

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form POS AM

December 02, 2013

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As filed with the Securities and Exchange Commission on December 2, 2013

Registration No. 333-170945

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2

TO

FORM S-3

REGISTRATION STATEMENT

*UNDER*

*THE SECURITIES ACT OF 1933*

CATALYST PHARMACEUTICAL PARTNERS, INC.

(Exact Name of Registrant as Specified in Its Charter)

<b>Delaware</b> <b>(State or Other Jurisdiction</b>	<b>2834</b> <b>(Primary Standard Industrial</b>	<b>76-0837053</b> <b>(I.R.S. Employer</b>
<b>of Incorporation or Organization)</b>	<b>Classification Code Number)</b> <b>355 Alhambra Circle</b>	<b>Identification Number)</b>

**Suite 1500**

**Coral Gables, Florida 33134**

**(305) 529-2522**

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

**Patrick J. McEnany**

**Catalyst Pharmaceutical Partners, Inc.**

**355 Alhambra Circle, Suite 1500**

**Coral Gables, Florida 33134**

**(305) 529-2522**

**(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)**

*Copy to:*

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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.

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

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**EXPLANATORY NOTE**

On December 15, 2010, the Company's Registration Statement on Form S-3 (Registration No. 333-170945), registering for sale \$30,000,000 of the Company's securities (the Registration Statement), became effective. On September 4, 2013, the Company registered an additional \$2,612,336 of securities under the Registration Statement on a Registration Statement on Form S-3MEF (Registration No. 333-190996). This Post-Effective Amendment No. 2 to Registration Statement on Form S-3 (this Post-Effective Amendment No. 2) is filed to report that, except as set forth below, all securities registered under the Registration Statement have been sold.

This Post-Effective Amendment No. 2 is being filed to continue the registration of the shares of common stock issuable from time to time upon the exercise of the common stock purchase warrants that were issued to purchasers in connection with sales of common shares and warrants previously completed under the Registration Statement. As of the date of this Post-Effective Amendment No. 2, common stock purchase warrants to purchase an additional 2,454,870 shares of common stock that were sold in offerings completed under the Registration Statement remain outstanding.

All fees pursuant to this Registration Statement have previously been paid and no fees are due upon the filing of this Post-Effective Amendment No. 2.

The Registrant hereby amends this Post-Effective Amendment No. 2 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 Post-Effective Amendment No. 2 shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Post-Effective Amendment No. 2 shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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**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 DECEMBER 2, 2013**

**Preliminary Prospectus**

**2,454,870 Shares of Common Stock Issuable**

**Upon the Exercise of Outstanding Warrants**

We are offering up to 2,454,870 shares of our common stock ( Shares ) upon the exercise of currently outstanding common stock purchase warrants (the Warrants ). The Shares and Warrants relate to offerings previously conducted under this Registration Statement, as follows: (i) 1,254,870 shares of our common stock that are issuable for a purchase price of \$1.30 per share from time to time upon the exercise of currently outstanding five-year warrants that we issued in a registered direct offering completed in October 2011, and (ii) 1,200,000 shares of our common stock that are issuable for a purchase price of \$2.08 per share from time to time upon the exercise of currently outstanding five-year warrants that were issued in a registered direct offering completed in August 2012. No securities are being offered pursuant to this prospectus other than the shares of our common stock that will be issued upon the exercise of those currently outstanding common stock purchase warrants.

Our common stock is listed on the Nasdaq Capital Market under the symbol CPRX . On November 29, 2013, the last reported price per share of our common stock as reported on the Nasdaq Capital Market was \$1.72 per share.

**Our business and investing in our securities involves significant risks. You should carefully read and consider the Risk Factors beginning on page 4 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 \_\_\_\_\_, 2013**

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**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.

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**SUMMARY**

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

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

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

**Our Business**

We are a development-stage specialty pharmaceutical company focused on the development and commercialization of novel prescription drugs targeting rare (orphan) neuromuscular and neurological diseases and disorders. We have three pharmaceutical products in development:

**Firdapse**

In October 2012, we licensed the North American rights to Firdapse , a proprietary form of amifampridine phosphate, or chemically known as 3,4-diaminopyridine phosphate, from BioMarin Pharmaceutical Inc. (BioMarin). As part of our agreements with BioMarin, we have taken over the sponsorship of an ongoing Phase 3 clinical trial evaluating Firdapse for the treatment of Lambert-Eaton Myasthenic Syndrome, or LEMS, a rare and sometimes fatal autoimmune disease characterized by muscle weakness. We also hope to evaluate Firdapse for the treatment of other neuromuscular orphan indications such as Congenital Myasthenic Syndrome and Myasthenia Gravis. We have recently been granted breakthrough therapy designation by the U.S. Food & Drug Administration (FDA) for Firdapse™ for the treatment of LEMS.

