

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 424B5

August 28, 2012

**Table of Contents**

**PROSPECTUS SUPPLEMENT**

(To Prospectus dated December 15, 2010)

**Filed Pursuant to Rule 424(b)(5)**

**Registration No. 333-170945**

## **4,000,000 Shares of Common Stock**

### **Warrants to Purchase up to 1,200,000 Shares of Common Stock**

We are offering 4,000,000 shares of our common stock and warrants to purchase 1,200,000 shares of our common stock in this offering (and the shares of common stock issuable from time to time upon exercise of these warrants). Each share of common stock is being sold together with a warrant to purchase 0.30 of one share of common stock at an exercise price of \$2.08 per share of common stock. The shares of common stock and warrants will be issued separately.

Our common stock is listed on the Nasdaq Capital Market under the symbol **CPRX**. On August 27, 2012, the last reported sale price of our common stock on the Nasdaq Capital Market was \$1.89 per share. As of August 27, 2012, the aggregate market value of our outstanding common stock held by non-affiliates was approximately \$47,020,792 based on 24,878,726 shares of outstanding common stock held by non-affiliates and a price of \$1.89 per share, which was the last reported sale price of our common stock on the Nasdaq Capital Market on August 27, 2012.

During the prior 12 calendar month period that ends on, and includes, the date of this prospectus supplement, we offered \$6,139,181 of securities pursuant to General Instruction I.B.6. of Form S-3.

There is no established trading market for the warrants, and we do not expect such 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.

We have engaged Roth Capital Partners, LLC as our exclusive placement agent in connection with this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities. See Plan of Distribution beginning on page S-25 of this prospectus supplement for more information regarding these arrangements.

**INVESTING IN OUR COMMON STOCK INVOLVES RISKS. SEE RISK FACTORS BEGINNING ON PAGE S-5.**

	<b>Per Share and corresponding Warrant</b>	<b>Total</b>
Public Offering Price	\$1.50	\$ 6,000,000
Placement Agent Fees(1)	\$0.09	\$ 360,000
Proceeds, before expenses, to us	\$1.41	\$ 5,640,000

(1) We have also agreed to reimburse the placement agent for certain of its out-of-pocket expenses. See Plan of Distribution on page S-25 of this prospectus supplement.

**Neither the Securities and Exchange Commission ( SEC ) nor any state securities commission or other regulatory body has approved or disapproved these securities, or determined if this prospectus supplement or the accompanying base prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

**Roth Capital Partners**

**The date of this prospectus supplement is August 28, 2012**

**Table of Contents****TABLE OF CONTENTS**

<u>Prospectus Supplement</u>	
<u>Forward-Looking Statements</u>	S-1
<u>Summary</u>	S-2
<u>The Offering</u>	S-4
<u>Risk Factors</u>	S-5
<u>Use of Proceeds</u>	S-21
<u>Dilution</u>	S-22
<u>Description of the Securities</u>	S-23
<u>Plan of Distribution</u>	S-25
<u>Legal Matters</u>	S-27
<u>Experts</u>	S-27
<u>Where You Can Find Additional Information</u>	S-27
<u>Incorporation by Reference</u>	S-27
<u>Prospectus</u>	
<u>About This Prospectus</u>	1
<u>About the Company</u>	1
<u>Information Regarding Forward-Looking Statements</u>	5
<u>Risk Factors</u>	6
<u>Use of Proceeds</u>	6
<u>Price Range of Common Stock and Dividend Policy</u>	6
<u>General Description of our Common Stock and Warrants</u>	7
<u>Plan of Distribution</u>	12
<u>Legal Matters</u>	13
<u>Experts</u>	13
<u>Where You Can Find Additional Information</u>	14
<u>Incorporation by Reference</u>	14

This document is in two parts. The first part is this prospectus supplement, which describes the terms of the offering of the securities offered hereby and also adds to and updates the information contained in the accompanying base prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying base prospectus. The second part is the accompanying base prospectus, which provides more general information. To the extent that there is any conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying base prospectus or any document incorporated by reference herein or therein, on the other hand, you should rely on the information in this prospectus supplement.

**You should rely only on the information contained in this prospectus supplement, contained in the accompanying base prospectus or incorporated herein or therein by reference. We have not authorized anyone to provide you with information that is different. We are offering to sell, and seeking offers to buy, the securities offered hereby only in jurisdictions where offers and sales are permitted. The information contained, or incorporated by reference, in this prospectus supplement and contained, or incorporated by reference, in the accompanying base prospectus is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement and the accompanying base prospectus, or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying base prospectus, including the documents we have referred you to in the section entitled **Where You Can Find Additional Information** below.**

**Table of Contents**

**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 identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements made in this prospectus are based on current expectations that involve numerous risks and uncertainties.

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 non-clinical studies, proof-of-concept studies and clinical studies and trials and other product development activities;

our ability to complete our studies and trials 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 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.



**Table of Contents**

**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.*

**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 development. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and other 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. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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 an 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 not be in a position to submit a 505(b)(2) NDA for CPP-109 until August 21, 2014.

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

## **Table of Contents**

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 currently 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 common stock currently trades on the Nasdaq Capital Market. On June 18, 2012, we were informed by the Nasdaq Stock Market ( Nasdaq ) that, as a result of our common stock no longer meeting the requirement that it trade at a bid price of at least \$1.00 per share, our common stock would be delisted from the Nasdaq Capital Market if, by December 17, 2012, we did not regain compliance with the requirement by our common stock trading at a bid price of at least \$1.00 per share for a period of at least ten consecutive trading days. On August 2, 2012, we received notice from Nasdaq confirming that we had regained compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as a result of our common stock closing with a bid price of at least \$1.00 for at least ten consecutive trading days.

