

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 10-Q

August 14, 2012

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**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 June 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)

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<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: <u>(305) 529-2522</u></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: 30,741,520 shares of common stock, \$0.001 par value per share, were outstanding as of August 10, 2012.

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<b>ASSETS</b>	<b>June 30, 2012 (unaudited)</b>	<b>December 31, 2011</b>
Current Assets:		
Cash and cash equivalents	\$ 7,514,843	\$ 6,029,067
Prepaid expenses	166,788	199,116
Total current assets	7,681,631	6,228,183
Property and equipment, net	13,556	12,186
Deposits	8,888	8,888
Total assets	\$ 7,704,075	\$ 6,249,257
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 222,983	\$ 263,934
Accrued expenses and other liabilities	454,059	569,867
Total current liabilities	677,042	833,801
Accrued expenses and other liabilities, non-current	22,004	9,518
Warrants liability, at fair value	594,114	1,645,240
Total liabilities	1,293,160	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; 30,741,520 shares and 24,701,420 shares issued and outstanding at June 30, 2012 and December 31, 2011, respectively	30,742	24,701
Additional paid-in capital	45,861,056	41,838,614
Deficit accumulated during the development stage	(39,480,883)	(38,102,617)
Total stockholders' equity	6,410,915	3,760,698
Total liabilities and stockholders' equity	\$ 7,704,075	\$ 6,249,257

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,		Cumulative Period from January 4, 2002 (date of inception) to June 30, 2012
	2012	2011	2012	2011	2012
Revenues - government grant	\$	\$	\$	\$	\$ 488,958
Operating costs and expenses:					
Research and development	532,741	905,635	1,260,068	1,809,588	26,903,776
General and administrative	534,623	491,828	1,172,006	1,107,125	15,277,754
Total operating costs and expenses	1,067,364	1,397,463	2,432,074	2,916,713	42,181,530
Loss from operations	(1,067,364)	(1,397,463)	(2,432,074)	(2,916,713)	(41,692,572)
Interest income	1,365	3,312	2,682	5,426	1,480,471
Change in fair value of warrants liability	776,919		1,051,126		731,218
Loss before income taxes	(289,080)	(1,394,151)	(1,378,266)	(2,911,287)	(39,480,883)
Provision for income taxes					
Net loss	\$ (289,080)	\$ (1,394,151)	\$ (1,378,266)	\$ (2,911,287)	\$ (39,480,883)
Loss per share basic and diluted	\$ (0.01)	\$ (0.06)	\$ (0.05)	\$ (0.14)	
Weighted average shares outstanding basic and diluted	26,851,410	21,654,680	25,781,106	20,793,155	

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

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**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(a development stage company)**

**CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY**

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

**For the six months ended June 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			90,180		90,180
Issuance of common stock and warrants, net		6,000	3,932,303		3,938,303
Net loss				(1,378,266)	(1,378,266)
<b>Balance at June 30, 2012</b>	\$	\$ 30,742	\$ 45,861,056	\$ (39,480,883)	\$ 6,410,915

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

**Table of Contents****CATALYST PHARMACEUTICAL PARTNERS, INC.****(a development stage company)****CONDENSED STATEMENTS OF CASH FLOWS****CONDENSED STATEMENTS OF CASH FLOWS (unaudited)**

	<b>For the Six Months Ended, June 30,</b>		<b>Cumulative Period from January 4, 2002 (date of inception) through June 30, 2012</b>
	<b>2012</b>	<b>2011</b>	
<b>Operating Activities:</b>			
Net loss	\$ (1,378,266)	\$ (2,911,287)	\$ (39,480,883)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,511	27,468	159,500
Stock-based compensation	90,180	118,827	5,712,341
Change in fair value of warrants liability	(1,051,126)		(731,218)
(Increase) decrease in:			
Government grant receivable		134,025	
Prepaid expenses and deposits	32,328	155	(175,676)
Increase (decrease) in:			
Accounts payable	(40,951)	372,078	222,983
Accrued expenses and other liabilities	(103,322)	(35,479)	412,711
Net cash used in operating activities	(2,445,646)	(2,294,213)	(33,880,242)
<b>Investing Activities:</b>			
Capital expenditures	(6,881)	(1,800)	(109,707)
Purchase of certificates of deposits		(2,001,688)	
Net cash used in investing activities	(6,881)	(2,003,488)	(109,707)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock and warrants, net	3,938,303	2,228,634	37,512,605
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	3,938,303	2,228,634	41,404,792
Net increase (decrease) in cash	1,485,776	(2,069,067)	7,414,843
Cash and cash equivalents at beginning of period	6,029,067	5,475,158	100,000
Cash and cash equivalents at end of period	\$ 7,514,843	\$ 3,406,091	\$ 7,514,843
<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.