Neither the chemical entity 3,4-diaminopyridine (3,4-DAP) nor its phosphate salt has ever been approved by the FDA for any indication. If we are the first pharmaceutical company to obtain approval for 3,4-diaminopyridine or its phosphate salt, we will be eligible to receive five years of marketing exclusivity with respect to the use of this product for any indication. Further, since Firdapse for the treatment of LEMS has previously been granted Orphan Drug Designation by the FDA, if we are the first company to obtain approval of 3,4-diaminopyridine or its phosphate salt, it would make us eligible to receive seven years of marketing exclusivity for this indication.

The Phase 3 trial is designed as a randomized double-blind, placebo-controlled discontinuation study followed by an open-label extension period in approximately 36-patients across 22 sites in the United States, Canada and Europe. We also expect to add at least 3 additional sites in the United States (U.S.), South America and Europe in the near future. Based on currently available information, we expect that we will complete enrollment in our trial around the end of the year and that we will report top-line results from the double-blind portion of this Phase 3 trial during the second quarter of 2014 (and, if the trial results are successful, we expect to submit a new drug application (NDA) to the FDA in the first half of 2015).

Further, an interim safety analysis was recently performed by the independent Data Monitoring Committee that is part of the routine oversight of the Phase 3 trial. Following this meeting, the committee recommended that we continue the trial as planned. This recommendation is based on the committee's review of unblinded safety and clinical data available from the on-going Phase 3 trial.





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### **CPP-115**

We are in the early stages of developing CPP-115, a GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is a more potent form of vigabatrin, but may have fewer side effects (e.g., visual field defects, or VFDs) than those associated with vigabatrin. We are hoping to develop CPP-115 for the treatment of epilepsy (initially infantile spasms) and for the treatment of other selected central neurological indications. CPP-115 has been granted Orphan Drug Designation by the FDA for the treatment of infantile spasms and Orphan Medicinal Product Designation in the European Union, or E.U., for West's syndrome (a form of infantile spasms). We plan to begin a multi-dose safety and tolerance study of CPP-115 during the first half of 2014.

### **CPP-109**

For several years, we evaluated CPP-109 (our formulation of vigabatrin, another GABA aminotransferase inhibitor) for the treatment of cocaine addiction. However, CPP-109 recently failed to meet the primary and two key secondary endpoints in a Phase 2(b) trial for cocaine addiction. As a result, we are no longer focusing our efforts on evaluating CPP-109 for addiction. In that regard, on November 8, 2013, effective October 1, 2013, we terminated our license agreement with Brookhaven National Laboratories under which we had previously been licensed nine patents relating to the use of vigabatrin as a treatment of a wide variety of substance addictions.

An academic investigator proof-of-concept study evaluating the use of CPP-109 for the treatment of Tourette Syndrome is currently ongoing and, if the results of that study show evidence of reduced number of tics, we will likely seek to develop CPP-109 or CPP-115 (which has the same mechanism of action as CPP-109) for this indication. Based on currently available information, we expect to have top line results for this academic investigator proof-of-concept study during the first half of 2014.

### **Recently Filed Securities Class Action Lawsuits**

In October and November 2013, three securities class action lawsuits were filed against us and certain of our executive officers and directors seeking unspecified damages in the U.S. District Court for the Southern District of Florida. The complaints purport to state a claim for violation of federal securities laws on behalf of a class of those who purchased our common stock between October 31, 2012 and October 18, 2013. In general, the complaints allege, among other things, that during the period between October 31, 2012 and October 18, 2013, we made alleged misrepresentations regarding the development of Firdapse. We expect that these lawsuits will be consolidated into a single class-action lawsuit. We believe that these lawsuits, which are at a very early stage, are without merit, and we intend to vigorously defend these lawsuits. While there can be no assurance, we do not expect these lawsuits to have a material adverse effect on us.

