

Catalyst Pharmaceutical Partners, Inc.

Form 10-Q

November 12, 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 September 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

**76-0837053**  
(IRS Employer

incorporation or organization)

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: 18,038,385 shares of common stock, \$0.001 par value per share, were outstanding as of November 6, 2009.

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**INDEX**

Item 1.	<b>CONDENSED FINANCIAL STATEMENTS</b>	
	<u>Condensed balance sheets at September 30, 2009 (unaudited) and December 31, 2008</u>	3
	<u>Condensed statements of operations for the three and nine months ended September 30, 2009 and 2008 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the nine months ended September 30, 2009 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the nine months ended September 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>	15
Item 3.	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>	26
Item 4T.	<b><u>CONTROLS AND PROCEDURES</u></b>	27
	<b><u>PART II. OTHER INFORMATION</u></b>	
Item 1.	<b><u>LEGAL PROCEEDINGS</u></b>	28
Item 1A.	<b><u>RISK FACTORS</u></b>	28
Item 2.	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	28
Item 3.	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	28
Item 4.	<b><u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u></b>	28
Item 5.	<b><u>OTHER INFORMATION</u></b>	28
Item 6.	<b><u>EXHIBITS</u></b>	28

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

	<b>September 30, 2009 (unaudited)</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 4,912,346	\$ 11,766,629
Interest receivable		12,153
Prepaid expenses	81,770	136,374
Total current assets	4,994,116	11,915,156
Property and equipment, net	73,231	96,376
Deposits	10,511	21,436
Total assets	\$ 5,077,858	\$ 12,032,968
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 163,067	\$ 332,707
Accrued expenses and other liabilities	102,627	1,097,410
Total current liabilities	265,694	1,430,117
Accrued expenses and other liabilities, non-current	49,596	42,636
Total liabilities	315,290	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 September 30, 2009 and December 31, 2008, respectively	14,065	14,060
Paid-in capital and additional paid-in capital	31,291,615	31,009,459
Deficit accumulated during the development stage	(26,543,112)	(20,463,304)
Total stockholders' equity	4,762,568	10,560,215
Total liabilities and stockholders' equity	\$ 5,077,858	\$ 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 September 30,		For the Nine Months Ended September 30,		Cumulative Period from January 4, 2002 (date of inception) to September 30, 2009
	2009	2008	2009	2008	
Revenues	\$	\$	\$	\$	\$
Operating costs and expenses:					
Research and development	850,998	2,451,579	4,549,883	5,438,082	19,405,405
General and administrative	441,316	463,199	1,555,786	1,664,405	8,579,048
Total operating costs and expenses	1,292,314	2,914,778	6,105,669	7,102,487	27,984,453
Loss from operations	(1,292,314)	(2,914,778)	(6,105,669)	(7,102,487)	(27,984,453)
Interest income	5,594	59,418	25,861	285,640	1,441,341
Loss before income taxes	(1,286,720)	(2,855,360)	(6,079,808)	(6,816,847)	(26,543,112)
Provision for income taxes					
Net loss	\$ (1,286,720)	\$ (2,855,360)	\$ (6,079,808)	\$ (6,816,847)	\$ (26,543,112)
Loss per share basic and diluted	\$ (0.09)	\$ (0.22)	\$ (0.43)	\$ (0.54)	
Weighted average shares outstanding basic and diluted	14,065,385	12,863,196	14,065,385	12,661,859	

**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, 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			267,047		267,047
Amortization of restricted stock units for services			15,114		15,114
Issuance of common stock		5	(5)		
Net loss				(6,079,808)	(6,079,808)
<b>Balance at September 30, 2009</b>	\$	\$ 14,065	\$ 31,291,615	\$ (26,543,112)	\$ 4,762,568

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

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

	For the Nine Months Ended September 30,		Cumulative Period from January 4, 2002 (date of inception) through September 30, 2009
	2009	2008	
<b>Operating Activities:</b>			
Net loss	\$ (6,079,808)	\$ (6,816,847)	\$ (26,543,112)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	23,145	24,598	78,331
Stock-based compensation	282,161	491,177	4,436,060
Change in assets and liabilities:			
Decrease in interest receivable	12,153	46,501	
Decrease (increase) in prepaid expenses and deposits	65,529	362,756	(92,281)
Increase (decrease) in accounts payable	(169,640)	38,668	163,067
Increase (decrease) in accrued expenses and other liabilities	(987,823)	493,451	94,699
Net cash used in operating activities	(6,854,283)	(5,359,696)	(21,863,236)
<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		4,464,996	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		(3,410)	(3,410)
Net cash provided by financing activities		4,444,592	26,769,623
Net (decrease) increase in cash	(6,854,283)	(916,449)	4,812,346
Cash and cash equivalents at beginning of period	11,766,629	15,943,896	100,000
Cash and cash equivalents at end of period	\$ 4,912,346	\$ 15,027,447	\$ 4,912,346
<b>Supplemental disclosure of non-cash operating activity:</b>			
Non-cash incentive received from lessor	\$	\$	\$ 52,320

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

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(a development stage company)**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

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

Catalyst Pharmaceutical Partners, Inc. (the Company) is a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of addiction and epilepsy. 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, 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 registered direct offerings via a shelf registration statement to institutional investors in 2008 and 2009. See Note 12.

***Capital Resources***

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. See Note 8. During October 2009, the Company sold 3,973,000 shares of its common stock under the same registration statement at a price of \$1.00 per share and received gross proceeds of approximately \$4.0 million before commissions and incurred expenses of approximately \$275,000. See Note 12. The Company has approximately \$21.5 million of authorized but unissued common stock available for future offerings under its shelf registration statement.

The Company will require additional capital to fund many of the clinical and non-clinical studies of CPP-109 and CPP-115. The Company will also require additional working capital to support its operations in periods after the first quarter of 2011.

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 the FASB Accounting Standard Codification ASC 915-10, *Development Stage Entities* (formerly Statement of Financial Accounting Standard, SFAS, No. 7, *Accounting and Reporting by Development Stage Enterprises*). The Company's primary focus is on the development and commercialization of its product candidates CPP-109 and CPP-115.
- b. **INTERIM FINANCIAL STATEMENTS.** The accompanying unaudited interim condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the 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 nine months ended September 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).** ASC 220-10 *Comprehensive Income*, (formerly 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, 2009 include (i) stock options to purchase up to 2,794,482 shares of common stock at exercise prices ranging from \$0.62 to \$6.00 per share and (ii) restricted stock units to receive 5,000 shares of common stock that will vest over the next quarter.

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) 10,000 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 oversaw 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 payable and accrued liabilities. At September 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 September 30, 2009, there were outstanding stock options to purchase 2,794,482 shares of common stock (including options to purchase 442,221 shares granted under the Plan), of which stock options to purchase 2,718,834 shares of common stock were exercisable as of September 30, 2009. Additionally, as of September 30, 2009, there were 55,484 restricted common stock units granted under the Plan, of which 50,484 were vested.

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

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Research and development	\$ 42,642	\$ 54,476	\$ 162,782	\$ 328,564
General and administrative	32,713	50,089	119,379	162,613
<b>Total stock-based compensation</b>	<b>\$ 75,355</b>	<b>\$ 104,565</b>	<b>\$ 282,161</b>	<b>\$ 491,177</b>

See Note 12 for information about stock option grants and cancellations after September 30, 2009.

j. **RECENT ACCOUNTING PRONOUNCEMENTS**

The Company adopted the provisions of ASC 820-10, *Fair Value Measurements and Disclosures*, (formerly SFAS No. 157 *Fair Value Measurements*), with respect to non-financial assets and non-financial liabilities effective January 1, 2009. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The adoption of ASC 820-10 did not have a material impact on the Company's condensed financial statements.

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

In May 2009, the FASB issued ASC 855-10 *Subsequent Events* (formerly SFAS No. 165, *Subsequent Events*), which establishes general standards of accounting for, and requires disclosures of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The Company adopted these provisions for the quarter ended June 30, 2009. The adoption did not have a material effect on the Company's condensed financial statements. For the quarter ended September 30, 2009 the Company evaluated subsequent events through November 11, 2009, the date the condensed financial statements were issued.

In June 2009, the FASB issued ASC 105-10 (formerly SFAS No. 168, *FASB Accounting Standards Codification and Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*). This pronouncement identifies the FASB Accounting Standards Codification as the authoritative source of GAAP. Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative GAAP for SEC registrants. This pronouncement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company has adopted this statement for the quarter ended September 30, 2009 and has updated GAAP references to the new codification in this Form 10-Q.

The Company adopted the provisions of ASC 808-10 *Collaborative Arrangements* (formerly Emerging Issues Task Force No. 07-1, *Accounting for Collaborative Arrangements*) effective January 1, 2009. This pronouncement 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. The adoption of this pronouncement had no impact on the Company's results of operations or financial condition.

**3. Prepaid Expenses.**

Prepaid expenses consist of the following:

	September 30, 2009	December 31, 2008
Prepaid insurance	\$ 44,994	\$ 85,750
Prepaid clinical research fees	10,802	35,489
Prepaid rent	6,099	5,701
Advances to CRO	5,880	
Other	13,995	9,434
Total prepaid expenses	\$ 81,770	\$ 136,374

**4. Property and Equipment.**

Property and equipment, net consists of the following:

	September 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	(78,331)	(55,186)
Total property and equipment, net	\$ 73,231	\$ 96,376

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

Depreciation expense was \$7,306 and \$8,158, and \$23,145 and \$24,598, respectively, for the three and nine month periods ended September 30, 2009 and 2008.

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

Accrued expenses and other liabilities consist of the following:

	September 30, 2009	December 31, 2008
Accrued clinical trial expenses	\$	\$ 1,064,539
Accrued license fees	41,435	
Deferred rent and lease incentive	12,585	9,966
Accrued compensation and benefits	25,686	1,932
Accrued professional fees	16,999	15,275
Other	5,922	5,698
<b>Current accrued expenses and other liabilities</b>	<b>102,627</b>	<b>1,097,410</b>
Deferred rent and lease incentive- non-current	33,160	42,636
Accrued license fees- non-current	16,436	
<b>Non-current accrued expenses and other liabilities</b>	<b>49,596</b>	<b>42,636</b>
<b>Total accrued expenses and other liabilities</b>	<b>\$ 152,223</b>	<b>\$ 1,140,046</b>

**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, other addictions and obsessive-compulsive disorders. This license agreement runs concurrently with the term of the last to expire of the licensed patents, the last of which currently expires in 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 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, 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.

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 September 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 September 30, 2009 and December 31, 2008 condensed balance sheets.

## **Table of Contents**

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

On August 27, 2009, the Company entered into a license agreement with Northwestern University ( Northwestern ), under which it acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered by Northwestern. Under the terms of the license agreement, Northwestern granted the Company an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. The Company has identified and designated the lead compound under this license as CPP-115.

Under the license agreement with Northwestern, the Company will be responsible for continued research and development of any resulting product candidates. The Company has the right to terminate the agreement in whole or in part after August 27, 2012, upon written notice. In addition, the Company is obligated to pay certain milestone payments in future years relating to clinical development activities or payable upon passage of time with respect to CPP-115, and royalties on any products resulting from the license agreement. As of September 30, 2009 the Company has paid Northwestern upfront payments aggregating \$10,000 and has accrued license fees of \$57,871 in the accompanying condensed balance sheet.

### **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 was 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). 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 granted the Company an extension to regain compliance with the Rule no later than the end of August 2009. During late August 2009, the Company decided to request a transfer of its listing to the Nasdaq Capital Market. On September 1, 2009, the Company was notified by the Nasdaq Stock Market that its application to transfer the listing of the Company's common stock from the Nasdaq Global Market to the Nasdaq Capital Market was approved. The Company's common stock began trading on the Nasdaq Capital Market on September 3, 2009.

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 incurred expenses of approximately \$377,000.

See Note 12 for information regarding an offering of the Company's common stock on October 6, 2009 under the shelf registration statement.

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

During the three and nine months ended September 30, 2009, the Company granted 30,000 and 64,000 common stock options to employees, officers, directors and consultants, 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 \$0.58 and \$1.15, respectively. No options were granted during the three months ended September 30, 2008. During the nine months ended September 30, 2008, the Company granted 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 \$2.87. The Company recorded stock-based compensation related to stock options totaling \$70,317 and \$99,528 and \$267,047 and \$362,484, respectively, during the three months and nine months ended September 30, 2009 and 2008. The total fair value of vested stock options during the three and nine months ended September 30, 2009 and 2008 was \$191,609 and \$250,268 and \$403,103 and \$496,531, 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,	
	2009	2008	2009	2008
Risk free interest rate	2.19 to 2.49%	2.98 to 3.23%	1.26 to 2.60%	2.40 to 3.23%
Expected term	4 to 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 September 30, 2009, there was approximately \$162,000 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 0.68 years.

*Restricted Stock Units*

No restricted stock units were granted during the three months ended September 30, 2009 and 2008 and the nine months ended September 30, 2009. During the nine months ended September 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 \$5,038 and \$15,114 and \$128,693, respectively, during the three and nine month periods ended September 30, 2009 and 2008. As of September 30, 2009, there was approximately \$5,000 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 three months.

*Additional Stock Option Grants*

See Note 12 for information about stock option grants and cancellations after September 30, 2009.

**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, 2009 and 2008, the Company paid approximately \$14,000 and \$14,000, and \$43,000 and \$141,000, respectively, in consulting fees to related parties.

**Table of Contents**

**11. Reclassifications.**

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

**12. Subsequent events.**

Subsequent to quarter end, during October 2009 the Company filed a prospectus supplement and offered for sale 3,973,000 shares of its common stock under its shelf registration statement at a price of \$1.00 per share. The Company received gross proceeds of approximately \$4.0 million before commissions and incurred expenses of approximately \$275,000. See Notes 1 and 8.

Subsequent to quarter end, on October 20, 2009, the Compensation Committee of the Company's Board of Directors granted five-year options to purchase an aggregate of 755,000 shares of the Company's authorized but unissued common stock to certain of the Company's officers, employees and consultants pursuant to the 2006 Stock Incentive Plan. Such options have an exercise price of \$0.90 per share, which was the market closing price of the Company's common stock on the date of grant. These stock options will vest over a two-year period. In connection with such grants, certain officers, employees and consultants voluntarily agreed to the cancellation of certain of the stock options that they previously held to purchase an aggregate of 743,688 shares of the Company's common stock. Additionally, on the same date the Compensation Committee granted five-year options to purchase 30,000 shares of the Company's common stock at an exercise price of \$0.90 per share to each of the Company's directors and to the Company's corporate secretary, aggregating options to purchase 180,000 shares. Such stock option grants vested immediately.



**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 new drug applications for CPP-109 and for CPP-115, our ability to complete such trials on a timely basis and within the budgets we establish for such trials, our ability to obtain the funding for such trials, our ability to protect our intellectual property, whether others develop and commercialize products competitive to our products, changes in the regulations affecting our business, our ability to attract and retain skilled employees, and changes in general economic conditions and interest rates. The risk factors section of our Annual Report on Form 10-K for the fiscal year ended December 31, 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 development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of drug addiction and epilepsy. We have obtained from Brookhaven National Laboratory an exclusive worldwide license for nine patents in the United States relating to the right to use vigabatrin to treat a wide variety of substance addictions and obsessive-compulsive disorders. We have also been granted rights to Brookhaven's vigabatrin-related foreign patents or patents pending in more than 30 countries. Our initial product candidate is CPP-109, which is our version of vigabatrin. CPP-109 has been granted Fast Track status by the U.S. Food & Drug Administration (FDA) for the treatment of cocaine addiction. This indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs. We have also recently signed a license agreement with Northwestern University under which we have obtained worldwide rights to several patented GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered by Northwestern. We intend to pursue development of one or more of these compounds, the lead compound which we call CPP-115, for several indications, including drug addiction and epilepsy.

The successful development of CPP-109, CPP-115 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 NDAs for CPP-109 and CPP-115; and

## **Table of Contents**

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 we will need additional capital to fund many of the future clinical and non-clinical trials of CPP-109 and CPP-115 that will be required before we are permitted to file an NDA for CPP-105 or CPP-115. There can be no assurance that we will ever be able to commercialize CPP-109 and/or CPP-115. See Liquidity and Capital Resources below.

## **Recent Developments**

### **Development of CPP-109**

#### *Results 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. 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. On May 29, 2009, we announced that the top-line data from this 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).

On September 30, 2009, we announced additional results of our U.S. Phase II clinical trial. Based on post-hoc analysis for vigabatrin levels in urine samples collected during the trial, we have concluded that less than 40% of the trial subjects were medication compliant. As a result, we now believe that the study was inadequately powered to properly test the efficacy of CPP-109 for the treatment of patients with cocaine addiction. On the basis of a comprehensive review of the study data, however, we concluded that: (i) CPP-109 was safe and well tolerated; and (ii) while there were no statistically significant differences between active and placebo groups for the protocol-specified primary and secondary efficacy endpoints, there were positive and consistent data trends observed in favor of CPP-109 across measures of cocaine abstinence, reduction in cocaine use, and reduction in use days.

When corrected for poor medication compliance, the following favorable outcome trends were observed: (i) the log<sub>10</sub> benzoylecgonine (the major metabolite of cocaine) levels measured in urine collected from subjects were consistently lower in the CPP-109 treatment group during the 12 week treatment period, generally indicating a reduction of cocaine use; and (ii) in those subjects who were compliant with study medication, the differences between CPP-109 and placebo were amplified, which suggest that CPP-109 may facilitate abstinence, reduce overall cocaine use as measured by urine benzoylecgonine levels (an objective measure of daily cocaine usage), and reduce cocaine usage days (an objective measure of dependence severity).

Consistent with previous published addiction trials conducted by other parties, the protocol of our cocaine trial assessed subjects' medication compliance based on self reporting and on counting the unused medication returned by subjects. Based on that methodology, we had an 85% compliance level. However, after post-hoc testing of urine samples from many of the trial's subjects, we have concluded that less than 40% of the trial subjects were compliant taking their medication. This low medication compliance effectively reduced the power of the study, because not all subjects in the treatment group were actually treated. However, analyses of subject responses, corrected for poor compliance, makes the response ratios observed in our trial more consistent with the results reported by Dr. Jonathan Brodie *et al.* in a double-blind, placebo-controlled, 103-patient Phase II trial evaluating vigabatrin for the treatment of cocaine addiction that was completed in Mexico in 2007 (the results of which trial were recently published in *The American Journal of Psychiatry*).

## **Table of Contents**

### *Results of 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 had planned to enroll 180 methamphetamine addicted patients at 15 addiction treatment clinical centers in the United States. However, in March 2009, in order to conserve cash, we converted our methamphetamine trial into a proof-of-concept study evaluating the results obtained from the 57 patients who had already been randomized into the trial. The patients we enrolled were treated for a period of 12 weeks and we evaluated data related to endpoints based on abstinence, reductions in methamphetamine use and craving for evidence of potential efficacy.

On September 30, 2009, we announced the top-line results of our proof-of-concept study. The results showed that there was a 2.5 times higher rate of abstinence in the last two weeks of the study in the vigabatrin group versus the placebo group. While we consider this to be an encouraging trend, the results were not statistically significant due to the low sample size. We also believe that medication compliance, similar to the cocaine trial, may have been below expectations.

### *CPP-109 (Vigabatrin) Safety Results*

Regarding the safety of CPP-109, no clinically significant abnormalities in visual fields and visual acuity were found in any subject in either our cocaine trial or our methamphetamine proof-of-concept study. Furthermore, additional safety tests conducted in the methamphetamine trial revealed no brain or clinically significant cardiovascular abnormalities in any subject. Finally, no significant differences were found in the rates of adverse events between the CPP-109 and placebo treated subjects in either study.

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

On the basis of our reported results described above and previously published studies of vigabatrin to treat addiction, we have decided to continue to develop CPP-109 for the treatment of cocaine addiction and methamphetamine addiction. Our decision was supported by a panel of experts who recently met and agreed with our conclusion. We are currently developing our clinical development plan for future studies of CPP-109 for the treatment of cocaine and methamphetamine addiction, and we expect to announce our future development plans for CPP-109 once they are finalized.

Some of the studies that we expect will be required to assess the efficacy of CPP-109 for the treatment of cocaine addiction and methamphetamine addiction, including at least one pivotal Phase III trial, will require us to obtain additional funding. Our current intent is to seek the funding for future CPP-109 trials from future sales of our securities, governmental grants from the National Institute on Drug Abuse (NIDA) or other entities that operate under the National Institute of Health umbrella, other government agencies, and/or from potential strategic partnerships. There can be no assurance that any such funding will be available on terms that are acceptable to us, or at all. Further, there can be no assurance that future clinical trials of CPP-109 evaluating its efficacy for use in the treatment of cocaine addiction or methamphetamine addiction will be successful or that we will ever be able to commercialize CPP-109 for the treatment of cocaine addiction and methamphetamine addiction.

### *Update on Sabril*

On August 21, 2009, Lundbeck, Inc. f/k/a Ovation Pharmaceuticals, Inc. ( Lundbeck ), a wholly-owned subsidiary of H. Lundbeck A/S in Denmark, publicly reported that the Food and Drug Administration ( FDA ) approved Sabril (the branded version of vigabatrin) for the treatment of infantile spasms and as an adjunctive (add-on) therapy for adult patients with refractory complex partial seizures. Lundbeck announced that because of the risks of visual field damage associated with vigabatrin, Sabril was approved under an FDA-mandated Risk Evaluation and Mitigation Strategy ( REMS Strategy ) and is only being made available through a special restricted distribution program approved by the FDA.

## **Table of Contents**

We believe that the approval of Sabril for the treatment of infantile spasms and refractory complex partial seizures is a positive development for us, since it appears to evidence that if we are able to prove to the FDA that CPP-109 is effective in treating cocaine addiction and methamphetamine addiction, that the FDA will consider approving the use of CPP-109 to treat these serious or life-threatening conditions for which there is currently no effective treatment.

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

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

### **License Agreement for New Compounds with Northwestern University**

On August 27, 2009, we entered into a license agreement with Northwestern University, under which we acquired worldwide rights to commercialize new GABA aminotransferase inhibitors and derivatives of vigabatrin which have been discovered and patented by Northwestern University. Under the terms of the license agreement, Northwestern University granted us an exclusive worldwide license to certain composition of matter patents related to the new class of inhibitors and a patent application relating to derivatives of vigabatrin. We have designated the lead compound to be developed under this license as CPP-115.

We believe that the newly licensed compounds are the only known GABA-aminotransferase inhibitors in existence or in development other than vigabatrin. We also believe that the newly licensed compounds may be significantly more potent than vigabatrin, but without its known side effect profile (visual field defects). We plan to seek to develop these compounds for the treatment of several indications, including drug addiction and epilepsy. However, these compounds are at a very early stage of development and there can be no assurance as to whether these new compounds will ever be determined to be safe and effective.

Under our license agreement with Northwestern, we will be responsible for continued research and development of any resulting product candidates. We have the right to terminate the agreement in whole or in part after August 27, 2012, upon written notice. As of September 30, 2009, we have paid Northwestern University upfront payments aggregating \$10,000 and we are obligated to pay certain additional fees, including \$25,000 in upfront fees and \$32,871 in expenses, and milestone payments in future years relating to our clinical development activities under this license or payable upon passage of time. We are also obligated to pay Northwestern royalties on any products resulting from the license agreement.

### **Recently completed registered direct public offering**

On October 6, 2009, we closed a registered direct public offering in which we sold 3,973,000 shares of our common stock for a price of \$1.00 per share to four institutional investors. Rodman & Renshaw acted as the placement agent with respect to the offering and Merriman Curhan Ford acted as our financial advisor with respect to the offering. In connection with the offering, we paid Rodman & Renshaw a placement agent fee equal to 5% of the gross proceeds of the offering, and we paid Merriman Curhan Ford an advisory fee equal to 1% of the gross proceeds of the offering. The net proceeds of the offering were approximately \$3.7 million, after deducting from the gross proceeds of the offering: (i) the 6% aggregate fees paid to Rodman & Renshaw and Merriman Curhan, and (ii) the estimated expenses of the offering.

**Table of Contents**

The following table sets forth our capitalization as of September 30, 2009 on a pro forma basis after giving effect to our October 6, 2009 sale of common stock:

	September 30, 2009	
	Actual	Pro Forma
Cash and cash equivalents	\$ 4,912,346	\$ 8,609,966
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding		
Common stock, \$0.001 par value, 100,000,000 shares authorized, 14,065,385 shares outstanding; 18,038,385 shares pro forma	14,065	18,038
Paid-in and additional paid-in capital	31,291,615	34,985,262
Deficit accumulated during the development stage	(26,543,112)	(26,543,112)
<b>Total stockholders' equity</b>	<b>4,762,568</b>	<b>8,460,188</b>
<b>Total capitalization</b>	<b>\$ 4,762,568</b>	<b>\$ 8,460,188</b>

We currently expect to use the net proceeds from the offering to fund future clinical and/or non-clinical studies of CPP-109 for the treatment of cocaine addiction, to complete one or more non-clinical studies relating to CPP-115 and for general corporate purposes.

**Transfer to the Nasdaq Capital Market**

On September 3, 2009, we transferred the listing of our common stock from the NASDAQ Global Market to the NASDAQ Capital Market. The NASDAQ Capital Market is a continuous trading market that operates in the same manner as The NASDAQ Global Market. The NASDAQ Capital Market includes the securities of approximately 450 companies. All companies listed on The NASDAQ Capital Market must meet certain financial requirements and adhere to NASDAQ's corporate governance standards. Our common stock continues to trade under the symbol CPRX.

**Recent Management Changes and Stock Option Grants**

On October 9, 2009, our Board of Directors approved two management changes:

Steven R. Miller, Ph.D, who was our Vice President, Pharmaceutical Development and Project Management, has assumed additional duties and was named Chief Scientific Officer. In his new role, Dr. Miller will assume expanded responsibilities in all of our product development activities, particularly new product development and expansion of our intellectual property portfolio; and

Jack Weinstein, who is our Vice President, Treasurer and Chief Financial Officer, has assumed formal responsibility for our business development activities. In that role, Mr. Weinstein will particularly focus on seeking partnering opportunities for our product candidates. On the same date, the Board extended the expiration date of our employment agreement with our Chairman and Chief Executive Officer, Patrick J. McEnany, from November 8, 2009 to November 8, 2011.

Further, on October 20, 2009, the Compensation Committee of our Board of Directors granted five-year stock options to purchase an aggregate of 755,000 shares of our authorized but unissued common stock to certain of our officers, employees and consultants pursuant to our 2006 Stock Incentive Plan. The new stock options have an exercise price of \$0.90 per share, which was the closing price of our common stock on the Nasdaq Capital Market on October 20, 2009 (the date on which the stock options were approved). The new stock options will vest over a two-year period. In connection with such grants, certain of our officers, employees and consultants voluntarily agreed to the cancellation of certain of the stock options that they previously held to purchase an aggregate of 743,688 shares of our common stock.



## **Table of Contents**

The Compensation Committee made the decision to grant additional stock options based on its views as to the importance of retaining and motivating our key managers with long-term non-cash compensation opportunities. Further, the decision to request that certain officers, consultants and employees agree to the cancellation of certain of their out-of-the-money stock options was made in an effort to keep the total number of options outstanding within a range that the Committee believed appropriate under the circumstances.

Additionally, on October 20, 2009 the Compensation Committee granted five-year stock options to purchase 30,000 shares of our common stock to each of our directors and our corporate secretary (aggregating options to purchase 180,000 shares). These stock option grants have an exercise price of \$0.90 per share and vested immediately.

### **Basis of presentation**

#### *Revenues*

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

#### *Research and development expenses*

Our research and development expenses consist of costs incurred for company-sponsored research and development activities. The major components of research and development costs include non-clinical study costs, 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 CPP-115, and we expect this to continue for the foreseeable future. Costs incurred in connection with research and development activities are expensed as incurred.

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies at a given point in time, we could be required to record significant additional research and development expenses in future periods. Clinical trial activities require significant up front expenditures. We anticipate paying significant portions of a trial's cost before such begins, and incurring additional expenditures as the trial progresses and reaches certain milestones.

