

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 424B5

August 28, 2012

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PROSPECTUS SUPPLEMENT

(To Prospectus dated December 15, 2010)

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-170945

4,000,000 Shares of Common Stock

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

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

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

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

There is no established trading market for the warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

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

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

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

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

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

Roth Capital Partners

The date of this prospectus supplement is August 28, 2012

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

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

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FORWARD LOOKING STATEMENTS

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

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

the scope, rate of progress and expense of our non-clinical studies, proof-of-concept studies and clinical studies and trials and other product development activities;

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

whether our studies and trials will be successful;

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

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

whether others develop and commercialize products competitive to our products;

changes in the laws and regulations affecting our business;

our ability to attract and retain skilled employees; and

changes in general economic conditions and interest rates.

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

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SUMMARY

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

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

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

Overview

We are a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction and epilepsy. We have two products in development. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and other central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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

Generally, the process of seeking approval of an NDA requires multiple clinical trials, including two pivotal U.S. Phase III clinical trials. In our case, because CPP-109 is intended to treat a serious condition for which there is no approved therapy, there is a possibility that if the data from the Phase II(b) trial are sufficiently compelling, the FDA will file an NDA submitted by us for CPP-109 on the basis of this trial, when combined with the data from the previous clinical trials and studies of vigabatrin to treat

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addition. However, it is more likely that the FDA will require at least one Phase III trial supported by the safety and efficacy data obtained from our Phase II(b) clinical trial before they will file an NDA for CPP-109, even if the data from our currently ongoing Phase II(b) clinical trial are compelling. Further, even if the FDA files an NDA for CPP-109 based on the results of our current Phase II(b) trial, we currently expect that we will not be in a position to submit an NDA for CPP-109 until August 21, 2014. Finally, if the FDA requires more than one Phase III clinical trial, our NDA submission could be delayed even further. There can be no assurance that the data from our ongoing Phase II(b) trial will be sufficiently compelling or that even if such data are sufficiently compelling, that the FDA will file an NDA submitted for CPP-109 based on the results of that trial.

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

Our Strategy

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

Focus on CPP-109 for cocaine addiction. A treatment for cocaine addiction addresses a significant unmet medical need, and we believe that our receipt of Fast Track status from the FDA for CPP-109 for cocaine addiction may facilitate the regulatory approval process. Enrollment for our U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction that we are conducting with NIDA and the VA began in the first quarter of 2011 and was completed in May 2012. This trial is currently ongoing and we expect to receive top-line results from this trial around the end of September 2012. Assuming success, we expect that this trial will serve as one of the adequate and well-controlled trials required to support approval of an NDA.

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

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

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

Company Information

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

THE OFFERING

Common stock offered by us	4,000,000 shares
Common stock to be outstanding after this offering	34,741,520 shares
Warrants offered by us	Each share of common stock is being sold together with 0.30 of a warrant to purchase one share of common stock at an exercise price of \$2.08 per share. The warrants will be exercisable immediately upon issue and will expire five years from the date of issuance. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants. See Description of Securities.
Use of proceeds	We intend to use the net proceeds from the sale of the securities: (i) to fund our product development efforts, and (ii) for general corporate purposes. See Use of Proceeds on page S-21 for additional information.
Risk Factors	See Risk Factors on page S-5 for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NASDAQ Capital Market listing	Our common stock is listed on the NASDAQ Capital Market under the symbol CPRX. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.
The number of shares of our common stock to be outstanding after this offering as shown above is based on 30,741,520 shares outstanding as of August 27, 2012 and excludes:	

2,019,888 shares of our common stock subject to outstanding options under our 2006 Stock Incentive Plan having a weighted average exercise price of \$1.19 per share;

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729,610 shares of our common stock subject to outstanding options outside of our 2006 Stock Incentive Plan having a weighted average exercise price of \$0.69 per share;

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

1,523,370 shares of our common stock that have been reserved for issuance upon exercise of outstanding warrants at an exercise price of \$1.30 per share;

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

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

RISK FACTORS

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

Risks Related to Our Business

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

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

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

We have had no revenues from product sales to date, currently have no products available for commercial sale, and have never had any products available for commercial sale. We expect to incur losses at least until we can commercialize CPP-109. Our net loss was \$6,391,062 for the year ended December 31, 2011 and \$1,378,266 for the six months ended June 30, 2012, and as of June 30, 2012 we had a deficit accumulated during the development stage of \$39,480,883. We may never obtain approval of an NDA for CPP-109 or CPP-115 and may never achieve profitability.

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Our business will require additional capital.