### **Company Information**

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

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**THE OFFERING**

<b>Securities being offered by us</b>	2,454,870 shares of our common stock issuable upon the exercise of the Warrants.
<b>Common stock to be outstanding after this offering if all of the warrants are exercised</b>	56,587,807 shares
<b>Use of proceeds</b>	We intend to use the net proceeds from the exercise of the warrants for general corporate purposes. See <i>Use of Proceeds</i> for further information.
<b>Risk Factors</b>	See <i>Risk Factors</i> , 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, if all of the warrants are exercised, as shown above is based on 56,587,807 shares outstanding as of December 2, 2013 (including: (i) 146,000 shares issued in October 2013 upon the exercise of outstanding common stock purchase warrants, and (ii) the 2,454,870 shares offered hereby) and excludes:

2,699,296 shares of our common stock subject to outstanding options under our 2006 Stock Incentive Plan having a weighted average exercise price of \$0.83 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;

217,604 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan; and

2,393,750 shares of our common stock that have been reserved for issuance upon the exercise of outstanding common stock purchase warrants at an exercise price of \$1.04 per share.



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**RISK FACTORS**

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

**Risks Related to Our Business**

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

We are a development stage company and, 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 business without revenues, especially in the pharmaceutical industry, where failures of 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 are in a position to commercialize Firdapse, which may never occur. Our net loss was \$4,076,386 and \$10,799,938 for the year ended December 31, 2012 and nine months ended September 30, 2013, respectively, and as of September 30, 2013 we had a deficit accumulated during the development stage of \$52,978,941. We may never obtain approval of an NDA for any of our product candidates and we may never achieve profitability.

***Our business will require additional capital.***

Without considering the proceeds from this offering, our business will require additional capital to meet our product development objectives. Based on currently available information, we estimate that we have sufficient working capital to support our operations through the end of 2014. The expectations described above are based on current information available to us. If the cost of our ongoing studies are greater than we expect, our assumptions may not prove to be accurate. There can be no assurance as to the exact amount of the funding we will require or as to whether any such required funding will be available to us when it is required.

We plan to raise additional funds in the future through public or private equity offerings, debt financings, capital lease transactions, corporate collaborations, governmental research grants or cost sharing arrangements with the National Institute of Neurological Disorders and Stroke (NINDS) or other appropriate agencies that operate under the umbrella of the National Institutes of Health 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.



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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 required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise 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 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.

***If we are not the first to get approval for Firdapse for the treatment of LEMS, we may not be able to bring it to market.***

In January of 2012, another pharmaceutical company began its own Phase 2 trial studying their own formulation of 3-4,DAP for the treatment of LEMS. While there can be no assurance we believe that Firdapse is further along in development and as a result we expect that we will be in a position to file an NDA first for 3-4,DAP and its phosphate salts. Under the Orphan Drug Act of 1983, the first pharmaceutical product to get approval for an indication receives the orphan exclusivity under the statute. If another pharmaceutical company is able to receive approval of an NDA for its formulation of 3-4,DAP for the treatment of LEMS before we are able to receive approval of Firdapse for the same indication, we would be barred from marketing Firdapse in the United States during the seven-year orphan exclusivity period, which would have a severe adverse effect on our results of operations. In addition, if another company were to receive five-year new chemical entity exclusivity for 3-4,DAP for any indication prior to approval of Firdapse, we would be barred from marketing Firdapse in the United States during this five-year exclusivity period.

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

Our development of CPP-115 is at an early stage, and it is going to be several years before we are in a position to file an NDA for CPP-115, if our future clinical trials of this product are successful. 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 or commercialize CPP-115.

***Our business is subject to substantial competition.***

The biotechnology and pharmaceutical industries are highly competitive. 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 than we have. We compete against pharmaceutical companies that are developing or currently marketing therapies that will compete with our product candidates. In addition, we compete against biotechnology companies, universities, government agencies, and other research institutions in the development of pharmaceutical products. While we believe that our product candidates will offer advantages over many of the currently available competing therapies, our business could be negatively impacted if our competitors' present or future offerings are more effective, safer or less expensive than ours, or more readily accepted by regulators, healthcare providers or third-party payers. For example, amifampridine, the active ingredient in Firdapse, has been available from compounding pharmacies for several years and will likely be available even if we are able to obtain FDA approval of Firdapse. Compounded amifampridine is expected to be substantially less expensive than Firdapse. The FDA Advisory Committee on Compounding, however, has previously issued a list of drugs

