

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 10-Q

November 14, 2012

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

[Mark One]

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the Quarterly Period Ended September 30, 2012**

**OR**

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Commission File No. 001-33057**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(Exact name of registrant as specified in its charter)**

Edgar Filing: CATALYST PHARMACEUTICAL PARTNERS, INC. - Form 10-Q

<b>Delaware</b> (State or other jurisdiction of  incorporation or organization)	<b>76-0837053</b> (IRS Employer  Identification No.)
<b>355 Alhambra Circle</b>  <b>Suite 1500</b>	
<b>Coral Gables, Florida</b> (Address of principal executive offices)	<b>33134</b> (Zip Code)
<b>Registrant's telephone number, including area code: (305) 529-2522</b>	

Indicate by checkmark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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 definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large Accelerated Filer <input type="checkbox"/>	Accelerated Filer <input type="checkbox"/>
Non-Accelerated Filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 34,754,020 shares of common stock, \$0.001 par value per share, were outstanding as of November 9, 2012.

---

CATALYST PHARMACEUTICAL PARTNERS, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1.	CONDENSED FINANCIAL STATEMENTS	
	<u>Condensed balance sheets at September 30, 2012 (unaudited) and December 31, 2011</u>	3
	<u>Condensed statements of operations for the three and nine months ended September 30, 2012 and 2011 and from January 4, 2002 (date of inception) through September 30, 2012 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the nine months ended September 30, 2012 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the nine months ended September 30, 2012 and 2011 and from January 4, 2002 (date of inception) through September 30, 2012 (unaudited)</u>	6
	<u>Notes to unaudited condensed financial statements</u>	7
Item 2.	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	17
Item 3.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>	28
Item 4.	<u>CONTROLS AND PROCEDURES</u>	28

PART II. OTHER INFORMATION

Item 1.	<u>LEGAL PROCEEDINGS</u>	29
Item 1A.	<u>RISK FACTORS</u>	29
Item 2.	<u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	29
Item 3.	<u>DEFAULTS UPON SENIOR SECURITIES</u>	29
Item 4.	<u>MINE SAFETY DISCLOSURE</u>	29
Item 5.	<u>OTHER INFORMATION</u>	29
Item 6.	<u>EXHIBITS</u>	29

**CATALYST PHARMACEUTICAL PARTNERS, INC.****(a development stage company)****CONDENSED BALANCE SHEETS**

	<b>September 30, 2012 (unaudited)</b>	<b>December 31, 2011</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 11,973,860	\$ 6,029,067
Prepaid expenses	111,632	199,116
Total current assets	12,085,492	6,228,183
Property and equipment, net	10,832	12,186
Deposits	8,888	8,888
Total assets	\$ 12,105,212	\$ 6,249,257
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 355,909	\$ 263,934
Accrued expenses and other liabilities	397,421	569,867
Total current liabilities	753,330	833,801
Accrued expenses and other liabilities, non-current	22,285	9,518
Warrants liability, at fair value	1,934,680	1,645,240
Total liabilities	2,710,295	2,488,559
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized: none issued and outstanding		
Common stock, \$0.001 par value, 100,000,000 shares authorized; 34,741,520 shares and 24,701,420 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	34,742	24,701
Additional paid-in capital	51,462,593	41,838,614
Deficit accumulated during the development stage	(42,102,418)	(38,102,617)
Total stockholders' equity	9,394,917	3,760,698
Total liabilities and stockholders' equity	\$ 12,105,212	\$ 6,249,257

**The accompanying notes are an integral part of these condensed financial statements.**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**
**(a development stage company)**
**CONDENSED STATEMENTS OF OPERATIONS (unaudited)**

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		Cumulative Period from January 4, 2002 (date of inception) to September 30, 2012
	2012	2011	2012	2011	2012
Revenues - government grant	\$	\$	\$	\$	\$ 488,958
Operating costs and expenses:					
Research and development	654,837	614,137	1,914,905	2,423,725	27,558,613
General and administrative	628,876	516,873	1,800,882	1,623,998	15,906,630
Total operating costs and expenses	1,283,713	1,131,010	3,715,787	4,047,723	43,465,243
Loss from operations	(1,283,713)	(1,131,010)	(3,715,787)	(4,047,723)	(42,976,285)
Interest income	2,744	3,169	5,426	8,595	1,483,215
Change in fair value of warrants liability	(1,340,566)		(289,440)		(609,348)
Loss before income taxes	(2,621,535)	(1,127,841)	(3,999,801)	(4,039,128)	(42,102,418)
Provision for income taxes					
Net loss	\$ (2,621,535)	\$ (1,127,841)	\$ (3,999,801)	\$ (4,039,128)	\$ (42,102,418)
Loss per share basic and diluted	\$ (0.08)	\$ (0.05)	\$ (0.14)	\$ (0.19)	
Weighted average shares outstanding basic and diluted	32,132,824	21,654,680	27,913,800	21,083,485	

**The accompanying notes are an integral part of these condensed financial statements.**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

(a development stage company)

**CONDENSED STATEMENT OF STOCKHOLDERS EQUITY (unaudited)**

**For the nine months ended September 30, 2012**

	Preferred Stock	Common Stock	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at December 31, 2011</b>	\$	\$ 24,701	\$ 41,838,614	\$ (38,102,617)	\$ 3,760,698
Issuance of common stock, net		41	(41)		
Issuance of stock options for services			135,765		135,765
Issuance of common stock and warrants, net		10,000	9,488,255		9,498,255
Net loss				(3,999,801)	(3,999,801)
<b>Balance at September 30, 2012</b>	\$	\$ 34,742	\$ 51,462,593	\$ (42,102,418)	\$ 9,394,917

The accompanying notes are an integral part of these condensed financial statements.

## CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

## CONDENSED STATEMENTS OF CASH FLOWS (unaudited)

	For the Nine Months Ended, September 30,		Cumulative Period from January 4, 2002 (date of inception) through September 30, 2012
	2012	2011	
<b>Operating Activities:</b>			
Net loss	\$ (3,999,801)	\$ (4,039,128)	\$ (42,102,418)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	8,236	34,920	162,225
Stock-based compensation	135,765	167,812	5,757,926
Change in fair value of warrants liability	289,440		609,348
(Increase) decrease in:			
Government grant receivable		134,025	
Prepaid expenses and deposits	87,484	52,401	(120,520)
Increase (decrease) in:			
Accounts payable	91,975	68,105	355,909
Accrued expenses and other liabilities	(159,679)	35,012	356,354
Net cash used in operating activities	(3,546,580)	(3,546,853)	(34,981,176)
<b>Investing Activities:</b>			
Capital expenditures	(6,882)	(1,800)	(109,708)
Purchase of certificates of deposits		(2,003,707)	
Net cash used in investing activities	(6,882)	(2,005,507)	(109,708)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock and warrants, net	9,498,255	2,228,634	43,072,557
Proceeds from issuance of preferred stock, net			3,895,597
Payment of employee withholding tax related to restricted stock units			(3,410)
Net cash provided by financing activities	9,498,255	2,228,634	46,964,744
Net increase (decrease) in cash	5,944,793	(3,323,726)	11,873,860
Cash and cash equivalents at beginning of period	6,029,067	5,475,158	100,000
Cash and cash equivalents at end of period	\$ 11,973,860	\$ 2,151,432	\$ 11,973,860
<b>Supplemental disclosures of non-cash operating activity</b>			
Non-cash incentive received from lessor	\$	\$	\$ 52,320

The accompanying notes are an integral part of these condensed financial statements.

