

Catalyst Pharmaceutical Partners, Inc.

Form 10-Q

November 13, 2008

**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, 2008**  
**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)

Delaware

76-0837053

(State or other jurisdiction of  
incorporation or organization)

(IRS Employer  
Identification No.)

355 Alhambra Circle  
Suite 1370  
Coral Gables, Florida

33134

(Address of principal executive offices)

(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 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 ☐ Smaller reporting company ☒  
(Do not check if a 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: 14,060,385 shares of common stock, \$0.001 par value per share, were outstanding as of November 7, 2008.

**CATALYST PHARMACEUTICAL PARTNERS, INC.  
INDEX**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<b><u>Item 1.</u></b>	<b><u>CONDENSED FINANCIAL STATEMENTS</u></b>
	<u>Condensed balance sheets at September 30, 2008 (unaudited) and December 31, 2007</u> 3
	<u>Condensed statements of operations for the three and nine months ended September 30, 2008 and 2007 (unaudited)</u> 4
	<u>Condensed statement of stockholders' equity for the nine months ended September 30, 2008 (unaudited)</u> 5
	<u>Condensed statements of cash flows for the nine months ended September 30, 2008 and 2007 (unaudited)</u> 6
	<u>Notes to unaudited condensed financial statements</u> 7
<b><u>Item 2.</u></b>	<b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>
	14
<b><u>Item 3.</u></b>	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>
	23
<b><u>Item 4T.</u></b>	<b><u>CONTROLS AND PROCEDURES</u></b>
	23
<b><u>PART II. OTHER INFORMATION</u></b>	
<b><u>Item 1.</u></b>	<b><u>LEGAL PROCEEDINGS</u></b>
	24
<b><u>Item 1A.</u></b>	<b><u>RISK FACTORS</u></b>
	24
<b><u>Item 2.</u></b>	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>
	24
<b><u>Item 3.</u></b>	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>
	24
<b><u>Item 4.</u></b>	<b><u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></b>
	24
<b><u>Item 5.</u></b>	<b><u>OTHER INFORMATION</u></b>
	24
<b><u>Item 6.</u></b>	<b><u>EXHIBITS</u></b>
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	



**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. CONDENSED FINANCIAL STATEMENTS****CATALYST PHARMACEUTICAL PARTNERS, INC.****(a development stage company)****CONDENSED BALANCE SHEETS**

	September 30, 2008 (unaudited)	December 31, 2007
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 15,027,447	\$ 15,943,896
Interest receivable	17,208	63,709
Prepaid expenses	173,319	524,081
Total current assets	15,217,974	16,531,686
Property and equipment, net	104,535	127,788
Deposits	25,448	20,448
Total assets	\$ 15,347,957	\$ 16,679,922
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 635,633	\$ 219,866
Accrued expenses and other liabilities	585,004	83,419
Total current liabilities	1,220,637	303,285
Accrued expenses and other liabilities, non-current	45,746	53,880
Total liabilities	1,266,383	357,165
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized: none outstanding		
Common stock, \$.001 par value, 100,000,000 shares authorized 14,060,385 shares and 12,527,564 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	14,060	12,528
Additional paid-in capital	30,783,068	26,208,936
Deficit accumulated during the development stage	(16,715,554)	(9,898,707)
Total stockholders' equity	14,081,574	16,322,757
Total liabilities and stockholders' equity	\$ 15,347,957	\$ 16,679,922

**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)**

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>		<b>Cumulative Period from January 4, 2002 (date of inception) to September 30, 2008</b>
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>	<b>2008</b>
Revenues	\$	\$	\$	\$	\$
Operating costs and expenses:					
Research and development	2,451,579	503,348	5,438,082	2,318,648	11,583,163
General and administrative	463,199	447,078	1,664,405	1,565,912	6,504,163
Total operating costs and expenses	2,914,778	950,426	7,102,487	3,884,560	18,087,326
Loss from operations	(2,914,778)	(950,426)	(7,102,487)	(3,884,560)	(18,087,326)
Interest income	59,418	216,079	285,640	690,005	1,371,772
Loss before income taxes	(2,855,360)	(734,347)	(6,816,847)	(3,194,555)	(16,715,554)
Provision for income taxes					
Net loss	\$ (2,855,360)	\$ (734,347)	\$ (6,816,847)	\$ (3,194,555)	\$ (16,715,554)
Loss per share basic and diluted	\$ (0.22)	\$ (0.06)	\$ (0.54)	\$ (0.26)	
Weighted average shares outstanding basic and diluted	12,863,196	12,527,564	12,661,859	12,524,678	

