

Catalyst Pharmaceutical Partners, Inc.

Form 10-Q

November 15, 2010

[Table of Contents](#)

**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, 2010

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

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**76-0837053**  
(IRS Employer  
Identification No.)

**355 Alhambra Circle**

**Suite 1370**

**Coral Gables, Florida**  
(Address of principal executive offices)

**33134**  
(Zip Code)

**Registrant's telephone number, including area code: (305) 529-2522**

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  Accelerated Filer   
Non-Accelerated Filer  (Do not check if a smaller reporting company) Smaller reporting company   
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: 19,394,737 shares of common stock, \$0.001 par value per share, were outstanding as of November 12, 2010.

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**INDEX**

**PART I. FINANCIAL INFORMATION**

Item 1.	<b><u>CONDENSED FINANCIAL STATEMENTS</u></b>	
	<u>Condensed balance sheets at September 30, 2010 (unaudited) and December 31, 2009</u>	3
	<u>Condensed statements of operations for the three and nine months ended September 30, 2010 and 2009 and from Inception (January 4, 2002) through September 30, 2010 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the nine months ended September 30, 2010 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the nine months ended September 30, 2010 and 2009 and from Inception (January 4, 2002) through September 30, 2010 (unaudited)</u>	6
	<u>Notes to unaudited condensed financial statements</u>	7
Item 2.	<b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	15
Item 3.	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>	24
Item 4.	<b><u>CONTROLS AND PROCEDURES</u></b>	24

**PART II. OTHER INFORMATION**

Item 1.	<b><u>LEGAL PROCEEDINGS</u></b>	25
Item 1A.	<b><u>RISK FACTORS</u></b>	25
Item 2.	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	25
Item 3.	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	25
Item 4.	<b><u>REMOVED AND RESERVED</u></b>	25
Item 5.	<b><u>OTHER INFORMATION</u></b>	25
Item 6.	<b><u>EXHIBITS</u></b>	25

**Table of Contents****CATALYST PHARMACEUTICAL PARTNERS, INC.**

(a development stage company)

**CONDENSED BALANCE SHEETS**

	September 30, 2010 (unaudited)	December 31, 2009
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 6,247,177	\$ 7,779,277
Prepaid expenses	108,567	108,147
Total current assets	6,355,744	7,887,424
Property and equipment, net	49,133	68,447
Deposits	10,511	10,511
Total assets	\$ 6,415,388	\$ 7,966,382
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 241,271	\$ 249,635
Accrued expenses and other liabilities	154,795	44,517
Total current liabilities	396,066	294,152
Accrued expenses and other liabilities, non-current	18,771	54,370
Total liabilities	414,837	348,522
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; 19,394,737 shares and 18,038,385 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	19,395	18,038
Additional paid-in capital	36,963,957	35,305,054
Deficit accumulated during the development stage	(30,982,801)	(27,705,232)
Total stockholders' equity	6,000,551	7,617,860
Total liabilities and stockholders' equity	\$ 6,415,388	\$ 7,966,382

**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 (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, 2010
	2010	2009	2010	2009	
Revenues	\$	\$	\$	\$	\$
Operating costs and expenses:					
Research and development	500,091	850,998	1,737,613	4,549,883	21,828,575
General and administrative	408,374	441,316	1,554,396	1,555,786	10,617,612
Total operating costs and expenses	908,465	1,292,314	3,292,009	6,105,669	32,446,187
Loss from operations	(908,465)	(1,292,314)	(3,292,009)	(6,105,669)	(32,446,187)
Interest income	4,480	5,594	14,440	25,861	1,463,386
Loss before income taxes	(903,985)	(1,286,720)	(3,277,569)	(6,079,808)	(30,982,801)
Provision for income taxes					
Net loss	\$ (903,985)	\$ (1,286,720)	\$ (3,277,569)	\$ (6,079,808)	\$ (30,982,801)
Loss per share basic and diluted	\$ (0.05)	\$ (0.09)	\$ (0.18)	\$ (0.43)	
Weighted average shares outstanding basic and diluted	18,821,881	14,065,385	18,305,735	14,065,385	

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

Table of Contents

## CATALYST PHARMACEUTICAL PARTNERS, INC.

(a development stage company)

## CONDENSED STATEMENT OF STOCKHOLDERS EQUITY (unaudited)

For the nine months ended September 30, 2010

	Preferred Stock	Common Stock	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at December 31, 2009</b>	\$	\$ 18,038	\$ 35,305,054	\$ (27,705,232)	\$ 7,617,860
Issuance of stock options for services			204,107		204,107
Issuance of common stock, net		1,352	1,454,801		1,456,153
Vesting of restricted stock units		5	(5)		
Net loss				(3,277,569)	(3,277,569)
<b>Balance at September 30, 2010</b>	\$	\$ 19,395	\$ 36,963,957	\$ (30,982,801)	\$ 6,000,551