## **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 and was completed in May 2012. This trial is currently ongoing and we expect to receive top-line results from this trial around the end of September 2012. 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 such as 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 received positive final results from this Phase I(a) study in May 2012. Subject to the availability of funding, we hope to begin further human clinical trials for CPP-115 during the early part of 2013.

---

**Table of Contents**

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.

**THE OFFERING**

Common stock offered by us	4,000,000 shares
Common stock to be outstanding after this offering	34,741,520 shares
Warrants offered by us	Each share of common stock is being sold together with 0.30 of a warrant to purchase one share of common stock at an exercise price of \$2.08 per share. The warrants will be exercisable immediately upon issue and will expire five years from the date of issuance. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants. See Description of Securities.
Use of proceeds	We intend to use the net proceeds from the sale of the securities: (i) to fund our product development efforts, and (ii) for general corporate purposes. See Use of Proceeds on page S-21 for additional information.
Risk Factors	See Risk Factors on page S-5 for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NASDAQ Capital Market listing	Our common stock is listed 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.

The number of shares of our common stock to be outstanding after this offering as shown above is based on 30,741,520 shares outstanding as of August 27, 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;



**Table of Contents**

729,610 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;

1,239,270 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan;

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;

6,000,000 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of \$1.04 per share; and

1,200,000 shares of our common stock issuable upon the exercise of the warrants offered hereby.

**RISK FACTORS**

Investing in our securities involves risk. Please see the risk factors under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011 as filed with the SEC on March 30, 2012, as well as any subsequent updates that may be filed with our quarterly reports on Form 10-Q. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus supplement and the accompanying base prospectus. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem to be immaterial may also affect our business operations.

**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 \$1,378,266 for the six months ended June 30, 2012, and as of June 30, 2012 we had a deficit accumulated during the development stage of \$39,480,883. We may never obtain approval of an NDA for CPP-109 or CPP-115 and may never achieve profitability.

## **Table of Contents**

### ***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 the U.S. Phase II(b) clinical trial of CPP-109 that we are jointly conducting with NIDA and the VA. 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 2014. 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 studies and trials. We will also require additional working capital to support our operations beyond the first quarter of 2014 (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.

## **Table of Contents**

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, 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

## **Table of Contents**

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, approximately 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 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;



## **Table of Contents**

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 may include Black Box warnings, limitations on promotion and distribution, and/or 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.

***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

## **Table of Contents**

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 minimize the data we will need to generate 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 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.

## **Table of Contents**

### **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.

#### ***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



## **Table of Contents**

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 design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. The process of obtaining regulatory approvals typically takes several years and requires the expenditure of substantial capital and other resources. Despite the time, expense and resources invested by us in the approval process, we may not be able to demonstrate that our product candidates are safe and effective, in which event we would not receive the regulatory approvals required to market them.

## **Table of Contents**

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

## **Table of Contents**

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.

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 an enforcement action against us, including warning letters, the seizure of products, suspension or withdrawal of approvals, shutting down of production and criminal prosecution. Any of these third-party suppliers or contract manufacturers will also be subject to audits by the FDA and other regulatory agencies. If any of our third-party suppliers or contract manufacturers fail to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our products could suffer significant interruptions and delays.

## Table of Contents

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;

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.

## **Table of Contents**

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.

***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. 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

## **Table of Contents**

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. 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 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.

## **Table of Contents**

*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 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.

## **Table of Contents**

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 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.



## **Table of Contents**

### **Risks Related to this Offering**

*Our management will have broad discretion in allocating the net proceeds of this offering, and may use the proceeds in ways in which you disagree.*

Our management has significant flexibility in applying the net proceeds we expect to receive in this offering because the net proceeds are not required to be allocated to any specific investment or transaction, and therefore you cannot determine at this time the value or propriety of our application of those proceeds, and you and other stockholders may not agree with our decisions. In addition, our use of the proceeds from this offering may not yield a significant return or any return at all for our stockholders. The failure by our management to apply these funds effectively could have a material adverse effect on our business, results of operations or financial condition. See **Use of Proceeds** on page S-7 for a further description of how management intends to apply the proceeds from this offering.

*You will experience immediate dilution in the book value per share of the common stock you purchase.*

Because the combined public offering price per share and corresponding warrant of the securities being offered is substantially higher than the 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 combined public offering price of \$1.50 per share and corresponding warrant, and attributing no value to the warrants, if you purchase shares in this offering, you will suffer immediate and substantial dilution of approximately \$1.16 per share in the net tangible book value of the common stock after giving effect to this offering. See **Dilution** on page S-22 for a more detailed discussion of the dilution you will incur if you purchase our securities in this offering.

*Sales of a substantial number of shares of our common stock, or the perception that such sales might occur, could adversely affect the trading price of our common stock.*

We currently have 30,741,520 shares of our common stock outstanding, 2,749,498 shares issuable upon the exercise of outstanding options, and 7,523,370 shares issuable upon the exercise of outstanding warrants. If this offering is completed we will have 34,741,520 shares outstanding and 11,472,868 shares issuable upon the exercise of the warrants and the outstanding options. Sales of a substantial number of shares of our common stock, or the perception that such sales might occur, could adversely affect the trading price of our common stock.

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

There is no established public trading market for the warrants being offered in this offering, and we do not expect such 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. Without an active market, the liquidity of the warrants will be limited.

*Holders of our warrants will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock.*

Until holders of warrants acquire shares of our common stock upon exercise of the warrants, holders of warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

## **Table of Contents**

### ***The warrants may not have any value.***

The warrants have an exercise price of \$2.08 per share of common stock and expire five years after the date of issuance. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

### ***If this offering is deemed to violate the terms of the underwriting agreement for our May 2012 offering, we could be subject to claims.***

The underwriting agreement we entered into in connection with our May 2012 public offering contains a provision under which we agreed, among other things, not to sell any securities for a certain period of time, subject to a number of exceptions. It is possible that the representative of the underwriters for the May 2012 offering could assert claims that this offering violates the terms of that underwriting agreement. Although we do not believe that any such claim would have a material adverse effect on our business, results of operations or financial condition, we are not able to quantify the risk of such claims being made or the effect that any such claims would have on our business.

