug or product in a timely manner or to meet FDA requirements;

changes in reimbursement levels;

changes in financial estimates by securities analysts;

actual or anticipated variations in operating results;

expiration or termination of licenses (particularly our licenses from Brookhaven and Northwestern), research contracts or other collaboration agreements;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

intellectual property, product liability or other litigation against us;

changes in the market valuations of similar companies;

changes in pharmaceutical company regulations or reimbursements as a result of healthcare reform or other legislation;

changes in economic conditions; and

sales of shares of our common stock, particularly sales by our officers, directors and significant stockholders, or the perception that such sales may occur.

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

We may be unable to maintain our listing on the Nasdaq Capital Market.

Nasdaq listing rules require that listed companies maintain certain standards, including maintaining $2.5 million in stockholder equity and/or $35 million total market value of listed securities, as well as a bid price of at least $1.00 per share. If we are unable to maintain the values set

forth above, the Nasdaq Stock Market could take steps to delist our common stock from the Nasdaq Capital Market. While we would attempt, in such a case, to seek alternative listing for our common stock, such delisting would immediately affect the liquidity, and likely the value, of our common stock.

We may allocate the net proceeds from this offering in ways that you and other shareholders may not approve.

We currently intend to use the net proceeds of this offering to fund the activities necessary to support submission of an NDA for CPP-109 for FDA approval and the costs to prepare for commercialization of CPP-109, assuming that the data from the currently ongoing Phase II(b) trial are compelling and the FDA files an NDA submitted by us for CPP-109 based on the data from the Phase II(b) trial, to manufacture sufficient

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CPP-115 for use in one or more future safety and/or proof-of-concept studies of CPP-115, and for general corporate purposes. See *Use of Proceeds*. However, because of the factors described above, we cannot at this time determine with specificity the particular uses of the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the offering price of $ per share (attributing none of the combined public offering price to the warrants offered hereby), if you purchase shares of common stock and warrants in this offering, you will suffer immediate and substantial dilution of approximately $ per share in the net tangible book value of the common stock. See the section entitled Dilution in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock and warrants in this offering. To the extent that the shares underlying the warrants are ultimately issued, there will be further dilution to investors. The existence or exercise of the outstanding warrants may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital.

There is no public market for the warrants to purchase common stock being sold in this offering.

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing or quotation of the warrants on any securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the warrants will be limited.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements , as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes , anticipates , proposes , plans , expects , intends , may , and other similar expressions are intended to ident 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.

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

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

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

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USE OF PROCEEDS

We estimate that the net proceeds of this offering, after deducting the underwriting discount and the estimated offering expenses payable by us, will be approximately $. We currently expect to use the net proceeds of this offering for the following purposes:

- to fund the activities necessary to support submission of an NDA for CPP-109 for FDA approval and to begin to prepare for the commercial launch of CPP-109, assuming that the data from the currently ongoing Phase II(b) trial are compelling and the FDA files an NDA submitted by us for CPP-109 based on the data from the Phase II(b) trial;

- to fund the manufacture of sufficient CPP-115 for use in one or more future safety and/or proof-of-concept studies of CPP-115; and

- for general corporate purposes.

We anticipate that if the proceeds of this offering are used for the purposes described above, we will have sufficient working capital following this offering to support our operations through the first quarter of 2014. Further, while we will use the proceeds of this offering to manufacture sufficient CPP-115 for use in future proof-of-concept studies of CPP-115, the proceeds of this offering will not be sufficient to fund any such studies.

Due to the factors set forth above, we cannot currently determine with absolute certainty how we will use the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering. Pending their use as described above, we intend to invest the net proceeds in high quality, short-term, interest-bearing securities. We will pay all of the costs associated with registering the securities covered by this prospectus.

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MARKET PRICE OF OUR COMMON STOCK

Market Information

Our common stock trades on the Nasdaq Capital Market under the symbol CPRX. From November 8, 2006 through September 2, 2009, our common stock traded on the Nasdaq Global Market under the same symbol. There was no public market for our common stock before November 8, 2006. The following table sets forth the high and low closing sales prices per share of our common stock as reported on the Nasdaq Capital Market for the period indicated.

	High	Low
Year Ended December 31, 2010		
First Quarter	$ 0.87	$ 0.56
Second Quarter	$ 2.00	$ 0.71
Third Quarter	$ 1.32	$ 0.90
Fourth Quarter	$ 1.19	$ 0.91
Year Ended December 31, 2011		
First Quarter	$ 1.38	$ 1.05
Second Quarter	$ 1.93	$ 1.10
Third Quarter	$ 1.82	$ 1.07
Fourth Quarter	$ 1.46	$ 0.96
Year Ended December 31, 2012		
First Quarter	$ 1.34	$ 1.05
Second Quarter (through May 18, 2012)	$ 1.09	$ 0.80

Stockholders

As of May 14, 2012, there were 53 holders of record of our common stock, which includes custodians who hold our securities for the benefit of others. We estimate that there are approximately 3,100 beneficial holders of our common stock.

DIVIDEND POLICY

We have not paid any dividends on our common stock to date and do not anticipate that we will pay dividends in the foreseeable future. Any payment of cash dividends on our common stock in the future will be dependent upon the amount of funds legally available, our earnings, if any, our financial condition, our anticipated capital requirements and other factors that the board of directors may think are relevant. However, we currently intend for the foreseeable future to follow a policy of retaining all of our earnings, if any, to finance the development and expansion of our business and, therefore, do not expect to pay any dividends on our common stock in the foreseeable future.

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DILUTION

Purchasers of the securities offered by this prospectus will suffer immediate and substantial dilution in the net tangible book value per share of the common stock they purchase. Our net tangible book value as of March 31, 2012 was $2,716,602, or approximately $0.11 per share of our common stock. Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of March 31, 2012.

Dilution in net tangible book value per share represents the difference between the amount per share and corresponding warrant paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 7,500,000 shares of common stock and warrants to purchase up to 3,750,000 shares of our common stock in this offering at a combined offering price of $ per share and corresponding warrant (attributing none of the combined public offering price to the warrants offered hereby), and after deducting the underwriting discount and the estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2012 would have been $, or approximately $ per share of our common stock. This represents an immediate increase in net tangible book value of $ per share of common stock to our already existing stockholders and an immediate dilution in net tangible book value of $ per share of common stock to purchasers in this offering. The following table illustrates this per share dilution:

Public offering price per unit		$
Net tangible book value per share as of March 31, 2012	$ 0.11	
Increase per share attributable to this offering	$	
As adjusted net tangible book value per share as of March 31, 2012		$
Dilution per share to new investors participating in this offering		$

The above table is based on 24,741,520 shares outstanding as of March 31, 2012 and excludes:

- 2,263,888 shares of our common stock subject to outstanding options under our 2006 Stock Incentive Plan having a weighted average exercise price of $1.19 per share;
- 1,459,220 shares of our common stock subject to outstanding options outside of our 2006 Stock Incentive Plan having a weighted average exercise price of $0.69 per share;
- 239,270 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan; and
- 1,523,370 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of $1.30 per share.

To the extent that any currently outstanding options or warrants are exercised, new options are issued under our 2006 Stock Incentive Plan, the warrants offered hereby are exercised, or we otherwise issue additional shares of common stock in the future, at a price less than the public offering price, there will be further dilution to new investors.

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SELECTED FINANCIAL DATA

The selected statement of operations data for the years ended December 31, 2011, 2010, 2009 and the balance sheet data as of December 31, 2011 and 2010, have been derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data for the three months ended March 31, 2012 and 2011 and for the cumulative period from inception (January 4, 2002) to March 31, 2012, and the selected balance sheet data as of March 31, 2012 have been derived from our unaudited condensed financial statements included elsewhere in this prospectus. The unaudited interim financial information has been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our financial position as of March 31, 2012 and the results of operations for the three months ended March 31, 2012 and 2011. The selected statement of operations data for the years ended December 31, 2008 and 2007 and the selected balance sheet data at December 31, 2009, 2008 and 2007 have been derived from financial statements that are not included in this prospectus. Historical results are not necessarily indicative of future results. This selected financial data should be read in conjunction with *Management s Discussion and Analysis of Financial Condition and Results of Operations* and our financial statements and related notes included elsewhere in this prospectus.