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which should not be compounded, and amifampridine was included on that list. Drugs that are not approved by FDA for the treatment of LEMS, such as dalfampridine, may nonetheless be prescribed by physicians for the treatment of LEMS. Further, 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 our pharmaceutical products. 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 our current product candidates, 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**

### ***Our product development efforts may fail.***

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

Our product candidates may be found to be ineffective or unsafe, or fail to receive necessary regulatory approvals;

Our product candidates 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. For example, for several years, we evaluated CPP-109 (our formulation of

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vigabatrin) for the treatment of cocaine addiction. However, CPP-109 recently failed to meet the primary and two key secondary endpoints in a Phase 2(b) trial for cocaine addiction, and we are no longer pursuing the evaluation of CPP-109 for addiction. Further, our lead compound, Firdapse , is for a very rare condition for which there is no effective FDA-approved treatment. As such, the clinical development plan we are pursuing after consulting with FDA including the endpoint, protocol design, and statistical analysis plan, may not allow the FDA to conclude that our Phase 3 trial of Firdapse is adequate to establish the clinical benefit of the drug. In addition, FDA has indicated that additional data from published studies, and data from a patient registry, would be useful in establishing the safety of Firdapse but we may not be able to obtain that data in a form that is satisfactory to the FDA. 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 our product candidates 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. As we have experienced in the past, a failure of one or more pre-clinical or clinical trials or 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, patient enrollment may take longer, 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

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

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

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, and third-party contract 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, 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, including Good Laboratory Practice (GLP) and Good Clinical Practice (GCP), 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.

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

In order to generate sales of any 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 requirement 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



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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 our product candidates.

***We may not be able to sufficiently scale-up manufacturing of our product candidates***

To date, our product candidates have been manufactured in small quantities for pre-clinical studies and clinical trials. In order to conduct larger trials for a product candidate and for commercialization of the resulting drug product if that product candidate is approved for sale, we will need to manufacture in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our product candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. If a contract manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to those improvements. Significant scale-up of manufacturing may require additional validation studies, which are costly and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up manufacture of any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed or there may be a shortage in supply, which could significantly harm our business.

***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 Firdapse or any of our other product candidates, 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 seven 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.

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### ***Our commercial success depends on reimbursement from third-party and governmental insurers.***

Sales of pharmaceutical products in the United States depend largely on reimbursement of patients' costs by private insurers, government health care programs including Medicare and Medicaid, and other organizations. These third-party 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 any 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 Processes (cGMP). We will also have to meet similar regulations in any foreign country where we may seek to commercialize our product candidates. 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 product candidates 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.

The FDA and other regulatory bodies must approve trade names for products. The FDA typically conducts a thorough review of a proposed trade name, including an evaluation of potential confusion with other trade names. We have not submitted a request for FDA approval of the trade name Firdapse. We may be required to submit an alternate trade name for FDA review, which could delay our ability to market the product.

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***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 our product candidates, we may have to conduct, at our own expense, pre-clinical tests in animals in order to support the safety of our product candidates. 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 are in the process of conducting a Phase 3 clinical trial for Firdapse and are currently planning further clinical trials for CPP-115. Even if the results of our clinical trials are promising, Firdapse may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Future clinical trials for Firdapse or CPP-115 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.

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 Visual Field Defects (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 Firdapse, CPP-115 or any other product we develop or license 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.

***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 current and future clinical studies and trials recruiting patients, particularly since the conditions we are studying are rare conditions. We compete for study and trial subjects with others conducting clinical trials testing other treatments for the indications we are studying for our product candidates. Further, unrelated third parties and investigators in the academic community have expressed interest in testing our product candidates. 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.

***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





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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;

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 impacted by the viability of our 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 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

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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.

As a condition of NDA approval for some of our products, the FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. For example, approved versions of vigabatrin, the active moiety in our CPP-109 product (which operates by the same mechanism of action as our CPP-115 product) were approved with an FDA-mandated REMS program due to the risks of visual field damage and are only available through a special restricted distribution program approved by the FDA. If any of our products were to be approved with a REMS, the potential market and profitability of the drug could be materially affected.

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.