**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, 2008**

	<b>Preferred Stock</b>	<b>Common Stock</b>	<b>Additional Paid-in Capital</b>	<b>Deficit Accumulated During the Development Stage</b>	<b>Total</b>
<b>Balance at December 31, 2007</b>	\$	\$ 12,528	\$ 26,208,936	\$ (9,898,707)	\$ 16,322,757
Issuance of stock options for services			362,484		362,484
Amortization of restricted stock units for services			30,893		30,893
Issuance of restricted stock units, net of cancellations		44	94,343		94,387
Issuance of common stock, net		1,488	4,086,412		4,087,900
Net loss				(6,816,847)	(6,816,847)
<b>Balance at September 30, 2008</b>	\$	\$ 14,060	\$ 30,783,068	\$ (16,715,554)	\$ 14,081,574

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 Nine Months Ended</b>		<b>Cumulative Period from January 4, 2002 (date of inception) through September 30, 2008</b>
	<b>September 30, 2008</b>	<b>2007</b>	
<b>Operating Activities:</b>			
Net loss	\$ (6,816,847)	\$ (3,194,555)	\$ (16,715,554)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	24,598	8,083	47,026
Stock-based compensation	491,177	477,083	3,927,508
Change in assets and liabilities:			
Decrease (increase) in interest receivable	46,501	20,228	(17,208)
Decrease (increase) in other prepaid expenses and deposits	362,756	(437,386)	(181,773)
Increase (decrease) in accounts payable	38,668	(218,594)	258,533
Increase (decrease) in accrued expenses and other liabilities	493,451	(147,444)	573,231
Net cash used in operating activities	(5,359,696)	(3,492,585)	(12,108,237)
<b>Investing Activities:</b>			
Capital expenditures	(1,345)	(55,923)	(94,041)
Net cash used in investing activities	(1,345)	(55,923)	(94,041)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock	4,464,996		23,254,532
Proceeds from issuance of preferred stock			3,895,597
Payment of shelf registration costs	(16,994)		(16,994)
Payment of employee withholding tax related to RSUs	(3,410)		(3,410)
Net cash provided by financing activities	4,444,592		27,129,725
Net (decrease) increase in cash	(916,449)	(3,548,508)	14,927,447
Cash and cash equivalents at beginning of period	15,943,896	20,434,702	100,000
Cash and cash equivalents at end of period	\$ 15,027,447	\$ 16,886,194	\$ 15,027,447
<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 September 30, 2008. The Company has been able to fund its cash needs to date through an initial funding from its founders, four subsequent private placements, an initial public offering (IPO), and an offering via a shelf registration to institutional investors (Shelf Offering).

***Capital Resources***

At the present time, the Company estimates that it will require additional funding to complete the Phase III clinical trial that its management believes the Company will be required to complete before the Company is in a position to file a new drug application, or NDA, for its initial product candidate, CPP-109. The Company will also require additional working capital to support its operations in periods after the middle of 2010. To that end, 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 shelf registration statement at a price of \$3.00 per share and received gross proceeds of approximately \$4.5 million before commissions and expenses of approximately \$377,000. At September 30, 2008, 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 above described shelf registration statement, the Company may raise the additional funds required through public or private equity offerings, debt financings, corporate collaborations or other means. The Company may also seek to raise additional 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 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 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 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.