	For the Three Months Ended March 31,		Year Ended December 31,					Cumulative period from inception (January 4, 2002) through March 31,
	2012	2011	2011	2010	2009	2008	2007	2012
Statement of Operations Data:								
Revenues government grant	$	$	$	$ 488,958	$	$	$	$ 488,958
Operating costs and expenses:								
Research and development	727,327	903,953	3,383,965	2,306,781	5,097,440	8,710,441	3,040,659	26,371,035
General and administrative	637,383	615,297	2,698,174	2,206,358	2,177,954	2,183,504	1,986,470	14,743,131
Total operating costs and expenses	1,364,710	1,519,250	6,082,139	4,513,139	7,275,394	10,893,945	5,027,129	41,114,166
Loss from operations	(1,364,710)	(1,519,250)	(6,082,139)	(4,024,181)	(7,275,394)	(10,893,945)	(5,027,129)	(40,625,208)
Interest income	1,317	2,114	10,985	17,858	33,466	329,348	887,636	1,479,106
Change in fair value of warrants liability	274,207		(319,908)					(45,701)
Loss before income taxes	(1,089,186)	(1,517,136)	(6,391,062)	(4,006,323)	(7,241,928)	(10,564,597)	(4,139,493)	(39,191,803)
Provision for income taxes								
Net loss	(1,089,186)	(1,517,136)	$ (6,391,062)	$ (4,006,323)	$ (7,241,928)	$ (10,564,597)	$ (4,139,493)	$ (39,191,803)
Net loss per share basic and diluted	(0.04)	(0.08)	$ (0.29)	$ (0.22)	$ (0.48)	$ (0.81)	$ (0.33)	
Weighted average shares outstanding basic and diluted	24,710,362	19,922,057	21,728,292	18,580,223	15,066,799	13,013,041	12,525,405	

	As of March 31,	As of December 31,				
	2012	2011	2010	2009	2008	2007
Balance Sheet Data:						
Cash and cash equivalents	$ 4,722,795	$ 6,029,067	$ 5,475,158	$ 7,779,277	$ 11,766,629	$ 15,943,896
Working capital	$ 4,086,226	5,394,382	5,476,443	7,593,272	10,485,039	16,228,401
Total assets	$ 4,988,771	6,249,257	5,831,488	7,966,382	12,032,968	16,679,922
Warrants liability	$ 1,371,033	1,645,240				
Total liabilities	$ 2,272,169	2,488,559	313,709	348,522	1,472,753	357,165
Stockholders equity	$ 2,716,602	3,760,698	5,517,779	7,617,860	10,560,215	16,322,757

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MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following information together with our financial statements and notes thereto that are included in this prospectus. This discussion contains forward-looking statements that involve risk, uncertainties, and assumptions. Actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, those presented under Risk Factors and elsewhere in this prospectus.

Introduction

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

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

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

Results of Operations. This section provides an analysis of our results of operations for the first quarter of 2012 compared to the same period in 2011 and for the three fiscal years ended December 31, 2011.

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

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

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

Overview

We are a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in clinical development; CPP-109 and CPP-115. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. We also hope to evaluate CPP-109 for the treatment of other addictions and other selected central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. CPP-109 and CPP-115 have both been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized, for this indication, that CPP-109 and CPP-115 are intended for the treatment of a serious or life-threatening condition and demonstrate the potential to address this unmet medical need. We believe that we control all current intellectual property for drugs that have a mechanism of action related to

inhibition of GABA aminotransferase.

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

- the scope, rate of progress and expense of our pre-clinical studies and trials, and other product development activities;
- the results of our pre-clinical studies and clinical studies and trials, and the number of clinical trials (and the scope of such trials) that will be required for us to seek and obtain approval of NDA s for CPP-109 and CPP-115; and
- the expense of filing, and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We are currently involved in the following product development activities: (i) we are jointly conducting with NIDA and the VA a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (and, based on current information, we expect to obtain top line results from this trial early in the first quarter of 2013); and (ii) we are conducting a Phase I(a) clinical study evaluating the safety of CPP-115 in healthy volunteers (and, based on current information, we expect to obtain the results from this trial during the second quarter of 2012).

Based on an analysis of our current financial condition and forecasts of available cash, we believe that we have sufficient resources to: (i) complete the above-described Phase I(a) clinical trial of CPP-115 and Phase II(b) clinical trial of CPP-109 and (ii) support our operations through the first quarter of 2013. However, there can be no assurance that we will actually have sufficient funds for these purposes. We will also require additional funding to complete any other pre-clinical and clinical studies and trials that may be required for us to submit NDAs for and commercialize CPP-109 and CPP-115 and (without considering the proceeds of this offering) to support our operations beyond the first quarter of 2013. There can be no assurance that we will obtain additional funding or ever be able to commercialize either of our product candidates. See *Liquidity and Capital Resources* below.

Basis of presentation

Revenues government grant

We are a development stage company and have no revenues from product sales to date. We will not have revenues from product sales until such time as we receive approval of CPP-109 or CPP-115, successfully commercialize our products or enter into a licensing agreement which may include up-front licensing fees, of which there can be no assurance.

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

Research and development expenses

Our research and development expenses consist of costs incurred for company-sponsored research and development activities. The major components of research and development costs include pre-clinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, consulting, scientific advisors and other third-party costs, salaries and employee benefits, stock-based

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compensation expense, supplies and materials and allocations of various overhead costs related to our product development efforts. To date, all of our research and development resources have been devoted to the development of CPP-109 and CPP-115, and we expect this to continue for the foreseeable future. Costs incurred in connection with research and development activities are expensed as incurred.

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

Selling and marketing expenses

We do not currently have any selling or marketing expenses, as we have not yet received approval for the commercialization of CPP-109 or CPP-115. We expect we will begin to incur such costs upon our submission of an NDA, so that we can have a sales force in place to commence our selling efforts immediately upon receiving approval of such NDA, of which there can be no assurance.

General and administrative expenses

Our general and administrative expenses consist primarily of salaries and personnel expenses for accounting, corporate and administrative functions. Other costs include administrative facility costs, regulatory fees, and professional fees for legal, information technology, accounting and consulting services.

Stock-based compensation

We recognize expense for the fair value of all stock-based awards to employees, directors, scientific advisors and consultants in accordance with U.S. generally accepted accounting principles. For stock options we use the Black-Scholes option valuation model in calculating the fair value of the awards.

Warrants Liability

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

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Income Taxes

We have incurred operating losses since inception. As of December 31, 2011 and 2010, we had net operating loss carryforwards of approximately $19,980,000 and $17,439,000, respectively. Our net deferred tax asset has a 100% valuation allowance as of December 31, 2011 and 2010, as we believe it is more likely than not that the deferred tax asset will not be realized. The net operating loss carry-forwards will expire at various dates beginning 2023 through 2031. If an ownership change, as defined under Internal Revenue Code 382, occurs, the use of these carry-forwards may be subject to limitations.

As required by ASC 740, *Income Taxes*, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Recent Accounting Pronouncements

In June 2011, the FASB issued changes to the presentation of comprehensive income. These changes give an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The option to present components of other comprehensive income as part of the statement of changes in stockholders equity was eliminated. The items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income were not changed. These changes become effective for fiscal years beginning after December 15, 2011, except for the reclassification adjustments out of accumulated other comprehensive income that become effective for fiscal years ending after December 15, 2012. We adopted these changes effective January 1, 2012, and the adoption of these changes did not have a material effect on our financial statements as we do not currently report any components of comprehensive income (loss) other than our net loss.

Results of Operations

Quarters Ended March 31, 2012 and 2011

Revenues.

We had no revenues for the three month periods ended March 31, 2012 and 2011.

Research and Development Expenses.

Quarter Ended March 31,	Amount	Change from Prior Year	Percentage of Total Operating Costs and Expenses
2012	$727,327	(19.5%)	53.3%
2011	$903,953	105.6%	59.5%

Research and development expenses for the three months periods ended March 31, 2012 and 2011 included stock-based compensation expense in each of the three months periods of $18,302 and $18,466, respectively. The stock-based compensation is non-cash and relates to the expense of stock options awards to certain employees.