#### *Selling and marketing expenses*

We do not currently have any selling or marketing expenses, as we have not yet received approval for the commercialization of CPP-109 or CPP-115. We expect to have a sales force in place to commence our selling efforts immediately upon receiving approval of such NDAs, of which there can be no assurance.

## **Table of Contents**

### *General and administrative expenses*

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

### *Stock-based compensation*

We recognize 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 ASC 505 and ASC 718, formerly 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, 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.

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

## **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.



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

We record stock-based compensation using the fair value recognition provisions of ASC 505 *Equity* and ASC 718 *Stock Compensation*, (formerly 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 three and nine months ended September 30, 2009 we granted 30,000 and 64,000 options, respectively. No options were granted during the three months ended September 30, 2008. During the nine months ended September 30, 2008 we granted 99,000 options. For the three months periods ended September 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 ranging from 2.19% to 2.49% and 2.98% to 3.23%. For the nine months periods ended September 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 2.40% to 3.23%.

See Note 12 of the Notes to Consolidated Financial Statements and *Recent Developments*, *Recent Management Changes* and *Stock Option Grants* for information about stock option grants and cancellations after September 30, 2009.

**Results of Operations**

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

*Research and Development Expenses.* Research and development expenses for the three and nine months ended September 30, 2009 and 2008 were \$850,998 and \$2,451,579 and \$4,549,883 and \$5,438,082, respectively, including stock-based compensation expense in each of the three and nine month periods of \$42,642 and \$54,476 and \$162,782 and \$328,564, respectively. Research and development expenses, in the aggregate, represented approximately 66% and 84%, and 75% and 77% of total operating costs and expenses, respectively, for the three and nine months ended September 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. Expenses for research and development for the three and nine month periods ended September 30, 2009 decreased compared to amounts expended in the same periods in 2008 as we incurred decreasing 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, as such studies were completed during the third quarter of 2009.

We expect that costs related to research and development activities will continue to decrease as we have completed our U.S. Phase II cocaine clinical trial and methamphetamine proof-of-concept study. These costs may be offset, however, by expenses related to any future trials that we may conduct.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the three and nine month periods ended September 30, 2009 and 2008. We anticipate that we will begin to incur sales and marketing expenses when we file NDAs for CPP-109 and CPP-115 and, in order to develop a sales organization to market CPP-109 and CPP-115 and other products we may develop upon the receipt of required approvals.

*General and Administrative Expenses.* General and administrative expenses for the three and nine months ended September 30, 2009 and 2008 were \$441,316 and \$463,199 and \$1,555,786 and \$1,664,405, respectively, including stock-based compensation expense in each of the three and nine months periods of \$32,713 and \$50,089 and \$119,379 and \$162,613, respectively. General and administrative expenses represented 34% and 16% and 25% and 23%, respectively, of total operating costs and expenses, for the three and nine months ended September 30, 2009 and 2008. The decreases of \$21,883 and \$108,619 in general and administrative expenses

---

## **Table of Contents**

for the three and nine months ended September 30, 2009 when compared to the same periods in 2008 are primarily due to decreases in professional, consulting, travel and stock-based compensation expenses. 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 increase in the fourth quarter of 2009 when compared to those costs incurred for the nine months ended September 30, 2009, mainly due to non-cash compensation expense related to options granted during the 2009 fourth quarter to certain of our officers, employees, consultants and directors.

*Stock-Based Compensation.* Total stock based compensation for the three and nine months ended September 30, 2009 and 2008 was \$75,355 and \$104,565 and \$282,161 and \$491,177, 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 September 30, 2009, we had outstanding stock options to purchase 2,794,482 shares of our common stock, of which options to purchase 2,718,834 shares were vested and options to purchase 75,648 shares were unvested. We also have granted restricted stock units to receive 55,484 shares of common stock as of September 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 September 2008 registered direct offering. The decrease in interest income in the three and nine month periods ended September 30, 2009 when compared to the same periods in 2008 is due to lower interest rates and lower investment amounts as we use the remaining proceeds from offerings 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, 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 two registered direct offerings under our shelf registration statement. At September 30, 2009, we had cash and cash equivalents of \$4.9 million and working capital of \$4.7 million. We also completed an offering of our securities on October 6, 2009 raising net proceeds of approximately \$3.7 million and at September 30, 2009, on a pro forma basis after giving effect to our October 6, 2009 offering, we had cash and cash equivalents of \$8.6 million and working capital of \$8.4 million. At December 31, 2008, we had cash and cash equivalents of \$11.8 million and working capital of \$10.5 million. At September 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 and CPP-115. We anticipate using current cash on hand to finance these activities. It will likely take several years to obtain the necessary regulatory approvals to commercialize CPP-109 and CPP-115 in the United States.

Our future funding requirements will depend on many factors, including:

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

the results of our 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;

## Table of Contents

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 many of the future clinical trials and non-clinical studies that will be required before we are in a position to file NDAs for CPP-109 and CPP-115. We will also require additional working capital to support our operations in periods after the first quarter of 2011.

