CATALYST PHARMACEUTICAL PARTNERS, INC.
Form POS AM
August 15, 2012
Table of Contents

As filed with the Securities and Exchange Commission on August 15, 2012

Registration No. 333-180617

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 4

ON FORM S-3

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	76-0837053
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

355 Alhambra Circle

Suite 1500

Coral Gables, Florida 33134

(305) 529-2522

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

Patrick J. McEnany

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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

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

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

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

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

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

Table of Contents

EXPLANATORY NOTE

This Post-Effective Amendment No. 4 on Form S-3 to Form S-1 (this Registration Statement) is filed in compliance with Section 10(a)(3) of the Securities Act of 1933 and Rule 401(b) under the Securities Act of 1933. This Registration Statement originally covered an offering of common stock and warrants that was completed in May 2012 and now covers the sale of the shares of our common stock issuable from time to time upon exercise of the warrants held by the holders.

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

Table of Contents

The information in this prospectus is not complete and may be changed. These securities may not be sold until the Registration Statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED AUGUST 15, 2012

Preliminary Prospectus

6,000,000 Shares of Common Stock Issuable

Upon Exercise of Outstanding Warrants

We are offering up to 6,000,000 shares of our common stock that are issuable for a purchase price of $1.04 per share from time to time upon exercise of currently outstanding five-year warrants that we issued in May 2012 as part of a public offering of common stock and warrants. No securities are being offered pursuant to this prospectus other than the shares of our common stock that will be issued upon exercise of those currently outstanding warrants.

Our common stock is listed on the Nasdaq Capital Market under the symbol CPRX . On August 14, 2012, the last reported price per share of our common stock as reported on the Nasdaq Capital Market was $1.58 per share.

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

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

The date of this prospectus is , 2012

Table of Contents

TABLE OF CONTENTS

Summary	1
Risk Factors	5
Cautionary Statement Regarding Forward-Looking Statements	23
Use of Proceeds	24
Dilution	25
Plan of Distribution	26
Description of Securities we are Offering	26
Legal Matters	31
Experts	31
Where You Can Find Additional Information	31
Incorporation of Information by Reference	31

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC. As permitted by the rules and regulations of the SEC, the registration statement filed by us includes additional information not contained in this prospectus. You may read the registration statement and the other reports we file with the SEC at the SEC s website or its offices described below under the heading Where You Can Find Additional Information .

You should rely only on the information that is contained in this prospectus or that is incorporated by reference into this prospectus. We have not authorized anyone to provide you with information that is in addition to or different from that contained in, or incorporated by reference into, this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it.

The shares of common stock offered by this prospectus are not being offered in any jurisdiction where the offer or sale of such common stock is not permitted. You should not assume that the information contained in, or incorporated by reference into, this prospectus is accurate as of any date other than the date of this prospectus or, in the case of the documents incorporated by reference, the date of such documents, regardless of the date of delivery of this prospectus or any sale of the common stock offered by this prospectus. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

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.

Our Business

We are a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in 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.

We are jointly conducting with the National Institute on Drug Abuse (NIDA) and the Department of Veterans Affairs Cooperative Studies Program (VA) a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (and, based on current information, including completion of patient enrollment during May 2012, we expect to report top line results from this trial around the end of September 2012).

Based on an analysis of our current financial condition and forecasts of available cash, we believe that we have sufficient resources to: (i) complete the above-described Phase II(b) clinical trial of CPP-109, (ii) to fund activities necessary to support the submission of an NDA for CPP-109 for FDA approval and to begin to prepare for the commercial launch of CPP-109, assuming that the data from the currently ongoing Phase II(b) trial are compelling and the FDA files an NDA submitted by the Company for CPP-109 based on the data from the Phase II(b) trial, (iii) to manufacture sufficient CPP-115 for use in one or more future safety and/or proof-of concept studies of CPP-115, and (iv) to support our operations through the first quarter of 2014.

However, there can be no assurance that we will actually have sufficient funds for these purposes. We will also require additional funding to complete any other pre-clinical and clinical studies and trials that may be required for us to submit new drug applications (NDAs) for and commercialize CPP-109 and CPP-115 and to support our operations beyond the first quarter of 2014. There can be no assurance that we will obtain additional funding or ever be able to commercialize either of our product candidates.