## **Risks Related to Our Dependence on Third Parties**

***We are dependent on our relationship and license agreements, and we rely upon the patent rights granted to us pursuant to the license agreements.***

All of our patent rights for Firdapse are derived from our license agreement with BioMarin. Pursuant to this license agreement, we have licensed rights under BioMarin's Firdapse patent in the United States, which expire in 2022. 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 BioMarin. If we violate or fail to perform any term or covenant of the license agreement, BioMarin 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 BioMarin, 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 Firdapse , and our business, results of operations, financial condition and prospects would be materially adversely affected.

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All of our patent rights for CPP-115 are derived from our license agreement with Northwestern University. 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 Firdapse, CPP-115 or CPP-109, our commercial success will depend in large part on our ability to use patents, especially those licensed to us by BioMarin 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 attempt to design around our patents or 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 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, 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.



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Although we believe there are a number of other parties with which we could engage to continue these activities, it may cause a delay in the affected study or trial and/or increase the cost of such study or trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

### **Risks Related to Our Intellectual Property**

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

While we are not currently aware of any third-party patents which we may infringe, there can be no assurance that we do not or will not infringe on patents held by third parties or that third parties will not claim that we have infringed on their patents. In the event that our technologies infringe or violate the patent or other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing or commercialization of our products that utilize such technologies. There may be patents held by others of which we are unaware that contain claims that our products or operations infringe. In addition, given the complexities and uncertainties of patent laws, there may be patents of which we are aware that we may ultimately be held to infringe, particularly if the claims of the patent are determined to be broader than we believe them to be. Adding to this uncertainty, in the U.S., patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, avoiding patent infringement may be difficult.

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

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

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

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

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.

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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. 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**

*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 agreement 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 our product candidates 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, conflicts may arise from the work in which other scientific advisers and/or collaborators are involved.

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*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 BioMarin and Northwestern), research contracts or other collaboration agreements;

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

intellectual property, product liability or other litigation against us;

changes in the market valuations of similar companies;

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

changes in economic conditions; and

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

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

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*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.

The intent of the stockholder rights plan is to protect our stockholders' interests by encouraging anyone seeking control of our company to negotiate with our board of directors. However, our stockholder rights plan could make it more difficult for a third party to acquire us without the consent of our board of directors, even if doing so may be beneficial to our stockholders. This plan may discourage, delay or prevent a tender offer or takeover attempt, including offers or attempts that could result in a premium over the market price of our common stock. This plan could reduce the price that shareholders might be willing to pay for shares of our common stock in the future. Furthermore, the anti-takeover provisions of our stockholder rights plan may entrench management and make it more difficult to replace management even if the stockholders consider it beneficial to do so.

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.

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

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

As of December 2, 2013 we had 54,132,937 shares of our common stock outstanding, of which 5,674,316 shares were held by our officers and directors. We also had outstanding: (i) common stock purchase warrants to purchase an aggregate of 4,848,620 additional shares of our common stock (including those offered pursuant to this Registration Statement) at exercise prices ranging from \$1.04 to \$2.08 per share, and (ii) stock options to purchase an aggregate of 3,428,906 shares at exercise prices ranging from \$0.47 to \$6.00 per share (2,745,574 of which are currently exercisable). Sales of restricted shares or shares underlying stock options and common stock purchase warrants, 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.

***Our Board of Directors has the ability to issue blank check preferred stock.***

Our Certificate of Incorporation authorizes the issuance of up to 5,000,000 shares of blank check preferred stock, with such designation rights and preferences as may be determined from time to time by our Board of Directors. Our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the voting power or other rights of the holders of our common stock. In the event of such issuances, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company, pursuant to our stockholder rights plan. Although we have no present intention to issue any additional shares of our preferred stock, there can be no assurance that we will not do so in the future.

***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.

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**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This Post-Effective Amendment No. 2 to Registration Statement on Form S-3 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 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 report are based on current expectations that involve numerous risks and uncertainties.

The successful development of our product candidates 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 our product candidates;

whether the third parties we retain to assist us in our trials and studies perform as contracted for and within the budgets established for their activities;

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

the risk that another pharmaceutical company will receive an approval for its formulation of 3-4,DAP for the treatment of LEMS before us;

whether others develop and commercialize products competitive to our products;



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changes in the laws and regulations affecting our business;

the impact of the class action lawsuits filed against us;

our ability to attract and retain skilled employees; and

changes in general economic conditions and interest rates.