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

Nasdaq listing rules require that listed companies maintain certain standards, including having \$2.5 million in stockholder equity and/or \$35 million total market value of listed securities, along with maintaining a bid price of at least \$1.00 per share. If we are unable to maintain these values, our common stock could be delisted 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.

## **USE OF PROCEEDS**

We expect that the net proceeds to us from this offering will be approximately \$5.5 million, after deducting placement agent fees and estimated offering expenses payable by us, assuming no exercise of the warrants offered hereby. We expect to use the net proceeds from this offering: (i) to fund our product development efforts, and (ii) for general corporate purposes.

As of the date of this prospectus supplement, we cannot specify with certainty 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. Pending the application of the net proceeds for these purposes, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

**Table of Contents****DILUTION**

The net tangible book value of our common stock as of June 30, 2012 was approximately \$6.4 million, or \$0.21 per share. Net tangible book value per share of our common stock is equal to our net tangible assets (tangible assets less total liabilities) divided by the number of shares of our common stock issued and outstanding as of June 30, 2012.

Dilution in net tangible book value per share represents the difference between the combined public offering price of the securities we are offering, and the as adjusted net tangible book value per share of our common stock after giving effect to this offering. After giving effect to the sale of 4,000,000 shares of our common stock and warrants to purchase 1,200,000 shares of our common stock in this offering at the combined public offering price of \$1.50 per share and corresponding warrant, attributing no value to the warrants offered hereby, and after deducting the placement agent's fees and the estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the warrants issued in this offering, our adjusted net tangible book value per share of our common stock at June 30, 2012 would have been approximately \$12.0 million, or approximately \$0.34 per share. This represents an immediate increase in net tangible book value per share of our common stock of approximately \$0.13 per share to existing stockholders and an immediate dilution of approximately \$1.16 per share to purchasers in this offering. The following table illustrates this per-share dilution:

Combined public offering price per share and corresponding warrant	\$ 1.50
Net tangible book value per share as of June 30, 2012	\$ 0.21
Increase per share attributable to this offering	\$ 0.13
As adjusted net tangible book value per share as of June 30, 2012	\$ 0.34
Dilution per share to new investors	\$ 1.16

The above table is based on 30,741,520 shares outstanding as of June 30, 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;

729,610 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;

1,239,270 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan.

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;

6,000,000 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of \$1.04 per share; and

1,200,000 shares of our common stock issuable upon the exercise of the warrants offered hereby.

To the extent that any outstanding options or warrants are exercised, new options are issued under our 2006 Stock Incentive Plan, 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.



**Table of Contents**

**DESCRIPTION OF SECURITIES**

We are offering 4,000,000 shares of common stock and warrants to purchase 1,200,000 shares of common stock. Each share of common stock is being sold together with 0.30 of a warrant to purchase one share of common stock at an exercise price of \$2.08 per share of common stock. The shares of common stock and warrants will be issued separately. This prospectus also relates to the offering of shares of our common stock upon exercise, if any, of the warrants.

The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and by-laws, which are filed as exhibits to our Registration Statement on Form S-1, registration no. 333-136039, filed with the SEC on July 25, 2006.

Our authorized capital stock consists of:

100,000,000 shares of common stock, par value \$0.001 per share; and

5,000,000 shares of preferred stock, par value \$0.001 per share.

As of August 27, 2012 we had outstanding:

30,741,520 shares of our common stock;

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;

729,610 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;

1,239,270 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan;

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; and

6,000,000 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of \$1.04 per share.

**Common Stock**

The material terms of our common stock are described under the caption **Common Stock** starting on page 7 of the accompanying base prospectus.

**Warrants**

*The following summary of certain terms and provisions of the warrants offered hereby is not complete and is subject to, and qualified in its entirety by reference to, the terms and provisions set forth in the form of warrant agreement attached as an exhibit to our Current Report on Form 8-K to be filed with the SEC. Prospective investors should carefully review the terms and provisions set forth in the form of warrant.*



## Table of Contents

Term. The warrants are exercisable beginning on the date of original issuance and at any time that is up to the date that is five years after the date of original issuance.

Exercise Price. The exercise price of the warrant is \$2.08 per share of common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, stock issuances, reclassifications or similar events affecting our common stock.

Exercisability. Holders may exercise the warrants beginning on the date of issuance and at any time during the applicable term of the warrant. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

Cashless Exercise. If at the time a holder exercises its warrant there is no available effective registration statement registering the issuance of the shares of our common stock issuable upon exercise of the warrants, then in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

Authorized Shares. During the period the warrant is outstanding, the Company will reserve from its authorized and unissued common stock a sufficient number of shares to provide for the issuance of shares of common stock underlying the warrant upon the exercise of the warrant.

Right as a Stockholder. Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

Waivers and Amendments. Any term of the warrants issued in the offering may be amended or waived with our written consent and the written consent of the holders of warrants representing a majority of the shares of common stock underlying the warrants then outstanding, except that no such action may increase the exercise price of any warrant or decrease the number of shares or class of stock obtainable upon exercise of any warrant without the written consent of the holder of the warrant.

Transfers. The warrants may be transferred at the option of the warrant holder upon surrender of the warrants with the appropriate instruments of transfer, subject to compliance with applicable law.

Trading. We do not plan on making an application to list the warrants on the Nasdaq Capital Market, any national securities exchange or other nationally recognized trading system. We do not expect a market for the warrants to develop.