Table of Contents

On May 22, 2012, we reported positive results from a Phase I(a) double-blind, placebo-controlled, clinical trial evaluating the safety, tolerability and pharmacokinetics profile of CPP-115. The study evaluated single ascending doses ranging from 5 mg to 500 mg (a dose greater than ten times the predicted effective dose based on animal models of 15-30 mg per day) of CPP-115 solution administered orally to 55 healthy volunteers. The key findings of the study included: (i) CPP-115 was well tolerated at all six doses administered in the study; there were no serious or adverse events, and no cardiovascular or respiratory events were reported in the study; (ii) CPP-115 was rapidly absorbed (time to peak blood concentration was about 30 minutes); (iii) the drug had an elimination half-life of four to six hours; and (iv) peak serum concentration of the drug (C_{max}) increased on a dose proportional basis over the range of doses studied, while there was a greater than proportional increase across the dose range in AUC, a method of measurement of the bioavailability of a drug based on a plot of blood concentrations sampled at frequent intervals.

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 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

Table of Contents

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.

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.

Table of Contents

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

Securities being offered by us	6,000,000 shares of common stock issuable upon the exercise of the warrants issued as a part of the securities sold in our May 2012 public offering. The warrants are exercisable until May 30, 2017 at an exercise price of $1.04 per share.
Common stock to be outstanding after this offering if all of the warrants are exercised	36,741,520 shares
Use of proceeds	We intend to use the net proceeds of this offering to fund our clinical development programs for CPP-109 and CPP-115 and for general corporate purposes. See *Use of Proceeds* for further information.
Risk Factors	See *Risk Factors,* as well as other information included in this prospectus, for a discussion of factors you should read and consider carefully before investing in our securities.
Trading Market	Our common stock is traded on the Nasdaq Capital Market under the symbol CPRX.

The number of shares of our common stock to be outstanding after this offering as shown above is based on 36,741,520 shares outstanding as of August 14, 2012 (including the 6,000,000 shares offered hereby) 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; and
- 1,523,370 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of $1.30 per share.

Table of Contents

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below as well as the other information in this prospectus before deciding to invest in or maintain your investment in our company. The risks described below are not intended to be an all-inclusive list of the potential risks relating to an investment in our securities. Any of the risk factors described below could significantly and adversely affect our business, prospects, financial condition and results of operations. Additional risks and uncertainties not currently known or that are currently considered to be immaterial may also materially and adversely affect our business. As a result, the trading price or value of our securities could be materially adversely affected and you may lose all or part of your investment.

Risks Related to Our Business

We are a development stage company. Our limited operating history makes it difficult to evaluate our future performance.

We are a development stage company. We are the successor by merger to a company that began operations in 2002. As such, we have a limited operating history upon which you can evaluate our current business and our prospects. The likelihood of our future success must be viewed in light of the problems, expenses, difficulties, delays and complications often encountered in the operation of a new business, especially in the pharmaceutical industry, where failures of new companies are common. We are subject to the risks inherent in the ownership and operation of a development stage company, including availability of capital, regulatory setbacks and delays, fluctuations in expenses, competition and government regulation. If we fail to address these risks and uncertainties, our business, results of operations, financial condition and prospects would be adversely affected.

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

We have had no revenues from product sales to date, currently have no products available for commercial sale, and have never had any products available for commercial sale. We expect to incur losses at least until we can commercialize CPP-109. Our net loss was $6,391,062 for the year ended December 31, 2011 and $1,378,266 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.

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

Table of Contents

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.

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.

Table of Contents

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 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;

Table of Contents

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;

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.

8

Table of Contents

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 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.

Table of Contents

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.

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.

Table of Contents

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 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.

Table of Contents

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.

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.

Table of Contents

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

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

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

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

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

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

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.

Table of Contents

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.

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;

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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 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

Table of Contents

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.

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.

Table of Contents

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.

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.

Table of Contents

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.