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For further information regarding the risks associated with our business, see the Risk Factors section beginning on page 4 of this prospectus and the Risk Factors section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

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 report, 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.

**USE OF PROCEEDS**

We estimate that the net proceeds of this offering will be approximately \$4.1 million (if all of the Warrants are exercised). We currently expect to use the net proceeds of this offering 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 September 30, 2013 was \$22,119,075, or approximately \$0.41 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 September 30, 2013.

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 2,454,870 shares of common stock in this offering at an exercise price of \$1.30 per share or \$2.08 per share, as applicable, our as adjusted net tangible book value as of September 30, 2013 would have been \$26,246,406, or approximately \$0.47 per share of our common stock. This represents an immediate increase in net tangible book value of \$0.06 per share of common stock to our already existing stockholders and an immediate dilution in net tangible book value of \$0.83 per share of common stock to holders of the warrants exercisable at \$1.30 per share and \$1.61 per share of common stock to holders of the warrants exercisable at \$2.08 per share, as applicable, to purchasers in this offering. The following table illustrates this per share dilution:

Public offering price per share		\$ 1.30/\$2.08
Net tangible book value per share as of September 30, 2013	\$ 0.41	
Increase per share attributable to this offering	\$ 0.06	
As adjusted net tangible book value per share as of September 30, 2013	\$ 0.47	
Dilution per share to investors participating in this offering		\$ 0.83/\$1.61

The above table is based on 53,986,937 shares outstanding as of September 30, 2013 and excludes:

The shares of common stock offered hereby that are issuable upon exercise of the warrants issued as part of our October 2011 and August 2012 public offerings;

2,759,296 shares of our common stock subject to outstanding options under our 2006 Stock Incentive Plan having a weighted average exercise price of \$0.86 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;

217,604 shares of our common stock that have been reserved for issuance in connection with our 2006 Stock Incentive Plan;

2,393,750 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

146,000 shares of our common stock that were issued upon the exercise of warrants subsequent to September 30, 2013.

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.

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**PLAN OF DISTRIBUTION**

We will deliver shares of our common stock upon exercise of the Warrants, a portion of which were issued in October 2011 and a portion of which was issued in August 2012. As of the date of this prospectus, these warrants were exercisable for a total of 2,454,870 shares of our common stock, and no more of these warrants will be issued under this Registration Statement. 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 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 October 2011 Warrants* and *Description of Securities we are offering August 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 54,132,937 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



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attempts not first approved by the board of directors (including takeovers which certain stockholders may deem to be in their best interests). To the extent takeover attempts are discouraged, temporary fluctuations in the market price of the common stock, which may result from actual or rumored takeover attempts, may be inhibited. These provisions, together with the ability of the board to issue preferred stock without further stockholder action, also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders, even if such removal or assumption would be beneficial to our stockholders. These provisions also could discourage or make more difficult a merger, tender offer or proxy contests, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of the common stock. The board of directors believes that these provisions are appropriate to protect our interest and the interests of our stockholders.

Issuance of Rights. 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.





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### **October 2011 Warrants**

The following summary description of the material features of the warrants we issued in October 2011 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 \$1.30 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.

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

**Exercise Price.** The exercise price of the warrant is \$1.30 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, stock issuances, reclassifications or similar events affecting our common stock.

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

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

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

**Fundamental Transactions.** In the event of a fundamental transaction involving our consolidation or merger with or into another entity where we are not the surviving entity, the sale of all or substantially all of our properties or assets or the reorganization, recapitalization or reclassification of our common stock or our liquidation, it is a condition to such fundamental transaction that any successor to us assume all of our obligations under the warrants and deliver in exchange for the warrants a written instrument substantially similar to the warrants entitling the holder to acquire the successor's capital stock at an exercise price that reflects the terms of the transaction. In addition, in the event of a fundamental transaction that is an all-cash transaction, a going private transaction or a transaction with a person or entity not traded on an eligible securities market, then we or any successor entity shall pay at the holder's option, exercisable at any time commencing on the earlier of the public disclosure of the fundamental transaction or the consummation of the fundamental transaction and continuing for 90 days after the public disclosure of the consummation of the fundamental transaction, an amount of cash equal to the value of the warrant as determined in accordance with the Black Scholes option pricing model.