**Table of Contents****PLAN OF DISTRIBUTION**

Roth Capital Partners, LLC, which we refer to as the placement agent, has agreed to act as the exclusive placement agent in connection with this offering subject to the terms and conditions of a placement agent agreement, dated August 28, 2012. The placement agent may engage selected dealers to assist in the placement of the shares and warrants. The placement agent is not purchasing or selling any shares and warrants offered by this prospectus supplement and the related prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of the shares and warrants, but has agreed to use its commercially reasonable best efforts to arrange for the sale of all of the shares and warrants offered hereby. We will enter into subscription agreements directly with investors in connection with this offering and we may not sell the entire amount of shares offered pursuant to this prospectus supplement and the related prospectus. The public offering price of the shares and warrants offered hereby has been determined based upon arm's-length negotiations between the purchasers and us.

The placement agent proposes to arrange for the sale to one or more purchasers of the shares and warrants offered pursuant to this prospectus supplement and the related prospectus through direct subscription agreements between the purchasers and us.

**Commissions and Expenses**

We have agreed to pay the placement agent an aggregate cash placement fee equal to six percent of the gross proceeds in this offering.

The following table shows the combined per share and total cash placement agent's fees we will pay to the placement agent in connection with the sale of the shares and warrants offered pursuant to this prospectus supplement and the related prospectus assuming the purchase of all of the shares and warrants offered hereby:

Per Share of Common Stock and Corresponding Warrant	\$ 0.09
Total	\$ 360,000

Because there is no minimum offering amount required as a condition to closing in this offering, the actual total placement agent fees, if any, are not presently determinable and may be substantially less than the maximum amount set forth above. We have also agreed to reimburse the placement agent for its out-of-pocket expenses in an amount not to exceed \$35,000 without our prior approval, such approval not to be unreasonably withheld. In accordance with the rules and regulations of the Financial Industry Regulatory Authority, Inc., or FINRA, in no event may the maximum compensation payable to FINRA members and independent broker-dealers exceed 8.0% of the gross proceeds of this offering.

Our obligation to issue and sell shares and warrants to the purchasers is subject to the conditions set forth in the subscription agreements, which may be waived by us at our discretion. A purchaser's obligation to purchase shares and warrants is subject to the conditions set forth in his or her subscription agreement as well, which may also be waived.

We currently anticipate that the sale of the shares and warrants will be completed on or about August 31, 2012. We estimate the total offering expenses of this offering that will be payable by us, excluding the placement agent's fees, will be approximately \$100,000, which includes legal and printing costs, various other fees and reimbursement of the placement agent's expenses. At the closing, The Depository Trust Company will credit the shares of common stock to the respective accounts of the purchasers. We will mail warrants directly to the investors at the respective addresses set forth in their subscription agreement with us.

**Indemnification**

We have agreed to indemnify the placement agent against liabilities under the Securities Act of 1933, as amended. We have also agreed to contribute to payments the placement agent may be required to make in respect of such liabilities.

**Lock-up Agreement**

We have agreed, subject to certain exceptions, for a period of 60 days after the date of this prospectus, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any common shares or any securities convertible into or exchangeable for our common shares either owned as of the date hereof or thereafter acquired without the prior written consent of the placement agent. The placement agent may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.





## **Table of Contents**

### **Electronic Distribution**

This prospectus supplement and the related prospectus may be made available in electronic format on websites or through other online services maintained by the placement agent, or by an affiliate. Other than this prospectus supplement and the related prospectus, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of this prospectus supplement and the related prospectus or the registration statement of which this prospectus supplement and the related prospectus forms a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement and subscription agreements. A copy of the placement agent agreement and the form of subscription agreement with the purchasers are included as exhibits to our current report on Form 8-K that will be filed with the SEC and incorporated by reference into the Registration Statement of which this prospectus supplement forms a part. See "Where You Can Find Additional Information" on page S-27.

### **Regulation M Restrictions**

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the units sold by it while acting as a principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Securities Exchange Act of 1934, as amended, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares and warrants by the placement agent acting as a principal. Under these rules and regulations, the placement agent:

must not engage in any stabilization activity in connection with our securities; and

must not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

## **Table of Contents**

### **LEGAL MATTERS**

The validity of the shares of common stock and common stock purchase warrants that we are offering hereby will be passed upon by Akerman Senterfitt, Miami, Florida. Lowenstein Sandler PC, Roseland, New Jersey, is acting as counsel for the placement agent in connection with this offering.

### **EXPERTS**

The audited financial statements incorporated by reference in this prospectus supplement and the accompanying base prospectus have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing in giving said report, which is also incorporated by reference in this prospectus supplement and the accompanying base prospectus.

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

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC 0330 for further information on the operating rules and procedures for the public reference room.

This prospectus supplement and the accompanying base prospectus do not contain all of the information included in the registration statement. We have omitted certain parts of the registration statement in accordance with the rules and regulations of the SEC. For further information, we refer you to the registration statement, including its exhibits and schedules. Statements contained in this prospectus supplement and any accompanying base prospectus supplement about the provisions or contents of any contract, agreement or any other document referred to are not necessarily complete. Please refer to the actual exhibit for a more complete description of the matters involved.