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**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 and epilepsy.

The Company has incurred operating losses in each period from inception through June 30, 2012. The Company has been able to fund its cash needs to date through an initial funding from its founders, four private placements, an initial public offering (IPO), a secondary public offering, a government grant and five registered direct equity offerings via shelf registrations statements to institutional investors. See Note 9.

***Capital Resources***

The Company is currently jointly conducting 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 (and, based on current information, including completion of patient enrollment during May 2012, the Company expects to report top line results from this trial around the end of September 2012).

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 based on animal models of 15-30 mg per day) of CPP-115 solution administered orally to 55 healthy volunteers. The key findings of the study included: (i) CPP-115 was well tolerated at all six doses administered in the study; there were no serious or adverse events, and no cardiovascular or respiratory events were reported in the study; (ii) CPP-115 was rapidly absorbed (time to peak blood concentration was about 30 minutes); (iii) the drug had an elimination half-life of four to six hours; and (iv) peak serum concentration of the drug ( $C_{max}$ ) increased on a dose proportional basis over the range of doses studied, while there was a greater than proportional increase across the dose range in AUC, a method of measurement of the bioavailability of a drug based on a plot of blood concentrations sampled at frequent intervals.

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). The warrants have an exercise price of \$1.04, are exercisable immediately and expire five years from the date of issuance. The warrants issued in the 2012 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 2012 offering are being accounted for as equity. See Note 9.

The Company expects to use the net proceeds from the 2012 offering (i) to fund activities necessary to support the submission of a new drug application (NDA) for CPP-109 for U.S. Food and Drug Administration (FDA) approval and to begin to prepare for the commercial launch of CPP-109, assuming that the data from the currently ongoing Phase II(b) trial are compelling and the FDA files an NDA submitted by the Company for CPP-109 based on the data from the Phase II(b) trial, (ii) to manufacture sufficient CPP-115 for use in one or more future safety and/or proof-of concept studies of CPP-115, and (iii) for general corporate purposes.

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 fund clinical and pre-clinical studies of CPP-109 and CPP-115, other than those described above, and to support the Company's operations in periods after the first quarter of 2014.

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

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 and CPP-115.

**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 six months ended June 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.

**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 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.

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

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 June 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.

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 June 30, 2012, there were outstanding stock options to purchase 3,479,108 shares of common stock, of which stock options to purchase 3,059,108 shares of common stock were exercisable as of June 30, 2012.

**Table of Contents****2. Basis of Presentation and Significant Accounting Policies (continued).**

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

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Research and development	\$ 18,303	\$ 18,671	\$ 36,605	\$ 37,137
General and administrative	26,787	46,405	53,575	81,690
Total stock-based compensation	\$ 45,090	\$ 65,076	\$ 90,180	\$ 118,827

- 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:

	June 30,	
	2012	2011
Options to purchase common stock	3,479,108	3,118,108
Warrants to purchase common stock	7,523,370	
Potential equivalent common stock excluded	11,002,478	3,118,108

Potentially dilutive options to purchase common stock as of June 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 June 30, 2012 have exercise price ranging from \$1.04 to \$1.30.

**3. Fair Value Measurements.****2011 Warrants**

The Company allocated approximately \$1.3 million of proceeds from its October 2011 registered direct offering 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

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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:

**Table of Contents****3. Fair Value Measurements (continued).**

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
Risk free interest rate	0.69%	0.92%
Expected term	4.84 years	5.34 years
Expected volatility	122%	119%
Expected dividend yield	%	%
Expected forfeiture rate	%	%

As a result, the Company recognized the change in the fair value of the warrants liability as non-operating income of \$776,919 and \$1,051,126 for the three and six months ended June 30, 2012, respectively. The resulting fair value of the warrants liability at June 30, 2012 and December 31, 2011 was \$594,114 and \$1,645,240, respectively.

**4. Prepaid Expenses.**

Prepaid expenses consist of the following:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
Prepaid insurance	\$ 74,223	\$ 178,536
Prepaid research fees	50,000	
Prepaid subscription fees	32,030	9,942
Prepaid rent	6,230	2,267
Other	4,305	8,371
 Total prepaid expenses	 \$ 166,788	 \$ 199,116

**5. Property and Equipment.**

Property and equipment, net consists of the following:

	<b>June 30, 2012</b>	<b>December 31, 2011</b>
Computer equipment	\$ 28,691	\$ 26,791
Furniture and equipment	49,450	44,469
	78,141	71,260
Less: Accumulated depreciation	(64,585)	(59,074)
 Total property and equipment, net	 \$ 13,556	 \$ 12,186

Depreciation expense was \$2,710 and \$21,030 and \$5,511 and \$27,468, respectively, for the three and six month periods ended June 30, 2012 and 2011.