Expenses for research and development for the three month period ended March 31, 2012 decreased compared to amounts expended in the same period in 2011 as we continued to incur costs associated with our currently ongoing NIDA/VA Phase II(b) clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and our Phase I(a) human clinical safety study for CPP-115. Expenses for the comparable period in 2011 included pre-clinical studies and drug development activities for CPP-115, which concluded during the fourth quarter of 2011 with the submission of IND for CPP-115. As a result of our ongoing studies and trials, we expect that our costs related to research and development activities will continue to be substantial in 2012.

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Selling and Marketing Expenses.

We had no selling and marketing expenses during the three month periods ended March 31, 2012 and 2011, as we have not yet received approval for the commercialization of CPP-109 or CPP-115. We expect to begin to incur sales and marketing expenses when we submit an NDA for CPP-109 or CPP-115, so that we will have a sales force in place to commence our selling efforts upon receiving approval of an NDA, of which there can be no assurance.

General and Administrative Expenses.

Quarter ended March 31,	Amount	Change From Prior Year	Percentage of Total Operating Costs and Expenses
2012	$637,383	3.6%	46.7%
2011	$615,297	0.7%	40.5%

General and administrative expenses for the three months ended March 31, 2012 and 2011 included stock-based compensation expense in each of the three month periods of $26,788 and $35,285, respectively. General and administrative expenses for the three months ended March 31, 2012 were comparable to those of the same period in 2011.

We expect general and administrative expenses to remain relatively stable in future periods as we continue the monitoring and oversight of our clinical trials evaluating CPP-109 and CPP-115.

Stock-Based Compensation.

Total stock-based compensation for the three months ended March 31, 2012 and 2011 was $45,090 and $53,571, respectively. Stock-based compensation was comparable to those of the same period in 2011.

Change in fair value of warrants liability.

In connection with our October 2011 equity offering, we issued warrants to purchase an aggregate of 1,523,370 shares of common stock. The fair value of these warrants is recorded in the liability section of the balance sheet and was estimated at $1.4 million and $1.6 million at March 31, 2012 and December 31, 2011, respectively. The fair value of the warrants liability is determined at the end of each reporting period with the resulting gains or losses recorded as the change in fair value of warrants liability in the statements of operations. For the three months ended March 31, 2012, we recognized a gain of $274,207 due to the change in the fair value of the warrants liability. The gain during the three months ended March 31, 2012 was principally a result of the decrease of our stock price between December 31, 2011 and March 31, 2012. Future changes in the fair value of the warrants liability will likely be due primarily to future fluctuations in the value of our common stock.

Interest Income.

We reported interest income in all periods relating to our investment of funds received from our registered direct offerings. The decrease in interest income in the three month periods ended March 31, 2012 when compared to the same period in 2011 is due to lower interest rates and lower average investment balances as we use the proceeds from offerings to fund our product-development activities and our operations. Substantially all such funds were invested in short-term interest bearing obligations.

Income taxes.

We have incurred net operating losses since inception. For the three month periods ended March 31, 2012 and 2011, 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.

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Net Loss

Net loss was $1,089,186 for the quarter ended March 31, 2012 ($0.04 per basic and diluted share), as compared to $1,517,136 for the quarter ended March 31, 2011 ($0.08 per basic and diluted share).

Years Ended December 31, 2011 and 2010

Revenues

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

Research and Development Expenses

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

Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2011 increased compared to amounts expended in the same period in 2010. During 2011, we continued our Phase II(b) trial studying CPP-109 for the treatment of cocaine addiction that was initiated in the fourth quarter of 2010, performed pre-clinical testing for CPP-115, and began our Phase I(a) trial for CPP-115.

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

Selling and Marketing Expenses

We had no selling and marketing expenses during 2011 and 2010. We anticipate that we will begin to incur sales and marketing expenses when we file NDA s for CPP-109 or CPP-115, in order to develop a sales organization to market products we may develop upon the receipt of required approvals.

General and Administrative Expenses

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

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

Stock-Based Compensation

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

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Change in fair value of warrants liability

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

Interest Income

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

Income Taxes

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

Net Loss

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

Years Ended December 31, 2010 and 2009

Revenues

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

Research and Development Expenses

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

Our expenses, excluding stock-based compensation, for research and development for the year ended December 31, 2010 decreased significantly compared to amounts expended in the same period in 2009. During 2009, we completed our U.S. Phase II clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and our proof-of-concept study evaluating CPP-109 for use in the treatment of methamphetamine addiction.

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In our research and development activities for 2010 and 2009, we recorded stock-based compensation relating to the value of stock options and restricted shares granted to certain employees and non-employees. The amount of stock-based compensation recorded in 2010 and 2009 relating to our research and development activities was $179,737 and $272,184, respectively. The weighted-average grant-date fair value of the stock options granted in 2010 and 2009 was $0.75 and $0.55, respectively.

Selling and Marketing Expenses

We had no selling and marketing expenses during 2010 and 2009. We anticipate that we will begin to incur sales and marketing expenses when we file NDA s for CPP-109 or CPP-115, in order to develop a sales organization to market products we may develop upon the receipt of required approvals.

General and Administrative Expenses

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

Included in general and administrative expenses in the years 2010 and 2009 was stock-based compensation expense of $270,352 and $329,254, respectively. General and administrative expenses include, among other expenses, office expenses, legal, accounting and consulting fees and travel expenses for our administrative employees, consultants and members of our Board. The increase in general and administrative expenses for the year ended December 31, 2010 when compared to the same period in 2009 is primarily due to increases in consulting and travel expenses, offset by decreases in stock-based compensation expense and professional fees.

Stock-Based Compensation

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

Interest Income

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

Income taxes

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

Net Loss

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

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Liquidity and Capital Resources

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

Since our inception, we have financed our operations primarily through the net proceeds of our private placements, an initial public offering (IPO) and from registered direct offerings under our shelf registration statements. At March 31, 2012, we had cash and cash equivalents of $4,722,795 and working capital of $4,086,226, as compared to cash and cash equivalents of $6,029,067 and working capital of $5,394,382 at December 31, 2011. At March 31, 2012 substantially all of our cash and cash equivalents were deposited with one financial institution. We periodically have cash balances at certain financial institutions in excess of federally insured limits.

We have to date incurred operating losses, and we expect these losses to increase substantially in the future as we expand our product development programs and prepare for the commercialization of CPP-109 and CPP-115. We anticipate using current cash on hand to finance these activities. It will likely take several years to obtain the necessary regulatory approvals to commercialize CPP-109 or CPP-115 in the United States.

We currently believe that we have the cash resources to complete our currently ongoing clinical trials and studies and to continue our operations through the first quarter of 2013 (without considering the proceeds of this offering). These expectations are based on current information available to us. If the cost of these studies is greater than we expect, or if such studies take longer to complete, our assumptions may not prove to be accurate.

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

In that regard, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other product development activities;
- future clinical trial results;
- the performance of our third-party suppliers or contract manufacturers;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;
- the cost and timing of establishing sales, marketing and distribution capabilities;

the effect of competition and market developments;

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

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

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

On December 3, 2010, we filed a shelf registration statement with the SEC to sell up to $30 million of common stock and warrants to purchase common stock. This shelf registration statement was declared effective by the SEC on December 15, 2010. The number of shares we can sell and the amount of proceeds we can raise from the sale of such shares are limited to 20% of our outstanding common stock (if priced at a discount to market and subject to certain exceptions) and 33% of our public float during a rolling 12-month period, respectively, pursuant to applicable NASDAQ marketplace and SEC rules. There can be no assurance we will be able to successfully sell any more shares under our 2010 shelf registration statement.

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

- On March 11, 2011, we raised net proceeds of approximately $2.2 million from the sale of 2,259,943 shares of our common stock; and
- On October 28, 2011, we raised net proceeds of approximately $3.2 million from the sale of 3,046,740 shares of our common stock and five-year warrants to purchase 1,523,370 shares of our common stock at an exercise price of $1.30 per share.

On June 2, 2008, we filed a shelf registration statement with the SEC to sell up to $30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. We completed three registered direct public offerings to institutional investors under our 2008 shelf registration statement:

- On September 12, 2008, we raised net proceeds of approximately $4.1 million from the sale of 1,488,332 shares of our common stock;
- On October 6, 2009, we raised net proceeds of approximately $3.7 million from the sale of 3,973,000 shares of our common stock; and
- On August 8, 2010, we raised net proceeds of approximately $1.5 million from the sale of 1,351,352 shares of our common stock.