### **INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be a part of this prospectus supplement. Information contained in this prospectus supplement and the accompanying prospectus and information that we file with the SEC in the future and incorporate by reference in this prospectus supplement and the accompanying prospectus will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (other than Current Reports on Form 8-K furnished under Item 2.02 or Item 7.01 and exhibits filed on such form that are related to such items) we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the prospectus supplement and until the termination of this offering:

The following documents filed with the SEC are incorporated by reference in this prospectus supplement:

1. Our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 30, 2012;
2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed with the SEC on May 15, 2012, and for the quarter ended June 30, 2012, filed with the SEC on August 14, 2012;
3. Our definitive proxy statement, filed with the SEC on April 17, 2012;
4. Our Current Reports on Form 8-K filed with the SEC on February 13, 2012, April 2, 2012, May 16, 2012, May 29, 2012, June 5, 2012, June 21, 2012, July 12, 2012, August 3, 2012, August 15, 2012 and August 28, 2012;



**Table of Contents**

5. Our description of our common stock contained in our Registration Statement on Form 8-A, filed with the SEC on September 29, 2006, along with Amendment No. 1 thereto, filed with the SEC on October 18, 2006; and
  
6. All documents subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, from the date of filing of such documents, before the filing of a post-effective amendment to this Registration Statement which indicates that all securities offered hereunder have been sold or which deregisters all securities then remaining unsold.

You may obtain a copy of any of these documents at no cost by requesting them from us or by writing or calling: Catalyst Pharmaceutical Partners, Inc., 355 Alhambra Circle, Suite 1500, Coral Gables, Florida, 33134, Attn: Investor Relations, or by calling (305) 529-2522. Copies of each of these filings are also available for no cost on our website, [www.catalystpharma.com](http://www.catalystpharma.com) , or on the SEC's web site, [www.sec.gov](http://www.sec.gov) .

**Table of Contents**

**PROSPECTUS**

**\$ 30,000,000**

**Common Stock**

We may, from time to time, sell shares of our common stock and warrants to purchase shares of our common stock, or a security consisting of a combination of these securities, in one or more offerings in amounts, at prices and on terms that we determine at the time of the offering, with an aggregate initial offering price not to exceed \$30,000,000. We will provide you of the specific terms of such securities to be sold in supplements to this prospectus. However, in no event will we sell more than  $\frac{1}{3}$  of our public float in any 12-month period. You should read this prospectus and any prospectus supplement carefully before you invest.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. THE RISKS ASSOCIATED WITH AN INVESTMENT IN OUR SECURITIES WILL BE DESCRIBED IN THE APPLICABLE PROSPECTUS SUPPLEMENT AND IN OUR FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION THAT ARE INCORPORATED BY REFERENCE HEREIN, ALL AS MORE PARTICULARLY DESCRIBED UNDER THE CAPTION RISK FACTORS ON PAGE 6 OF THIS PROSPECTUS.**

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol `CPRX`. On December 14, 2010, the last reported sale price for our common stock on the Nasdaq Capital Market was \$0.97 per share.

Shares of common stock or warrants to purchase shares of common stock, or securities consisting of a combination of these securities, may be sold by us to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled `Plan of Distribution` in this prospectus. If any underwriters are involved in the sale of any common stock or common stock purchase warrants or securities consisting of a combination of these securities, with respect to which this prospectus is delivered, the names of such underwriters and any applicable discounts or commissions, and any over-allotment options will be set forth in a prospectus supplement. The price to the public and the net proceeds we expect to receive from such sale will also be set forth in the prospectus supplement.

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

The date of this prospectus is December 15, 2010

**Table of Contents**

**TABLE OF CONTENTS**

<u>About This Prospectus</u>	1
<u>About the Company</u>	1
<u>Information Regarding Forward-Looking Statements</u>	5
<u>Risk Factors</u>	6
<u>Use of Proceeds</u>	6
<u>Price Range of Common Stock and Dividend Policy</u>	6
<u>General Description of our Common Stock and Warrants</u>	7
<u>Plan of Distribution</u>	12
<u>Legal Matters</u>	13
<u>Experts</u>	13
<u>Where You Can Find Additional Information</u>	14
<u>Incorporation by Reference</u>	14

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we have filed with the Securities and Exchange Commission (the SEC), utilizing a shelf registration process. Under this shelf registration process, we may sell shares of our common stock, warrants to purchase shares of our common stock and securities consisting of a combination of these securities in one or more offerings. All such offerings will not exceed a total dollar amount of \$30,000,000. However, in no event will we sell more than  $\frac{1}{3}$  of our public float (the market value of our common stock held by non-affiliates) in any 12 month period. This prospectus provides you with a general description of our common stock. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of the applicable offering. The prospectus supplement may also add, change, or update information contained in this prospectus. You should read both this prospectus and any prospectus supplement, together with any additional information described under the heading Incorporation by Reference.

We have not authorized any dealer, salesperson or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying supplement to this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying supplement to this prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying supplement to this prospectus constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

Reference in this prospectus to we, our, us, the Company, or Catalyst refer to Catalyst Pharmaceutical Partners, Inc., a Delaware corporation.

**ABOUT THE COMPANY**

We are a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting addiction and diseases of the central nervous system such as epilepsy. We have two products in development. We are currently evaluating our lead product candidate, CPP-109 (our version of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the U.S. Food & Drug Administration (FDA) for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective pharmacological treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and obsessive-compulsive disorders. Further, we are in the early stages of developing CPP-115, which is another GABA aminotransferase inhibitor that, based on non-clinical studies, we believe is more potent than vigabatrin but has 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 epilepsy, drug addiction and pain management. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.



## **Table of Contents**

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 non-clinical and clinical trials, proof-of-concept studies, and other product development activities;

the results of our non-clinical and clinical 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 ( NDA s ) for CPP-109 and CPP-115; and

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

## **Recent Developments**

### ***CPP-109***

On April 13, 2010, we signed a definitive Clinical Trial Agreement ( CTA ) with the National Institute on Drug Abuse ( NIDA ) to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Trial ). As part of the CTA, NIDA, under their agreement with the Veterans Administration Cooperative Studies Program, has agreed to provide substantial resources towards the completion of the Trial. It is anticipated that this double-blind, placebo-controlled trial, which will be conducted at twelve leading addiction research facilities across the United States, will recruit approximately 200 patients. The Trial, which will be overseen by the Veterans Administration ( V.A. ), was initiated in November 2010 and we expect to have top line data in the second quarter of 2012. The 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 to be one of the adequate and well controlled trials required to support approval of an NDA for CPP-109.