---

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(a development stage company)**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**1. Organization and Description of Business.**

Catalyst Pharmaceutical Partners, Inc. (the Company) is a development-stage specialty pharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases and disorders of the central nervous system with a focus on the treatment of addiction, epilepsy and Lambert-Eaton Myasthenic Syndrome (LEMS).

The Company has incurred operating losses in each period from inception through September 30, 2012. The Company has been able to fund its cash needs to date through several public and private offerings of its common stock and warrants and through a government grant. See Note 9.

Subsequent to quarter end, on October 26, 2012, the Company entered into a strategic collaboration with BioMarin Pharmaceutical, Inc. (BioMarin) for Firdapse, a Phase III orphan drug for the treatment of LEMS, which is a rare, debilitating and sometimes fatal autoimmune disease with the primary symptoms of muscle weakness. As part of the collaboration, the Company licensed the exclusive North American rights to Firdapse and BioMarin made a \$5,000,000 investment in the Company, pursuant to the terms of a Convertible Promissory Note and Note Purchase Agreement, to rapidly advance the development of Firdapse in the United States. See Note 12.

The Company conducted jointly with the National Institute of Drug Abuse (NIDA) and the Department of Veterans Affairs Cooperative Studies Program (VA) a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Phase II(b) Trial). Subsequent to quarter end, on November 8, 2012, the Company announced that the CPP-109 Phase II(b) Trial did not meet the primary endpoint. See Note 12.

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

***Capital Resources***

On May 24, 2012, the Company sold 6,000,000 shares of the Company's common stock together with warrants to purchase 6,000,000 shares of the Company's common stock pursuant to a Form S-1 Registration Statement (file no. 333-180617), at a price of \$0.80 per share and corresponding warrant, and received gross proceeds of approximately \$4.8 million (before underwriting commission and other expenses totaling approximately \$862,000).

On August 28, 2012, the Company filed a prospectus supplement and offered to sell to institutional investors 4,000,000 shares of its common stock together with common stock purchase warrants to purchase 1,200,000 shares of the Company's common stock under the 2010 Shelf Registration Statement at a price of \$1.50 per share and corresponding warrant and received gross proceeds of approximately \$6.0 million before underwriting commission and other expenses totaling approximately \$440,000. See Note 9.



**1. Organization and Description of Business (continued).**

The warrants issued in the May 24, 2012 public offering and the August 28, 2012 registered direct offering do not contain features (such as net cash settlement or anti-dilution features) that would preclude the Company from accounting for these warrants as equity. Accordingly, the warrants issued in the May 2012 and the August 2012 offerings are being accounted for as equity.

Based on currently available information, the Company estimates that it has sufficient working capital to support its operations through the first quarter of 2014. The Company will require additional capital to support the Company's operations in periods after the first quarter of 2014.

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

**2. Basis of Presentation and Significant Accounting Policies.**

**a. DEVELOPMENT STAGE COMPANY.** Since inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage and the Company's financial statements are presented in accordance with U.S. generally accepted accounting principles applicable to a development stage company. The Company's primary focus is on the development and commercialization of its product candidates CPP-109, CPP-115 and Firdapse.

**b. INTERIM FINANCIAL STATEMENTS.** The accompanying unaudited interim financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S. have been condensed or omitted.

In the opinion of management, the accompanying unaudited interim financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of the dates and for the periods presented. Accordingly, these statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2011 included in the 2011 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the three and nine months ended September 30, 2012 are not necessarily indicative of the results to be expected for any future period or for the full 2012 fiscal year.

**c. USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

## 2. Basis of Presentation and Significant Accounting Policies (continued).

- d. **CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist mainly of U.S. Treasury bills, certificates of deposit and money market funds. The Company has substantially all of its cash and cash equivalents deposited with one financial institution.
- e. **PREPAID EXPENSES.** Prepaid expenses consist primarily of prepaid insurance, prepaid subscription fees and prepaid research fees. Prepaid research fees consists of advances for the Company's product development activities, including drug manufacturing, contracts for pre-clinical studies, clinical trials, regulatory affairs and consulting. Such advances are recorded as expense as the related goods are received or the related services are performed.
- f. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company's financial instruments consist of cash and cash equivalents, accounts payables, accrued expenses and other liabilities and warrants liability. At September 30, 2012 and December 31, 2011, the fair value of these instruments approximated their carrying value.
- g. **FAIR VALUE MEASUREMENTS.** Current Financial Accounting Standards Board (FASB) fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions that market participants would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which are typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

	Balances as of September 30, 2012	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	\$ 11,973,860	\$ 11,973,860	\$	\$
Warrants liability	\$ 1,934,680	\$	\$	\$ 1,934,680

## 2. Basis of Presentation and Significant Accounting Policies (continued).

	Balances as of December 31, 2011	Fair Value Measurements at Reporting Date Using		
		Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash and cash equivalents	\$ 6,029,067	\$ 6,029,067	\$	\$
Warrants liability	\$ 1,645,240	\$	\$	\$ 1,645,240

**h. WARRANTS LIABILITY.** In October 2011, the Company issued 1,523,370 warrants to purchase shares of the Company's common stock in connection with a registered direct offering under the 2010 shelf registration statement. The Company accounted for these warrants as a liability measured at fair value due to a provision included in the warrants agreement that provides the warrants holders with an option to require the Company (or its successor) to purchase their warrants for cash in an amount equal to their Black-Scholes Option Pricing Model (the Black-Scholes Model) value, in the event that certain fundamental transactions, as defined, occur. The fair value of the warrants liability is estimated using the Black-Scholes Model which requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized each reporting period in the Change in fair value of warrants liability line in the statement of operations.

**i. STOCK-BASED COMPENSATION.** The Company recognizes expense in the statement of operations for the fair value of all share-based payments to employees, directors, consultants and scientific advisors, including grants of stock options and other share-based awards. For stock options, the Company uses the Black-Scholes Model, the single-option award approach, and the straight-line attribution method. Using this approach, compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally three to five years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

As of September 30, 2012, there were outstanding stock options to purchase 2,742,202 shares of common stock, of which stock options to purchase 2,322,202 shares of common stock were exercisable as of September 30, 2012.