**Table of Contents**

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

- 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, 2007 included in the Form 10-K filed by the Company with the SEC. The results of operations for the nine months ended September 30, 2008 are not necessarily indicative of the results to be expected for any future period or for the full 2008 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 September 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) restricted stock units to receive 10,000 shares of common stock that will vest over the next two years.

Potentially dilutive common stock equivalents as of September 30, 2007 include (i) stock options to purchase up to 2,568,149 shares of common stock at exercise prices ranging from \$0.69 to \$6.00 per share and (ii) restricted stock units to receive 15,000 shares of common stock, none of which were vested.

- 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 periodically throughout the period.
- g. **PREPAID EXPENSES.** Prepaid expenses consist primarily of 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 and methamphetamine clinical trials. Such advances are recorded as expense as the related goods are received or the related services are performed.



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

- h. **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"). See Note 9.

As of September 30, 2008, there were outstanding stock options to purchase 2,667,149 shares of common stock (including options to purchase 314,888 shares granted under the Plan), of which stock options to purchase 2,466,890 shares of common stock were exercisable as of September 30, 2008. Additionally, as of September 30, 2008 there were 55,484 restricted common stock units granted under the Plan, of which 45,484 were vested.

For the three and nine month periods ended June 30, 2008 and 2007, the Company recorded non-cash, stock-based compensation expense as follows:

	<b>For the three months ended September 30,</b>		<b>For the nine months ended September 30,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
Research and development	\$ 54,476	\$ 75,997	\$ 328,564	\$ 315,710
General and administrative	50,089	18,485	162,613	161,373
Total stock-based compensation	\$ 104,565	\$ 94,482	\$ 491,177	\$ 477,083

i. **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). The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on the Company's results of operations or financial condition. The Company is currently assessing the impact of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities on its financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( *SFAS No. 159* ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The provisions of SFAS No. 159 were effective for the Company beginning January 1, 2008. The adoption of SFAS No. 159 did not

have a material impact on the Company's results of operations or financial position.

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

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force ( EITF ) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. The guidance in EITF Issue 07-3 requires the Company to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, the Company would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is applied prospectively to new contracts entered into on or after December 15, 2007. The Company adopted EITF Issue 07-3 effective January 1, 2008. The adoption of EITF Issue 07-3 did not have a material impact on the Company's results of operations or financial condition.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States for non-governmental entities. SFAS No. 162 is effective 60 days following approval by the Securities and Exchange Commission of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*". The Company does not expect SFAS No. 162 to have a material impact on its financial statements.

**3. Prepaid Expenses.**

Prepaid expenses consist of the following:

	September 30, 2008	December 31, 2007
Advances to CRO	\$ 746	\$ 314,503
Prepaid clinical research fees	94,914	121,303
Prepaid insurance	60,048	82,162
Other	17,611	6,113
Total prepaid expenses	\$ 173,319	\$ 524,081

**4. Property and Equipment.**

Property and equipment, net consists of the following:

	September 30, 2008	December 31, 2007
Computer equipment	\$ 27,211	\$ 25,866
Furniture and equipment	44,175	44,175
Leasehold improvements	80,176	80,176
	151,562	150,217
Less: Accumulated depreciation	(47,027)	(22,429)
Total property and equipment, net	\$ 104,535	\$ 127,788



Depreciation expense for the three and nine month periods ended September 30, 2008 and 2007, was \$8,158 and \$3,413, and \$24,598 and \$8,083, respectively.

**Table of Contents****5. Accrued Expenses and Other Liabilities.**

Accrued expenses and other liabilities consist of the following:

	September 30, 2008	December 31, 2007
Deferred rent and lease incentive	\$ 9,966	\$ 9,470
Accrued compensation and benefits	24,909	40,831
Accrued professional fees	2,025	10,000
Accrued clinical trial expense	537,412	
Other	10,692	23,118
Current accrued expenses and other liabilities	585,004	83,419
Deferred rent and lease incentive-non-current	45,746	53,880
Non-current accrued expense and other liabilities	45,746	53,880
Total accrued expenses and other liabilities	\$ 630,750	\$ 137,299

**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 trials, 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 drug addictions, including cocaine and methamphetamine, 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 2021. 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 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 September 30, 2008 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.