**6. Accrued Expenses and Other Liabilities.**

Accrued expenses and other liabilities consist of the following:

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	<b>June 30, 2012</b>	<b>December 31, 2011</b>
Accrued compensation and benefits	\$ 147,936	\$ 239,442
Accrued professional fees	84,141	111,920
Accrued pre-clinical and clinical trial expenses	107,575	101,568
Accrued license fees	105,000	102,500
Other	9,407	14,437
Current accrued expenses and other liabilities	454,059	569,867
Deferred rent- non-current	22,004	9,518
Non-current accrued expenses and other liabilities	22,004	9,518
Total accrued expenses and other liabilities	\$ 476,063	\$ 579,385

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### 7. 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 June 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 June 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 June 30, 2012, the Company has paid \$136,590 in connection with the license and has accrued license fees of \$105,000 in the accompanying June 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.



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### **7. 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, has agreed to provide substantial resources towards the completion of the Phase II(b) Trial. This 207 subject double-blind, placebo-controlled trial is being conducted at thirteen leading addiction research facilities across the United States. The Phase II(b) Trial, which is being overseen by the VA, was initiated in November 2010, and the Company expects to report top-line data from the Phase II(b) Trial around the end of September 2012. The Phase II(b) Trial is designed to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and if successful, the Company believes that it will qualify to be one of the adequate and well controlled trials required to support approval of an NDA for CPP-109. 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 June 30, 2012, the Company had paid approximately \$1.4 million of this amount and had accounts payable of approximately \$14,000 and accrued liabilities of approximately \$42,000 in the accompanying condensed balance sheet as of June 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.

### **8. 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.

### **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. See Note 12.

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

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. 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 under the 2010 Shelf Registration Statement 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. 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 under the 2010 Shelf Registration Statement 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.

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 warrants issued in the 2012 offering 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.

### **10. Stock Compensation.**

#### *Stock Options*

No stock options were granted during the three and six month periods ended June 30, 2012 and 2011. The Company recorded stock-based compensation related to stock options totaling \$45,090 and \$65,076 and \$90,180 and \$118,827 during the three and six month periods ended June 30, 2012 and 2011, respectively. No options vested during the three and six month periods ended June 30, 2012 and 2011.

During the six month period ended June 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 June 30, 2012, there was approximately \$222,000 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 1.61 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 six month periods ended June 30, 2012 and 2011, the Company paid approximately \$10,000 and \$32,000 and \$21,000 and \$53,000, respectively, in consulting fees to related parties.

### **12. Subsequent Events.**

Subsequent to quarter end, on July 12, 2012, the Company announced that it now expects to report top-line results from its Phase II(b) clinical trial evaluating its product candidate, CPP-109, for the treatment of cocaine addiction around the end of September 2012, versus the previous guidance reporting that such results would not be available until early in the first quarter of 2013.

Subsequent to quarter end, on August 2, 2012, the Company received notice from The Nasdaq Stock Market (Nasdaq) confirming that as a result of the Company's common stock closing with a bid price of at least \$1.00 for at least ten consecutive trading days, the Company had regained compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market. See Note 9.

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### **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 second 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 six month periods ended June 30, 2012 as compared to the same periods ended June 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 and epilepsy. We have two products in development. We are currently evaluating our lead drug candidate, CPP-109 (our formulation of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted "Fast Track" status by the FDA for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and other central nervous system indications. Further, we are in the early stages of developing CPP-115, another GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is more potent than vigabatrin and may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy (initially infantile spasms) and other selected central nervous disease indications. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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

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

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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 and CPP-115; and

the expense of filing, and potentially prosecuting, defending and enforcing any patent claims and other intellectual property rights. We are jointly conducting with NIDA and the VA a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction (and, based on current information, including completion of patient enrollment during May 2012, we expect to report top line results from this trial around the end of September 2012).

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

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

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

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

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

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

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

## **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 or CPP-115, 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. 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, and we expect this to continue for the foreseeable future. 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.

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### *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 CPP-109 or CPP-115. 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. 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 June 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, future fluctuations in the price of our common stock may 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 June 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

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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 six month periods ended June 30, 2012 and 2011.