For the three and nine month periods ended September 30, 2012 and 2011, the Company recorded stock-based compensation expense as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 18,503	\$ 18,877	\$ 55,108	\$ 56,014
General and administrative	27,082	30,108	80,657	111,798
Total stock-based compensation	\$ 45,585	\$ 48,985	\$ 135,765	\$ 167,812

## 2. Basis of Presentation and Significant Accounting Policies (continued).

- j. **NET LOSS PER SHARE.** Basic income (loss) per share is computed by dividing net income (loss) for the period by the weighted average number of common shares outstanding during the period. The calculation of basic and diluted net loss per share is the same for all periods presented, as the effect of potential common stock equivalents is anti-dilutive due to the Company's net loss position for all periods presented. The potential shares, which are excluded from the determination of basic and diluted net loss per share as their effect is anti-dilutive, are as follows:

	September 30,	
	2012	2011
Options to purchase common stock	2,742,202	3,096,220
Warrants to purchase common stock	8,723,370	
Potential equivalent common stock excluded	11,465,572	3,096,220

Potentially dilutive options to purchase common stock as of September 30, 2012 and 2011 have exercise prices ranging from \$0.69 to \$6.00 and \$0.62 to \$6.00, respectively. Potentially dilutive warrants to purchase common stock as of September 30, 2012 have exercise prices ranging from \$1.04 to \$2.08.

## 3. Prepaid Expenses.

Prepaid expenses consist of the following:

	September 30, 2012	December 31, 2011
Prepaid insurance	\$ 33,641	\$ 178,536
Prepaid research fees	50,000	
Prepaid subscription fees	17,168	9,942
Prepaid rent	6,230	2,267
Other	4,593	8,371
Total prepaid expenses	\$ 111,632	\$ 199,116

## 4. Property and Equipment.

Property and equipment, net consists of the following:

	September 30, 2012	December 31, 2011
Computer equipment	\$ 28,691	\$ 26,791
Furniture and equipment	49,451	44,469
	78,142	71,260
Less: Accumulated depreciation	(67,310)	(59,074)
Total property and equipment, net	\$ 10,832	\$ 12,186

Depreciation expense was \$2,725 and \$7,452 and \$8,236 and \$34,920, respectively, for the three and nine month periods ended September 30, 2012 and 2011.

**5. Accrued Expenses and Other Liabilities.**

Accrued expenses and other liabilities consist of the following:

	<b>September 30, 2012</b>	<b>December 31, 2011</b>
Accrued compensation and benefits	\$ 127,912	\$ 239,442
Accrued professional fees	110,052	111,920
Accrued pre-clinical and clinical trial expenses	52,384	101,568
Accrued license fees	101,250	102,500
Other	5,823	14,437
Current accrued expenses and other liabilities	397,421	569,867
Deferred rent- non-current	22,285	9,518
Non-current accrued expenses and other liabilities	22,285	9,518
Total accrued expenses and other liabilities	\$ 419,706	\$ 579,385

**6. Commitments.**

**a. LICENSE AGREEMENT WITH BROOKHAVEN.** The Company has entered into a license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy (Brookhaven), whereby the Company has obtained an exclusive license for several patents and patent applications in the U.S. and outside the U.S. relating to the use of vigabatrin as a treatment for cocaine, other addictions and obsessive-compulsive disorders. This license agreement runs concurrently with the term of the last to expire of the licensed patents, the last of which currently expires in 2022. The Company paid a fee to obtain the license of \$50,000. Under the license agreement, the Company has agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval of CPP-109, \$250,000 in each of the second and third years following approval and \$500,000 per year thereafter until the license agreement expires. The Company is also obligated to reimburse Brookhaven for certain of their patent related expenses. The Company believes that as of September 30, 2012 and December 31, 2011, it had a contingent liability of approximately \$166,000 related to this obligation. Of these costs, approximately \$69,000 will become payable in six equal monthly installments at the time the Company submits an NDA to the FDA, and the remaining \$97,000 will become payable commencing within 60 days of obtaining FDA regulatory approval to sell any product. The Company also has the right to enter into sub-license agreements, and if it does, a royalty of 20% of any sub-license fees will be payable to Brookhaven. Brookhaven has formally advised the Company that they believe that the amount potentially due from the Company to Brookhaven for reimbursement of patent related expenses is approximately \$1.3 million. The Company has advised Brookhaven that it disputes their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by the Company of an NDA for CPP-109. As the Company has not yet filed an NDA for CPP-109, no amounts relating to this matter are accrued in the accompanying September 30, 2012 and December 31, 2011 condensed balance sheets.

**b. LICENSE AGREEMENT WITH NORTHWESTERN UNIVERSITY.** On August 27, 2009, the Company entered into a license agreement with Northwestern University (Northwestern), under which it acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin that have been discovered by Northwestern. Under the terms of the license agreement, Northwestern granted the Company an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. The Company has identified and designated the lead compound under this license as CPP-115. Under the license agreement with Northwestern, the Company will be responsible for continued research and development of any resulting product candidates. As of September 30, 2012, the Company has paid \$141,590 in connection with the license and has accrued license fees of \$101,250 in the accompanying September 30, 2012 condensed balance sheet for expenses, maintenance fees and milestones. In addition, the Company is obligated to pay certain milestone payments in future years relating to clinical development activities with respect to CPP-115, and royalties on any products resulting from the license agreement. The next milestone payment of \$150,000 is due on the earlier of successful completion of the first Phase II clinical trial of CPP-115 or August 27, 2015.

**c. LICENSE AGREEMENT WITH NEW YORK UNIVERSITY AND THE FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH.** On December 13, 2011, the Company entered into a license agreement with New York University (NYU) and the Feinstein Institute for Medical Research (FIMR) under which it acquired worldwide rights to commercialize GABA aminotransferase inhibitors in the treatment for Tourette Syndrome. The Company is obligated to pay certain milestone payments in future years relating to clinical development activities and royalties on any products resulting from the license agreement.

**6. Commitments (continued).**

- d. AGREEMENT WITH NIDA.** On April 13, 2010, the Company signed a definitive Clinical Trial Agreement (CTA) with NIDA to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Phase II(b) Trial). As part of the CTA, NIDA, under their agreement with the VA, agreed to provide substantial resources towards the completion of the Phase II(b) Trial. This 207 subject double-blind, placebo-controlled trial was conducted at thirteen leading addiction research facilities across the United States. The Phase II(b) Trial, which was overseen by the VA, was initiated in November 2010. The VA was responsible for management and statistical analyses of the data being collected from the trial. Subsequent to quarter end, on November 8, 2012, the Company announced that the CPP-109 Phase II(b) Trial did not meet the primary endpoint. See Note 12. At present, the Company estimates that it will pay approximately \$1.5 million of direct costs in connection with contracts related to the Phase II(b) trial. As of September 30, 2012, the Company had paid approximately \$1.4 million of this amount and had accounts payable of approximately \$3,000 and accrued liabilities of approximately \$49,000 in the accompanying condensed balance sheet as of September 30, 2012 related to these contracts. These amounts exclude internal costs, such as salaries, benefits and other costs, of the Company's personnel working on the Phase II(b) trial.
- e. AGREEMENTS FOR DRUG DEVELOPMENT, PRE-CLINICAL AND CLINICAL STUDIES.** The Company has entered into agreements with contract manufacturers for the manufacture of drug and study placebo for the Company's trials and studies, with contract research organizations (CRO) to conduct and monitor the Company's trials and studies and with various entities for laboratories and other testing related to the Company's trials and studies. The contractual terms of the agreements vary, but most require certain advances as well as payments based on the achievement of milestones. Further, these agreements are cancellable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.

**7. Income Taxes.**

The Company is subject to income taxes in the U.S. federal jurisdiction and various states jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for any years before 2009. If the Company were to subsequently record an unrecognized tax benefit, associated penalties and tax related interest expense would be reported as a component of income tax expense.

**8. Assets and Liabilities at Fair Value****2011 Warrants**

The Company allocated approximately \$1.3 million of proceeds from its October 2011 registered direct offering (See Note 9) to the fair value of common stock purchase warrants issued in connection with the offering that are classified as a liability (the 2011 warrants). The 2011 warrants are classified as a liability because of provisions in such warrants that allow for the net cash settlement of such warrants in the event of certain fundamental transactions (as defined in the warrant agreement). The valuation of the 2011 warrants is determined using the Black-Scholes Model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the 2011 warrants liability should be classified within Level 3 of the fair value hierarchy by evaluating each input for the Black-Scholes Model against the fair value hierarchy criteria and using the lowest level of input as the basis for the fair value classification. There are six inputs: closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of the Company's common stock; annual rate of dividends; and the risk free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrants agreement. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair value hierarchy as it is a quoted price in an active market. The risk free rate of return is a Level 2 input, while the historical volatility is a Level 3 input in accordance with the fair value accounting guidance. Since the lowest level input is a Level 3, the Company determined the 2011 warrants liability is most appropriately classified within Level 3 of the fair value hierarchy. This liability is subject to fair value mark-to-market adjustment each period. The calculated value of the 2011 warrants liability was determined using the Black-Scholes option-pricing model with the following assumptions:

	September 30, 2012	December 31, 2011
Risk free interest rate	0.56%	0.92%
Expected term	4.59 years	5.34 years
Expected volatility	126%	119%
Expected dividend yield	0%	0%
Expected forfeiture rate	0%	0%

As a result, the Company recognized the change in the fair value of the warrants liability as a non-operating loss of \$1,340,566 and \$289,440 for the three and nine months ended September 30, 2012, respectively. The resulting fair value of the warrants liability at September 30, 2012 and December 31, 2011 was \$1,934,680 and \$1,645,240, respectively.

**9. Stockholders' Equity.**

On June 18, 2012, the Company received a staff deficiency letter from The Nasdaq Stock Market (Nasdaq) notifying the Company that it was not in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. The Nasdaq Listing Rules (the Rules) require listed securities to maintain a minimum bid price of \$1.00 per share and, based on the then closing bid prices for the last 30 consecutive business days, the Company no longer met that requirement. Under the Rules, the Company had a grace period of 180 days to regain compliance, and on August 2, 2012, the Company received notice from Nasdaq confirming that the Company had regained compliance as a result of the Company's common stock having closed with a bid price of at least \$1.00 for at least ten consecutive trading days.



**9. Stockholders Equity (continued).**

*2010 Shelf Registration Statement*

On December 3, 2010, the Company filed a shelf registration statement on Form S-3 (the 2010 Shelf Registration Statement) with the SEC to sell up to \$30 million of common stock and common stock purchase warrants. This shelf registration statement (file No. 333-170945) was declared effective by the SEC on December 15, 2010. The Company has, to date, conducted three registered direct offerings under the 2010 Shelf Registration Statement:

- (a) On March 8, 2011, the Company filed a prospectus supplement and offered to sell to institutional investors 2,259,943 shares of its common stock at a price of \$1.12 per share and received gross proceeds of approximately \$2.5 million before underwriting commission and incurred expenses of approximately \$300,000.
- (b) On October 28, 2011, the Company filed a prospectus supplement and offered to sell to institutional investors 3,046,740 shares of its common stock together with common stock purchase warrants to purchase 1,523,370 shares of the Company's common stock at a price of \$1.15 per share and corresponding warrant and received gross proceeds of approximately \$3.5 million before underwriting commission and other expenses totaling approximately \$305,000. The warrants issued in this registered direct offering, which expire on April 28, 2017 and have an exercise price of \$1.30 per share, have been accounted for as a liability. See Note 8.
- (c) On August 28, 2012, the Company filed a prospectus supplement and offered to sell to institutional investors 4,000,000 shares of its common stock together with common stock purchase warrants to purchase 1,200,000 shares of the Company's common stock at a price of \$1.50 per share and corresponding warrant and received gross proceeds of approximately \$6.0 million before underwriting commission and other expenses totaling approximately \$440,000. These warrants, which expire five years from their date of issuance and have an exercise price of \$2.08 per share, have been accounted for as equity instruments, since they do not contain features (such as net cash settlement or anti-dilution features) that would preclude the Company from accounting for these warrants as equity. See Note 1.

On May 24, 2012, the Company sold 6,000,000 shares of its common stock together with common stock purchase warrants to purchase 6,000,000 shares of the Company's common stock, at a price of \$0.80 per share and corresponding warrant. These securities were issued pursuant to a Form S-1 registration statement that became effective on May 23, 2012 (file no. 333-180617). The Company received gross proceeds of approximately \$4.8 million from this offering, before underwriting commission and other expenses totaling approximately \$862,000. The May 2012 warrants, which expire five years from their date of issuance and have an exercise price of \$1.04 per share, have been accounted for as equity instruments, since they do not contain features (such as net cash settlement or anti-dilution features) that would preclude the Company from accounting for these warrants as equity.

**10. Stock Compensation.**

*Stock Options*

No stock options were granted during the three and nine month periods ended September 30, 2012 and 2011. The Company recorded stock-based compensation related to stock options totaling \$45,585 and \$48,985 and \$135,765 and \$167,812 during the three and nine month periods ended September 30, 2012 and 2011, respectively. No options vested during the three and nine month periods ended September 30, 2012 and 2011.

During the nine month period ended September 30, 2012, options to purchase 195,000 shares of the Company's common stock were exercised on a cashless basis, resulting in the issuance of an aggregate of 40,100 shares of the Company's common stock.

As of September 30, 2012, there was approximately \$176,000 of unrecognized compensation expense related to non-vested stock compensation awards granted under the 2006 Stock Incentive Plan. The cost is expected to be recognized over a weighted average period of approximately 1.46 years.



**11. Related Party Transactions.**

The Company has consulting arrangements with its Chief Medical Officer and with several members of its Scientific Advisory Board. During the three and nine month periods ended September 30, 2012 and 2011, the Company paid approximately \$11,000 and \$11,000 and \$32,000 and \$64,000, respectively, in consulting fees to related parties.

**12. Subsequent Events.**

Subsequent to quarter end, on October 26, 2012, the Company entered into a strategic collaboration with BioMarin for Firdapse. The key components of the collaboration included: (i) the Company licensing the exclusive North American rights to Firdapse pursuant to a License Agreement, dated as of October 26, 2012 (the License Agreement) between the Company and BioMarin and (ii) BioMarin making a \$5,000,000 investment in the Company pursuant to the terms of a Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012 (the Investment Agreement). See Note 1.

Under the Investment Agreement, on October 26, 2012, BioMarin invested \$5,000,000 into the Company. Initially, such amount shall be treated as a loan to the Company. However, the amount of the loan shall automatically convert into shares of the Company's authorized but unissued common stock on the earlier of: (i) March 31, 2013, or (ii) the date that is thirty (30) days after the Company publicly releases top-line data from its Phase II(b) Trial for CPP-109 (which results were publicly released on November 8, 2012), except in certain limited circumstances as more particularly described in the License Agreement. The conversion price of the shares of the Company's common stock to be acquired by BioMarin upon conversion of its \$5 million investment in the Company will be the dollar weighted average price (as defined in the Investment Agreement) of the Company's common stock for the fifteen (15) business day period prior to the Conversion Date, multiplied by 0.9, *provided, however*, that the conversion price shall not be less than \$0.75 per share or more than \$2.50 per share. The Investment Agreement also provides that the Company will use the \$5 million solely for the purpose of developing Firdapse.

As part of the License Agreement, the Company will take over a Phase III Trial currently being operated by BioMarin and will be obligated to use its diligent efforts to seek to obtain regulatory approval for and to commercialize the Product in the United States. The Company is obligated to use diligent efforts to complete the double-blind treatment phase of the Phase III trial within 24 months of entering into the License Agreement, and BioMarin has the right to terminate the License Agreement if such treatment phase has not been completed in such 24-month period (unless the Company is using diligent effort to pursue the completion of such treatment phase and has spent at least \$5 million in connection with the conduct of the Phase III Trial during such 24 month period).

Subsequent to quarter end, on November 8, 2012, the Company announced top-line results from its U.S. Phase II(b) clinical trial evaluating the use of CPP-109 to treat cocaine addiction. The data from the trial showed that CPP-109 did not meet the primary endpoint, that a significantly larger proportion of CPP-109 treated subjects than placebo-treated subjects were cocaine-free during the last two weeks of the treatment period (weeks 8 and 9). The data also showed that the two key secondary endpoints, a significantly larger increase in cocaine negative urines and a significant decrease in the weekly fraction of use days in medication-treated subjects during weeks 3-9, also were not met. The clinical trial did not reveal any unexpected serious adverse effects.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Introduction

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

*Overview.* This section provides a general description of our business, trends in our industry, as well as a discussion regarding recent developments in our business.

*Basis of Presentation.* This section provides information about key accounting estimates and policies that we followed in preparing our financial statements for the third quarter of fiscal 2012.

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

*Results of Operations.* This section provides an analysis of our results of operations for the three and nine month periods ended September 30, 2012 as compared to the same periods ended September 30, 2011.

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

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

### Overview

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

Firdapse. Subsequent to quarter end, we licensed the North American rights to Firdapse<sup>TM</sup>, a Phase III orphan drug for the treatment of LEMS, which is a rare and sometimes fatal autoimmune disease with the primary symptoms of muscle weakness. As part of that arrangement, BioMarin made a \$5 million investment in us. The terms of our agreements with respect to this collaboration are described below.

CPP-115. We are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

## Edgar Filing: CATALYST PHARMACEUTICAL PARTNERS, INC. - Form 10-Q

CPP-109. We have been evaluating CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction and Tourette Syndrome. However, CPP-109 recently failed to meet the primary endpoint in our Phase II(b) trial for cocaine addiction. As a result, we have put our program to develop this product for addiction on hold until we better understand why our clinical trial of the drug failed to achieve its primary endpoint. Once we have the full data set, which we expect to receive during the first half of 2013, we will meet with our collaborator on the Phase II(b) trial, NIDA, to determine next steps, if any, in the clinical development program for CPP-109 for addiction.

---

*Acquisition of North American Rights to Firdapse™*

**Investment Agreement.** On October 26, 2012, we entered into the Investment Agreement with BioMarin pursuant to which BioMarin invested \$5,000,000. Initially, such amount shall be treated as a loan. However, the amount of the loan shall automatically convert into shares of our authorized but unissued common stock on the earlier of: (i) March 31, 2013, or (ii) the date that is thirty (30) days after we publicly release top-line data from our Phase II(b) clinical trial evaluating the use of our product candidate, CPP-109, for the treatment of cocaine addiction (the Conversion Date), except in certain limited circumstances as more particularly described below and in the Investment Agreement. The top line results from our Phase II(b) trial were publicly released on November 8, 2012. The conversion price of the shares of our common stock to be acquired by BioMarin upon conversion of their \$5 million investment in our Company will be the dollar weighted average price (as defined in the Investment Agreement) of our common stock for the fifteen (15) business day period prior to the Conversion Date, multiplied by 0.9, provided, however, that the conversion price shall not be less than \$0.75 per share or more than \$2.50 per share.

The Investment Agreement also provides that we will use the \$5 million solely for the purpose of developing Firdapse and that for such period that BioMarin owns more than 10% of our outstanding common stock, BioMarin will exclusively use the exemption from registration provided under Rule 144 to make sales of our common stock shares acquired in the investment transaction. We also agreed in the Investment Agreement not to make certain asset sales or sales of our securities during the period between the date of the Investment Agreement and the Conversion Date without the prior written consent of BioMarin. Finally, the Investment Agreement provides that we are obligated to repay the \$5 million to BioMarin, with interest, if an event of default (as defined in the Investment Agreement) occurs prior to the conversion of the loan amount into shares of our common stock.

**Product Development Plans for Firdapse.** Firdapse is a proprietary form of 3,4-diaminopyridine (amifampridine phosphate), or 3,4-DAP, for the treatment of LEMS. BioMarin acquired the rights to Firdapse in October 2009 as a result of its acquisition of Huxley Pharmaceuticals, Inc. (Huxley). Firdapse was granted marketing approval in the European Union (EU) in December 2009, which, because Firdapse had previously been granted orphan medicinal product designation in the EU, included ten year marketing exclusivity in the EU. BioMarin will continue to sell Firdapse in the EU following this transaction.

Pursuant to the License Agreement, we licensed the rights to Firdapse in North America. At the time of the license agreement, BioMarin was conducting a Phase III clinical trial of Firdapse (the Phase III Trial), which trial is being transferred to and will be continued by us pursuant to the License Agreement. The Phase III Trial began in the second quarter of 2011 and is a randomized double-blind, placebo-controlled discontinuation study followed by an open-label extension period in approximately 30 patients across 10 sites in the United States (US) and Europe. The primary objective of the trial is to evaluate the efficacy and safety, including the long-term safety, of Firdapse. The primary endpoint is a change from baseline in the Quantitative Myasthenia Gravis score at 14 days and the secondary endpoint is change from baseline in the timed 25-foot walk test at 14 days. At present, we expect to complete the double-blind treatment portion of the Phase III trial in the second half of 2014.

The US Food and Drug Administration (FDA) has previously granted orphan drug designation to Firdapse for the treatment of LEMS, which means that if we are the first to obtain approval for Firdapse in the US, it will be eligible to obtain seven year marketing exclusivity.

LEMS is a rare autoimmune disease with the primary symptoms of muscle weakness. The muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels leading to a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at approximately 3,000 patients in the US and Canada. Approximately 50 percent of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. The weakness is generally more marked in the proximal muscles, particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with swallowing. Patients often report dry mouth, impotence, constipation and feelings of light headedness on standing. These problems can be life threatening when the weakness involves respiratory muscles. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyographic testing and the presence of autoantibodies against voltage gated calcium channels.

There are no approved drugs in the US for the treatment of LEMS. Current options rely on intravenous immunoglobulin, plasmapheresis and/or immuno suppressant drugs. Firdapse is the only version of amifampridine phosphate (3,4-DAP) in Phase III trials for LEMS. However, we believe that another pharmaceutical company is conducting a Phase II clinical trial in the US for its version of amifampridine (3,4-DAP) for the treatment of LEMS.

While our initial efforts will be on seeking the approval of Firdapse for the treatment of LEMS in the US, we also intend to explore other potential orphan central nervous system indications for Firdapse, such as Myasthenia Gravis and Congenital Myasthenic Syndrome.

License Agreement. On October 26, 2012, we entered into the License Agreement with BioMarin pursuant to which we licensed the North American rights to Firdapse. As part of the License Agreement, we are taking over the Phase III Trial and will be obligated to use diligent efforts to seek to obtain regulatory approval for and to commercialize the Firdapse in the US. We are also obligated to use diligent efforts to complete the double-blind treatment phase of the Phase III trial within 24 months of entering into the License Agreement, and BioMarin has the right to terminate the License Agreement if such treatment phase has not been completed in such 24-month period (unless we are using diligent effort to pursue the completion of such treatment phase and have spent at least \$5 million in connection with the conduct of the Phase III Trial during such 24 month period). We currently anticipate that the remaining development program costs required to file a New Drug Application (NDA) for Firdapse will be approximately \$17 million.

Under the License Agreement, we have agreed to make: (i) certain royalty payments to BioMarin based on the net sales in North America; (ii) certain royalty payments to a third-party licensor of the rights being sublicensed to us based on the net sales in North America, and (iii) certain milestone payments to such third-party licensor and to the former stockholders of Huxley that BioMarin is obligated to make (which milestone payments are due, in part, upon acceptance by the FDA of a filing of an NDA for Firdapse for the treatment of LEMS, and, in part, on the unconditional approval by the FDA of an NDA for Firdapse for the treatment of LEMS). We have also agreed to share in the cost of certain post-marketing studies that are being conducted by BioMarin if such studies are required as a condition for approval of Firdapse by the FDA.

#### *Update on CPP-115*

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

#### *Update on CPP-109*

We jointly conducted with the National Institute of Drug Abuse (NIDA) and the Department of Veterans Affairs Cooperative Studies Program (VA) a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (the Phase II(b) Trial). The VA was responsible for management and statistical analyses of the data collected from the trial. Subsequent to quarter end, on November 8, 2012, we announced top-line results from the Phase II(b) trial. The data from the trial showed that CPP-109 did not meet the primary endpoint, that a significant larger proportion of CPP-109 treated subjects than placebo-treated subjects were cocaine-free during the last two weeks of the treatment period (weeks 8 and 9). The data also showed that the two key secondary endpoints, a significantly larger increase in cocaine negative urines and a significant decrease in the weekly fraction of use days in medication-treated subjects during weeks 3-9, also were not met. The clinical trial did not reveal any unexpected serious adverse effects.

We expect the remaining protocol-specified analyses for other secondary and exploratory clinical endpoints and safety data to be completed during the first half of next-year, after all the follow-up clinical data have been received to be able to fully unblind the trial data. After obtaining the full data set, we expect to meet with our collaborator on the Phase II(b) trial, NIDA, to determine next steps, if any, in the clinical development program for CPP-109 for cocaine addiction.

During September 2012, we announced that researchers at Mount Sinai School of Medicine in New York had commenced a safety and tolerability trial of vigabatrin in young adults with treatment refractory Tourette Disorder to evaluate whether CPP-109 can potentially reduce the severity of debilitating tics. The study is being conducted at Mount Sinai School of Medicine's Behavioral Science Unit. Catalyst is providing CPP-109 study medication and financial support to facilitate the study.

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

#### *Other Matters*

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

#### *Resignation of Vice President, Commercial Operations*

Richard P. Rieger has resigned as Vice President, Commercial Operations, effective November 16, 2012. Mr. Rieger's resignation was for personal reasons and not because of any disagreements with our management over operations.

#### *Capital resources*

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

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



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

the expense of filing, and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights. Based on currently available information, we estimate that we have sufficient working capital to support our operations through the first quarter of 2014. We will require additional capital to support our operations in periods after the first quarter of 2014.

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

There can be no assurance that we will actually have sufficient funds for the purposes described above or that we will obtain sufficient future funding to support our product development efforts. There is also no assurance that we will ever be in a position to commercialize any of our product candidates. See *Liquidity and Capital Resources* below.

#### **Basis of presentation**

##### *Revenues*

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

##### *Research and development expenses*

Our research and development expenses consist of costs incurred for Company-sponsored research and development activities, as well as occasional support for selected investigator-sponsored research. The major components of research and development costs include pre-clinical study costs, clinical manufacturing costs, clinical study and trial expenses, insurance coverage for clinical trials, consulting, scientific advisors and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials and allocations of various overhead costs related to our product development efforts. To date, all of our research and development resources have been devoted to the development of CPP-109 and CPP-115. Costs incurred in connection with research and development activities are expensed as incurred.

Our cost accruals for clinical studies and trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study and trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical study and trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events or milestones, the successful enrollment of subjects, the allocation of responsibilities among the parties to the agreements, and the completion of portions of the clinical study or trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to pre-clinical and clinical studies and trials are

recognized based on our estimate of the degree of completion of the event or events specified in the specific study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies or trials at a given point in time, we could be required to record significant additional research and development expenses in future periods. Pre-clinical and clinical study and trial activities require significant up front expenditures. We anticipate paying significant portions of a study or trial's cost before such study or trial begins, and incurring additional expenditures as the study or trial progresses and reaches certain milestones.

#### *Selling and marketing expenses*

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

#### *General and administrative expenses*

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

#### *Stock-based compensation*

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

#### *Warrants Liability*

We issued warrants to purchase 1,523,370 shares of our common stock as part of the equity financing that we completed in October 2011 and warrants to purchase 1,510,870 of these shares remain outstanding. In accordance with U.S. generally accepted accounting principles, because these warrants allow for net cash settlement in the event of certain fundamental transactions (as defined in the warrants agreement), we have recorded the fair value of the 2011 warrants as a liability in the accompanying balance sheets at September 30, 2012 and December 31, 2011 using a Black-Scholes Model. We will remeasure the fair value of the 2011 warrants liability at each reporting date until the 2011 warrants are exercised or have expired. Changes in the fair value of the warrants liability are reported in the statements of operations as income or expense. The fair value of the warrants liability is subject to significant fluctuation based on changes in the inputs to the Black-Scholes Model, including our common stock price, expected volatility, expected life, the risk-free interest rate and dividend yield. The market price for our common stock has been and may continue to be volatile. Consequently, historic fluctuations in the price of our common stock have caused significant increases or decreases in the fair value of the 2011 warrants and future fluctuations in the price of our common stock will likely cause significant increases or decreases in the fair value of the 2011 warrants.