Our business will require additional capital to meet our product development objectives. We presently have funds that will allow us to complete the U.S. Phase II(b) clinical trial of CPP-109 that we are jointly conducting with NIDA and the VA. Based on currently available information and without considering the net proceeds of this offering, we estimate that we have sufficient working capital to support our operations through the end of the first quarter of 2014. The expectations described above are based on current information available to us. If the cost of these studies is greater than we expect, or it takes longer to complete and obtain the results of these studies, our assumptions may not prove to be accurate.

At the present time, we will require additional funding to complete studies or trials other than those described above, including any Phase III clinical trial that we may be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction and any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and epilepsy. Since these studies and trials have not yet been developed, we cannot estimate what our funding requirements will be with respect to such additional studies and trials. We will also require additional working capital to support our operations beyond the first quarter of 2014 (without considering the proceeds of this offering). There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

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

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

Our business is subject to substantial competition.

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

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

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

Our business exposes us to potential liability risks that may arise from the clinical testing, manufacture, and/or sale of CPP-109 or CPP-115. Patients have received substantial damage awards in some jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of pharmaceutical products used in clinical trials or after FDA approval. Liability claims may be expensive to defend and may result in large judgments against us. We currently carry liability insurance with an aggregate annual coverage limit of \$15,000,000 per claim and \$15,000,000 in the aggregate, with a deductible of \$10,000 per occurrence. Our insurance may not reimburse us for certain claims or the coverage may not be sufficient to cover claims made against us. We cannot predict all of the possible harms or side effects that may result from the use of CPP-109, CPP-115 or any potential future products we may acquire and use in clinical trials or after FDA approval and, therefore, the amount of insurance coverage we currently hold may not be adequate to cover all liabilities we might incur. If we are sued for any injury allegedly caused by our products, our liability could exceed our ability to pay the liability. Whether or not we are ultimately successful in any adverse litigation, such litigation could consume substantial amounts of our financial and managerial resources, all of which could have a material adverse effect on our business, financial condition, results of operations, prospects and stock price.

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

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

Risks Related to the Development of Our Drug Candidates

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

There is limited clinical evidence currently indicating that CPP-109 will be a safe and effective treatment for any addiction in humans. To date, one double-blind, placebo controlled trial and two open-label clinical studies have been completed in Mexico relating to the use of vigabatrin in the treatment of cocaine addiction and methamphetamine addiction. Only 76 persons receiving vigabatrin completed these trials in the aggregate. Further, these studies were conducted in Mexico at a single substance abuse center and were not subject to FDA oversight in any respect, including study design and protocol. In the U.S., one double-blind, placebo

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controlled trial and one double-blind, placebo controlled proof-of-concept study have been completed. Only 121 persons in the aggregate received CPP-109 (vigabatrin) in these trials. None of these studies, individually or in the aggregate, provided enough evidence regarding safety or efficacy to support an NDA filing with the FDA. Further, approximately 200 persons have received vigabatrin in clinical trials assessing its efficacy to treat addiction, which is a limited number of subjects.

Our product development efforts may fail.

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

CPP-109 or CPP-115 may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;

CPP-109 or CPP-115 may not be economical to market or take substantially longer to obtain necessary regulatory approvals than anticipated; or

Competitors may market equivalent or superior products.

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

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

We will only obtain regulatory approval to commercialize CPP-109 or CPP-115 if we can demonstrate to the satisfaction of the FDA (or the equivalent foreign regulatory authorities) in adequate and well-controlled clinical studies and trials that the drug is safe and effective for its intended use and that it otherwise meets approval requirements. A failure of one or more pre-clinical or clinical studies can occur at any stage of product development. We may experience numerous unforeseen events during, or as a result of, testing that could delay or prevent us from obtaining regulatory approval for, or commercializing our product candidates, including but not limited to:

regulators or institutional review boards (IRBs) may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

conditions may be imposed upon us by the FDA regarding the scope or design of our clinical trials, or we may be required to resubmit our clinical trial protocols to IRBs for reinspection due to changes in the regulatory environment;

the number of subjects required for our clinical trials may be larger than we anticipate, patient enrollment may take longer than we anticipate, or patients may drop out of our clinical trials at a higher rate than we anticipate;

we may have to suspend or terminate one or more of our clinical trials if we, regulators, or IRBs determine that the participants are being subjected to unreasonable health risks;

our third-party contractors, clinical investigators or contractual collaborators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;

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our tests may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional testing; and

the costs of our pre-clinical and/or clinical trials may be greater than we anticipate.