Risks Related to Our Common Stock and this Offering

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

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

We have relationships with our scientific advisers and collaborators at academic and other institutions. Such individuals are employed by entities other than us and may have commitments to, or consulting advisory contracts with, such entities that may limit their availability to us. Although each scientific advisor and collaborator has agreed not to perform services for another person or entity that would create an appearance of a conflict of interest, the Chairman of our Scientific Advisory Board, Stephen L. Dewey,

Table of Contents

Ph.D., is actively involved in the investigation of neurological mechanisms involved in the addiction process. His research might result in pharmaceutical products that are competitive with, or superior to, CPP-109 or CPP-115. Similarly, other similar conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

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

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

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

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

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

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

Table of Contents

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

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

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

As of the date of this prospectus, we had 30,741,520 shares of our common stock outstanding. We also had outstanding an aggregate of 2,749,498 options to purchase shares of common stock, of which 2,329,498 shares were exercisable, common stock purchase warrants to purchase 1,523,370 shares of common stock and the shares of common stock underlying the warrants covered by this Registration Statement. We have registered for future sale: (i) 3,688,828 shares of common stock that we may issue under our 2006 Stock Incentive Plan and (ii) 729,610 shares of common stock underlying our outstanding stock options that were granted pursuant to written agreements. The outstanding options make a part of the shares registered both under and outside of our 2006 Stock Incentive Plan. Sales of restricted shares or shares underlying stock options, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

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

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

- developments concerning our clinical studies and trials and our pre-clinical studies;
- announcements of product development successes and failures by us or our competitors;
- new products introduced or announced by us or our competitors;
- adverse changes in the abilities of our third-party manufacturers to provide drug or product in a timely manner or to meet FDA requirements;
- changes in reimbursement levels;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in operating results;
- expiration or termination of licenses (particularly our licenses from Brookhaven and Northwestern), research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

intellectual property, product liability or other litigation against us;

changes in the market valuations of similar companies;

Table of Contents

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

changes in economic conditions; and

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

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

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

Nasdaq listing rules require that listed companies maintain certain standards, including 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.

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

We currently intend to use the net proceeds of this offering to fund future clinical studies of CPP-109 and CPP-115, and for general corporate purposes. See *Use of Proceeds*. However, because of the factors described above, we cannot at this time determine with specificity the particular uses of the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.

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

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock as of June 30, 2012, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. See *Dilution* for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements , as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes , anticipates , proposes , plans , expects , intends , may , and other similar expressions are intended to ident forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. The forward-looking statements made in this prospectus are based on current expectations that involve numerous risks and uncertainties.

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

- the scope, rate of progress and expense of our pre-clinical studies, proof-of-concept studies and clinical studies and trials and other product development activities;
- our ability to complete our studies on a timely basis and within the budgets we establish for such trials;
- whether our studies and trials will be successful;
- the 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.

23

Table of Contents

USE OF PROCEEDS

We estimate that the net proceeds of this offering will be approximately $6.2 million. We currently expect to use the net proceeds of this offering for the following purposes:

- to fund future clinical studies of CPP-109 and CPP-115; and
- for general corporate purposes.

Due to the factors set forth above, we cannot currently determine with absolute certainty how we will use the proceeds from this offering. As a result, our management will retain broad discretion in the allocation and use of the net proceeds from this offering. We will pay all of the costs associated with registering the securities covered by this prospectus.

Table of Contents

DILUTION

Purchasers of the securities offered by this prospectus will suffer immediate and substantial dilution in the net tangible book value per share of the common stock they purchase. Our net tangible book value as of June 30, 2012 was $6,410,915, or approximately $0.21 per share of our common stock. Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of June 30, 2012.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of 6,000,000 shares of common stock in this offering at an exercise price of $1.04 per share, our as adjusted net tangible book value as of June 30, 2012 would have been $12,650,915, or approximately $0.34 per share of our common stock. This represents an immediate increase in net tangible book value of $0.13 per share of common stock to our already existing stockholders and an immediate dilution in net tangible book value of $0.70 per share of common stock to purchasers in this offering. The following table illustrates this per share dilution:

Public offering price per share		$ 1.04
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 investors participating in this offering		$ 0.70

The above table is based on 30,741,520 shares outstanding as of June 30, 2012 and excludes:

- The shares of common stock offered hereby that are issuable upon exercise of the warrants issued as part of our May 2012 public offering;
- 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; and
- 1,523,370 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of $1.30 per share.