#### *Income taxes*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of September 30, 2012 and December 31, 2011, as we believe it is more likely than not that the deferred tax asset will not be realized. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of any of our carry-forward tax losses may be subject to limitation.

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

### *Recently Issued Accounting Standards*

There are no recently issued accounting standards that are expected to have a material effect on our financial statements.

### **Critical Accounting Policies and Estimates**

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosures of contingent assets and liabilities. For a full discussion of our accounting policies please refer Note 2 to the Financial Statements included in our 2011 Annual Report on Form 10-K filed with the SEC. Our most critical accounting policies and estimates include: accounting for development stage, research and development expenses and stock-based compensation, measurement of fair value, fair value of warrants liability, income taxes and reserves. We continually evaluate our judgments, estimates and assumptions. We base our estimates on the terms of underlying agreements, our expected course of development, historical experience and other factors that we believe are reasonable based on the circumstances, the results of which form our management's basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2011 Annual Report on Form 10-K.

### **Results of Operations**

#### *Revenues.*

We had no revenues for the three and nine month periods ended September 30, 2012 and 2011.

#### *Research and Development Expenses.*

Research and development expenses for the three and nine month periods ended September 30, 2012 and 2011 were \$654,837 and \$614,137 and \$1,914,905 and \$2,423,725, respectively, including stock-based compensation expense in each of the three and nine month periods of \$18,503 and \$18,877 and \$55,108 and \$56,014, respectively. Research and development expenses, in the aggregate, represented approximately 51% and 54% and 52% and 60%, respectively, of total operating costs and expenses for the three and nine month periods ended September 30, 2012 and 2011. The stock-based compensation is non-cash and relates to the expense of stock options awards to certain employees. Expenses for research and development for the nine month period ended September 30, 2012 decreased compared to amounts expended in the same period in 2011 as we continued to incur costs associated with our NIDA/VA Phase II(b) clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and we completed our Phase I(a) human clinical safety study for CPP-115. Expenses for the comparable period in 2011 included pre-clinical studies and drug development activities for CPP-115 which concluded during Q4-11 with the submission of an IND for CPP-115. As a result of our ongoing studies and trials, we expect that costs related to research and development activities will continue to be substantial in 2012.

#### *Selling and Marketing Expenses.*

We had no selling and marketing expenses during the three and nine month periods ended September 30, 2012 and 2011, as we have not yet received approval for the commercialization of any of our product candidates. We expect to begin to incur sales and marketing expenses when we submit an NDA for any of our product candidates, so that we will have a sales force in place to commence our selling efforts upon receiving approval of an NDA, of which there can be no assurance.

#### *General and Administrative Expenses.*

General and administrative expenses for the three and nine months ended September 30, 2012 and 2011 were \$628,876 and \$516,873 and \$1,800,882 and \$1,623,998, respectively, including stock-based compensation expense in each of the three and nine month periods of \$27,082 and \$30,108 and \$80,657 and \$111,798, respectively. General and administrative expenses represented 49% and 46% and 48% and 40%, respectively, of total operating costs and expenses for the three and nine months ended September 30, 2012 and 2011. The increase in general and administrative expenses for the three and nine months ended September 30, 2012 as compared to the same periods in 2011 is mainly due to increases in payroll and benefits, travel expenses and professional fees in connection with our due diligence and licensing efforts for Firdapse.

*Stock-Based Compensation.*

Total stock-based compensation for the three and nine months ended September 30, 2012 and 2011 was \$45,585 and \$48,985 and \$135,765 and \$167,812, respectively. The reduction in expense from the comparable period in 2011 is primarily due to previously granted awards to consultants which completely vested during 2011.

*Change in fair value of warrants liability.*

In connection with our October 2011 equity offering, we issued warrants to purchase an aggregate of 1,523,370 shares of common stock. The fair value of these warrants is recorded in the liability section of the balance sheet and was estimated at \$1,934,680 and \$1,645,240 at September 30, 2012 and December 31, 2011, respectively. The fair value of the 2011 warrants liability is determined at the end of each reporting period with the resulting gains or losses recorded as the change in fair value of warrants liability in the statements of operations. For the three and nine months ended September 30, 2012, we recognized other expense of \$1,340,566 and \$289,440, respectively, due to the change in the fair value of the 2011 warrants liability. The losses during the three and nine months ended September 30, 2012 were principally a result of the increase of our stock price between June 30, 2012 and September 30, 2012 and December 31, 2011 and September 30, 2012. Changes in the value of our common stock have historically caused significant increases or decreases in the fair value of the 2011 warrants liability and future fluctuations in the value of our common stock will likely cause significant increases or decreases in the fair value of the 2011 warrants liability.

*Interest Income.*

We reported interest income in all periods relating to our investment of funds received from our public and private offerings. The decrease in interest income in the three and nine month periods ended September 30, 2012 when compared to the same period in 2011 is due to lower interest rates and lower average investment balances as we use the proceeds from offerings to fund our product-development activities and our operations. Substantially all such funds were invested in short-term interest bearing obligations.

*Income taxes.*

We have incurred net operating losses since inception. For the three and nine month periods ended September 30, 2012 and 2011, we have applied a 100% valuation allowance against our deferred tax asset as we believe that it is more likely than not that the deferred tax asset will not be realized.

**Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through the net proceeds of public and private offerings of our common stock and a government grant. At September 30, 2012, we had cash and cash equivalents aggregating \$12.0 million and working capital of \$11.3 million. At December 31, 2011, we had cash and cash equivalents of \$6.0 million and working capital of \$5.4 million. At September 30, 2012, substantially all of our cash and cash equivalents were deposited with one financial institution, and such balances were in excess of federally insured limits throughout the quarter.

We have to date incurred operating losses, and we expect these losses to continue into the future as we seek to conduct the clinical studies and trials required before we can commercialize any of our product candidates. We anticipate using current cash on hand to finance these activities. It will likely take several years to obtain the necessary regulatory approvals to commercialize any of our product candidates in the US.

At September 30, 2012 we had cash and cash equivalents of \$11,973,860 and on October 26, 2012, we received a cash infusion from BioMarin of \$5,000,000. Based on currently available information, we estimate that we have sufficient working capital to support our operations through the first quarter of 2014. We will require additional capital to support our operations in periods after the first quarter of 2014. These expectations are based on current information available to us. If the estimated costs of our ongoing studies are greater than we expect, or if such studies take longer to complete, our assumptions may not prove to be accurate.