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

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

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

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

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

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

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

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such studies and trials to assure that the data and the results are credible and accurate and that the human study and trial participants are adequately protected. Our reliance on third parties does not relieve us of these obligations and requirements, and we may fail to obtain regulatory approval for our product candidates if these requirements are not met.

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

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

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

We may encounter difficulties in our future clinical studies and trials recruiting patients due to the nature of the addiction mechanism and our resulting target patient population. Because addicts are typically addicted to multiple substances, we may not be able to recruit a sufficient number of eligible participants within our anticipated timeframe or at all. In addition, due to the neurological and physiological mechanisms and implications of substance addiction, it is likely that many of our clinical study and trial participants will either not comply with trial protocols, or not complete the study or trial. An unusually low rate of compliance or completion will present challenges, such as determining the statistical significance of study or trial results. Additionally, we compete for study and trial subjects with others conducting clinical trials testing other treatments for addictions. Finally, unrelated third parties and investigators in the academic community have expressed interest in testing vigabatrin for the treatment of drug abuse. If these third-party tests are unsuccessful, or if they show significant health risk to the test subjects, our development efforts may also be adversely affected.

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Risks Related to Commercialization of our Drug Candidates

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

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

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

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

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

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

If we are successful in obtaining approval to commercialize CPP-109 or CPP-115, we will need to significantly expand our operations, which could put significant strain on our management and our operational and financial resources. We currently have six employees and conduct much of our operations through outsourcing arrangements. To manage future growth, we will need to hire, train, and manage additional employees. Concurrent with expanding our operational and marketing capabilities, we will also need to

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increase our product development activities. We may not be able to support, financially or otherwise, future growth, or hire, train, motivate, and manage the required personnel. Our failure to manage growth effectively could limit our ability to achieve our goals.

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

Any clinical trials we might develop and implement may not be completed in a timely manner or at all. Our product candidates may not be found to be safe and effective, and may not be approved by regulatory authorities for the proposed indication. Further, regulatory authorities and IRBs that must approve and monitor the safety of each clinical study may suspend a clinical study at any time if the patients participating in such study are deemed to be exposed to any unacceptable health risk. We may also choose

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to suspend human clinical studies and trials if we become aware of any such risks. We might encounter problems in our clinical trials, including problems associated with VFDs or other side effects that will cause us, regulatory authorities, or IRBs to delay or suspend such trial or study.

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

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

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

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

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

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

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

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

reliance on the third party for regulatory compliance and quality assurance;

reliance on the continued financial viability of the third parties;

limitations on supply availability resulting from capacity and scheduling constraints of the third parties;

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

All of our patent rights for CPP-109 are derived from our license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven). Pursuant to this license agreement, we have licensed rights under nine patents in the United States, and have broad foreign filings in major international markets, that were filed and obtained by Brookhaven relating to the use of vigabatrin for a range of indications, including the treatment of a wide variety of substance addictions. The eight issued patents expire between 2018 and 2022, with the principal patents expiring in 2018. We also have the right to future foreign patents obtained by Brookhaven relating to the use of vigabatrin in treating addiction. These rights are subject to the right of the U.S. government, under limited circumstances, to practice the covered inventions for or on its own behalf. We may lose our rights to these patents and patent applications if we breach our

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obligations under the license agreement, including, without limitation, our financial obligations to Brookhaven. If we violate or fail to perform any term or covenant of the license agreement, Brookhaven may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Brookhaven, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-109, and our business, results of operations, financial condition and prospects would be materially adversely affected.

All of our patent rights for CPP-115 are derived from our license agreement with Northwestern University (Northwestern). Pursuant to this license agreement, we have exclusive worldwide rights to two patents in the United States. These were filed and obtained by Northwestern relating to compositions of matter for a class of molecules, including CPP-115. Both patents expire in 2023. Additionally, we have licensed rights from Northwestern to a pending patent for derivatives of vigabatrin that are unrelated to CPP-115. These rights are subject to the right of Northwestern, under limited circumstances, to practice the covered inventions for or on its own behalf for research. We may lose our rights to these patents and patent applications if we breach our obligations under the license agreement, including, without limitation, our financial obligations, including milestone payments, to Northwestern. If we violate or fail to perform any term or covenant of the license agreement, Northwestern may terminate the license agreement upon satisfaction of any applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of the license agreement, whether by us or by Northwestern, will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under the license agreement, we would not be able to commercialize CPP-115, and our business, results of operations, financial condition and prospects would be materially adversely affected.

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

If we obtain approval to market CPP-109 or CPP-115, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by Brookhaven and Northwestern, respectively, to exclude others from competing with us. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims