

Catalyst Pharmaceutical Partners, Inc.

Form 10-Q

August 06, 2009

[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 June 30, 2009**

**OR**

**TRANSITION REPORT PURSUANT TO 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: 14,065,385 shares of common stock, \$0.001 par value per share, were outstanding as of July 31, 2009.

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**INDEX**

Item 1.	<b>CONDENSED FINANCIAL STATEMENTS</b>	
	<u>Condensed balance sheets at June 30, 2009 (unaudited) and December 31, 2008</u>	3
	<u>Condensed statements of operations for the three and six months ended June 30, 2009 and 2008 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the six months ended June 30, 2009 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the six months ended June 30, 2009 and 2008 (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>	14
Item 3.	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>	23
Item 4T.	<b><u>CONTROLS AND PROCEDURES</u></b>	23
	<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1.	<b><u>LEGAL PROCEEDINGS</u></b>	24
Item 1A.	<b><u>RISK FACTORS</u></b>	24
Item 2.	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	24
Item 3.	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	24
Item 4.	<b><u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></b>	24
Item 5.	<b><u>OTHER INFORMATION</u></b>	24
Item 6.	<b><u>EXHIBITS</u></b>	24

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

	<b>June 30, 2009 (unaudited)</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 6,265,577	\$ 11,766,629
Interest receivable		12,153
Prepaid expenses	124,673	136,374
Total current assets	6,390,250	11,915,156
Property and equipment, net	80,537	96,376
Deposits	10,511	21,436
Total assets	\$ 6,481,298	\$ 12,032,968
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 275,663	\$ 332,707
Accrued expenses and other liabilities	195,282	1,097,410
Total current liabilities	470,945	1,430,117
Accrued expenses and other liabilities, non-current	36,420	42,636
Total liabilities	507,365	1,472,753
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized: none issued and outstanding		
Common stock, \$.001 par value, 100,000,000 shares authorized; 14,065,385 shares and 14,060,385 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	14,065	14,060
Paid in capital and additional paid-in capital	31,216,260	31,009,459
Deficit accumulated during the development stage	(25,256,392)	(20,463,304)
Total stockholders' equity	5,973,933	10,560,215
Total liabilities and stockholders' equity	\$ 6,481,298	\$ 12,032,968

**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 June 30,		For the Six Months Ended June 30,		Cumulative Period from January 4, 2002 (date of inception) to June 30, 2009
	2009	2008	2009	2008	
Revenues	\$	\$	\$	\$	\$
Operating costs and expenses:					
Research and development	1,376,253	1,902,144	3,698,885	2,986,503	18,554,407
General and administrative	392,559	561,533	1,114,470	1,201,206	8,137,732
Total operating costs and expenses	1,768,812	2,463,677	4,813,355	4,187,709	26,692,139
Loss from operations	(1,768,812)	(2,463,677)	(4,813,355)	(4,187,709)	(26,692,139)
Interest income	6,925	86,237	20,267	226,222	1,435,747
Loss before income taxes	(1,761,887)	(2,377,440)	(4,793,088)	(3,961,487)	(25,256,392)
Provision for income taxes					
Net loss	\$ (1,761,887)	\$ (2,377,440)	\$ (4,793,088)	\$ (3,961,487)	\$ (25,256,392)
Loss per share basic and diluted	\$ (0.13)	\$ (0.19)	\$ (0.34)	\$ (0.32)	
Weighted average shares outstanding basic and diluted	14,065,385	12,567,226	14,065,385	12,560,085	

**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 six months ended June 30, 2009**

	Preferred Stock	Common Stock	Paid-in and Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at December 31, 2008</b>	\$	\$ 14,060	\$ 31,009,459	\$ (20,463,304)	\$ 10,560,215
Issuance of stock options for services			196,730		196,730
Amortization of restricted stock units for services			10,076		10,076
Issuance of common stock		5	(5)		
Net loss				(4,793,088)	(4,793,088)
<b>Balance at June 30, 2009</b>	\$	\$ 14,065	\$ 31,216,260	\$ (25,256,392)	\$ 5,973,933

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)**

	<b>For the Six Months Ended June 30,</b>		<b>Cumulative Period from January 4, 2002 (date of inception) through June 30, 2009</b>
	<b>2009</b>	<b>2008</b>	
<b>Operating Activities:</b>			
Net loss	\$ (4,793,088)	\$ (3,961,487)	\$ (25,256,392)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	15,839	16,440	71,025
Stock-based compensation	206,806	386,612	4,360,705
Change in assets and liabilities:			
Decrease in interest receivable	12,153	39,542	
Decrease (increase) in prepaid expenses and deposits	22,626	247,757	(135,184)
Increase (decrease) in accounts payable	(57,044)	(38,589)	275,663
Increase (decrease) in accrued expenses and other liabilities	(908,344)	470,286	174,178
Net cash used in operating activities	(5,501,052)	(2,839,439)	(20,510,005)
<b>Investing Activities:</b>			
Capital expenditures		(1,345)	(94,041)
Net cash used in investing activities		(1,345)	(94,041)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock			22,877,436
Proceeds from issuance of preferred stock			3,895,597
Payment of shelf registration costs		(16,994)	
Payment of employee withholding tax related to RSUs		(2,010)	(3,410)
Net cash provided by (used in) financing activities		(19,004)	26,769,623
Net (decrease) increase in cash	(5,501,052)	(2,859,788)	6,165,577
Cash and cash equivalents at beginning of period	11,766,629	15,943,896	100,000
Cash and cash equivalents at end of period	\$ 6,265,577	\$ 13,084,108	\$ 6,265,577
<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 acquisition, development and commercialization of prescription drugs for the treatment of drug addiction and obsessive-compulsive disorders. 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 June 30, 2009. 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) in 2006, and a registered direct offering via a shelf registration to institutional investors in 2008.

***Capital Resources***

The Company is currently analyzing the data from its clinical trial evaluating its product candidate, CPP-109, in the treatment of cocaine addiction and its proof-of-concept study evaluating CPP-109 for the treatment of methamphetamine addiction. The Company expects to complete its analysis of the trial data by the end of the third quarter of 2009. Following such complete analysis, the Company expects to be in a position to determine the appropriate future development plans for CPP-109, including the clinical and non-clinical trials that will be required in order for the Company to file an NDA for CPP-109, and the estimated costs of such future trials. There can be no assurance that the Company will ever receive an approval to commercialize CPP-109.

The Company will require additional capital to fund any future clinical and non-clinical studies of CPP-109. The Company will also require additional working capital to support its operations in periods after 2010.

In June 2008, the Company filed a registration statement on Form S-3 in order to be able to sell up to \$30,000,000 of its authorized but unissued common stock through future offerings. During September 2008, the Company sold 1,488,332 shares of its common stock under such registration statement at a price of \$3.00 per share and received gross proceeds of approximately \$4.5 million before commissions and incurred expenses of approximately \$377,000. At June 30, 2009, the Company had approximately \$25.5 million of authorized but unissued common stock available for future offerings under its shelf registration statement. See Note 8.

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 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.



---

**Table of Contents**

**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 Statement of Financial Accounting Standard No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company's primary focus is on the development and commercialization of CPP-109, which is the Company's version of the chemical compound gamma-vinyl-GABA (commonly referred to as vigabatrin) as a potential treatment for drug addiction, including cocaine addiction, methamphetamine addiction and certain obsessive-compulsive disorders.
- 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 United States 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, 2008 included in the 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, 2009 are not necessarily indicative of the results to be expected for any future period or for the full 2009 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. **COMPREHENSIVE INCOME (LOSS).** SFAS No. 130, *Reporting Comprehensive Income (Loss)*, requires 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 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 presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive.

Potentially dilutive common stock equivalents as of June 30, 2009 include (i) stock options to purchase up to 2,781,149 shares of common stock at exercise prices ranging from \$0.69 to \$6.00 per share and (ii) restricted stock units to receive 5,000 shares of common stock that will vest over the next six months.

Potentially dilutive common stock equivalents as of June 30, 2008 include (i) stock options to purchase up to 2,667,149 shares of common stock at exercise prices ranging from \$0.69 to \$6.00 per share and (ii) 15,241 shares of restricted common stock.

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

- 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 include advances under research and development contracts, including advances to the Contract Research Organization ( CRO ) that is overseeing the Company's U.S. Phase II cocaine clinical trial and methamphetamine proof-of-concept study. 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, interest receivable, accounts payables and accrued liabilities. At June 30, 2009 the fair value of these instruments approximated their carrying value.
- i. **STOCK COMPENSATION PLANS.** Through July 2006 the Company did not have a formal stock option plan, although stock options were granted pursuant to written agreements. In July 2006 the Company adopted the 2006 Stock Incentive Plan (the Plan ). As of June 30, 2009, there were outstanding stock options to purchase 2,781,149 shares of common stock (including options to purchase 428,888 shares granted under the Plan), of which stock options to purchase 2,667,557 shares of common stock were exercisable as of June 30, 2009. Additionally, as of June 30, 2009 there were 55,484 restricted common stock units granted under the Plan, of which 50,484 were vested.

For the three and six month periods ended June 30, 2009 and 2008, the Company recorded stock-based compensation expense as follows:

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Research and development	\$ 48,440	\$ 99,532	\$ 120,140	\$ 274,088
General and administrative	16,092	23,676	86,666	112,524
<b>Total stock-based compensation</b>	<b>\$ 64,532</b>	<b>\$ 123,208</b>	<b>\$ 206,806</b>	<b>\$ 386,612</b>

- j. **RECENT ACCOUNTING PRONOUNCEMENTS**  
 In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ). This standard provides guidance for using fair value to measure assets and liabilities. The standard also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, but does not expand the use of fair value in any new circumstances. There are numerous previously issued statements dealing with fair values that are amended by SFAS No. 157. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued Staff Position ( FSP ) FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13* , which scopes out leasing transactions accounted for under SFAS No. 13, *Accounting for Leases* .

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

In February 2008, FSP FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued, which delays the effective date of SFAS No. 157 to fiscal years and interim periods within those fiscal years beginning after November 15, 2008 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Effective January 1, 2008, the Company adopted SFAS No. 157 for all financial assets and financial liabilities. Effective January 1, 2009, the Company adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities. The adoption of SFAS No. 157 for financial and nonfinancial assets and liabilities did not have a material impact on the Company's results of operations or financial condition.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* (SFAS No. 165), which modifies current guidance in the auditing literature of the American Institute of Certified Public Accountants (AICPA) Auditing Standards (AU) Section 560, and is effective for interim or annual financial periods ending after June 15, 2009. The modifications require the two types of subsequent events to be named, as either recognized or non-recognized subsequent events, modify the definition of subsequent events to refer to events of transactions that occur after the balance sheet date but before the financial statements are issued, and require entities to disclose the date through which they have evaluated subsequent events and the basis for that date. The Company adopted the provisions of SFAS No. 165 as of June 30, 2009 and evaluated the impact of subsequent events through August 6, 2009, representing the date at which the June 30, 2009 condensed financial statements were issued. No recognized or non-recognized subsequent events were identified requiring recognition in the condensed financial statements or disclosure in the accompanying notes to the condensed financial statements.

In June 2009, the FASB issued SFAS No. 168, *FASB Accounting Standards Codification and Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162* (SFAS No. 168). The codification contains the authoritative standards that are applicable to both public nongovernmental entities and nonpublic nongovernmental entities (Codification). This Codification will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. On the effective date of SFAS No. 168, the Codification will supersede all then-existing non-Securities and Exchange Commission (SEC) accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become non-authoritative. SFAS No. 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company does not believe that the adoption of SFAS No. 168 will have a material impact on its condensed financial statements.

In December 2007, the FASB ratified Emerging Issues Task Force No. 07-1, *Accounting for Collaborative Arrangements* (EITF Issue No. 07-1). EITF No. 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF Issue No. 07-1 on January 1, 2009 had no impact on the Company's results of operations or financial condition.

**3. Prepaid Expenses.**

Prepaid expenses consist of the following:

	June 30, 2009	December 31, 2008
Prepaid insurance	\$ 82,408	\$ 85,750
Prepaid clinical research fees	10,802	35,489
Prepaid rent	5,943	5,701
Other	25,520	9,434
<b>Total prepaid expenses</b>	<b>\$ 124,673</b>	<b>\$ 136,374</b>

**Table of Contents****4. Property and Equipment.**

Property and equipment, net consists of the following:

	June 30, 2009	December 31, 2008
Computer equipment	\$ 27,211	\$ 27,211
Furniture and equipment	44,175	44,175
Leasehold improvements	80,176	80,176
	151,562	151,562
Less: Accumulated depreciation	(71,025)	(55,186)
Total property and equipment, net	\$ 80,537	\$ 96,376

Depreciation expense was \$7,799 and \$15,839, and \$8,233 and \$16,440, respectively, for the three and six month periods ended June 30, 2009 and 2008.

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

Accrued expenses and other liabilities consist of the following:

	June 30, 2009	December 31, 2008
Accrued clinical trial expenses	\$ 90,056	\$ 1,064,539
Deferred rent and lease incentive	12,144	9,966
Accrued compensation and benefits	54,726	1,932
Accrued professional fees	33,149	15,275
Other	5,207	5,698
Current accrued expenses and other liabilities	195,282	1,097,410
Deferred rent and lease incentive- non-current	36,420	42,636
Non-current accrued expenses and other liabilities	36,420	42,636
Total accrued expenses and other liabilities	\$ 231,702	\$ 1,140,046

**6. Commitments.**

The Company has contracted with a CRO, various drug manufacturers, and other vendors to assist in the execution of the Company's clinical trial and proof-of-concept study, analysis, and the preparation of material necessary for the filing of an NDA with the U.S. Food and Drug Administration (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 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 and other addictions. 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. The Company paid a fee to obtain the license in the amount of \$50,000. Under the license agreement, the Company has agreed to pay

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

Brookhaven a fee of \$100,000 in the year of the approval of an NDA 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. The Company is also obligated to reimburse Brookhaven for certain of their patent related expenses. The Company believes that as of June 30, 2009 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 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.

## **Table of Contents**

### **6. Commitments. (continued)**

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 as of June 30, 2009 was approximately \$1.2 million. The Company believes that it is only liable to Brookhaven for the approximately \$166,000 described above, and it 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, 2009 and December 31, 2008 condensed balance sheets.

### **7. Income Taxes.**

The Company is subject to income taxes in the U.S. federal jurisdiction and various states jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for the 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 May 19, 2009, the Company received a staff deficiency letter from The NASDAQ Stock Market notifying the Company that, based on the Company's stockholders' equity as reported in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2009, the Company is not in compliance with the minimum stockholders' equity requirement of \$10 million for continued listing on the NASDAQ Global Market as set forth in NASDAQ Listing Rule 5450(b)(1)(A). As of June 30, 2009, the Company's stockholders' equity was approximately \$6.0 million. This notification had no immediate effect on the Company's listing on the NASDAQ Global Market or on the trading of the Company's common stock. On June 3, 2009 and June 19, 2009 the Company provided The NASDAQ Stock Market with a plan to regain compliance with the NASDAQ Global Market continued listing requirements. The NASDAQ Stock Market staff has determined to grant the Company an extension to regain compliance with the Rule no later than the end of August 2009. If the Company fails to achieve and sustain compliance, it will provide written notice that the Company's common stock will be delisted from the NASDAQ Global Market. At such time, the Company may appeal NASDAQ's delisting determination to a NASDAQ Listing Qualifications Panel or may seek to apply to list its common stock on the NASDAQ Capital Market, assuming the Company meets the listing standards of that market at the time of any such application. There can be no assurance that the Company will be able to maintain its listing on the NASDAQ Stock Market.

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 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. On September 12, 2008, the Company filed a prospectus supplement and offered for sale 1,488,332 shares of its common stock at \$3.00 per share pursuant to the registration statement. The Company received gross proceeds of approximately \$4.5 million before commissions and incurred expenses of approximately \$377,000.

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

No options were granted during the quarter ended June 30, 2009. During the six months ended June 30, 2009, the Company granted 34,000 common stock options to employees, officers, directors and consultants, generally at exercise prices equal to the quoted market value of the stock at the date of grant, with a weighted-average grant date fair value of \$1.66. During the three and six months ended June 30, 2008, respectively, the Company granted 40,000 and 99,000 common stock options to employees, officers, directors and consultants, generally at exercise prices equal to the quoted market value of the stock at the date of grant, with a weighted-average grant date fair value of \$2.35 and \$2.87, respectively. The Company recorded stock-based compensation related to stock options totaling \$59,494 and \$110,280 and \$196,730 and \$262,956, respectively, during the three months and six months ended June 30, 2009 and 2008. The total fair value of vested stock options during the three and six months ended June 30, 2009 and 2008 was \$85,325 and \$85,322 and \$211,494 and \$246,263, respectively.

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

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Risk free interest rate	2.60%	3.11%	1.26 to 2.60%	2.84 to 3.11%
Expected term	5 years	4 to 5 years	4 to 5 years	4 to 5 years
Expected volatility	90%	80%	90%	80%
Expected dividend yield	%	%	%	%
Expected forfeiture rate	%	%	%	%

As of June 30, 2009, there was approximately \$234,000 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 0.98 years.

*Restricted Stock Units*

No restricted stock units were granted during the three months ended June 30, 2009 and 2008 and the six months ended June 30, 2009. During the six months ended June 30, 2008, the Company granted 30,000 restricted stock units. The Company recorded stock-based compensation related to restricted stock units totaling \$5,038 and \$10,076 and \$12,928 and \$123,656, respectively, during the three and six month periods ended June 30, 2009 and 2008. As of June 30, 2009, there was approximately \$10,000 of total restricted stock unit compensation expense related to non-vested awards not yet recognized, which is expected to be recognized over a weighted average period of six months.

**10. Related Party Transactions.**

Since its inception in 2002, the Company has entered into various consulting agreements with non-employee officers and with members of the Company's Scientific Advisory Board. During the three and six month periods ended June 30, 2009 and 2008, the Company paid approximately \$14,000 and \$14,000, and \$28,000 and \$126,000, 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 year presentation.

---

**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 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 a new drug application for CPP-109, our version of vigabatrin, our ability to complete such trials on a timely basis and within the budgets we establish 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, 2008 describes the 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 biopharmaceutical company focused on the development and commercialization of prescription drugs for the treatment of drug addiction and obsessive-compulsive disorders. Our initial product candidate is CPP-109, which is our version of the chemical compound gamma-vinyl-GABA, commonly referred to as vigabatrin. We are currently completing a clinical trial evaluating the use of CPP-109 in the treatment of cocaine addiction and a proof-of-concept study evaluating the use of CPP-109 in the treatment of methamphetamine addiction. We also believe that CPP-109 has the potential to treat other addictions, including addictions to nicotine, prescription pain medications, alcohol, and marijuana, as well as obsessive-compulsive disorders such as obesity and compulsive gambling. We intend to develop CPP-109 to treat other forms of addiction, such as those described above, subject to the availability of funding for such purposes.

The successful development of CPP-109 or any other product we may develop, acquire, 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 clinical trials, proof-of-concept studies, and our other product development activities;

the results of our 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 an NDA for CPP-109; and

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

Based on an analysis of our current financial condition and forecasts of available cash, we believe that our current resources will allow us to complete our U.S. Phase II cocaine trial and our methamphetamine proof-of-concept study and to continue our operations through the end of 2010 without the need to obtain additional funding. However, we will need additional capital to fund any future clinical and non-clinical trials of CPP-109. See "Liquidity and Capital Resources" below.



## **Table of Contents**

### **Recent Developments**

#### **Status of U.S. Phase II clinical trial for cocaine addiction**

In 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with cocaine addiction. We retained Health Decisions, Inc. as the Contract Research Organization (CRO) to oversee this trial on our behalf. We estimate that the cost of this trial will be approximately \$7,850,000 of which approximately \$7,335,000 has been incurred through June 30, 2009. The trial enrolled 186 cocaine addicted patients at 11 addiction treatment clinical centers in the United States. Patients were treated for a period of 12 weeks, with an additional 12 weeks of follow-up. To be eligible to participate in this trial, participants had to meet specific clinical standards for cocaine addiction, as specified in DSM-IV, a set of diagnostic guidelines established for clinical professionals. Additionally, trial participants could not meet the DSM-IV criteria for dependence on most other addictive substances. Further, eye safety studies were conducted on all trial participants before and after the trial to determine the extent of visual field defects among such participants, if any. Additional detailed information about our cocaine trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

On May 29, 2009, we announced top-line results from our U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with cocaine addiction. The top-line data from the trial showed that CPP-109 did not demonstrate statistical significance in the primary endpoint that a significantly larger proportion of CPP-109-treated subjects than placebo-treated subjects were cocaine-free during the last two weeks of the treatment period (Weeks 11 and 12). The clinical trial did not reveal any unexpected serious adverse events. Complete analyses of the clinical trial data (secondary clinical end-points and safety data) are ongoing. The secondary endpoints we are measuring are based on reductions in cocaine use and craving. Based on the results of these analyses, we will evaluate what measures, if any, could be applied to improve the outcome of future studies and will also determine next steps to be taken regarding the development of CPP-109 for the treatment of cocaine addiction. In addition, we intend to investigate the reasons for the disparity between these trial results and previously published clinical and non-clinical results evaluating vigabatrin as a treatment for cocaine addiction. We expect to complete these analyses by the end of the third quarter of 2009 and will then formulate our future development plans.

#### **Status of the U.S. proof-of-concept study for methamphetamine addiction**

During June 2008, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We retained Health Decisions, Inc. as the CRO to oversee this trial on our behalf. We had planned to enroll 180 methamphetamine addicted patients at 15 addiction treatment clinical centers in the United States. However, on March 3, 2009 we announced that we had decided to halt enrollment in this trial and to convert it to a proof-of-concept study evaluating the results obtained from 57 patients who had been randomized into the trial. We made this decision to conserve cash in light of current economic conditions. The patients we enrolled were treated for a period of 12 weeks. Consistent with this study now being a proof-of-concept study, we will evaluate data related to endpoints based on abstinence, reductions in methamphetamine use and craving for evidence of potential efficacy. We estimate that the cost of this proof-of-concept study will be approximately \$4,180,000, of which approximately \$4,160,000 has been incurred through June 30, 2009. We expect to report results from this proof-of-concept trial by the end of the third quarter of 2009. Additional information about our methamphetamine study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### **Future development plans for CPP-109**

We expect to complete, by the end of the third quarter of 2009, our analysis of the results of our cocaine trial and our methamphetamine proof-of-concept study. Following our complete analysis of the data, we expect to be in a position to determine the appropriate future development plans for CPP-109, including the clinical and non-clinical trials that will be required for us to file an NDA for CPP-109 and the estimated costs of such trials. We will need additional capital to fund any such future trials, and there can be no assurance that we will ever receive an approval to commercialize CPP-109.

## **Table of Contents**

### **Discussions with strategic partners**

While we have had discussions in the past with potential strategic partners interested in working with us on the development and/or sales and marketing of CPP-109, no agreements have been entered into to-date with any potential strategic partners.

### **Notice of Failure to Satisfy a Continued Listing Rule or Standard**

On May 19, 2009, we received a staff deficiency letter from The NASDAQ Stock Market notifying us that, based on the our stockholders' equity as reported in the Quarterly Report on Form 10-Q for the period ended March 31, 2009, we were not in compliance with the minimum stockholders' equity requirement of \$10 million for continued listing on the NASDAQ Global Market as set forth in NASDAQ Listing Rule 5450(b)(1)(A). As of June 30, 2009, our stockholders' equity was approximately \$6.0 million. This notification had no immediate effect on our listing on the NASDAQ Global Market or on the trading of our common stock. On June 3, 2009 and June 19, 2009 we provided The NASDAQ Stock Market with a plan to regain compliance with the NASDAQ Global Market continued listing requirements. The NASDAQ Staff has determined to grant us an extension to regain compliance with the Rule no later than the end of August 2009. If we fail to achieve and sustain compliance, it will provide written notice that our common stock will be delisted from the NASDAQ Global Market. At such time, we may appeal NASDAQ's delisting determination to a NASDAQ Listing Qualifications Panel or may apply to list our common stock on the NASDAQ Capital Market, assuming we meet the listing standards of that market at the time of any such application. There can be no assurance that we will be able to maintain our listing on the NASDAQ Stock Market.

### **Update on clinical studies that we support**

We provided financial support for an investigator-initiated 103 patient, Phase II, randomized, double-blind, placebo controlled trial that was conducted at a single site in Mexico City, Mexico, during 2007 evaluating the use of vigabatrin to treat cocaine addicts. We reported on the positive top-line results from that trial in December 2007.

We are advised by Jonathan Brodie, MD, PhD, who is one of our scientific advisors, that an article reporting on the results of that trial has been published by The American Journal of Psychiatry, a world-leading peer-reviewed medical journal. The paper entitled: *Randomized, Double-Blind, Placebo-Controlled Trial Of Vigabatrin For The Treatment Of Cocaine Dependence In Mexican Parolees* was authored by Dr. Brodie, Brady G. Case, MD, Emilia Figueroa, MD, Stephen L. Dewey, PhD, James A. Robinson, MEd, Joseph A. Wanderling, MA and Eugene M. Laska, PhD and suggests that vigabatrin may be effective in the treatment of cocaine addiction.

### **Intent to seek governmental funding opportunities**

We are taking steps to seek governmental grants from the National Institutes of Health ( NIH ), the National Institute of Drug Abuse ( NIDA ), or other appropriate agencies that operate under the NIH umbrella, for a portion of the required funding for future clinical and non-clinical trials. Several of our clinical collaborators are also seeking funding for pilot studies evaluating the use of CPP-109 for the treatment of various addictions. There can be no assurance as to whether we and/or any of our potential clinical collaborators will receive any government grants to support our/their research.

### **Basis of presentation**

#### *Revenues*

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

## **Table of Contents**

### *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 clinical manufacturing costs, clinical trial expenses, 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 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 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 it 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. We expect to 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*

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 costs related to the issuance of stock-based awards to employees, directors, consultants and scientific advisors by using the estimated fair value of the award at the date of grant, in accordance with SFAS 123R.

### *Income taxes*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of June 30, 2009 and December 31, 2008, 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.

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), on January 1, 2007. Previously, we had accounted for tax contingencies in accordance with Statement of Financial Accounting Standards No. 5, *Accounting for Contingencies*. As required by FIN 48, which clarifies SFAS No. 109, *Accounting for 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

---

## **Table of Contents**

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. At the adoption date, we applied FIN 48 to all tax positions for which the statute of limitation remained open. No resulting unrecognized tax benefits were identified in connection with the implementation of FIN 48, and none have been identified subsequent to our implementation of FIN 48.

### **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 generally accepted accounting principles, or 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 clinical trials are based on actual and estimated costs of the services received and efforts expended pursuant to contracts with multiple research institutions and the 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 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.

#### *Stock-based compensation*

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123R, *Share-Based Payment*. We utilize the Black-Scholes option pricing 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 options awards. During the six months ended June 30, 2009 and the three and six months ended June 30, 2008, the Company granted 34,000, 40,000 and 99,000 options, respectively. For the three month periods ended June 30, 2009 and 2008, respectively, the assumptions used were an estimated annual volatility of 90% and 80%, average expected holding periods of four to five years, and risk-free interest rates of 2.60% and 3.11%. For the six months periods ended June 30, 2009 and 2008, respectively, the assumptions used were an estimated annual volatility of 90% and 80%, average expected holding periods of four to five years, and risk-free interest rates of 1.26% to 2.60% and 2.84% to 3.11%.

**Table of Contents**

**Results of Operations**

*Revenues.* We had no revenues for the three and six month periods ended June 30, 2009 and 2008.

*Research and Development Expenses.* Research and development expenses for the three and six months ended June 30, 2009 and 2008 were \$1,376,253 and \$1,902,144 and \$3,698,885 and \$2,986,503, respectively, including stock-based compensation expense in each of the three and six month periods of \$48,440 and \$99,532 and \$120,140 and \$274,088, respectively. Research and development expenses, in the aggregate, represented approximately 78% and 77%, and 77% and 71% of total operating costs and expenses, respectively, for the three and six months ended June 30, 2009 and 2008. 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, directors and scientific advisors. Research and development expenses for the three months ended June 30, 2009 decreased from those in the same period in 2008, as clinical site expenses for the U.S. Phase II cocaine trial decreased as it neared completion. Expenses for research and development for the six month period ended June 30, 2009 grew compared to amounts expended in the same period in 2008 as we incurred expenses for services related to 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 continue to decrease as we near completion of our U.S. Phase II cocaine clinical trial and methamphetamine proof-of-concept study. These costs may be offset by expenses related to other product development activities if additional funding becomes available.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the three and six month periods ended June 30, 2009 and 2008. We anticipate that we will begin to incur sales and marketing expenses when we file an NDA for CPP-109, in order to develop a sales organization to market CPP-109 and other products we may develop upon the receipt of required approvals.

*General and Administrative Expenses.* General and administrative expenses for the three and six months ended June 30, 2009 and 2008 were \$392,559 and \$561,533 and \$1,114,470 and \$1,201,206, respectively, including stock-based compensation expense in each of the three and six months periods of \$16,092 and \$23,676 and \$86,666 and \$112,524, respectively. General and administrative expenses represented 22% and 23% and 23% and 29%, respectively, of total operating costs and expenses, for the three and six months ended June 30, 2009 and 2008. The decreases of \$168,974 and \$86,736 in general and administrative expenses for the three and six months ended June 30, 2009 when compared to the same periods in 2008 are due primarily to decreases in professional and consulting fees, printing costs, travel and entertainment and non-cash stock based compensation. General and administrative expenses include among other expenses, management's 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. We expect general and administrative costs to remain relatively constant through the end of 2009 when compared to those costs incurred for the six months ended June 30, 2009.

*Stock-Based Compensation.* Total stock based compensation for the three and six months ended June 30, 2009 and 2008 was \$64,532 and \$123,208 and \$206,806 and \$386,612, respectively. The reduction in expense from the comparable period in 2008 is mostly due to a decrease in the amount of granted awards vesting immediately. As of June 30, 2009, we had outstanding stock options to purchase 2,781,149 shares of our common stock, of which options to purchase 2,667,557 shares were vested and options to purchase 113,592 shares were unvested. We also have granted restricted stock units to receive 55,484 shares of common stock as of June 30, 2009, of which 50,484 shares had vested at that date.

*Interest Income.* We reported interest income in all periods relating to our investment of funds received from our private placements, IPO and Shelf Offering. The decrease in interest income in the three and six month periods ended June 30, 2009 when compared to the same period in 2008 is due to lower interest rates and lower investment amounts as we use the remaining proceeds from our IPO and Shelf Offering to fund our 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.

## **Table of Contents**

*Income taxes.* We have incurred net operating losses since inception. For the three and six month periods ended June 30, 2009 and 2008, 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 the Shelf Offering. At June 30, 2009, we had cash and cash equivalents of \$6.3 million and working capital of \$5.9 million. At December 31, 2008, we had cash and cash equivalents of \$11.8 million and working capital of \$10.5 million. At June 30, 2009, 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. We anticipate using current cash on hand to finance these activities. It may take several years to obtain the necessary regulatory approvals to commercialize CPP-109 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 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

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

At the present time, we estimate that we will require additional funding to undertake any future clinical trials and non-clinical trials that may be required before we are in a position to file an NDA for CPP-109. We will also require additional working capital to support our operations in periods after 2010.

We expect to raise any required additional funds through public or private equity offerings, corporate 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

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

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. There can be no assurance that we can obtain the necessary funding for our future product development efforts.

---

## Table of Contents

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. There can be no assurance that we will be able to successfully sell any additional shares under this shelf registration.

On September 12, 2008, we filed a prospectus supplement and offered for sale 1,488,332 shares of our common stock at \$3.00 per share pursuant to the registration statement, and the prospectus. We received gross proceeds of approximately \$4.5 million before commissions and incurred expenses of approximately \$377,000 for the sale of 1,488,332 shares of common stock to institutional investors.

As of June 30, 2009, we had approximately \$25.5 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 additional shares under our shelf registration statement.

### *Cash Flows*

Net cash used in operating activities was \$5,501,052 and \$2,839,439, respectively, for the six months ended June 30, 2009 and 2008. During the six months ended June 30, 2009, net cash used in operating activities was primarily attributable to our net loss of \$4,793,088 and decreases of \$57,044 in accounts payable and \$908,344 in accrued expenses and other liabilities. This was offset in part by \$222,645 of non-cash expenses and decreases of \$22,626 in prepaid expenses and deposits, and \$12,153 in interest receivable. During the six months ended June 30, 2008, net cash used in operating activities was primarily attributable to our net loss of \$3,961,487 and a decrease in accounts payable of \$38,589. This was offset in part by \$403,052 of non-cash expenses, and decreases of \$39,542 in accrued interest receivable and \$247,757 in prepaid expenses and deposits, and an increase of \$470,286 in accrued expenses and other liabilities. Non-cash expenses include depreciation and stock-based compensation expense.

No cash was provided by (used in) investing activities during the six months ended June 30, 2009. Net cash used in investing activities for the six months ended June 30, 2008 was \$1,345. Such funds were used primarily for purchases of computer equipment and furniture.

No cash was provided by (used in) financing activities for the six months ended June 30, 2009. Net cash used in financing activities for the six months ended June 30, 2008 was \$19,004. Of these funds, \$16,994 was used for the payment of shelf registration costs and \$2,010 for the payment of employee withholding tax related to vesting of restricted stock units.

### *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 June 30, 2009 and December 31, 2008. See Dispute with Brookhaven below.

*Payments to our contract manufacturer.* We estimate that we will pay our contract manufacturer approximately \$1,097,000, with payments to be based on the achievement of milestones relating to the schedule of work that it has agreed to perform for us. At June 30, 2009, we had paid approximately \$936,000 of this amount.