During November 2007, Brookhaven formally advised the Company that they believe that the amount potentially due from the Company to Brookhaven for patent related expenses as of that date was approximately \$1,000,000. The Company believes that it is potentially 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. The Company intends to consult with Brookhaven in an effort to resolve this dispute. However, 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 filed yet an NDA for CPP-109, no amounts relating to this matter are accrued in the accompanying September 30, 2008 and December 31, 2007 condensed balance sheets.



**Table of Contents****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 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 shelf registration statement. The Company received gross proceeds of approximately \$4.5 million before commissions and expenses of approximately \$377,000. These shares were sold to institutional investors.

In addition, on June 2, 2008 the Company filed two registration statements on Form S-8 to register: (i) shares of restricted common stock and shares of common stock underlying stock options issued under its 2006 Stock Incentive Plan, and (ii) shares of common stock underlying the stock options granted by the Company prior to its IPO.

**9. Stock Compensation.***Stock Options*

During the nine month periods ended September 30, 2008 and 2007, the Company granted 99,000 and 194,000 common stock options, respectively, to employees, officers, directors and consultants, at exercise prices equal to the market value of the stock at the date of grant, with a weighted-average grant date fair value of \$2.87 and \$2.65, respectively. No options were granted during the three month periods ended September 30, 2008 and 2007. The Company recorded stock-based compensation related to stock options totaling \$99,528 and \$89,444 and \$362,484 and \$461,969, respectively, during the three months and nine months ended September 30, 2008 and 2007. The total fair value of vested stock options during the three and nine months ended September 30, 2008 and 2007 was \$250,268 and \$218,661 and \$496,531 and \$433,736, 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 September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Risk free interest rate	2.98 to 3.23%	4.57%	2.40 to 3.23%	4.57%
Expected term	4 to 5 years	4 to 5 years	4 to 5 years	4 to 5 years
Expected volatility	80%	100%	80%	100%
Expected dividend yield	%	%	%	%
Expected forfeiture rate	%	%	%	%

As of September 30, 2008, there was approximately \$468,000 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 0.91 years.

**Table of Contents**

**9. Stock Compensation. (continued)**

*Restricted Stock Units*

No restricted stock units were granted during the three months ended September 30, 2008 and 2007. During the nine months ended September 30, 2008 and 2007, the Company granted 30,000 and 15,000 restricted stock units, respectively. The Company recorded stock-based compensation related to restricted stock units totaling \$5,038 and \$5,038 and \$128,693 and \$15,114, respectively, during the three and nine month periods ended September 30, 2008 and 2007. As of September 30, 2008, there was \$25,188 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 1.25 years.

**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 nine month periods ended September 30, 2008 and 2007, the Company paid approximately \$14,000 and \$15,000, and \$141,000 and \$42,000, respectively, in consulting fees to related parties.

**11. Subsequent Events.**

Subsequent to the end of the quarter, the Company entered into an agreement to initiate, within the next few months, a Phase II double-blind, placebo controlled clinical trial evaluating CPP-109 for the treatment of Binge Eating Disorder. We estimate that the total cost of this 40 patient clinical trial will be approximately \$480,000.

**12. 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, in 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, 2007 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 development-stage biopharmaceutical company focused on the acquisition, development and commercialization of prescription drugs for the treatment of drug addiction and obsessive compulsive disorders. Our initial product candidate is CPP-109.

In November 2006, we completed an initial public offering in which we raised net proceeds of approximately \$17.6 million. We are using these proceeds to complete clinical and non-clinical studies evaluating the use of CPP-109 to treat cocaine and methamphetamine addiction and where feasible to conduct proof-of-concept studies for other indications, such as alcohol and nicotine addiction and certain eating disorders.

During July 2007, we initiated a randomized, double-blind, placebo-controlled U.S. Phase II clinical trial in patients with cocaine addiction. During June 2008, we initiated a similar U.S. Phase II clinical trial evaluating CPP-109 as a treatment for methamphetamine addiction (see Recent Developments section below).

In September 2008, we completed a registered direct offering of shares of our common stock pursuant to a shelf registration statement in which we raised net proceeds of approximately \$4.1 million. We are using these proceeds to conduct one or more proof-of-concept studies of CPP-109 and for general corporate 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 and our other product development activities;

the results of future clinical trials, and the number of clinical trials (and the scope of such trials) that will be required 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.

## **Table of Contents**

We currently estimate that we will require additional funding to complete the Phase III clinical trial that we believe will be required before we are in a position to file an NDA, or new drug application, for CPP-109. We also expect to require additional funding to support our operations in periods after the middle of 2010. There can be no assurance that such funding will be available when required or on terms acceptable to us. See Liquidity and Capital Resources below.

## **Recent Developments**

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

During July 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 have retained Health Decisions, Inc. as the Contract Research Organization (CRO) to oversee the trial on our behalf. We estimate that the total cost of this trial will be approximately \$6,983,000, and through September 30, 2008, we have incurred expenses of approximately \$3,954,000 related to this trial.

The trial is expected to enroll 180 cocaine addicted patients at 11 addiction treatment clinical centers in the United States. Patients will be treated for a period of 12 weeks, with an additional 12 weeks of follow-up. The primary endpoint of the trial is to demonstrate that a larger proportion of CPP-109-treated subjects than placebo-treated subjects will be cocaine-free during their last two weeks of treatment (weeks 11 and 12). Additionally, we will be measuring several secondary endpoints based on reductions of cocaine use and craving. To be eligible to participate in this trial, participants must meet specific clinical standards for cocaine dependence, as specified in DSM-IV, a set of diagnosis guidelines established for clinical professionals. Additionally, trial participants cannot meet the DSM-IV criteria for dependence on most other addictive substances. Further, eye safety studies will be conducted on all trial participants before and after the trial to determine the extent of visual field defects that may occur as a result of the trial among such participants, if any. We began enrolling patients in our trial in January 2008 after the protocol for our trial was accepted by the U.S. Food and Drug Administration ( FDA ). Based on currently available information, we expect to have initial top-line results from this trial in the second quarter of 2009. However, the date we obtain the results from our study will ultimately depend on the timing of patient enrollment into our study, which cannot be predicted with absolute certainty. Additional information about our cocaine trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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

During June 2008, we initiated a similar randomized, double-blind, placebo-controlled U.S. Phase II clinical trial evaluating the use of CPP-109 in treating patients with methamphetamine addiction. We have retained Health Decisions, Inc. as the CRO to oversee the trial on our behalf. We estimate that the total cost of this trial will be approximately \$7,636,000, and through September 30, 2008, we have incurred expenses of approximately \$1,349,000 related to this trial.

The trial is expected to enroll 180 methamphetamine addicted patients at 15 addiction treatment clinical centers in the United States. Patients will be treated for a period of 12 weeks, with an additional 12 weeks of follow-up. The primary endpoint of the trial is to demonstrate that a larger proportion of CPP-109-treated subjects than placebo-treated subjects will be methamphetamine-free during their last two weeks of treatment (weeks 11 and 12). Additionally, we will be measuring several secondary endpoints based on reductions of methamphetamine use and craving. To be eligible to participate in this trial, participants must meet specific clinical standards for methamphetamine dependence, as specified in DSM-IV, a set of diagnosis guidelines established for clinical professionals. Additionally, trial participants cannot meet the DSM-IV criteria for dependence on most other addictive substances. Further, eye safety studies will be conducted on all trial participants before and after the trial to determine the extent of visual field defects that may occur as a result of the trial among such participants, if any. Based on currently available information, we expect to have initial top-line results from this trial during the third quarter of 2009. However, the date we obtain the results from our study will ultimately depend on the timing of patient enrollment into our study, which cannot be predicted with absolute certainty. Additional information about our methamphetamine trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **Table of Contents**

### **Contemplated proof-of-concept clinical trials**

We expect to initiate in the near future a 40-patient Phase II double-blind, placebo-controlled clinical trial evaluating CPP-109 for the treatment of Binge Eating Disorder. Binge Eating Disorder impacts a subset of the obese population and affects more than four million people in the United States. Those afflicted frequently eat large amounts of food while feeling a loss of control over their eating. We are very interested in this disorder for several reasons. First, Brookhaven National Laboratories, our exclusive licensing partner, recently published positive results from a series of animal studies that they have conducted evaluating the use of vigabatrin to treat obesity. In addition, research conducted by scientists sponsored by the National Institute on Drug Abuse (NIDA) has shown that addiction and compulsive eating both involve impaired impulse control and distorted valuation of the rewards to be derived from a certain behavior i.e., drug-taking or eating. Studies have indicated that there is a neurological overlap between addiction and eating disorders.

We are also currently contemplating a Phase II double-blind, placebo controlled clinical trial evaluating the use of CPP-109 for the treatment of alcohol addiction, and we may in the future, subject to the availability of funding, seek to conduct additional Phase II clinical trials to evaluate CPP-109 for the treatment of other addictions, including nicotine.

### **Discussions with strategic partners**

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

### **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.

#### *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.



## **Table of Contents**

### *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 we will begin to incur such costs upon our filing of an NDA, so that we can have a sales force in place to commence our selling efforts immediately upon receiving approval of such NDA, of which there can be no assurance.

### *General and administrative expenses*

Our general and administrative expenses consist primarily of salaries, 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 and consultants 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 September 30, 2008 and December 31, 2007, 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 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.

## **Table of Contents**

### *Pre-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. No options were granted during the three months ended September 30, 2008. For the three and nine months periods ended September 30, 2008, respectively, the assumptions used were an estimated annual volatility of 80%, average expected holding periods of four to five years, and risk-free interest rates of 2.98% to 3.23% and 2.40% to 3.23%. For the three and nine months periods ended September 30, 2007, respectively, the assumptions used were an estimated annual volatility of 100%, average expected holding periods of four to five years, and risk-free interest rates of 4.57%.

## **Results of Operations**

*Revenues.* We had no revenues for the three and nine month periods ended September 30, 2008 and 2007.

*Research and Development Expenses.* Research and development expenses for the three and nine months ended September 30, 2008 and 2007 were \$2,451,579 and \$503,348 and \$5,438,082 and \$2,318,648, respectively, including stock-based compensation expense in each of the three and nine month periods of \$54,476 and \$75,997, and \$328,564 and \$315,710, respectively. Research and development expenses, in the aggregate, represented approximately 84% and 53% and 77% and 60% of total operating costs and expenses, respectively, for the three and nine months ended September 30, 2008 and 2007. 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 and scientific advisors. Our expenses for research and development for the three and nine months ended September 30, 2008 grew significantly compared to amounts expended in the same periods in 2007 as we incurred expenses for services related to the initiation of our Phase II clinical trials evaluating CPP-109 for use in the treatment of cocaine addiction and methamphetamine addiction and incurred expenses for raw materials and finished products for use in our current clinical trials. In addition, payroll expenses and benefits increased for the three and nine months ended September 30, 2008 as compared to the same periods in 2007, as we expanded our research and development staff.

We expect that research and development activities will continue to increase substantially now that we have initiated our U.S. Phase II cocaine and methamphetamine clinical trials, and plan to expand our product development activities generally.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the three and nine months ended September 30, 2008 and 2007. 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.

## **Table of Contents**

*General and Administrative Expenses.* General and administrative expenses were \$463,199 and \$447,078, and \$1,664,405 and \$1,565,912, respectively, for the three and nine months ended September 30, 2008 and 2007. These expenses include \$50,089 and \$18,485 and \$162,613 and \$161,373, respectively, in stock-based compensation expense relating to the vesting of stock options and restricted stock grants. General and administrative expenses represented 16% and 47% and 23% and 40%, respectively, of total operating costs and expenses, for the three and nine months ended September 30, 2008 and 2007. The increase of \$98,493 in general and administrative expenses for the nine months ended September 30, 2008 when compared to the same period in 2007 is due primarily to increases in payroll expenses and benefits, professional fees and depreciation, as we expanded our administrative staff and facilities, offset by a decrease in franchise taxes. The increase of \$16,121 for the three months ended September 30, 2008 from the same period in 2007 is primarily due to increases in payroll expenses and benefits, professional fees and depreciation, as we expanded our administrative staff and facilities. 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.

*Stock-Based Compensation.* Total stock based compensation for the three and nine months ended September 30, 2008 and 2007 was \$104,565 and \$94,482 and \$491,177 and \$477,083, respectively. As of September 30, 2008, we had outstanding stock options to purchase 2,667,149 shares of our common stock, of which options to purchase 2,466,890 shares were vested and options to purchase 200,259 shares were unvested. We also have granted restricted stock units to receive 55,484 shares of common stock as of September 30, 2008, of which 45,484 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 nine month periods ended September 30, 2008 when compared to the same periods in 2007 is due to lower interest rates and lower investment amounts as we use the 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.

*Income taxes.* We have incurred net operating losses since inception. For the three and nine month periods ended September 30, 2008 and 2007, 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 September 30, 2008, we had cash and cash equivalents, including U.S. Treasury bills, of \$15.0 million and working capital of \$14.0 million. At December 31, 2007, we had cash and cash equivalents of \$15.9 million and working capital of \$16.2 million. At September 30, 2008, substantially all of our cash and cash equivalents were deposited with one financial institution. Throughout the third quarter of 2008 we periodically had cash balances at certain financial institutions in excess of federally insured limits.

We have to date incurred operating losses, and we expect these losses to increase substantially in the future as we expand our product development programs and prepare for the commercialization of 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;

future clinical trial results;

**Table of Contents**

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 complete the Phase III clinical trial that we believe we will be required to complete 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 the middle of 2010.

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

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 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 25% of outstanding common stock and 33% of our public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules.

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 shelf registration statement and the prospectus supplement. We received gross proceeds of approximately \$4.5 million, before commissions and expenses of approximately \$377,000, from the sale of these shares to institutional investors.

At September 30, 2008, 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 this registration statement.

*Cash Flows*

Net cash used in operations was \$5,359,696 and \$3,492,585, respectively, for the nine months ended September 30, 2008 and 2007. During the nine months ended September 30, 2008, net cash used in operating activities was primarily attributable to our net loss of \$6,816,847, offset in part by \$515,775 of non-cash expenses, decreases of \$46,501 in accrued interest, and \$362,756 in prepaid expenses and other assets and increases of \$38,668 in accounts payable and \$493,451 in accrued expenses and other liabilities. Non-cash expenses include depreciation and stock-based compensation expense. During the nine months ended September 30, 2007, net cash used in operating activities was primarily attributable to our net loss of \$3,194,555, an increase in prepaid expenses and deposits of \$437,386 and decreases of \$218,594 in accounts payable and \$147,444 in accrued expenses. This was offset in part by \$485,166 of non-cash expenses and a decrease of \$20,228 in interest receivable.



## **Table of Contents**

Net cash used in investing activities was \$1,345 and \$55,923, respectively, for the nine months ended September 30, 2008 and 2007. Such funds were used primarily for purchases of computer equipment and furniture.

Net cash provided by financing activities for the nine months ended September 30, 2008 was \$4,444,592. This amount is attributable mostly to proceeds from the sale of common stock shares pursuant to the shelf registration and prospectus supplement of \$4,464,996, offset by \$16,994 used for the payment of shelf registration costs and \$3,410 for the payment of employee withholding tax related to vesting of restricted stock units. No cash was provided by (used in) financing activities for the nine months ended September 30, 2007.

### *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 potential obligation is approximately \$166,000 at September 30, 2008 and December 31, 2007. See Dispute with Brookhaven below.

*Payments to our contract manufacturer.* We estimate that we will pay our contract manufacturer approximately \$1,095,000, with payments based on the achievement of milestones relating to the schedule of work that it has agreed to perform for us. At September 30, 2008, we had paid approximately \$901,000 of this amount.