To the extent that any 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

PLAN OF DISTRIBUTION

We will deliver shares of our common stock upon exercise of the warrants we issued in May 2012. As of the date of this prospectus, these warrants were exercisable for a total of 6,000,000 shares of our common stock, and no more of these warrants will be issued. We will not issue fractional shares upon exercise of these warrants. Each of these warrants contains instructions for exercise. In order to exercise any of these warrants, the holder must deliver to us or our transfer agent the information required in the warrants, along with payment for the exercise price of the shares to be purchased. We will then deliver shares of our common stock in the manner described below in the section titled *Description of Securities we are offering May 2012 Warrants* .

DESCRIPTION OF SECURITIES WE ARE OFFERING

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 30,741,520 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

The following summary of the material features of our 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* .

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.

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

Table of Contents

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

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

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.

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.

Table of Contents

May 2012 Warrants

The following summary description of the material features of the warrants we issued in May 2012 is necessarily general and is qualified in its entirety by reference to the form of warrant, a copy of which has been filed with the SEC as an exhibit to the registration statement of which this prospectus is a part. See *Where You Can Find More Information* .

Each warrant represents the right to purchase one share of common stock at an exercise price of $1.04 per share. Each warrant may be exercised after the date of issuance through and including the date that is five years after the warrant is first exercisable.

Exercise. The warrants may be exercised on or prior to the expiration date at the offices of the company, with the delivery of a written notice in the form attached to the warrant completed and executed as indicated, accompanied by full payment of the exercise price for the number of warrants being exercised in the form discussed below. Within three trading days, certificates representing the shares of common stock purchased will be delivered to the warrantholder, or at the warrantholder s request, the warrant shares will be credited to the warrantholder s account with the Depository Trust Company. The warrants may be exercised in whole or in part.

Payment. The holder shall pay the exercise price in immediately available funds; provided, however, if at any time there is (i) no effective registration statement registering the relevant common stock and (ii) no effective registration statement registering the resale of or no current prospectus available for the resale of the relevant common stock by the holder, the holder may elect to satisfy its obligation to pay the exercise price through a cashless exercise .

Fractional Shares. No fractional shares will be issued upon an exercise of the warrants. If, upon exercise of the warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price.

Limitations on Exercise. The number of shares of our common stock that may be acquired by a holder upon any exercise of a warrant shall be limited so that the total number of shares of our common stock then beneficially owned by such holder does not exceed 9.99% of the total number of issued and outstanding shares of our common stock (including for such purpose the shares of common stock issuable upon such exercise). Our obligation to issue shares of common stock upon the exercise of a warrant shall be suspended until such time, if any, as shares of common stock may be issued in compliance with such limitation. This limitation on exercise will not apply to any holder who owned more than the percentage limitation of our shares set forth above prior to the issuance of the warrants in this offering.

Adjustment. The exercise price and the number of shares underlying the warrants are subject to appropriate adjustment in the event of stock splits, stock dividends on our common stock, stock combinations or similar events affecting our common stock. In addition, in the event we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property, then following such event, the holders of the warrants will be entitled to receive upon exercise of such warrants the kind and amount of securities, cash or other property which the holders would have received had they exercised such warrants immediately prior to such reorganization event.

Rights as Stockholders. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record in all matters to be voted on by stockholders.

Table of Contents

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;
- 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.

Table of Contents

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 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 of 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, 8th Floor, New York, New York 10004. They can be reached via telephone at (212) 509-4000.

Table of Contents

LEGAL MATTERS

Akerman Senterfitt, Miami, Florida, has rendered an opinion with respect to the validity of the securities covered by this prospectus. Certain members, employees and of counsel of that firm beneficially own shares, warrants or options to acquire shares of our common stock.

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.

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.

INCORPORATION OF INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information we have filed with the SEC. The information we incorporate by reference into this prospectus is an important part of this prospectus. Any statement in a document we incorporate by reference into this prospectus will be considered to be modified or superseded to the extent a statement contained in this prospectus or any other subsequently filed document that is incorporated by reference into this prospectus modifies or supersedes that statement. The modified or superseded statement will not be considered to be a part of this prospectus, except as modified or superseded.