---

## **Table of Contents**

*Payments to our CRO.* We estimate that we will pay our CRO approximately \$6,560,000 and \$3,340,000 for our U.S. Phase II cocaine trial and methamphetamine proof-of-concept study, respectively, with payments based on the achievement of milestones relating to the agreed upon service agreement. At June 30, 2009, we had paid approximately \$5,536,000 and \$3,167,000 of these amounts, respectively.

*Payments for laboratories and other trial related tests.* We estimate that we will pay approximately \$825,000, in connection with laboratories and other tests related to our U.S. Phase II cocaine clinical trial. At June 30, 2009, we had paid approximately \$719,000 of this amount. In addition, we estimate we will pay approximately \$527,000 in connection with laboratories related to our methamphetamine proof-of-concept study. At June 30, 2009, we have paid approximately \$384,000 of this amount, \$11,000 of which has been advanced upon signing of the contracts and as such has been included in prepaid expenses in the accompanying condensed balance sheet at June 30, 2009.

*Employment agreements.* We had entered an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately \$341,000 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 as of June 30, 2009 was 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 June 30, 2009 and December 31, 2008 balance sheets.

### *Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of June 30, 2009 and December 31, 2008 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**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ( *SFAS No. 157* ). This standard provides guidance for using fair value to measure assets and liabilities. The standard also responds to investors' requests for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurements on earnings. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value, but does not expand the use of fair value in any new circumstances. There are numerous previously issued statements dealing with fair values that are amended by SFAS No. 157. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued Staff Position ( *FSP* ) FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13* , which scopes out leasing transactions accounted for under SFAS No. 13, *Accounting for Leases*. In February 2008, FSP FAS 157-2, *Effective Date of FASB Statement No. 157* , was issued, which delays the effective date of SFAS No. 157 to fiscal years and interim periods within those fiscal years beginning after November 15, 2008 for nonfinancial assets and nonfinancial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Effective January 1, 2008, we adopted SFAS No. 157 for all financial assets and financial liabilities. Effective January 1, 2009, we adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities. The adoption of SFAS No. 157 for financial and nonfinancial assets and liabilities did not have a material impact on our results of operations or financial condition.

---

**Table of Contents**

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* ( *SFAS No. 165* ), which modifies current guidance in the auditing literature of the American Institute of Certified Public Accountants (AICPA) Auditing Standards (AU) Section 560, and is effective for interim or annual financial periods ending after June 15, 2009. The modifications require the two types of subsequent events to be named, as either recognized or non-recognized subsequent events, modify the definition of subsequent events to refer to events or transactions that occur after the balance sheet date but before the financial statements are issued, and require entities to disclose the date through which they have evaluated subsequent events and the basis for that date. We adopted the provisions of SFAS No. 165 as of June 30, 2009 and evaluated the impact of subsequent events through August 6, 2009, representing the date at which the June 30, 2009 condensed financial statements were issued. No recognized or non-recognized subsequent events were identified requiring recognition in the condensed financial statements or disclosure in the accompanying notes to the condensed financial statements.

In June 2009, the FASB issued SFAS No. 168, *FASB Accounting Standards Codification and Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162* ( *SFAS No. 168* ). The codification contains the authoritative standards that are applicable to both public nongovernmental entities and nonpublic nongovernmental entities (Codification). This Codification will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. On the effective date of SFAS No. 168, the Codification will supersede all then-existing non-Securities and Exchange Commission (SEC) accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification will become non-authoritative. SFAS No. 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. We do not believe that the adoption of SFAS No. 168 will have a material impact on our condensed financial statements.

In December 2007, the FASB ratified Emerging Issues Task Force No. 07-1, *Accounting for Collaborative Arrangements* ( *EITF Issue No. 07-1* ). EITF No. 07-1 requires certain income statement presentation of transactions with third parties and of payments between parties to the arrangement, along with disclosure about the nature and purpose of the arrangement. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF Issue No. 07-1 on January 1, 2009 had no impact on our results of operations or financial condition.

**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 information required by this section.

**ITEM 4T. 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 June 30, 2009, 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, 2008, 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS**

At our Annual Meeting of Stockholders held on June 9, 2009, our stockholders elected six directors (P. McEnany, P. Coelho, H. Huckel, C. O'Keeffe, D. Tierney and M. Wallace) to serve a term of one year or until their successors are elected and qualified, or until their earlier death, resignation or removal. The security holders elected all nominated Directors with votes cast as follows: Mr. McEnany: 11,666,665 shares for and 142,336 shares withheld; Mr. Coelho: 11,724,562 shares for and 84,439 shares withheld; Dr. Huckel: 11,666,665 shares for and 142,336 shares withheld; Mr. O'Keeffe: 11,658,873 shares for and 150,128 shares withheld; Dr. Tierney: 11,724,562 shares for and 84,439 shares withheld; and Mr. Wallace: 11,724,262 shares for and 84,739 shares withheld. There were no abstentions or broker non-votes applicable to the election of Directors.

**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



**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: August 6, 2009

**Table of Contents**

**Exhibit Index**

**Exhibit**

<b>Number</b>	<b>Description</b>
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