#### *Research and Development Expenses.*

Research and development expenses for the three and six month periods ended June 30, 2012 and 2011 were \$532,741 and \$905,635 and \$1,260,068 and \$1,809,588, respectively, including stock-based compensation expense in each of the three and six month periods of \$18,303 and \$18,671 and \$36,605 and \$37,137, respectively. Research and development expenses, in the aggregate, represented approximately 50% and 65% and 52% and 62%, respectively, of total operating costs and expenses for the three and six month periods ended June 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 six month period ended June 30, 2012 decreased compared to amounts expended in the same period in 2011 as we continued to incur costs associated with our currently ongoing 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 six month periods ended June 30, 2012 and 2011, as we have not yet received approval for the commercialization of CPP-109 or CPP-115. We expect to begin to incur sales and marketing expenses when we submit an NDA for CPP-109 or CPP-115, 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 six months ended June 30, 2012 and 2011 were \$534,623 and \$491,828 and \$1,172,006 and \$1,107,125, respectively, including stock-based compensation expense in each of the three and six month periods of \$26,787 and \$46,405 and \$53,575 and \$81,690, respectively. General and administrative expenses represented 50% and 35% and 48% and 38%, respectively, of total operating costs and expenses for the three and six months ended June 30, 2012 and 2011. General and administrative expenses for the three and six months ended June 30, 2012 were comparable to those of the same periods in 2011.

#### *Stock-Based Compensation.*

Total stock-based compensation for the three and six months ended June 30, 2012 and 2011 was \$45,090 and \$65,076 and \$90,180 and \$118,827, 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 approximately \$594,000 and \$1.6 million at June 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





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warrants liability in the statements of operations. For the three and six months ended June 30, 2012, we recognized a gain of \$776,919 and \$1,051,126, respectively, due to the change in the fair value of the 2011 warrants liability. The gains during the three and six months ended June 30, 2012 were principally a result of the decrease of our stock price between December 31, 2011 and June 30, 2012. Future changes in the value of our common stock may 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 registered direct offerings. The decrease in interest income in the three and six month periods ended June 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 six month periods ended June 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 private placements, an IPO, a secondary public offering and five registered direct offerings under our shelf registration statements. At June 30, 2012, we had cash and cash equivalents aggregating \$7.5 million and working capital of \$7.0 million. At December 31, 2011, we had cash and cash equivalents of \$6.0 million and working capital of \$5.4 million. At June 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 CPP-109 and CPP-115. 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 CPP-109 and CPP-115 in the United States.

We currently believe that we have the cash resources to complete our currently ongoing clinical trials and studies and to continue our operations through the first quarter of 2014. These expectations are based on current information available to us. If the cost of these studies is 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 studies or trials other than those described above, including any Phase III clinical trial that we may be required to complete before we are in a position to file an NDA for CPP-109 for cocaine addiction and any additional human studies of CPP-115 evaluating the safety and efficacy of its use in treating addiction and epilepsy. Since these 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 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;

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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 \$2,445,646 and \$2,294,213, respectively, for the six month periods ended June 30, 2012 and 2011. During the six months ended June 30, 2012, net cash used in operating activities was primarily attributable to our net loss of \$1,378,266, a \$1,051,126 change in fair value of warrants liability, a \$40,951 decrease in accounts payable and a \$103,322 decrease in accrued expenses and other liabilities. This was offset in part by \$95,691 of non-cash expenses and a decrease of \$32,328 in prepaid expenses and deposits. During the six months ended June 30, 2011, net cash used in operating activities was primarily attributable to our net loss of \$2,911,287 and a decrease of \$35,479 in accrued expenses and other liabilities. This was offset in part by \$146,295 of non-cash expenses, the collection of \$134,025 in government grant receivable, a decrease of \$155 in prepaid expenses and deposits and an increase of \$372,078 in accounts payable. Non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities during the six month period ended June 30, 2012 was \$6,881 for the purchase of computers and furniture and equipment. Net cash used in investing activities was \$2,003,488 during the six month period ended June 30, 2011 consisting of \$2,001,688 to purchase certificates of deposit and \$1,800 for the purchase of computer equipment.

Cash provided by financing activities during the six month period ended June 30, 2012 was \$3,938,303, consisting of the net proceeds from the sale of common stock and warrants through a secondary public offering. Net cash provided by financing activities during the six month period ended June 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

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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 June 30, 2012 and December 31, 2011. See Dispute with Brookhaven below.

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*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 June 30, 2012, we had paid \$136,590 of these amounts and had accrued license fees of \$105,000 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 evaluating CPP-109 for the treatment of cocaine addiction that we are jointly conducting with NIDA and the VA. We currently estimate that we will pay approximately \$1.5 million in connection with this agreement. As of June 30, 2012, we had paid approximately \$1.4 million of this amount and had accounts payable of approximately \$14,000 and accrued liabilities of approximately \$42,000 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 \$1.6 million, in connection with our drug development work, including pre-clinical and clinical studies and trials, consulting and data analysis. At June 30, 2012, we have paid approximately \$918,000 of this amount, and had accounts payable of approximately \$66,000 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 June 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.

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

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

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

whether our studies and trials will be successful;

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

the 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.

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**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 June 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 June 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.



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**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

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101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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**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: August 14, 2012

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**Exhibit Index**

Exhibit

Number	Description
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