We incorporate by reference into this prospectus the information contained in the documents below, which is considered to be a part of this prospectus:

- our Annual Report on Form 10-K for the year ended December 31, 2011, filed with the SEC on March 30, 2012;
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed with the SEC on May 15, 2012;
- our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, filed with the SEC on August 14; 2012;
- our Current Reports on Form 8-K filed with the SEC on February 13, 2012, April 2, 2012, May 16, 2012, May 22, 2012, May 29, 2012, June 5, 2012, June 21, 2012, July 12, 2012 and August 3, 2012;
- 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

Table of Contents

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, or on the SEC s web site, www.sec.gov.

Table of Contents

PART II

INFORMATION NOT REQUIRED IN THIS PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

We estimate that expenses in connection with the distribution (including the May 2012 public offering) described in this registration statement will be as set forth below. We will pay all of the expenses with respect to the distribution and such amounts, with the exception of the Securities and Exchange Commission registration fee, are estimates.

SEC registration fee	$ 2,400
FINRA filing fee	2,285
Legal fees and expenses	170,000
Accounting fees and expenses	68,000
Underwriters expenses payable by the Company	150,000
Miscellaneous expenses	157,012
Total	$ 549,697

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Section 145 of the Delaware General Corporation Law provides for the indemnification of officers, directors, and other corporate agents in terms sufficiently broad to indemnify such persons under certain circumstances for liabilities (including reimbursement for expenses incurred) arising under the Securities Act. The registrant s Restated Certificate of Incorporation and the registrant s Amended and Restated Bylaws provide for indemnification of the registrant s directors, officers, employees and other agents to the extent and under the circumstances permitted by the Delaware General Corporation Law. The registrant has also entered into agreements with its directors and officers that will require the registrant, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent not prohibited by law.

ITEM 16. EXHIBITS

The Exhibit Index that follows the signature page of this registration statement lists the exhibits that are filed with this registration statement, and such Exhibit Index is incorporated herein by reference.

Table of Contents

ITEM 17. UNDERTAKINGS

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously discussed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of the Registration Statement.

(2) That, for the purpose of determining liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of that offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be a part of and included in the registration statement as of the date it is first used after effectiveness; provided, however, that no statement made in a registration statement or prospectus that is a part of the registration statement will, as to a purchaser with a time of contract of sale prior to such use, supersede or modify any statement made in the registration statement or prospectus that was a part of the registration statement or made in any such document immediately prior to such date of first use.

Table of Contents

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement to be signed on behalf of the undersigned, thereunto authorized, in the city of Coral Gables, State of Florida, on the 15th day of August, 2012.

CATALYST PHARMACEUTICAL PARTNERS, INC.

By: /s/ PATRICK J. MCENANY
Patrick J. McEnany
Chairman, President and CEO

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons, in the capacities and on the dates indicated.

Signature	Title	Date
/s/ PATRICK J. MCENANY **Patrick J. McEnany**	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	August 15, 2012
/s/ ALICIA GRANDE **Alicia Grande**	Vice President, Treasurer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 15, 2012
* **Hubert E. Huckel, M.D.**	Director	August 15, 2012
* **Philip H. Coelho**	Director	August 15, 2012
* **David S. Tierney, M.D.**	Director	August 15, 2012
* **Milton J. Wallace**	Director	August 15, 2012
* **Charles B. O Keeffe**	Director	August 15, 2012
* /s/ PATRICK J. MCENANY **Patrick J. McEnany** **as Attorney-In-Fact**		

Table of Contents

INDEX OF EXHIBITS TO REGISTRATION STATEMENT

Exhibit No.	Description of Exhibit
2.1	Agreement and Plan of Merger, dated August 14, 2006, between the Company and Catalyst Pharmaceutical Partners, Inc., a Florida corporation(1)
3.1	Certificate of Incorporation(1)
3.2	Amendment to Certificate of Incorporation(1)
3.3	By-laws (1)
5.1	Opinion of Akerman Senterfitt **
23.1	Consent of Independent Registered Public Accounting Firm*
23.2	Consent of Akerman Senterfitt (included in Exhibit 5.1)**
24.1	Power of Attorney**

(1) Filed by reference to the Company s Registration Statement on Form S-1 (File No. 333-136039)
* Filed herewith
** Previously Filed