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 (unaudited)**

	For the Nine Months Ended September 30,		Cumulative Period from January 4, 2002 (date of inception) through September 30, 2010
	2010	2009	
<b>Operating Activities:</b>			
Net loss	\$ (3,277,569)	\$ (6,079,808)	\$ (30,982,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	19,314	23,145	104,727
Stock-based compensation	204,107	282,161	4,959,444
Changes in assets and liabilities:			
Decrease in interest receivable		12,153	
Decrease (increase) in prepaid expenses and deposits	(420)	65,529	(119,078)
Increase (decrease) in accounts payable	(8,364)	(169,640)	241,271
Increase (decrease) in accrued expenses and other liabilities	74,679	(987,823)	116,042
Net cash used in operating activities	(2,988,253)	(6,854,283)	(25,680,395)
<b>Investing Activities:</b>			
Capital expenditures			(96,339)
Net cash used in investing activities			(96,339)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock, net	1,456,153		28,031,724
Proceeds from issuance of preferred stock			3,895,597
Payment of employee withholding tax related to RSUs			(3,410)
Net cash provided by financing activities	1,456,153		31,923,911
Net (decrease) increase in cash	(1,532,100)	(6,854,283)	6,147,177
Cash and cash equivalents at beginning of period	7,779,277	11,766,629	100,000
Cash and cash equivalents at end of period	\$ 6,247,177	\$ 4,912,346	\$ 6,247,177
<b>Supplemental disclosure 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.

---

**Table of Contents**

**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 biopharmaceutical company focused on the development and commercialization of prescription drugs targeting addiction and diseases of the central nervous system such as epilepsy and neuropathic pain. The Company was incorporated in Delaware in July 2006. It is the successor by merger to Catalyst Pharmaceutical Partners, Inc., a Florida corporation, which commenced operations in January 2002.

The Company has incurred operating losses in each period from inception through September 30, 2010. 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), and three registered direct offerings via a shelf registration statement to institutional investors completed in 2008, 2009 and 2010. See below and Note 8.

***Capital Resources***

In June 2008, the Company filed a registration statement on Form S-3 to sell up to \$30,000,000 of its authorized, but unissued common stock through future offerings. On August 5, 2010, the Company sold 1,351,352 shares of its common stock under its shelf registration statement at a price of \$1.11 per share and received gross proceeds of approximately \$1.5 million before incurred expenses of approximately \$44,000. As of September 30, 2010, the Company had approximately \$20 million of authorized, but unissued common stock available for future offerings under its shelf registration statement. See Note 8.

On April 13, 2010, the Company announced that it had signed a Clinical Trial Agreement (CTA) with the National Institute on Drug Abuse (NIDA) to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109, the Company's formulation of vigabatrin, for the treatment of cocaine addiction. As part of the CTA, NIDA, under their agreement with the Veteran's Administration Cooperative Studies Program, has agreed to provide substantial resources towards the estimated \$10 million trial cost. The Company expects to contribute approximately \$2.8 million in resources towards this trial. It is anticipated that this trial, which is expected to be an approximately 200 patient double-blind, placebo-controlled trial, will be initiated during the fourth quarter of 2010 and that top line data from this trial will be available in the second quarter of 2012.

Subsequent to quarter end, on November 1, 2010 the Company was notified that it had been certified to receive a cash grant aggregating \$488,958 under the Qualifying Therapeutic Discovery Projects Program (section 48D of the Internal Revenue Code). The grant relates to two qualifying therapeutic projects, CPP-109 for the treatment of stimulant dependence and CPP-115 for the treatment of various forms of epilepsy and for stimulant dependence. See Note 12.

At the present time, the Company estimates that it will require additional funding of approximately \$3 million to conduct the non-clinical trials that the Company currently believes will be required before the Company can file an Investigational New Drug Application (IND) for CPP-115 and to fund a Phase I human clinical trial of CPP-115. The Company believes that it already has the resources to complete the U.S. Phase II(b) clinical trial of CPP-109 that the Company is jointly conducting with NIDA. The Company also believes that it has sufficient working capital to support its operations through at least the second quarter of 2012. However, the Company will need additional funding beyond the \$3 million described above to complete any other clinical trials required to file a New Drug Application (NDA) for CPP-109 and/or CPP-115.



---

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

In addition to the filing of the shelf registration statement described above, the Company may raise the additional funds required through public or private equity offerings, debt financings, corporate or government 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 condensed 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 condensed 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, 2009 included in the 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, 2010 are not necessarily indicative of the results to be expected for any future period or for the full 2010 fiscal year.

- c. **USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles ( GAAP ) 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. **COMPREHENSIVE INCOME (LOSS).** U.S. generally accepted accounting principles require that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly into stockholders' equity. The Company has reported comprehensive income (loss) in the statement of stockholders' equity as net income (loss).
- e. **EARNINGS (LOSS) PER SHARE.** Basic earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common stock equivalents, such as unvested restricted common stock and stock options. Due to the net loss for all periods

Edgar Filing: Catalyst Pharmaceutical Partners, Inc. - Form 10-Q

presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive.

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

Potentially dilutive common stock equivalents as of September 30, 2010 consisted of stock options to purchase up to 2,670,619 shares of common stock at exercise prices ranging from \$0.62 to \$6.00 per share.

Potentially dilutive common stock equivalents as of September 30, 2009 included (i) stock options to purchase up to 2,794,482 shares of common stock at exercise prices ranging from \$0.62 to \$6.00 per share and (ii) 5,000 unvested shares of restricted common stock.

- f. **CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments, including U.S. Treasury bills, purchased with an original maturity of three months or less to be cash equivalents. The Company has substantially all of its cash and cash equivalents deposited with one financial institution. The Company had cash balances at certain financial institutions in excess of federally insured limits throughout the period.
- g. **PREPAID EXPENSES.** Prepaid expenses consist primarily of prepaid insurance and advances for the Company's research and product development activities, including drug manufacturing, contracts for non-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.
- h. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company's financial instruments consist of cash and cash equivalents, accounts payables and accrued expenses and other liabilities. At September 30, 2010, the fair value of these instruments approximated their carrying value.
- i. **STOCK COMPENSATION PLANS.** 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 option valuation model and the single-option award approach and 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, 2010, there were outstanding stock options to purchase 2,670,619 shares of common stock (including options to purchase 1,474,372 shares granted under the 2006 Stock Incentive Plan), of which stock options to purchase 2,167,286 shares of common stock were exercisable as of September 30, 2010.

For the three and nine month periods ended September 30, 2010 and 2009, the Company recorded stock-based compensation expense as follows:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2010	2009	2010	2009
Research and development	\$ 11,318	\$ 42,642	\$ 133,749	\$ 162,782
General and administrative	24,654	32,713	70,358	119,379
<b>Total stock-based compensation</b>	<b>\$ 35,972</b>	<b>\$ 75,355</b>	<b>\$ 204,107</b>	<b>\$ 282,161</b>

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

- j. **RECENT ACCOUNTING PRONOUNCEMENTS.** In February 2010, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update 2010-09, *Amendments to Certain Recognition and Disclosure Requirements*, ( ASU 2010-09 ) which amends ASC 855, *Subsequent Events*, to address certain implementation issues related to an entity's requirement to perform and disclose subsequent-events procedures. ASU 2010-09 requires SEC filers to evaluate subsequent events through the date financial statements are issued and exempts SEC filers from disclosing the date through which subsequent events have been evaluated. ASU 2010-09 was effective immediately upon issuance. The adoption of ASU 2010-09 did not have a material effect on the Company's financial statements.

**3. Prepaid Expenses.**

Prepaid expenses consist of the following:

	September 30, 2010	December 31, 2009
Prepaid insurance	\$ 56,425	\$ 82,145
Prepaid research fees	38,719	7,283
Prepaid rent	385	8,035
Other	13,038	10,684
<b>Total prepaid expenses</b>	<b>\$ 108,567</b>	<b>\$ 108,147</b>

**4. Property and Equipment.**

Property and equipment, net consists of the following:

	September 30, 2010	December 31, 2009
Computer equipment	\$ 29,509	\$ 29,509
Furniture and equipment	44,175	44,175
Leasehold improvements	80,176	80,176
	153,860	153,860
Less: Accumulated depreciation	(104,727)	(85,413)
<b>Total property and equipment, net</b>	<b>\$ 49,133</b>	<b>\$ 68,447</b>

Depreciation expense was \$6,234 and \$7,306, and \$19,314 and \$23,145, respectively, for the three and nine month periods ended September 30, 2010 and 2009.

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

Accrued expenses and other liabilities consist of the following:

Edgar Filing: Catalyst Pharmaceutical Partners, Inc. - Form 10-Q

	September 30, 2010	December 31, 2009
Accrued non-clinical and clinical trial expenses	\$ 34,956	\$ 273
Deferred rent and lease incentive	14,390	13,037
Accrued license fees	42,685	18,936
Accrued compensation and benefits	28,096	
Accrued professional fees	13,500	10,000
Other	21,168	2,271
<b>Current accrued expenses and other liabilities</b>	<b>154,795</b>	<b>44,517</b>
Accrued license fees- non-current		24,770
Deferred rent and lease incentive- non-current	18,771	29,600
<b>Non-current accrued expenses and other liabilities</b>	<b>18,771</b>	<b>54,370</b>
<b>Total accrued expenses and other liabilities</b>	<b>\$ 173,566</b>	<b>\$ 98,887</b>

---

**Table of Contents****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 substance 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 2023. 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. At September 30, 2010 and December 31, 2009, the Company believes it had a contingent liability of approximately \$166,000 relating to this obligation, a portion of which will become payable in six equal monthly installments at the time the Company submits an NDA to the U.S. Food and Drug Administration ( FDA ), and the balance of which will be due 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 \$1.2 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, 2010 and December 31, 2009 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 Northwestern license agreement, the Company will be responsible for continued research and development of any resulting product candidates. As of September 30, 2010, the Company had paid \$56,436 in connection with the license. In addition, the Company accrued license fees totaling \$42,685 and \$43,706 as of September 30, 2010 and December 31, 2009, respectively, in connection with license expenses, maintenance fees and milestones. The Company is also 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 first such milestone payment of \$50,000 is due on the earlier of the filing of an IND for CPP-115 or August 27, 2012.

---

**Table of Contents**

**6. Commitments (continued).**

- c. **AGREEMENTS FOR DRUG DEVELOPMENT, NON-CLINICAL AND CLINICAL STUDIES.** The Company has contracted with various consultants, drug manufacturers, and other vendors to assist in drug development work, clinical and non-clinical studies, data analysis and the preparation of material necessary for the filing of INDs and NDAs with the FDA. The contracts are cancelable at any time, but obligate the Company to reimburse the providers for any costs incurred through the date of termination. The Company currently estimates that it will pay an aggregate of approximately \$1.1 million under these agreements. Through September 30, 2010, the Company had paid approximately \$789,000 of this amount. In addition, the Company had approximately \$39,000 in prepaid expenses, \$155,000 in accounts payable and \$35,000 in accrued expenses in the accompanying balance sheet as of September 30, 2010 relating to these contracts.

**7. Income Taxes.**

The Company is subject to income taxes in the U.S. federal jurisdiction and various state 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 years before 2003. 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. Stockholders Equity.**

On November 13, 2009, 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 April 26, 2010, 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.

On June 2, 2008, the Company filed a shelf registration statement with the SEC to sell up to \$30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. Under this registration statement, the Company may sell common stock periodically pursuant to a Prospectus Supplement to provide additional funds for its operations. The number of shares that the Company can sell and the amount of the gross proceeds that the Company can raise are limited to 20% of the number of shares of outstanding common stock and 33% of the Company s public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules. In September 2008, the Company sold 1,488,332 shares of its common stock at \$3.00 per share under its shelf registration statement and received gross proceeds of approximately \$4.5 million before commissions and incurred expenses of approximately \$377,000. In October 2009, the Company sold an additional 3,973,000 shares of its common stock under its shelf registration statement at a price of \$1.00 per share and received gross proceeds of approximately \$4.0 million before commissions and incurred expenses of approximately \$275,000. In August 2010, the Company sold an additional 1,351,352 shares of its common stock under its shelf registration statement at a price of \$1.11 per share and received gross proceeds of approximately \$1.5 million before incurred expenses of approximately \$44,000.

**Table of Contents****9. Stock Compensation.***Stock Options*

No stock options were granted during the three and nine month periods ended September 30, 2010. During the three and nine months ended September 30, 2009, the Company granted 30,000 and 64,000 common stock options to employees, officers, directors and consultants, at exercise prices equal to the market value of the stock at the date of grant. The Company recorded stock-based compensation related to stock options totaling \$35,972 and \$204,107 during the three and nine months ended September 30, 2010 and \$70,317 and \$267,047 during the three and nine month ended September 30, 2009, respectively. The weighted-average grant date fair value of stock options granted during the three and nine month periods ended September 30, 2009 was \$0.58 and \$1.15, respectively. No stock options vested during the three months ended September 30, 2010. The total fair value of vested stock options was \$9,483 during the nine months ended September 30, 2010 and \$191,609 and \$403,103 during the three and nine month periods ended September 30, 2009, respectively.

The calculated value of the stock options was determined using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2010	2009	2010	2009
Risk free interest rate	0.97%	2.19 to 2.49%	0.97 to 2.44%	1.26 to 2.60%
Expected term	4 to 5 years	4 to 5 years	4 to 5 years	4 to 5 years
Expected volatility	100%	90%	100%	90%
Expected dividend yield	%	%	%	%
Expected forfeiture rate	%	%	%	%

As of September 30, 2010, there was approximately \$143,000 of unrecognized compensation expense related to non-vested stock compensation awards granted under the Plan. The cost is expected to be recognized over a weighted average period of approximately 1.05 years.

*Restricted Stock Units*

No restricted stock units were granted during the three and nine month periods ended September 30, 2010 and 2009. There was no stock-based compensation related to restricted stock units during 2010, as all such units had vested as of January 1, 2010. The Company recorded stock-based compensation related to restricted stock units totaling \$5,038 and \$15,114, respectively, during the three month and nine month periods ended September 30, 2009.

*Additional Stock Option Grants*

See Note 12 for information about stock option grants subsequent to September 30, 2010.

**10. Related Party Transactions.**

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers, directors and with members of the Company's Scientific Advisory Board. During the three and nine month periods ended September 30, 2010 and 2009, the Company paid approximately \$21,000 and \$14,000 and \$60,000 and \$43,000, respectively, in consulting fees to related parties.

**11. Reclassifications.**

Certain prior period amounts in the condensed financial statements have been reclassified to conform to the current period presentation.



**Table of Contents**

**12. Subsequent Events.**

See Note 1 for information about the receipt of notification of Section 48D cash grants subsequent to the quarter ended September 30, 2010.

Subsequent to quarter end, on November 5, 2010 the Compensation Committee of the Company's Board of Directors granted five-year options to purchase an aggregate of 300,000 shares of the Company's authorized but unissued common stock to certain of the Company's officers and employees. Such options have an exercise price of \$1.09 per share, which was the market closing price of the Company's common stock on the date of grant, and will vest over a two year period. Additionally, on the same date the Compensation Committee granted five-year options to purchase an aggregate of 165,000 shares of the Company's common stock to the Company's directors and to the Company's corporate secretary. Such stock option grants also have an exercise price of \$1.09 per share and vested immediately. All such options were granted under the Company's 2006 Stock Incentive Plan. See Note 9.

---

**Table of Contents**

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

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This report and the information incorporated by reference into it include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements in these sections. All statements regarding our expected financial position and operating results, our business strategy, our product development efforts, including the anticipated timing of receipt of results from our clinical and non-clinical trials, our financing plans and trends relating to our business and industry are forward-looking statements. These statements can sometimes be identified by our use of forward-looking words such as may, will, anticipate, estimate, expect, intend and similar expressions. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the results, performance or achievements expressed or implied by our forward-looking statements. We cannot promise that our expectations described in such forward-looking statements will turn out to be correct. Factors that may impact such forward-looking statements include, among others, our ability to successfully complete clinical trials required for us to file new drug applications for CPP-109 and for CPP-115, our ability to complete such trials on a timely basis and within the budgets we establish for such trials, our ability to obtain the funding for such trials, our ability to protect our intellectual property, whether others develop and commercialize products competitive to our products, changes in the regulations affecting our business, our ability to attract and retain skilled employees, and changes in general economic conditions and interest rates. The risk factors section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009 describes a number of significant risks associated with our business. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**Overview**

We are a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting addiction and diseases of the central nervous system such as epilepsy and neuropathic pain. We have two products in development. We are currently evaluating our lead product candidate, CPP-109 (our version of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the U.S. Food & Drug Administration (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 pharmacological 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 obsessive-compulsive disorders. Further, we are in the early stages of developing CPP-115, which is another GABA aminotransferase inhibitor that, based on non-clinical studies, we believe is more potent than vigabatrin but has 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 epilepsy, drug addiction and neuropathic pain. 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 non-clinical and clinical trials, proof-of-concept studies, and other product development activities;

## **Table of Contents**

the results of our non-clinical and clinical 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, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

### **Recent Developments**

#### ***CPP-109***

On April 13, 2010, we signed a definitive Clinical Trial Agreement (CTA) with the National Institute on Drug Abuse (NIDA) to jointly conduct a U.S. Phase II(b) clinical trial evaluating CPP-109 for the treatment of cocaine addiction. As part of the CTA, NIDA, under their agreement with the Veterans Administration Cooperative Studies Program, has agreed to provide substantial resources towards the estimated \$10 million trial cost. We expect to contribute approximately \$2.8 million in resources towards this trial. It is anticipated that this trial which will be an approximately 200 patient double-blind, placebo-controlled trial that will be initiated during the fourth quarter of 2010 will have top line data in the second quarter of 2012. This trial will be conducted at twelve leading addiction research facilities across the United States. This clinical trial is designed to confirm the safety and efficacy of CPP-109 for the treatment of cocaine addiction and if successful, we believe will qualify to be one of the adequate and well controlled trials required to support approval of an NDA.

During July 2010, we announced that the European Patent Office (EPO) granted to Brookhaven a European patent for the use of vigabatrin for the prevention of addiction to opioids (e.g. oxycodone, hydrocodone) used in pain management. By dampening dopamine release and thus, the euphoria associated with opioids, the opioid/vigabatrin combination may lower or prevent addictive liability without adversely affecting pain relief.

#### ***CPP-115***

On November 1, 2010 we announced key results for an initial series of safety and efficacy evaluations in a number of animal and in-vitro laboratory tests:

In visual safety testing of treated rats exposed for 90 days to CPP-115, vigabatrin and placebo, CPP-115 caused substantially less retinal damage than vigabatrin at well above the expected therapeutic doses.

The oral pharmacokinetic behavior (PK) of CPP-115 in rats supports further development as an orally delivered pharmacotherapy.

CPP-115 was found to not inhibit or induce metabolic enzymes and is not itself metabolized. As a result, drug-drug interactions or other metabolism-related side effects are unlikely. Additionally, non-metabolized drugs are advantageous for treating drug addicts; a population that often has impaired liver function.

With the exception of its biochemical target, GABA-aminotransferase, CPP-115 did not show any clinically significant binding to 111 of the most prevalent receptors, proteins and transporters. Additionally, CPP-115 showed no binding to other GABA-related targets (GABA receptors and transporters). Therefore, CPP-115 is very specific and is not likely to induce drug-drug interactions or unintended side effects.

CPP-115 did not show any interference with the hERG channel and is therefore not likely to induce heart arrhythmias.

CPP-115 did not show any abnormalities in an in-vitro battery of genotoxicity test and thus is not likely to be carcinogenic.

## **Table of Contents**

CPP-115 did not show any inhibition of AST and ALT at doses far above the expected therapeutic dosage. This is in contrast to vigabatrin's known inhibition at therapeutic doses of these key liver transaminase enzymes.

CPP-115, like vigabatrin, was found to significantly reduce seizures in accepted animal models of epilepsy, as evaluated by the National Institutes of Health's Anticonvulsant Screening Program (ASP), at lower doses than vigabatrin.

CPP-115 was found to eliminate cocaine-related conditioned place preference and significantly reduce cocaine-induced dopamine surge, key tests needed to demonstrate a drug's effectiveness as a potential treatment for stimulant addiction. These effects were observed at doses more than 100 times lower than that needed by vigabatrin to achieve the same effect.

We are currently advancing the development of CPP-115 by undertaking the remainder of the studies necessary to file an IND.

Additionally, on September 1, 2010, CPP-115 was granted orphan drug designation by the FDA for the treatment of infantile spasms.

There can be no assurance that CPP-115 will ultimately be proven to be safe and effective to treat epilepsy, drug addiction or neuropathic pain, or that CPP-115 will ultimately be determined not to have a similar visual field side effect profile to vigabatrin.

### ***Update on non-clinical and clinical studies that we support***

We have been advised that one of our clinical collaborators received a \$1.2 million grant from the U.S. Department of Defense to conduct an animal study of the use of vigabatrin in combination with opiates to effectively manage pain while reducing the potential for opiate addiction. This research is being conducted by a research team led by Wynne K. Schiffer, Ph.D. and Stephen L. Dewey, Ph.D. of The Feinstein Institute for Medical Research at the North Shore LIJ Hospital and by Jonathan D. Brodie, M.D., Ph.D. from the Department of Psychiatry at New York University's School of Medicine. Drs. Dewey and Brodie are the co-inventors on the vigabatrin-related patents that we have licensed from Brookhaven and are members of our Scientific Advisory Board. The study is being conducted at the Feinstein Institute. Opioid abuse is one of the many substance addiction indications covered under our exclusive license of Brookhaven's vigabatrin use patent portfolio. We have supplied CPP-109 (our version of vigabatrin) to facilitate this study.

We have been advised that a clinical researcher at the University of Pennsylvania expects to commence an investigator-sponsored proof-of-concept study of CPP-109 in patients dependent on both cocaine and alcohol by early 2011. We expect to supply CPP-109 (our version of vigabatrin), placebo and approximately \$50,000 in funding to facilitate the conduct of this study.

We are also collaborating with other investigators by providing CPP-109 and access to our CPP-109 IND for studies that we believe will add value to our own research and development. Future potential studies include studies for evaluating CPP-109 for the treatment of alcohol, nicotine, cocaine and methamphetamine addiction.

### ***Discussions with strategic partners***

We periodically have discussions with potential strategic partners interested in working with us on the development of CPP-109 and CPP-115. Such discussions may not result in relationships that we determine to pursue, and no agreements have been entered into to-date.

## **Table of Contents**

### *NASDAQ Listing*

Our common stock currently trades on the Nasdaq Capital Market. On November 13, 2009, 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 May 12, 2010, 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 April 26, 2010, 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.

### *Addition to Scientific Advisory Board*

On November 15, 2010, we announced that Dr. Richard B. Silverman has joined our Scientific Advisory Board. Dr. Silverman is the inventor of CPP-115.

### **Basis of presentation**

#### *Revenues*

We are a development stage company and have had no revenues 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. We will report as revenues the funds received under Section 48D. See Liquidity and Capital Resources below.

#### *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 non-clinical study costs, clinical manufacturing costs, clinical 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 non-clinical and clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical 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, the successful enrollment of patients, and the completion of portions of the clinical 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 clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies at a given point in time, we could be required to record significant additional research and development expenses in future periods. Clinical trial activities require significant up front expenditures. We anticipate paying significant portions of a trial's cost before such trial begins, and incurring additional expenditures as the 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 CPP-109 or CPP-115. We expect to have a sales force in place to commence our selling efforts immediately upon receiving approval of such NDAs, of which there can be no assurance.



## **Table of Contents**

### *General and administrative expenses*

Our 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 option valuation model in calculating the fair value of these awards, and recognize stock-based compensation expense ratably over the vesting period.

### *Income taxes*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of September 30, 2010 and December 31, 2009, 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 become 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 than not 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.

## **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. 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 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.

The list below is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management's judgment in selecting any available alternative would not produce a materially different result. Our condensed financial statements and the notes thereto included elsewhere in this report contain accounting policies and other disclosures as required by GAAP.

### *Non-clinical study and clinical trial expenses*

Research and development expenditures are charged to operations as incurred. Our expenses related to non-clinical and clinical trials are based on actual and estimated costs of the services received and efforts expended pursuant to contracts with multiple research institutions and any CRO that conducts and manages our clinical trials. The financial terms of these agreements are subject to negotiation and will vary from contract to contract and may result in uneven payment flows. Generally, these agreements will set forth the scope of the work to be performed at a fixed fee or unit price. Payments under these contracts will depend on factors such as the successful enrollment of patients or the completion of non-clinical and clinical trial milestones. Expenses related to clinical trials generally are accrued based on contracted amounts applied to the level of patient enrollment and activity according to the protocol. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we would be required to modify our estimates accordingly on a prospective basis.