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

Cash Flows

Quarters Ended March 31, 2012 and 2011

Net cash used in operating activities was $1,301,291 and $831,119, respectively, for the three month periods ended March 31, 2012 and 2011. During the three months ended March 31, 2012, net cash used in operating activities was primarily attributable to our net loss of $1,089,186, a $274,207 change in fair value of warrants liability, an increase in prepaid expenses and deposits of $43,606 and a decrease of $28,578 in accrued expenses and other liabilities. This was offset in part by $47,891 of non-cash expenses and an increase of $86,395 in accounts payable. During the three months ended March 31, 2011, net cash used in operating activities was primarily attributable to our net loss of $1,517,136 and an increase of $61,735 in prepaid expenses and deposits. This was offset in part by $60,189 of non-cash expenses and the collection of $134,025 in government grant receivable and increases of $319,486 in accounts payable and $234,052 in accrued expenses and other liabilities. Non-cash expenses include depreciation and stock-based compensation expense.

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Net cash used in investing activities during the three month period ended March 31, 2012 was $4,981 for the purchase of furniture and equipment. No cash was provided by (used in) investing activities during the three month period ended March 31, 2011.

No cash was provided by (used in) financing activities during the three months period ended March 31, 2012. Net cash provided by financing activities during the three month period ended March 31, 2011 was $2,228,634, consisting of the net proceeds from the sale of shares of common stock under our 2010 shelf registration statement.

Years Ended December 31, 2011 and 2010

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

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

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

Contractual Obligations (1)

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

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

(1) We have not included in the table above milestone or royalty payment obligations where we are not able to determine when or if the related milestones will be achieved, or when or if the events triggering payment of the obligations will occur.

We have entered into the following contractual arrangements:

Payments to Brookhaven under our license agreement. We have agreed to pay Brookhaven a fee of $100,000 in the year of NDA approval for CPP-109, $250,000 in each of the second and third years following approval, and $500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed products for certain of their patent-related expenses. We believe that such potential obligation is approximately $166,000 at March 31, 2012. See *Dispute with Brookhaven* below.

Payments to Northwestern under our license agreement. We have agreed to pay Northwestern an upfront fee of $35,000, expense reimbursements of approximately $33,000, and certain milestone

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payments in future years relating to clinical development activities with respect to CPP-115 or payable upon passage of time, and royalties on any products resulting from the license agreement. The first milestone payment of $50,000 was made during December 2011 after the filing of an IND for CPP-115. At March 31, 2012, we had paid $127,812 in connection with this agreement, and had accrued license fees of $103,750 in the accompanying condensed balance sheet.

Payments under our agreement with NIDA. We have agreed to supply the study drug (and matching placebo) as well as fund certain expenses for the U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction that we are jointly conducting with NIDA and the VA. We currently estimate that we will pay approximately $1.5 million in connection with this agreement. As of March 31, 2012 we had paid approximately $1.3 million of this amount and had accounts payable of approximately $19,000 and accrued liabilities of approximately $67,000 in the accompanying condensed balance sheet in connection with these agreements.

Payments for drug development, pre-clinical and clinical studies and trials. We estimate that we will pay various consultants, drug manufacturers and other vendors approximately $1.2 million in connection with our drug development work, including pre-clinical and clinical studies and trials, consulting and data analysis. At March 31, 2012, we had paid approximately $738,000 of this amount and had accounts payable of approximately $62,000 in the accompanying condensed balance sheet related to these contracts.

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

Leases for office space. We have entered into lease agreements for our office space that require payments of approximately $6,000 per month.

Dispute with Brookhaven

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses is approximately $1.3 million. We believe that we are only liable to Brookhaven for approximately $166,000, and we have advised Brookhaven that we dispute their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by the Company of an NDA for CPP-109.

Off-Balance Sheet Arrangements

We currently have no debt. Capital lease obligations as of March 31, 2012 and December 31, 2011 were not material. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

Critical Accounting Policies and Estimates

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

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

Pre-clinical study and clinical trial expenses

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

Warrants Liability

We issued warrants to purchase shares of our common stock in our October 2011 offering that may require us to purchase unexercised warrants for a cash amount equal to their fair value following the announcement of specified events defined as Fundamental Transactions (Fundamental Transactions) involving the company, which is deemed to occur if we are acquired in an all cash transaction or by a company that is not listed on a national securities exchange, or when the common stock is no longer listed on a national securities exchange. The cash settlement provisions require use of the Black-Scholes model in calculating the cash payment value in the event of a Fundamental Transaction. As a consequence of these provisions, the warrants are classified as a liability on our balance sheets. The cash settlement value at the time of any future Fundamental Transaction will depend upon the value of the following inputs at that time: the price per share of our common stock, the volatility of our common stock, the expected term of the warrant, the risk-free interest rate based on U.S. Treasury security yields, and our dividend yield. The fair value of the warrants is determined using a Black-Scholes model. The valuation of warrants is subjective and is affected by changes in inputs to the valuation model including the price per share of our common stock, the historical volatility of our stock price, risk-free rates based on U.S. Treasury security yields, the expected term of the warrants and our dividend yield. Changes in these assumptions can materially affect the fair value estimate. We could ultimately incur amounts to settle the warrant at a cash settlement value that is significantly different than the carrying value of the liability on our financial statements. We will continue to classify the fair value of the warrants as a liability until the warrants are exercised, expire, or are amended in a way that would no longer require these warrants to be classified as a liability. Changes in the fair value of the common stock warrants liability are recognized as a component of other income (expense) in the statement of operations.

Stock-based compensation

We recognize stock-based compensation for the fair value of all share-based payments, including grants of stock options and restricted stock units. For stock options, we use the Black-Scholes option valuation model to determine the fair value of stock options on the date of grant. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield. For 2011 and the first quarter of 2012, expected volatility is based on reviews of historical volatility of our common stock. For 2010 and prior, our expected volatility was based on the historical volatility of other publicly traded development stage companies in the same industry, due to our short history as a public company. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. During 2011 and the first quarter of 2012, we

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estimated the expected option life for options granted to employees and directors based upon the simplified method. Under this method, the expected option life is presumed to be the mid-point between the vesting date and the end of the contractual term. We will continue to use the simplified method until we have sufficient historical exercise data to estimate the expected life of the options. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated expected life of our stock options awards. No stock options were granted in the first quarter of 2012. For the years ended December 31, 2011, 2010 and 2009, the assumptions used were an estimated annual volatility of 130%, 100% and 90%, average expected holding periods of three to five years, four to five years and four to five years, and risk-free interest rates of 0.29% to 1.55%, 0.81% to 2.44% and 1.26% to 2.60%, respectively.

Caution Concerning Forward-Looking Statements

This prospectus contains forward-looking statements , as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes , anticipates , proposes , plans , expects , intends , may , and other similar expressions are intended to ident 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.

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

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

changes in general economic conditions and interest rates.

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

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BUSINESS

Catalyst Pharmaceutical Partners, Inc. is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in clinical development; CPP-109 and CPP-115. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. We also hope to evaluate CPP-109 for the treatment of other addictions and other selected central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. CPP-109 and CPP-115 have both been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 and CPP-115 are intended for the treatment of a serious or life-threatening condition and demonstrate the potential to address unmet medical needs. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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

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

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

We are currently involved in the following product development activities: (i) we are jointly conducting with the National Institute on Drug Abuse (NIDA) and the Veterans Administration (VA) a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (and, based on current information, we expect to obtain top line results from this trial early in the first quarter of 2013); and (ii) we are conducting a Phase I(a) clinical study evaluating the safety of CPP-115 in healthy volunteers (and, based on current information, we expect to obtain the results from this trial during the second quarter of 2012).

Based on an analysis of our current financial condition and forecasts of available cash and without considering the proceeds of this offering, we believe that we have sufficient resources to: (i) complete the above-described Phase I(a) clinical study of CPP-115 and the Phase II(b) clinical trial of CPP-109 and (ii) support our operations through the first quarter of 2013. However, there can be no assurance that we will actually have sufficient funds for these purposes. We will require additional funding to complete any other pre-clinical studies and trials that may be required to submit NDAs for and commercialize CPP-109 and CPP-115 and (without considering the proceeds of this offering) to support our operations beyond the first quarter of 2013. There can be no assurance that we will obtain additional funding or ever be able to commercialize either of our product candidates. See *Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources* above.

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Our Drug Candidates

The following table summarizes key information regarding our drug candidates:

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

Mechanism of Action

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

GABA, the most abundant inhibitory neurotransmitter in the brain, inhibits over-excitation of neurons. When GABA binds to a GABA receptor, it raises the action potential threshold of that neuron and inhibits the post-synaptic neuron from firing and triggering the release of neurotransmitters that send a signal to subsequent neurons. This is the mechanism explaining the efficacy of CPP-109 vigabatrin as an adjunctive treatment for refractory complex partial seizures in adults. In the case of addiction, increased GABA reduces the perception of pleasure and reward by dampening levels of dopamine release brought about by all drugs of abuse, but most notably by stimulants like cocaine and methamphetamine. Addictive drugs have been shown to block or overwhelm mechanisms involved in the removal of dopamine from synaptic clefts in the mesolimbic pathways of the brain, resulting in highly elevated levels of dopamine available to stimulate receptors and a dramatically heightened sense of pleasure or reward. GABA also helps induce relaxation and sleep, and contributes to functions such as motor control and vision.

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

History and Side Effect Profile of Vigabatrin

Vigabatrin has been marketed for decades in over 30 countries by Sanofi-Aventis and its predecessors under the brand names Sabril®, Sabrilex® and Sabrilan® (hereinafter referred to as Sabril®) as an adjunct (add-on) treatment for adult epilepsy and as a primary treatment for the management of infantile spasms. The composition of matter patents for Sabril® in the U.S. expired more than ten years ago. On August 21, 2009, the FDA approved two NDAs for Sabril® for the treatment of infantile spasms and as an adjunctive therapy for adult patients with refractory complex partial seizures who have failed treatments with several other anti-epileptic drugs. The NDAs are for different formulations of Sabril® and both NDAs are held by Lundbeck. Due to the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) program and is only available through a special restricted distribution program approved by the FDA.

In chronic use for the treatment of epilepsy, vigabatrin has been generally well tolerated with lower than average neurological side effects compared to other approved epilepsy therapies. The most common side effects reported have been drowsiness and fatigue. However, one clearly established adverse side effect is the

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development, of peripheral visual field defects, or VFDs. VFDs occur in approximately 33% of patients when cumulative dosage levels of vigabatrin approach approximately 1,500 grams. These VFDs are manifest as a constriction of the peripheral field of vision (i.e. tunnel vision).

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

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

CPP-109 (Vigabatrin) To Treat Addiction

In 2002, we obtained from Brookhaven an exclusive license for several patent and patent applications to develop vigabatrin as a treatment for cocaine and other addictions. We have been granted Fast Track status for CPP-109 from the FDA for cocaine addiction. Under the Federal Food, Drug, and Cosmetic Act, or FDCA, the FDA is directed to facilitate the development and expedite review of drugs and biologics intended to treat serious or life-threatening conditions that demonstrate the potential to address unmet medical needs for such conditions. Fast Track designation emphasizes communication between us and the FDA and affords us benefits that may help to expedite the approval process. For example, Fast Track designation affords us the potential to submit an NDA for CPP-109 on a rolling, or modular, basis, allowing the FDA to review sections of the NDA in advance of receiving our full submission. The designation also means that we may have increased communications with the FDA regarding the design of our clinical studies, which we hope will expedite the development and review of our application for the approval of CPP-109 for cocaine addiction and provide greater certainty overall in the regulatory pathway. However, there can be no assurance that our receipt of Fast Track status will assist us in the regulatory process for CPP-109.

CPP-115 for the Treatment of Addiction and Epilepsy

In August 2009, we licensed the exclusive worldwide rights to commercialize certain composition of matter patents relating to a new class of novel GABA aminotransferase inhibitors and derivatives of vigabatrin. We intend to develop these compounds for a broad range of central nervous system illnesses that could benefit from the inhibition of GABA aminotransferase. CPP-115 is our lead compound from this group of composition of matter patents.

The development efforts of CPP-115 were led by Dr. Richard B. Silverman, the John Evans Professor of Chemistry at Northwestern University (Northwestern). Dr. Silverman, who holds 44 patents, is the inventor of pregabalin, also known as Lyrica®, which is marketed by Pfizer. His goal in inventing the compound that became CPP-115 was to mimic the mechanism of action of vigabatrin, while making it both more potent and specific.

CPP-115 works by the same mechanism of action as CPP-109; the inhibition of GABA aminotransferase, which leads to increased brain GABA levels that reduce epileptogenesis or dampen the addiction reinforcing dopamine surge. We believe that CPP-115 and vigabatrin are the only two GABA aminotransferase inhibitors, either under development or marketed at this time, and that our patent estates for CPP-109 and CPP-115 are the only existing, currently in force, intellectual property rights for drugs with this primary mode of action.

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Based on testing to date, CPP-115 has been shown to be at least 200 times more potent than CPP-109, our version of vigabatrin, in both in-vitro and animal model studies. The increased potency could enable the development of dosage forms potentially administrable by other routes of administration compared with the marketed oral, immediate release formulations of vigabatrin, Sabril®. Further, based on pre-clinical testing completed to date, CPP-115 has a superior specificity to GABA aminotransferase and may have reduced side effects (e.g., VFDs) compared with Sabril®.

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

Our Strategy

Our strategy is to become a leading specialty pharmaceutical company focused on the in-licensing and development of proprietary drug candidates for the treatment of selected diseases of the central nervous system. Our near-term strategy is to focus on the regulatory approval of CPP-109 for the treatment of cocaine addiction and to initially demonstrate the safety and efficacy of CPP-115 for the treatment of addiction and epilepsy. Our long-term strategy is to gain approvals for additional indications for CPP-109, including methamphetamine addiction, and to initially gain approval for CPP-115 to treat addiction and epilepsy. Specifically, we intend to:

Focus on CPP-109 for cocaine addiction. A treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status from the FDA for CPP-109 for cocaine addiction may facilitate the regulatory approval process. Enrollment for our U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction we are conducting with NIDA and the VA began in the first quarter of 2011. This trial is currently ongoing and we expect to receive top-line results from this trial early in the first quarter of 2013. Assuming success, we expect that this trial will serve as one of the adequate and well-controlled trials required to support approval of an NDA.

Develop additional indications for CPP-109. The mechanism of action of CPP-109 and pre-clinical data indicate it may be suitable as a potential treatment for addictions to methamphetamine, nicotine, prescription pain medications, alcohol and marijuana, as well as for obsessive-compulsive disorders including binge eating patterns and compulsive gambling. We hope to develop CPP-109 for one or more of these additional indications, subject to the availability of funding.

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

Identify and initiate strategic partnering discussions for specific indications in the U.S. and Europe. We believe that there may be several potential pharmaceutical partners interested in jointly developing and marketing CPP-109 and CPP-115 in the U.S. and/or Europe. We have held preliminary discussions with several parties regarding potential transactions, but no agreements have been entered into to date.

Our Potential Markets

Drug Addiction

Historically, individuals suffering from addiction have been treated primarily through behavioral modification and therapy. These treatments have shown a high rate of relapse. We believe that a pharmacological treatment for cocaine addiction and/or other stimulant addictions, including methamphetamine, would complement and significantly improve the effectiveness of counseling programs.

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Despite the significant public health implications, there are very few therapies approved for the treatment of addiction, either in the United States or in the rest of the world. Further, there are no therapies currently approved for addiction to stimulant substances, such as cocaine and methamphetamine. We believe that currently approved drugs for addiction treatment, as well as compounds under development (other than CPP-109 and CPP-115), are subject to the following limitations:

- no single compound has broad applicability for treatment of multiple addictions;
- many of these compounds are receptor active , which means they have drug-like effects themselves and have the potential for abuse or addiction;
- increasing dosages over time may be required due to development of tolerance; and
- they are often ineffective at eliminating drug cravings or responding to increasing levels of drug use.

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

Addictive drugs are used recreationally because of the transient, pleasurable effect they have on the user. Recent scientific evidence has established that drug abuse can interfere with the brain s normal balance of neurotransmitter release and reuptake, resulting in addiction. If this balance is not restored, addicted individuals, even after significant periods of abstinence, may be incapable of suppressing cravings or quitting through willpower alone, even with the assistance of professional counseling.

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

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

Addiction is a worldwide health problem that affects millions of people and has wide-ranging negative social consequences. According to NIDA, there are no pharmacologic treatments for cocaine addiction currently approved for marketing by the FDA. We believe that other therapies being developed for the treatment of cocaine addiction, but not yet approved for marketing, suffer from the significant limitations discussed earlier which have not been exhibited to date by CPP-109 or CPP-115.

A June 2011 report of the National Center on Addiction and Substance Abuse at Columbia University titled Adolescent Substance Abuse : America s #1 Public Health Problem found that in annual federal, state and local government spending as a result of substance abuse and addiction was at least $467.7 billion almost $1,500 for every man, woman, and child in the United States. A 2009 report from the same group found that for every dollar federal and state governments spent on substance abuse and addiction in 2005, 95.6 cents went to shoveling up the wreckage and only 1.9 cents to prevention and treatment, 0.4 cents to research, 1.4 cents to taxation or regulation and 0.7 cents to interdiction.

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

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

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

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

Addiction is not only a U.S. health problem. In 2009, according to the United Nations Office on Drugs and Crime, there were between 4.3 million and 4.7 million users of cocaine and between 2.5 million and 3.2 million users of amphetamine-type stimulants between the ages of 15 and 64 across Europe who had used these drugs within the past year. We believe that the direct and indirect costs of cocaine and methamphetamine use are indicative of a significant global public health problem, representing a significant unmet medical need for which no adequate pharmaceutical therapies exist.

Epilepsy

Epilepsy is a brain disorder in which clusters of nerve cells, or neurons, in the brain sometimes signal abnormally. In epilepsy, the normal pattern of neuronal activity becomes disturbed, causing strange sensations, emotions, and behavior or sometimes convulsions, muscle spasms, and loss of consciousness. Epilepsy is a disorder with many possible causes. Anything that disturbs the normal pattern of neuron activity from illness to brain damage to abnormal brain development can lead to seizures. Epilepsy may develop because of an abnormality in brain wiring, an imbalance of nerve signaling chemicals called neurotransmitters, imbalance of sensitivity to neurotransmitters, or some combination of these factors.

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

An infantile spasm (IS) is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood. The onset of infantile spasms is usually in the first year of life, typically between 4-8 months. The seizures primarily consist of a sudden bending forward of the body with stiffening of the arms and legs; some children arch their backs as they extend their arms and legs. Spasms tend to occur upon awakening or after feeding, and often occur in clusters of up to 100 spasms at a time. Infants may have dozens of clusters and several hundred spasms per day. Infantile spasms usually stop by age five, but may be replaced by other seizure types.

In complex partial seizures, consciousness is altered. Patients may exhibit automatisms (automatic repetitive behavior) such as walking in a circle, sitting and standing, or smacking their lips together. Often accompanying

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these symptoms are the presence of unusual thoughts, such as the feeling of déjà vu, uncontrollable laughing, fear, visual hallucinations, and experiencing unusual unpleasant odors. These symptoms are thought to be caused by abnormal discharges in the temporal lobe.

According to the Epilepsy Foundation, there are about 3 million epilepsy patients in the United States, with approximately 200,000 new cases diagnosed in the U.S. each year. Worldwide, 50 million people are estimated to have epilepsy. The incidence of epilepsy appears to depend somewhat on the age of the individual. The risk of epilepsy from birth through age 20 is approximately 1%. Within this group, incidence is highest during the first year of life and increases somewhat at the onset of puberty. From age 20 to 55 it decreases again, but increases after age 55.

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

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

Our Clinical Trials

CPP-109

In 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II(a) clinical trial evaluating the use of CPP-109 in treating subjects addicted to cocaine. The trial enrolled 186 cocaine addicted patients at 11 addiction treatment research centers and clinical research centers throughout the United States. Patients were treated for a period of 12 weeks, with an additional 12 weeks of follow-up. On May 29, 2009, we announced that the top-line data from this trial showed that CPP-109 did not demonstrate statistical significance in the primary endpoint; which means that it did not demonstrate a significantly larger proportion of CPP-109 treated subjects than placebo-treated subjects were cocaine free during the last two weeks of the treatment period (weeks 11 and 12).

On September 30, 2009, we announced additional results from our U.S. Phase II(a) cocaine clinical trial. Based on post hoc analyses for vigabatrin levels in urine samples collected during the trial, we concluded that less than 40% of the trial subjects were medication compliant. As a result, we now believe that the trial was inadequately powered to properly test the efficacy of CPP-109 for the treatment of patients with cocaine addiction. On the basis of a comprehensive review of the trial data, however, we concluded that: (i) CPP-109 was safe and well tolerated; and (ii) while there were no statistically significant differences between active and placebo groups for the protocol-specified primary and secondary efficacy endpoints, cocaine use as measured by benzoylecgonine (the major metabolite of cocaine) levels in urine collected from subjects were consistently lower in the CPP-109 treatment group during the 12 week treatment period, generally indicating a reduction of cocaine use; and (iii) in those subjects who were compliant with study medication, the differences between CPP-109 and placebo were amplified, which suggests that CPP-109 may facilitate abstinence, reduce overall cocaine use as measured by urine benzoylecgonine levels (an objective measure of daily cocaine usage), and reduce cocaine usage days (an objective measure of dependence severity).

Consistent with previously published addiction trials conducted by other parties, the protocol of our cocaine trial assessed subjects medication compliance based on self-reporting and on counting the unused medication returned by subjects. The subjects self-reported a compliance level of greater than 85%, which was inconsistent with our urine data. This low medication compliance effectively reduced the power of the study, because not all

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subjects in the treatment group were actually treated. However, analyses of subject responses, corrected for poor medication compliance, makes the response ratios observed in our trial more consistent with the results reported by Dr. Jonathan Brodie et al. in a double-blind, placebo-controlled, 103-patient Phase II trial evaluating vigabatrin for the treatment of cocaine addiction that was completed in Mexico in 2007 (the results of which trial were published in *The American Journal of Psychiatry* in November 2009). See *Clinical and Pre-Clinical Studies of Our Product Candidates Undertaken by Others* below.

During June 2008, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We had planned to enroll 180 methamphetamine addicted patients at 15 addiction treatment clinical centers in the United States. However, in March 2009, in order to conserve cash, we converted our methamphetamine trial into a proof-of-concept study evaluating the results obtained from the 57 patients who had already been randomized into the trial. The patients we enrolled were treated for a period of 12 weeks and we evaluated data related to endpoints based on abstinence, reductions in methamphetamine use and craving for evidence of potential efficacy.

On September 30, 2009, we announced the top-line results of our proof-of-concept study. The results showed that there was a 2.5 times higher rate of abstinence in the last two weeks of the study in the vigabatrin group versus the placebo group. While we consider this to be an encouraging trend, the results were not statistically significant due to the small sample size. We also believe that medication compliance, similar to our previously discussed cocaine trial, was below expectations.

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

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

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

The CTA terminates on April 13, 2015 or upon the completion of the Phase II(b) Trial, whichever comes first, except that the CTA may be extended for two further periods of two years each by agreement of the parties if it is necessary to complete the Phase II(b) Trial. Either party may terminate the CTA upon 60 days notice without cause, or upon 30 days written notice for cause. Both NIDA and we have continuing rights under the

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CTA if the CTA is terminated. Among other obligations, this includes an obligation of each party to continue their respective obligations under the CTA until all study subjects enrolled in the trial at the time of such termination have completed the trial and continuing duties of confidentiality.

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

Lundbeck s exclusivity for Sabril® tablets as an adjunctive therapy to treat refractory complex partial seizures in adults will expire on August 21, 2014. We currently expect to submit a 505(b)(2) application in submitting an NDA for CPP-109. A 505(b)(2) application is one that relies, at least partially, upon data that a company does not own or have right of reference to, including published literature. A 505(b)(2) application can also rely upon the FDA s previous rulings on safety and efficacy for previously approved products. Additional information in a 505(b)(2) application includes data on manufacturing, bioequivalence, and bioavailability, studies to support any change relative to the previously approved product, information with respect to any patents that claim the drug or use of the drug for which approval is sought, and appropriate certification with respect to patents listed for the previously approved drug on which investigations relied upon for NDA approval were conducted or that claim a use of the listed drug. See *Regulatory Matters The Hatch Waxman Act* below. There can be no assurance whether, or to what extent, the FDA will accept any 505(b)(2) NDA that we may submit for CPP-109.