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

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

**Trading.** The warrants are not traded on the Nasdaq Capital Market and are not listed on any national securities exchange or any other nationally recognized trading system. No market has, to date, developed for the warrants and we do not expect a market for the warrants to develop in the future.

## **August 2012 Warrants**

The following summary description of the material features of the warrants we issued in August 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 \$2.08 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.

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

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

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

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

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



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

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

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

**Trading.** The warrants are not traded on the Nasdaq Capital Market and are not listed on any national securities exchange or any other nationally recognized trading system. No market has, to date, developed for the warrants and we do not expect a market for the warrants to develop in the future.

## **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;

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

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

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

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

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

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

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

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

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

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

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

Delaware law provides that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which our directors and officers may be entitled to under our bylaws, any agreement, a vote of stockholders or otherwise. Our certificate of incorporation and bylaws eliminate the personal liability of directors to the maximum extent permitted by Delaware law. In addition, our certificate of incorporation and bylaws provide that we may fully indemnify any person who is or was a party to or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding (whether civil, criminal, administrative or investigative) by reason of the fact that such person is or was one of our directors, officers, employees or other agents, against expenses (including attorneys

fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding.



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### **Listing**

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

### **Transfer Agent and Registrar**

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

## **LEGAL MATTERS**

Akerman LLP, Miami, Florida, has rendered an opinion with respect to the validity of the securities covered by this prospectus. Certain partners and employees 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 and elsewhere in the registration statement 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, 2012, filed with the SEC on April 1, 2013;

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our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, filed with the SEC on May 15, 2013;

our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed with the SEC on August 14, 2013;

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our Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, filed with the SEC on November 13, 2013;

our Current Reports on Form 8-K (or amendments thereto) filed with the SEC on January 4, 2013, February 14, 2013, February 26, 2013, March 27, 2013, April 2, 2013, May 16, 2013, June 3, 2013, June 17, 2013, June 25, 2013, June 27, 2013, August 2, 2013, August 15, 2013, August 22, 2013, August 27, 2013, August 29, 2013, September 5, 2013, September 10, 2013, October 15, 2013, October 25, 2013, October 29, 2013 and November 14, 2013;

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

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.

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

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN THIS PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth all expenses to be paid (or previously paid) by the registrant, other than underwriting discounts and commissions, in connection with this offering and previous filings with regard to the original Registration Statement. All amounts shown are estimates except for the registration fee.

SEC registration fee	\$ 2,495
Legal fees and expenses	20,000
Accounting fees and expenses	10,000
Miscellaneous expenses	5,000
<b>Total</b>	<b>\$ 37,495</b>

**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.

**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, as amended (the Securities Act );

(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

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(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information to be included in a post-effective amendment by those paragraphs is contained in reports furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are incorporated by reference into this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is a part of this registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, 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 the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is a part of the registration statement will, as to a purchaser with a time of contract sale prior to such effective date, supersede or modify any statement that was 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 effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act 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 be considered to offer or sell such securities to such purchaser:

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- (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 by or 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, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act and (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act) 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 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 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 and will be governed by the final adjudication of such issue.
- (d) The undersigned registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**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-3 and has duly caused this Post-Effective Amendment No. 2 to Form S-3 Registration Statement to be signed on behalf of the undersigned, thereunto authorized, in the city of Coral Gables, State of Florida, on the 2<sup>nd</sup> day of December, 2013.

**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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Patrick J. McEnany Patrick J. McEnany	Chairman of the Board of Directors, President and Chief Executive Officer (Principal Executive Officer)	December 2, 2013
/s/ Alicia Grande Alicia Grande	Vice President, Treasurer and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	December 2, 2013
*	Director	December 2, 2013
Hubert E. Huckel, M.D.		
*	Director	December 2, 2013
Philip H. Coelho		
*	Director	December 2, 2013
David S. Tierney, M.D.		
*	Director	December 2, 2013
Charles B. O Keeffe		



\* /s/ Patrick J. McEnany

Patrick J. McEnany

as Attorney-In-Fact

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**INDEX OF EXHIBITS TO REGISTRATION STATEMENT**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
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 LLP **
23.1	Consent of Independent Registered Public Accounting Firm*
23.2	Consent of Akerman LLP (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