**Table of Contents***Stock-based compensation*

We recognize stock-based compensation for the fair value of all share-based payments, including grants of stock options and restricted stock units. For stock options we use the Black-Scholes option valuation model to determine the fair value of stock options on the date of grant. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield. Our expected volatility is based on the historical volatility of other publicly traded companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated expected life of our stock option awards. For the three month periods ended September 30, 2010 and 2009, the assumptions used were an estimated annual volatility of 100% and 90%, average expected holding periods of four to five years, and risk-free interest rates of 0.97% and 2.19% to 2.49%, respectively. For the nine month periods ended September 30, 2010 and 2009, the assumptions used were an estimated annual volatility of 100% and 90%, average expected holding periods of four to five years, and risk-free interest rates of 0.97% to 2.44% and 1.26% to 2.60%, respectively.

**Results of Operations**

*Revenues.* We had no revenues for the three and nine month periods ended September 30, 2010 and 2009.

*Research and Development Expenses.* Research and development expenses for the three and nine months ended September 30, 2010 and 2009 were \$500,091 and \$850,998 and \$1,737,613 and \$4,549,883, respectively, including stock-based compensation expense in each of the three and nine months periods of \$11,318 and \$42,642 and \$133,749 and \$162,782, respectively. Research and development expenses, in the aggregate, represented approximately 55% and 66% and 53% and 75% of total operating costs and expenses, respectively, for the three and nine months ended September 30, 2010 and 2009. The stock-based compensation is non-cash and relates to the expense of stock options awards and restricted stock unit awards to our employees, officers, consultants and scientific advisors. Expenses for research and development for the three and nine month periods ended September 30, 2010 decreased compared to amounts expended in the same period in 2009 during which we completed our Phase II clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and our proof-of-concept study evaluating CPP-109 for use in the treatment of methamphetamine addiction.

We expect that costs related to research and development activities will increase for the remainder of 2010, as we conduct additional non-clinical trials for CPP-115 and initiate the NIDA/VA U.S. Phase II(b) clinical trial evaluating CPP-109 as a treatment for cocaine addiction.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the three and nine month periods ended September 30, 2010 and 2009. We anticipate that we will not begin to incur sales and marketing expenses until we file NDAs for CPP-109 and/or CPP-115.

*General and Administrative Expenses.* General and administrative expenses for the three and nine months ended September 30, 2010 and 2009 were \$408,374 and \$441,316 and \$1,554,396 and \$1,555,786, respectively, including stock-based compensation expense in each of the three and nine month periods of \$24,654 and \$32,713 and \$70,358 and \$119,379, respectively. General and administrative expenses represented 45% and 34% and 47% and 25%, respectively, of total operating costs and expenses for the three and nine months ended September 30, 2010 and 2009. General and administrative expenses for the three and nine months periods ended September 30, 2010 were consistent with comparable periods in 2009. General and administrative expenses include among other expenses, management salaries and benefits, office expenses, legal and accounting fees and travel expenses for certain employees and consultants, directors and members of our Scientific Advisory Board.

*Stock-Based Compensation.* Total stock-based compensation for the three and nine months ended September 30, 2010 and 2009 was \$35,972 and \$75,355 and \$204,107 and \$282,161, respectively. The reduction in expense for the nine month ended September 30, 2010 from the comparable period in 2009 is mostly due to granted awards to directors which vested immediately in 2009. There were no such grants in 2010.

## **Table of Contents**

*Interest Income.* We reported interest income in all periods relating to our investment of funds received from our private placements, IPO and registered direct offerings. The decrease in interest income in the three and nine month periods ended September 30, 2010 when compared to the same periods in 2009 is due to lower interest rates and lower investment amounts as we use the proceeds from our offerings to fund operations. All such funds were invested in bank savings accounts, money market funds, short term interest-bearing obligations, certificates of deposit and direct or guaranteed obligations of the United States government.

*Income taxes.* We have incurred net operating losses since inception. For the three and nine month periods ended September 30, 2010 and 2009, 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, the IPO and registered direct offerings under our shelf registration statement. At September 30, 2010, we had cash and cash equivalents of \$6.2 million and working capital of \$6.0 million. At December 31, 2009, we had cash and cash equivalents of \$7.8 million and working capital of \$7.6 million. At September 30, 2010, substantially all of our cash and cash equivalents were deposited with one financial institution. We had cash balances at certain financial institutions 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 trials and non-clinical studies that will be 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.

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;

the results of our non-clinical and clinical trials;

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, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

## Edgar Filing: Catalyst Pharmaceutical Partners, Inc. - Form 10-Q

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

On November 1, 2010, we were advised that we had been awarded cash grants aggregating \$488,958 for two qualifying therapeutic projects, CPP-109 for the treatment of stimulant dependence and CPP-115 for the treatment of various forms of epilepsy and for stimulant dependence, under section 48D of the Internal Revenue Code. We received approximately \$355,000 of these funds in November 2010 and expect to receive the balance (approximately \$134,000) during the first quarter of 2011. We will report the amounts received as revenue.

## Table of Contents

At the present time, we estimate that we will require additional funding of approximately \$3 million to conduct the non-clinical trials that we currently believe will be required before we can file an IND for CPP-115 and to fund a Phase I human clinical trial of CPP-115. We believe that we already have the resources to complete the U.S. Phase II(b) clinical trial of CPP-109 that we are jointly conducting with NIDA. We also believe that we have sufficient working capital to support our operations through at least the second quarter of 2012. However, we will need additional funding beyond the \$3 million described above to complete any other clinical trials required to file an NDA for CPP-109 and/or CPP-115.