Generally, the process of seeking approval of an NDA requires multiple clinical trials, including two pivotal U.S. Phase III clinical trials. In our case, because CPP-109 is intended to treat a serious condition for which there is no approved therapy, there is a possibility that if the data from the Phase II(b) Trial are sufficiently compelling, that the FDA will file an NDA submitted by us for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat addiction. However, it is more likely that the FDA will require at least one Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will file an NDA submitted by us for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA files an NDA submitted by us for CPP-109 based on the results of our current Phase II(b) trial, it is unlikely that we will be in a position to submit an NDA for CPP-109 until August 21, 2014. Finally, if the FDA requires more than one Phase III clinical trial, our NDA submission could be delayed even further. There can be no assurance that the data from our ongoing Phase II(b) Trial will be sufficiently compelling or that even if such data are sufficiently compelling, that the FDA will file an NDA submitted by us for CPP-109 based on the results of that trial.

CPP-115

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

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

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

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

With the exception of its biochemical target, GABA-aminotransferase, CPP-115 did not show any clinically significant binding to 111 of the most prominent receptors, proteins and transporters. Additionally, CPP-115 showed no binding to other GABA-related targets (GABA receptors and transporters). Therefore, CPP-115 is very specific and not likely to induce drug-drug interactions or unintended side effects.

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

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

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

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

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

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

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

The primary focus of our product development efforts is on our clinical trials and pre-clinical studies. However, we have in the past supported and will continue in the future to support pre-clinical studies and clinical trials by academic investigators of the use of vigabatrin for the treatment of addiction and various forms of epilepsy and other central nervous system disorders, including members of our Scientific Advisory Board and the academic institutions with which they are affiliated. In some cases, we may provide unrestricted sponsorship funds for such studies. In other cases, we may provide alternative assistance to the investigator, most typically providing CPP-109 or CPP-115 drug substance or dosage form as well as matching placebo. We expect to continue supporting investigator studies in the future to the extent that they meet criteria acceptable to us. Such criteria include research on the use of vigabatrin and/or CPP-115 to treat addiction, various forms of epilepsy and/or other central nervous system disorders, to assist investigators in designing their studies so that such studies are most appropriately conducted and, to the extent possible, to make sure that these investigator studies potentially complement, and do not adversely impact, our activities.

A study describing the positive results obtained in an investigator-initiated, Phase II, randomized double-blind, placebo-controlled trial conducted in Mexico in 2007 was published in the November 2009 issue of The American Journal of Psychiatry, a world leading peer-reviewed medical journal. The paper, entitled Randomized, Double-Blind, Placebo-Controlled Trial of Vigabatrin for the Treatment of Cocaine Dependence in Mexican Parolees, was authored by Jonathan D. Brodie, M.D., Ph.D., Brady G. Case, M.D., Emilia Figueroa, M.D., Stephen L. Dewey, Ph.D., James A. Robinson, M.Ed., Joseph A. Wanderling, M.A. and Eugene M. Laska,

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Ph.D. Drs. Dewey, Brodie and Laska are members of our Scientific Advisory Board. The trial provided evidence that vigabatrin may be effective in the treatment of cocaine addiction. One hundred and three (103) community-based, non-hospitalized cocaine addicted individuals participated in this trial conducted at a single site in Mexico City, Mexico. Of the 103 participants, 50 were treated with vigabatrin and 53 received placebo. A total of 53 subjects completed the 9 week treatment period. Twice-weekly urine screening tests were obtained from each subject in order to objectively evaluate each subject s cocaine use. All subjects were also offered one group counseling session per week. The primary outcome measure of the trial was no self-reported cocaine use or positive urine tests for cocaine use during the last three weeks of the nine-week trial.

Eighteen subjects fulfilled the criteria for the primary outcome measure. Fourteen of the 50 subjects treated with vigabatrin (28.0%) versus four of the 53 subjects treated with placebo (7.5%) met the primary outcome measure. This result was statistically significant with a p-value of 0.009 (A p-value represents the probability that, if the test is repeated, a similar observation will be made. In addition, 12 of the abstinent subjects on vigabatrin versus 2 of the abstinent placebo subjects remained abstinent for 4 additional weeks (p=0.002). Generally, a p-value of less than 0.05 indicates that the different results between treatment groups were unlikely to be random). Additional findings included increased retention and self-reported abstinence from alcohol favoring vigabatrin.

Two of our collaborators have received a $1.2 million grant from the U. S. Department of Defense to conduct an animal study of the use of vigabatrin in combination with opiates to effectively manage pain while reducing the potential for opiate addiction. This research is being conducted by a research team led by Wynne K. Schiffer, Ph.D. and Stephen L. Dewey, Ph.D. of The Feinstein Institute for Medical Research at North Shore Long Island Jewish Health System (LIJ) and by Jonathan D. Brodie, M.D., Ph.D. from the Department of Psychiatry at New York University s School of Medicine. Opioid abuse is one of the many substance addiction indications covered under our exclusive license of Brookhaven s vigabatrin use patent portfolio. We are supplying study materials (CPP-109) to facilitate this study.

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

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

CPP-115 is being evaluated by the Anticonvulsant Screening Program (ASP) of the National Institute of Neurological Disorders and Stroke (NINDS), one of the institutes within the National Institutes of Health

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(NIH). To date, CPP-115 has been tested in about 20 animal models of epilepsy, including maximal electric shock (MES) in both rats and mice, corneal kindling in mice, minimal clonic seizure (6 Hz) model in mice, and subcutaneous picrotoxin (scPIC). CPP-115 was also evaluated for potential efficacy in neuroprotection and neuropathic pain models. CPP-115 has shown significant potential in a variety of epilepsy models and NIH is continuing the evaluation of CPP-115 in other models of epilepsy. An evaluation of CPP-115 in additional models for neuropathic pain is also ongoing.

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

Competitive Landscape

Disease Background and Our Market Opportunity

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

Drug Addiction. Research has established that neurochemical signals responsible for craving and addiction can be modulated through a GABA-ergic mechanism. We have been developing CPP-109 for the treatment of drug addiction and will also be evaluating CPP-115 for potential use in the treatment of drug addiction as well. Due to the differing stages of development for these two drugs, we expect CPP-109 to be approved as the first drug to treat cocaine addiction with CPP-115 following later for both epilepsy and then cocaine, methamphetamine and/or other forms of drug addiction.

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

CPP-109

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

Cocaine-mimetics. The mechanism of action of these drugs is similar to cocaine. None of these approaches have, to our knowledge, shown any efficacy.

Cocaine-antagonists. These compounds are intended to prevent a cocaine induced dopamine surge by limiting the release of dopamine (drugs that act on GABA receptors, for example) or drugs that block the effects of a cocaine induced dopamine surge (dopamine receptor antagonists, for example). All of the known drugs in this class, with the exception of the GABA-AT inhibitors (CPP-109 and CPP-115) are receptor active and could require increasing dosing over time. None of these compounds are presently approved for marketing to treat addiction.

Dopamine ß-hydroxylase inhibitors. These compounds block the enzyme that converts dopamine to norepinephrine, which raises dopamine levels in the central nervous system (CNS). We believe that this strategy is designed to address withdrawal, rather than craving and euphoria. This approach, to our knowledge, has yet to show any efficacy.

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

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Addiction Vaccines. These vaccines are designed to block cocaine or methamphetamine transport into the brain. They are not broadly immunogenic in humans to date and require several injections. They also may not address issues relating to craving or other behaviors associated with cocaine or methamphetamine addiction. We also believe that they can be overwhelmed by increasing dosages of the abuse drug. To date, reported data from clinical trials have not shown that the vaccines are capable of facilitating the attainment and maintenance of abstinence, a key therapeutic goal.