Pursuant to the CTA, we will provide the study drug (and matching placebo) for the Trial and materials required to package them suitably for use in the Trial. In conjunction with NIDA, we have developed the Trial protocol and informed consent and have submitted such documents to the FDA for approval. We will also be responsible for, among other duties, funding patient recruitment activities and advertising for the 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 V.A. statisticians who will interpret the study data, and, if requested, funding the treatment costs of up to 25 of the study subjects. Further, pursuant to the CTA, NIDA has provided input on the protocol and informed consent and will, under their agreement with the Veterans Administration Cooperative Studies Program, solicit, recruit and fund qualified study sites and investigators and recruit and treat at least 175 of the study subjects. NIDA will also provide clinical monitoring for all sites.

The CTA terminates on April 13, 2015 or upon the completion of the 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 Trial. Either party may terminate the CTA upon 60 days notice without cause, or upon 30 days written notice for cause. Both NIDA and us have continuing rights under the 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 study and continuing duties of confidentiality.

## **Table of Contents**

During July 2010, we announced that the European Patent Office granted to Brookhaven National Laboratory ( 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. We license this patent from Brookhaven. We also announced on December 9, 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 this patent from Brookhaven.

### ***CPP-115***

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

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

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

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 prevalent 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 is 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 tests and thus is not likely to be carcinogenic.

CPP-115 did not show any inhibition of AST and ALT 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, at lower doses than vigabatrin.

## **Table of Contents**

CPP-115 was found to eliminate cocaine-related 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 100 times lower than that needed by vigabatrin to achieve the same effect.

We are currently advancing the development of CPP-115 by undertaking the remainder of the non-clinical studies necessary to file an Investigational New Drug Application (IND) with the FDA.

Additionally, on September 1, 2010, CPP-115 was granted orphan drug designation by the FDA for the treatment of infantile spasms.

There can be no assurance that CPP-115 will ultimately be proven to be safe and effective to treat epilepsy, drug addiction or for use in pain management, or that CPP-115 will be determined not to have a similar visual field defect profile to vigabatrin.

### ***Update on non-clinical and clinical studies that we support***

We have been advised that one of our clinical collaborators 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 the North Shore LIJ Hospital and by Jonathan D. Brodie, M.D., Ph.D. from the Department of Psychiatry at New York University's School of Medicine. Drs. Dewey and Brodie are the co-inventors on the vigabatrin-related patents that we have licensed from Brookhaven and are members of our Scientific Advisory Board. The study is being conducted at the Feinstein Institute. Opioid abuse is one of the many substance addiction indications covered under our exclusive license of Brookhaven's vigabatrin use patent portfolio. We have supplied CPP-109 (our version of vigabatrin) to facilitate this study.

We have been advised that a clinical researcher at the University of Pennsylvania expects to commence an investigator-sponsored proof-of-concept study of CPP-109 in patients dependent on both cocaine and alcohol by early 2011. We expect to supply CPP-109 (our version of vigabatrin), placebo and approximately \$50,000 in funding to facilitate the conduct of this study.

We are also collaborating with other investigators by providing CPP-109 and access to our CPP-109 IND for studies that we believe will add value to our own research and development. Future potential studies include studies evaluating CPP-109 for the treatment of alcohol, nicotine, cocaine and methamphetamine addiction.

### **Discussions with potential strategic partners**

We periodically have discussions with potential strategic partners interested in working with us on the development of CPP-109 and/or CPP-115. Such discussions may not result in relationships that we determine to pursue, and no agreements have been entered into to date.

### **NASDAQ Listing**

Our common stock currently trades on the Nasdaq Capital Market. On November 13, 2009, we were informed by the Nasdaq Stock Market (Nasdaq) that, as a result of our common stock no longer meeting the requirement that it trade at a bid price of at least \$1.00 per share, our common stock would be delisted from the Nasdaq Capital Market if, by May 12, 2010, we did not regain compliance with the

## **Table of Contents**

requirement by our common stock trading at a bid price of at least \$1.00 per share for a period of at least ten consecutive trading days. On April 26, 2010, we received notice from Nasdaq confirming that we had regained compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as a result of our common stock closing with a bid price of at least \$1.00 for at least ten consecutive trading days.

### **Addition to Scientific Advisory Board**

On November 15, 2010, we announced that Dr. Richard B. Silverman has joined our Scientific Advisory Board. Dr. Silverman is the inventor of CPP-115.

## **INFORMATION REGARDING FORWARD LOOKING STATEMENTS**

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

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 non-clinical and clinical trials, proof-of-concept studies, and other product development activities;

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

whether our trials and studies will be successful;

the results of our non-clinical and clinical trials, and the number and scope of such trials that will be required for us to seek and obtain approval of NDAs for CPP-109 and CPP-115;

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

whether others develop and commercialize products competitive to our products;

changes in the laws and regulations affecting our business including changes that may result from any future healthcare reform legislation that may become law;

**Table of Contents**

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.

**RISK FACTORS**

Before making an investment decision, you should carefully consider the risks described under **Risk Factors** in the applicable prospectus supplement and in our most recent Annual Report on Form 10-K, or any updates in subsequent Quarterly Reports on Form 10-Q, together with all of the other information appearing in this prospectus or incorporated in this prospectus by reference and any applicable prospectus supplement, in light of your particular investment objectives.

**USE OF PROCEEDS**

Except as may otherwise be provided in a prospectus supplement, we will use the net proceeds from sales of the securities to fund non-clinical and clinical studies with respect to our two product candidates, CPP-109 and CPP-115, and for general working capital purposes. When particular securities are offered, the prospectus supplement relating to that offering will set forth our intended use of the net proceeds received from the sale of these securities. Pending the application of the net proceeds for these purposes, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

**PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY**

Our common stock trades on the Nasdaq Capital Market under the symbol CPRX. Previously, from November 8, 2006 to 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 Global Market or the Nasdaq Capital Market for the period indicated.

	<b>High</b>	<b>Low</b>
<b>Year Ended December 31, 2010</b>		
Fourth Quarter (through December 14, 2010)	\$ 1.19	\$ 0.97
Third Quarter	\$ 1.32	\$ 0.90
Second Quarter	\$ 2.00	\$ 0.71
First Quarter	\$ 0.87	\$ 0.56
<b>Year Ended December 31, 2009</b>		
Fourth Quarter	\$ 1.17	\$ 0.60
Third Quarter	\$ 1.39	\$ 0.41
Second Quarter	\$ 2.25	\$ 0.61
First Quarter	\$ 2.75	\$ 1.25

## **Table of Contents**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

### **GENERAL DESCRIPTION OF OUR COMMON STOCK AND WARRANTS**

The following summary of the material features of our common stock and our warrants to purchase shares of common stock does not purport to be complete and is subject to, and qualified in its entirety by the provisions of our Certificate of Incorporation, our Bylaws and other applicable law. See [Where You Can Find Additional Information](#) .

Our authorized capital currently consists of 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. As of the date of this prospectus, we had 19,394,737 shares of our common stock outstanding. There are no shares of preferred stock outstanding.

We are a Delaware corporation, and were incorporated on July 24, 2006. We are the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation, which was incorporated in January 2002.

#### **Common Stock**

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

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

#### **Common Stock Purchase Warrants**

We may issue warrants to purchase shares of our common stock. We may issue the warrants independently or together with the underlying common stock, and the warrants may be attached to or separate from the underlying common stock. We may also issue warrants under separate warrant agreements to be entered into between us and each of the initial holders of such warrants.

The following description is a summary of selected provisions relating to the warrants that we may issue. The summary is not complete. When warrants are offered in the future, a prospectus supplement will explain the particular terms of those securities and the extent to which these general provisions may apply. The specific terms of the warrants as described in a prospectus supplement will supplement and, if applicable, may modify or replace the general terms described in this section.

## **Table of Contents**

This summary and any description of warrants in the applicable prospectus supplement is subject to and is qualified in its entirety by reference to all of the provisions of any specific warrant document or agreement which we will file with the SEC for incorporation by reference into any prospectus supplement we may file. See [Where You Can Find Additional Information](#) and [Incorporation by Reference](#) for information on how to obtain a warrant document when it is filed.

### **Terms**

The applicable prospectus supplement may describe the terms of any warrants that we may offer, including, but not limited to:

the title of the warrants;

the total number of warrants;

the price or prices at which the warrants will be issued;

the date on which the right to exercise the warrants will commence and the date on which the right will expire;

if applicable, the minimum or maximum number of warrants that may issued at any one time;

if applicable, the date on and after which the warrants and the related underlying common stock will be separately transferable;

if applicable, a discussion of material United States income tax considerations;

if applicable, the terms of redemption of the warrants;

the procedures and conditions relating to the exercises of the warrants; and

any other terms of the warrants, including terms, procedures, and limitations relating to the exchange and exercise of the warrants. We may issue warrants under one or more Warrant Agreements, each to be entered into between us and each initial holder of such warrants.

We may issue warrants in non-global form, i.e. bearer form. If any warrants are issued in non-global form, warrant certificates may be exchanged for new warrant certificates of different denominations, and holders may exchange, transfer or exercise their warrants subject to the terms indicated in the applicable prospectus supplement or other offering material.

Prior to the exercise of their warrants, holders of warrants will not have any rights of holders of common stock purchasable upon their exercise and will not be entitled to dividend payments, if any, or voting rights of the common stock purchasable upon their exercise.

## **Table of Contents**

A warrant will generally entitle the holder thereof to purchase for cash an amount of common stock at an exercise price that will be stated in, or that will be determinable as described in, the applicable prospectus supplement or other offering material. After the close of business on the expiration date, unexercised warrants will become void. Warrants may be redeemed as set forth in the applicable prospectus supplement or other offering material.

Warrants may be exercised as set forth in the applicable prospectus supplement or other offering material. Upon receipt of payment and the warrant certificate properly completed and duly executed as indicated in the prospectus supplement or other offering material, we will forward, as soon as practicable, the common stock purchasable upon such exercise. If less than all of the warrants represented by such warrant certificate are exercised, a new warrant certificate will be issued for the remaining warrants.

## **Provisions of the Certificate and Bylaws**

A number of provisions of our certificate of incorporation and bylaws concern matters of corporate governance and the rights of stockholders. Certain of these provisions, as well as the ability of our board of directors to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof, may be deemed to have an anti-takeover effect and may discourage takeover attempts not first approved by the board of directors (including takeovers which certain stockholders may deem to be in their best interests). To the extent takeover attempts are discouraged, temporary fluctuations in the market price of the common stock, which may result from actual or rumored takeover attempts, may be inhibited. These provisions, together with the ability of the board to issue preferred stock without further stockholder action, also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders, even if such removal or assumption would be beneficial to our stockholders. These provisions also could discourage or make more difficult a merger, tender offer or proxy contests, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of the common stock. The board of directors believes that these provisions are appropriate to protect our interest and the interests of our stockholders.

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

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



## **Table of Contents**

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

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

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

## **Certain Anti-Takeover Matters**

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

either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder is approved by our board of directors before the date the interested stockholder attained that status;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participates do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or after that date, the business combination is approved by our board of directors and authorized at a meeting of stockholders, and not by written consent, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder. Section 203 defines business combination to include the following:

any merger or consolidation involving the corporation and the interested stockholder;

## **Table of Contents**

any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

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

## **Limitation of Liability and Indemnification Matters**

Our certificate of incorporation limits the liability for monetary damages for breach of fiduciary duty by members of our board of directors, except for liability that cannot be eliminated under Delaware law. Under Delaware law, our directors have a fiduciary duty to us which is not eliminated by this provision in our certificate of incorporation. In addition, each of our directors is subject to liability under Delaware law for breach of their duty of loyalty for acts or omissions which are found by a court of competent jurisdiction to be not in good faith or which involve intentional misconduct or knowing violations of law for actions leading to improper personal benefit to the director and for payments of dividends or approval of stock repurchases or redemptions that are prohibited by Delaware law. This provision does not affect our directors responsibilities under any other laws, such as federal securities laws.

Delaware law provides that the directors of a company will not be personally liable for monetary damages for breach of their fiduciary duty as directors, except for liability for any of the following:

any breach of a director's duty of loyalty to us or our stockholders;

acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

unlawful payment of dividends or unlawful stock repurchases or redemptions; or

any transaction from which the director derived an improper personal benefit.

Delaware law provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which our directors and officers may be entitled to under our bylaws, any agreement, a vote of stockholders or otherwise. Our certificate of incorporation and bylaws eliminate the

## **Table of Contents**

personal liability of directors to the maximum extent permitted by Delaware law. In addition, our certificate of incorporation and bylaws provide that we may fully indemnify any person who is or was a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was one of our directors, officers, employees or other agents, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding.

### **Listing**

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol `CPRX` .

### **Transfer Agent and Registrar**

Our transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. They are located at 17 Battery Park, 8<sup>th</sup> Floor, New York, New York 10004. They can be reached via telephone at (212) 509-4000.

## **PLAN OF DISTRIBUTION**

We may sell the securities from time-to-time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities: (1) through underwriters or dealers, (2) through agents, and/or (3) directly to one or more purchasers. However, in any given 12-month period, we may sell only one third ( $\frac{1}{3}$ ) of our public float. We may distribute the securities from time to time in one or more transactions at:

a fixed price or prices, which may change;

market prices prevailing at the time of sale;

prices relating to the prevailing market prices;

varying prices determined at the time of sale; or

negotiated prices.

The applicable prospectus supplement with respect to a particular offering of securities will describe the terms of the offering of the securities, including:

the name or names of any underwriters, and if required, any dealers or agents;

the purchase price of the securities and the proceeds we will receive from the sale;

any underwriting discounts and other items constituting underwriters' compensation;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchange or market on which the securities may be listed.

## **Table of Contents**

We may solicit directly offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in a prospectus supplement any agent involved in the offer or sale of our securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale. If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale and we will provide the name of any underwriter in the prospectus supplement which the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

With respect to underwritten public offerings, negotiated transactions and block trades, we will provide in the applicable prospectus supplement any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments they may be required to make in respect thereof.

To facilitate the offering of securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over allotments or short positions by making purchases in the open market or by exercising their over allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in other transactions with us, or perform other services for us, in the ordinary course of their business.

## **LEGAL MATTERS**

Certain legal matters in connection with any offering of securities made by this prospectus will be passed upon for us by Akerman Senterfitt.

## **EXPERTS**

The audited financial statements incorporated by reference in this Prospectus have been so incorporated by reference in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing in giving said report.

## **Table of Contents**

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

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at (800) SEC 0330 for further information on the operating rules and procedures for the public reference room.

This prospectus does not contain all of the information included in the registration statement. We have omitted certain parts of the registration statement in accordance with the rules and regulations of the SEC. For further information, we refer you to the registration statement, including its exhibits and schedules. Statements contained in this prospectus and any accompanying prospectus supplement about the provisions or contents of any contract, agreement or any other document referred to are not necessarily complete. Please refer to the actual exhibit for a more complete description of the matters involved.

### **INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be a part of this prospectus, except for any information superseded by information in this prospectus or by any information in a prospectus supplement accompanying this prospectus.

The following documents filed with the SEC are incorporated by reference in this prospectus:

1. Our Annual Report on Form 10-K for the year ended December 31, 2009, filed with the SEC on March 31, 2010;
2. Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, filed with the SEC on May 17, 2010, for the quarter ended June 30, 2010, filed with the SEC on August 12, 2010, and for the quarter ended September 30, 2010, filed with the SEC on November 15, 2010;
3. Our Current Reports on Form 8-K filed with the SEC on February 17, 2010, February 23, 2010, April 1, 2010, April 13, 2010, April 26, 2010, August 4, 2010, August 6, 2010, September 21, 2010, November 1, 2010, November 2, 2010, November 4, 2010, November 16, 2010, and November 18, 2010;
4. Our description of our common stock contained in our Registration Statement on Form 8-A, filed with the SEC on September 29, 2006, along with Amendment No. 1 thereto, filed with the SEC on October 18, 2006; and
5. All documents subsequently filed by the Company pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act, from the date of filing of such documents, before the filing of a post-effective amendment to this Registration Statement which indicates that all securities offered hereunder have been sold or which deregisters all securities then remaining unsold.

**Table of Contents**

You may obtain a copy of any of these documents at no cost by requesting them from us or by writing or calling: Catalyst Pharmaceutical Partners, Inc., 355 Alhambra Circle, Suite 1370, Coral Gables, Florida, 33134, Attn: Investor Relations, or by calling (305) 529-2522. Copies of each of these filings are also available for no cost on our website, [www.catalystpharma.com](http://www.catalystpharma.com), or on the SEC's web site, [www.sec.gov](http://www.sec.gov).