*Payments to our CRO.* We estimate that we will pay our CRO approximately \$6,047,000 and \$6,504,000, respectively, for our U.S. Phase II cocaine trial and U.S. Phase II methamphetamine trial, with payments based on the achievement of milestones relating to the agreed upon service agreement. At September 30, 2008, we had paid approximately \$2,755,000 and \$902,000 of these amounts, respectively.

*Payments for laboratories and other trial related tests.* We estimate that we will pay approximately \$627,000, in connection with laboratories and other tests related to our U.S. Phase II cocaine clinical trial. At September 30, 2008, we had paid approximately \$335,000 of this amount, \$27,000 of which have been advanced upon signing of the contracts and as such have been included in prepaid expenses in the accompanying condensed balance sheet at September 30, 2008. In addition, we estimate we will pay approximately \$662,000 in connection with laboratories related to our U.S. Phase II methamphetamine trial. At September 30, 2008, we have paid approximately \$230,000 of this amount, \$68,000 of which have been advanced upon signing of the contracts and as such have been included in prepaid expenses in the accompanying condensed balance sheet at September 30, 2008.

*Payments for the Binge Eating Disorder trial.* We estimate that we will pay total cost of approximately \$480,000 in connection with the Phase II clinical trial evaluating CPP-109 for the treatment of Binge Eating Disorder. No payments had been made as of September 30, 2008 related to this clinical trial.

*Employment agreements.* We have an employment agreement with our chief executive officer that requires us to make base salary payments of approximately \$324,000 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.

## **Table of Contents**

### *Dispute with Brookhaven*

During November 2007, Brookhaven formally advised us that they believe that the amount potentially due for patent related expenses as of that date was approximately \$1,000,000. We believe that we are potentially 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. We intend to consult with Brookhaven in an effort to resolve this dispute. However, 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 filed an NDA for CPP-109, no amounts are accrued relating to this matter in the accompanying September 30, 2008 and December 31, 2007 balance sheets.

### *Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of September 30, 2008 and December 31, 2007 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). The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on our financial statements. We are currently assessing the impact of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities on our financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 *The Fair Value Option for Financial Assets and Financial Liabilities* ( *SFAS No. 159* ). SFAS No. 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The provisions of SFAS No. 159 were effective for us beginning January 1, 2008. The adoption of SFAS No. 159 did not have a material impact on our financial statements.

In June 2007, the FASB ratified a consensus opinion reached by the Emerging Issues Task Force ( *EITF* ) on EITF Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*. The guidance in EITF Issue 07-3 requires us to defer and capitalize nonrefundable advance payments made for goods or services to be used in research and development activities until the goods have been delivered or the related services have been performed. If the goods are no longer expected to be delivered nor the services expected to be performed, we would be required to expense the related capitalized advance payments. The consensus in EITF Issue 07-3 was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2007 and is applied prospectively to new contracts entered into on or after December 15, 2007. We adopted EITF Issue 07-3 effective January 1, 2008. The adoption of EITF Issue 07-3 did not have a material impact on our financial statements.

**Table of Contents**

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*". SFAS No. 162 identifies the sources of accounting principles to be used in the preparation of financial statements that are presented in conformity with generally accepted accounting principles in the United States for non-governmental entities. SFAS No. 162 is effective 60 days following approval by the Securities and Exchange Commission of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*". We do not expect SFAS No. 162 to have a material impact on our financial statements.

**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 September 30, 2008, 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, 2007, 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**

**(c) Issuer Security Purchases**

During the nine months ended September 30, 2008, the Company repurchased 996 shares that had been issued to its employees from shares that had been issued as a bonus pursuant to the Company's 2006 Stock Incentive Plan. The repurchased shares were used to satisfy tax withholding obligations and were repurchased pursuant to the terms of the Plan.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS**

None

**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  
Chief Financial Officer

Date: November 13, 2008

**Table of Contents**

**Exhibit Index**

<b>Exhibit 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