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

On August 21, 2009, the FDA approved two NDAs for Sabril® for the treatment of infantile spasms and as an adjunctive (add-on) therapy for adult patients with refractory complex partial seizures who have responded inadequately to several alternative treatments. The NDAs are for different formulations of Sabril®, and both NDAs are held by Lundbeck. Because of the risks of visual field damage associated with vigabatrin, Sabril® was approved under an FDA-mandated REMS program.

We are not aware of any on-going or planned studies by Lundbeck intended to evaluate Sabril® for any addiction indication, and we believe that any attempted commercialization by Lundbeck of Sabril® for the treatment of cocaine and/or other addictions would violate our licensed patents (and we have advised Lundbeck of our belief in that regard). We would vigorously assert our intellectual property rights if Lundbeck sought to market Sabril® for the treatment of any addictive or obsessive compulsive conditions covered by our patents. There can be no assurance we would be successful in that regard.

CPP-115 for Epilepsy

Epilepsy represents a large and growing market opportunity. Sales of drugs currently marketed for the treatment of epilepsy totaled approximately $8.9 billion in the United States during 2006, according to IMS Health. These sales included prescriptions of these drugs for both epilepsy and other indications, including neuropathic pain.

The market for epilepsy treatments is highly competitive. Large pharmaceutical companies, including Pfizer (Neurontin®, Lyrica®, Dilantin®, Zarontin®), J&J (Topamax®), UCB (Keppra®), Abbott (Depakote®), GSK (Lamictal®), Roche (Klonopin®), and Novartis (Trileptal®) sell, or are developing, epilepsy therapies. However, as stated earlier, approximately one-third of all epilepsy patients are refractory to treatment with any currently available epilepsy treatments. It is difficult to determine sales of products specifically for epilepsy as many of these products are used in other indications such as neuropathic pain, migraine, dementia, and bipolar disorders.

Intellectual Property Rights

Licensing and Patents

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

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technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents, trademarks or copyrights, or are effectively maintained as trade secrets, know-how or other proprietary information. See *Risk Factors.*

Brookhaven License Agreement

We have been granted an exclusive, worldwide license from Brookhaven to eight patents relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions, with expiration dates for the issued patents between 2018 and 2022, with the principal patents expiring in 2018. Additionally, we received approval from the European Union (EU) with respect to one of our principal patents, which has allowed us to seek registration for this patent in eighteen EU member states.

The license agreement, which is dated as of April 30, 2006 and which supersedes a previous license agreement that was entered into in 2002, grants us an exclusive worldwide license, including the right to sublicense, to make, have made, use, and/or sell licensed products and practice the licensed process with respect to the medical application in humans of vigabatrin under certain patent rights. These rights are subject to the United States government s rights to practice the licensed process for its own use. The purpose of this agreement is to permit us to commercialize products upon the receipt of government regulatory approval for the use of vigabatrin for the treatment of human drug addiction and addiction-related behavior. In exchange for such rights, we paid Brookhaven an initial fee of $50,000 and have agreed to pay a fee of $100,000 in the year of NDA approval for CPP-109, $250,000 in each of the second and third years following approval, and $500,000 per year thereafter until the last patent expires. In addition, upon the filing of an NDA for CPP-109 and the approval of an NDA for CPP-109, we will be obligated to reimburse Brookhaven for certain expenses it incurs in connection with the filing, prosecution and maintenance of all patents and patent applications included in the patent rights we have licensed. We also have the right to enter into sub-license agreements, and if we do a royalty of 20% of any sub-license fees will be payable to Brookhaven.

We have also agreed to consult with Brookhaven on at least a quarterly basis with respect to drug development steps taken and progress made toward the objective of gaining marketing approval from the FDA for any licensed product from the beginning of our agreement through the date the FDA grants us its approval to sell any licensed product. We have also agreed to have in effect and maintain a liability insurance policy in an amount of at least $1,000,000 to cover claims arising out of the manufacture and use of licensed products and such policy shall designate Brookhaven as an additional insured. We have agreed to increase and maintain, throughout the life of the agreement and for five years after its termination, liability insurance coverage in the amount of at least $5,000,000 upon acceptance by the FDA of our application to commence Phase III clinical trials involving licensed products. Our agreement with Brookhaven expires simultaneously with the expiration of the last to expire patent it has licensed to us.

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

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses as of December 31, 2011 was approximately $1.3 million. We believe that we are only contingently liable to Brookhaven for approximately $166,000, and we have advised Brookhaven that we are disputing their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until we submit an NDA for CPP-109.

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Northwestern University License Agreement

On August 27, 2009, we entered into a license agreement with Northwestern under which we acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered and patented by Northwestern. Under the terms of the license agreement, Northwestern granted us an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. We have designated the lead compound to be developed under this license as CPP-115.

We believe that the newly licensed compounds are the only known GABA aminotransferase inhibitors in existence or in development other than vigabatrin. We also believe, based on our pre-clinical testing to date of CPP-115, that the newly licensed compounds are significantly more potent than vigabatrin with less visual side effects than vigabatrin. We plan to seek to develop these compounds for the treatment of several indications, including epilepsy (specifically, complex partial seizures and infantile spasms) and drug addiction. However, these compounds are at a very early stage of development and there can be no assurance as to whether these new compounds will ever be determined to be safe and effective.

Under our license agreement with Northwestern, we will be responsible for continued research and development of any resulting product candidates. We have the right to terminate the agreement in whole or in part after August 27, 2012, upon written notice. As of March 31, 2012, we have paid Northwestern upfront payments and milestone fees aggregating $85,000 and maintenance and patent fees aggregating $42,872, and we are obligated to pay certain additional fees and milestone payments in future years relating to our clinical development activities under this license or payable upon passage of time. The next milestone payment of $100,000 is due on the earlier of successful completion of the Phase I(a) clinical trial for CPP-115 or August 27, 2013. We are also obligated to pay Northwestern royalties on any products resulting from the license agreement. We also have the right to enter into sub-license agreements, and if we do, a royalty on any sub-license fees will be payable to Northwestern.

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

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

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

Manufacturing and Supply

CPP-109

Since the composition of matter patent for vigabatrin has previously expired, we will not, to our knowledge, violate any patents if we commercialize CPP-109. We have entered into a new agreement to formulate and manufacture CPP-109 for use in our future clinical trials. We also intend in the future to manufacture commercial quantities of CPP-109 on a contract basis, if the FDA approves an NDA for CPP-109.

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Our supplier has agreed to manufacture CPP-109 and matching placebo for us in quantities that we believe will be sufficient to conduct our current clinical trial evaluating CPP-109 for the treatment of cocaine addiction. Our contract contains no renewal provisions. Pursuant to our agreement, we have agreed to indemnify our supplier against: (i) costs relating to any potential injury suffered by persons who take CPP-109 that our supplier manufactures; (ii) any losses arising from our negligence in labeling, handling or storing CPP-109; (iii) any specifications which we give them that are incorrect or do not meet FDA-approved standards; (iv) any misrepresentation or breach by us of the agreement; and (v) any patent infringement claims that may result from the use of CPP-109.

Further, our supplier has agreed to indemnify us against any losses related to its negligence or willful misconduct in the manufacture of CPP-109; any misrepresentation by our supplier in the agreement; and any claims by third parties that our supplier infringed or misappropriated any intellectual property in its manufacture of CPP-109.

Any NDA that we file for CPP-109 will require a manufacturing plan. If the manufacturing plan and data are insufficient, the NDA will not be approved. Further, even if we receive approval of an NDA for CPP-109, if our manufacturer does not follow good manufacturing practices (cGMP), in the manufacture of our products, it may delay product launches or our ability to manufacture or ship product, adversely affecting our business.

Since we intend to contract with a third party to manufacture our products, if the FDA approves an NDA for CPP-109, our contract manufacturer will be required to comply with all applicable environmental laws and regulations that affect the manufacturing process. As a result, we do not believe that we will have any significant exposure to environmental issues.

CPP-115

We have entered into a contract to manufacture the active pharmaceutical ingredient (API) sufficient to meet the needs of our ongoing pre-clinical studies and Phase I(a) human safety study of CPP-115. While we have taken steps to insure that the amount of API ordered under this contract is sufficient for our needs, there is no absolute assurance of this.

We have no plans at this time to build or acquire the manufacturing capability needed to prepare either the CPP-115 API or