We expect to raise any required additional funds through public or private equity offerings, corporate or governmental collaborations or other means. We also intend to seek governmental grants for a portion of the required funding for our clinical trials and non-clinical trials. 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 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.

On June 2, 2008, we filed a shelf registration statement with the SEC to sell up to \$30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. Under this registration statement, shares may be sold periodically to provide additional funds for our operations. The number of shares we can sell and the amount of proceeds we can raise from the sale of such shares are limited to 20% of outstanding common stock and 33% of our public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules.

To date we have completed three registered direct public offerings to institutional investors under our shelf registration statement:

On September 12, 2008, we raised gross proceeds of approximately \$4.5 million on the sale of 1,488,332 shares of our common stock; and

On October 2, 2009, we raised gross proceeds of approximately \$4.0 million on the sale of 3,973,000 shares of our common stock; and

On August 9, 2010, we raised gross proceeds of approximately \$1.5 million on the sale of 1,351,352 shares of our common stock. Currently, we have approximately \$20.0 million of authorized but unissued common stock available for future offerings under the shelf registration. However, there can be no assurance that we will be able to sell any additional shares under our shelf registration statement.

### *Cash Flows*

Net cash used in operating activities was \$2,988,253 and \$6,854,283, respectively, for the nine month periods ended September 30, 2010 and 2009. During the nine months ended September 30, 2010, net cash used in operating activities was primarily attributable to our net loss of \$3,277,569 and a decrease of \$8,364 in accounts payable. This was offset in part by \$223,421 of non-cash expenses, and an increase of \$74,679 in accrued expenses and other liabilities. During the nine months ended September 30, 2009, net cash used in operating activities was primarily attributable to our net loss of \$6,079,808 and decreases of \$169,640 in accounts payable and \$987,823 in accrued expenses and other liabilities. This was offset in part by \$305,306 of non-cash expenses and decreases of \$65,529 in prepaid expenses and deposits and \$12,153 in interest receivable. Non-cash expenses include depreciation and stock-based compensation expense.

## Table of Contents

No cash was provided by (used in) investing activities during the nine month periods ended September 30, 2010 and 2009.

Net cash provided by financing activities for the nine months ended September 30, 2010 was \$1,456,153. This amount was attributable to proceeds from the sale of common stock shares pursuant to a shelf registration and prospectus supplement of \$1,500,000, offset by \$43,847 of shelf registration costs. No cash was provided by (used in) financing activities during the nine month period ended September 30, 2009.

### *Contractual Obligations*

We have entered into the following contractual arrangements:

*Payment 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, 2010 and December 31, 2009. See *Dispute with Brookhaven* below.

*Payment to Northwestern University under our license agreement.* We have agreed to pay Northwestern an upfront fee of \$35,000, reimbursement of approximately \$33,000 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. The first such milestone payment of \$50,000 is due on the earlier of the filing of an IND or August 27, 2012. At September 30, 2010, we had paid Northwestern \$56,436 under this agreement, and had accrued license fees of \$42,685 in the accompanying condensed balance sheet.

*Payments for drug development, non-clinical and clinical studies.* We currently estimate that we will pay various consultants, drug manufacturers, and other vendors approximately \$1.1 million, in connection with our drug development work, including clinical and non-clinical studies, data analysis and the preparation of material necessary for the filing of NDAs with the FDA. At September 30, 2010, we have paid approximately \$789,000 of this amount, \$39,000 of which had been advanced and as such have been included in prepaid expenses. In addition, at September 30, 2010, we had approximately \$155,000 in accounts payable and \$35,000 in accrued expenses in the accompanying condensed balance sheet related to these contracts.

*Employment agreements.* We have an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately \$358,000 per annum.

*Leases for office space.* We have entered into lease agreements for our office space that require 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 \$1.2 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 the Company of an NDA for CPP-109. As we have not filed an NDA for CPP-109, no amounts are accrued relating to this matter in the accompanying September 30, 2010 and December 31, 2009 balance sheets.



**Table of Contents**

*Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of September 30, 2010 and December 31, 2009 were not material. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

**Recent Accounting Pronouncements**

For discussion of recently issued accounting standards, please see Item 1, Condensed Financial Statements in part I of this Form 10-Q.

**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(c) 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, 2010, 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. There have been 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.

**Table of Contents**

**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 Annual Report on Form 10-K for the year ended December 31, 2009, 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. REMOVED AND RESERVED**

**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
- 99.1 Press Release issued on November 15, 2010 announcing that Dr. Richard B. Silverman has joined the Company's Scientific Advisory Board.



**Table of Contents**

**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/ Jack Weinstein  
Jack Weinstein  
Vice President, Treasurer and Chief Financial Officer

Date: November 15, 2010

**Table of Contents**

**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
99.1	Press Release issued on November 15, 2010 announcing that Dr. Richard B. Silverman has joined the Company's Scientific Advisory Board