We will require additional funding to complete additional studies or trials of our product candidates, including any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and/or epilepsy. Since these additional studies or trials have not yet been developed, we cannot estimate what our funding requirements will be with respect to such studies or trials. We will also require additional funding to complete the development of Firdapse<sup>TM</sup>. Finally, we will require additional working capital to support our operations beyond the first quarter of 2014. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

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

the scope, rate of progress and cost of our clinical trials and other product development activities;

future clinical trial results;

the performance of our third-party suppliers or contract manufacturers;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;

the cost and timing of establishing sales, marketing and distribution capabilities;

the effect of competition and market developments;

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

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

We expect to raise any required additional funds through public or private equity offerings (including through our 2010 shelf registration statement), corporate collaborations or other means. We also intend to seek governmental grants for a portion of the required funding for our clinical trials and pre-clinical trials. We may also seek to raise additional capital to fund additional product development efforts, even if we have sufficient funds for our planned operations. Any sale by us of additional equity or convertible debt securities could result in dilution to our stockholders. There can be no assurance that any such required additional funding will be available to us at all or available on terms acceptable to us. Further, to the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our technologies or grant sublicenses on terms that are not favorable to us. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs, which could have an adverse effect on our business.

#### *Cash Flows*

Net cash used in operating activities was \$3,546,580 and \$3,546,853, respectively, for the nine month periods ended September 30, 2012 and 2011. During the nine months ended September 30, 2012, net cash used in operating activities was primarily attributable to our net loss of \$3,999,801 and a decrease of \$159,679 in accrued expenses and other liabilities. This was offset in part by \$144,001 of non-cash expenses and \$289,440 of change in the fair value of warrants liability, a \$87,484 decrease in prepaid



expenses and deposits and a \$91,975 increase in accounts payable. During the nine months ended September 30, 2011, net cash used in operating activities was primarily attributable to our net loss of \$4,039,128. This was offset in part by \$202,732 of non-cash expenses, the collection of \$134,025 in government grant receivable, a decrease of \$52,401 in prepaid expenses and deposits and increases of \$68,105 in accounts payable and \$35,012 in accrued expenses and other liabilities. Non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities during the nine month period ended September 30, 2012 was \$6,882 for the purchase of computers and furniture and equipment. Net cash used in investing activities was \$2,005,507 during the nine month period ended September 30, 2011 consisting of \$2,003,707 to purchase certificates of deposit and \$1,800 for the purchase of computer equipment.

Cash provided by financing activities during the nine month period ended September 30, 2012 was \$9,498,255, consisting of \$3,938,303 from net proceeds from the sale of common stock and warrants through a secondary public offering and \$5,559,952 from the net proceeds from the sale of shares and warrants under the 2010 shelf registration statement. Net cash provided by financing activities during the nine month period ended September 30, 2011 was \$2,228,634, consisting of the net proceeds from the sale of shares of common stock under our 2010 shelf registration statement.

#### *Contractual Obligations*

We have entered into the following contractual arrangements:

*Payments to Brookhaven under our license agreement.* We have agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval for CPP-109, \$250,000 in each of the second and third years following approval, and \$500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed products for certain of their patent-related expenses. We believe that such obligation is approximately \$166,000 at September 30, 2012 and December 31, 2011. See *Dispute with Brookhaven* below.

*Payments to Northwestern University under our license agreement.* We have agreed to pay Northwestern an upfront fee of \$35,000, reimbursement of approximately \$42,000 in expenses, and certain milestone payments in future years relating to clinical development activities with respect to CPP-115 or payable upon passage of time, and royalties on any products resulting from the license agreement. At September 30, 2012, we had paid \$141,590 of these amounts and had accrued license fees of \$101,250 in the accompanying condensed balance sheet.

*Payments under our agreement with NIDA.* We have agreed to supply the study drug (and matching placebo) as well as fund certain expenses for the U.S. Phase II(b) clinical trial that evaluated CPP-109 for the treatment of cocaine addiction that we conducted jointly with NIDA and the VA. We currently estimate that we will pay approximately \$1.5 million in connection with this agreement. As of September 30, 2012, we had paid approximately \$1.4 million of this amount and had accounts payable of approximately \$49,000 and accrued liabilities of approximately \$3,000 in the accompanying condensed balance sheet related to these contracts.

*Payments for drug development, pre-clinical and clinical studies and trials.* We estimate that we will pay various consultants, drug manufacturers, and other vendors approximately \$1.7 million, in connection with our drug development work, including pre-clinical and clinical studies and trials, consulting and data analysis. At September 30, 2012, we have paid approximately \$1.3 million of this amount, and had accounts payable of approximately \$94,000 in the accompanying condensed balance sheet related to these contracts.

*Employment agreements.* We have entered into an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately \$387,000 per annum in 2012. The agreement expires in November 2013.

*Lease for office space.* We have entered into a lease agreement for our office space that requires payments of approximately \$6,000 per month.

*Dispute with Brookhaven*

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

*Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of September 30, 2012 and December 31, 2011 were not material. We have an operating lease for our corporate office facility. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

**Caution Concerning Forward-Looking Statements**

This Current Report on Form 10-Q contains forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes, anticipates, proposes, plans, expects, intends, may, and other similar expressions 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 CPP-109, CPP-115, Firdapse™ or any other product we may acquire, develop or license is highly uncertain. We cannot reasonably estimate or know the nature, timing, or estimated expenses of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence due to the numerous risks and uncertainties associated with developing such products, including the uncertainty of:

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

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

whether our studies and trials will be successful;

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

the ability of our third-party suppliers or contract manufacturers to maintain compliance with cGMP;

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

whether others develop and commercialize products competitive to our products;





changes in the laws and regulations affecting our business;

our ability to attract and retain skilled employees; and

changes in general economic conditions and interest rates.

Our current plans and objectives are based on assumptions relating to the development of our current product candidates. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements made herein, which reflect our views only as of the date of this 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.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

As a smaller reporting company as defined by Item 10 of Regulation S-K we are not required to provide the information required by this section.

### **ITEM 4. CONTROLS AND PROCEDURES**

- a. We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2012, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.
- b. During the three months ended September 30, 2012, there were no changes in our internal controls or in other factors that could have a material effect, or are reasonably likely to have a material effect, on our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

The Company is not a party to any legal proceedings.

### ITEM 1A. RISK FACTORS

There are many factors that affect our business, our financial condition, and the results of our operations. In addition to the information set forth in this quarterly report, you should carefully read and consider Item 1A. Risk Factors in Part I, and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, of our 2011 Annual Report on Form 10-K filed with the SEC, which contain a description of significant factors that might cause our actual results of operations in future periods to differ materially from those currently expected or desired.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None

### ITEM 4. MINE SAFETY DISCLOSURE

Not applicable

### ITEM 5. OTHER INFORMATION

None

### ITEM 6. EXHIBITS

31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase

\*\* Pursuant to Rule 406 of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.



**SIGNATURES**

Pursuant to the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Catalyst Pharmaceutical Partners, Inc.**

By: /s/ Alicia Grande  
Alicia Grande  
Vice President, Treasurer and Chief Financial Officer

Date: November 14, 2012

---

**Exhibit Index**

Exhibit

Number	Description
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase
101.DEF**	XBRL Taxonomy Extension Definition Linkbase
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase

\*\* Pursuant to Rule 406 of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.