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

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 shelf 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 shelf 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. Subsequent to quarter end, during October 2009 we filed an additional prospectus supplement and offered for sale 3,973,000 shares of our common stock under the same shelf registration statement at a price of \$1.00 per share. We received gross proceeds of approximately \$4.0 million before commissions and incurred expenses of approximately \$275,000.

As of November 12, 2009, we had approximately \$21.5 million of authorized but unissued common stock available for future offerings under the shelf registration statement. 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 \$6,854,283 and \$5,359,696, respectively, for the nine months ended September 30, 2009 and 2008. During the nine months ended September 30, 2009, net cash used in operating activities was primarily attributable to our net loss of \$6,079,808 and decreases of \$169,640 in accounts payable and \$987,823 in accrued expenses and other liabilities. This was offset in part by \$305,306 of non-cash expenses and decreases of \$65,529 in prepaid expenses and deposits, and \$12,153 in interest receivable. 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 interest receivable and \$362,756 in prepaid expenses and deposits, and increases of \$38,668 in accounts payables and \$493,451 in accrued expenses and other liabilities. Non-cash expenses include depreciation and stock-based compensation expense.

## **Table of Contents**

No cash was provided by (used in) investing activities during the nine months ended September 30, 2009. Net cash used in investing activities for the nine months ended September 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 nine months ended September 30, 2009. 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 a 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.

### *Contractual Obligations*

We have entered into the following contractual arrangements:

*Payment to Brookhaven under our license agreement.* We have agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval for CPP-109, \$250,000 in each of the second and third years following approval, and \$500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed products for certain of their patent-related expenses. We believe that such obligation is approximately \$166,000 at September 30, 2009 and December 31, 2008. See *Dispute with Brookhaven* below.

*Payment to Northwestern University under our license agreement.* We have agreed to pay Northwestern an upfront fee of \$35,000, reimbursement of approximately \$33,000 in expenses, and certain milestone payments in future years relating to clinical development activities with respect to CPP-115 or payable upon passage of time, and royalties on any products resulting from the license agreement. At September 30, 2009 we had paid \$10,000 of this amount, and had accrued license fees of \$57,871 in the accompanying condensed balance sheet.

*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 September 30, 2009, we had paid approximately \$943,000 of this amount.

*Payments to our CRO.* We estimate that we will pay our CRO approximately \$6,101,000 and \$3,341,000 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 September 30, 2009, we had paid approximately \$5,960,000 and \$3,341,000 of these amounts, respectively.

*Payments for laboratories and other trial related tests.* We estimate that we will pay approximately \$837,000, in connection with laboratories and other tests related to our U.S. Phase II cocaine clinical trial. At September 30, 2009, we had paid approximately \$818,000 of this amount. In addition, we estimate we will pay approximately \$405,000 in connection with laboratories related to our methamphetamine proof-of-concept study. At September 30, 2009, we have paid approximately \$405,000 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 September 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 \$358,000 per annum.

*Leases for office space.* We have entered into lease agreements for our office space that require payments of approximately \$6,000 per month.



## **Table of Contents**

### *Dispute with Brookhaven*

Brookhaven has formally advised us that they believe that the amount due them for patent related expenses as of September 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 September 30, 2009 and December 31, 2008 balance sheets.

### *Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of September 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**

We adopted the provisions of ASC 820-10, *Fair Value Measurements and Disclosures*, (formerly SFAS No. 157 *Fair Value Measurements*), with respect to non-financial assets and non-financial liabilities effective January 1, 2009. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The adoption of ASC 820-10 did not have a material impact on our condensed financial statements.

In May 2009, the FASB issued ASC 855-10 *Subsequent Events* (formerly SFAS No. 165, *Subsequent Events*), which establishes general standards of accounting for, and requires disclosures of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. We adopted these provisions for the quarter ended June 30, 2009. The adoption did not have a material effect on our condensed financial statements. For the quarter ended September 30, 2009 we evaluated subsequent events through November 11, 2009, the date the condensed financial statements were issued.

In June 2009, the FASB issued ASC 105-10 (formerly SFAS No. 168, *FASB Accounting Standards Codification and Hierarchy of Generally Accepted Accounting Principles, a replacement of FASB Statement No. 162*). This pronouncement identifies the FASB Accounting Standards Codification as the authoritative source of GAAP. Rules and interpretive releases of the SEC under federal securities laws are also sources of authoritative GAAP for SEC registrants. This pronouncement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. We adopted this statement for the quarter ended September 30, 2009 and have updated GAAP references to the new codification.

We adopted the provisions of ASC 808-10 *Collaborative Arrangements* (formerly Emerging Issues Task Force No. 07-1, *Accounting for Collaborative Arrangements*) effective January 1, 2009. This pronouncement 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. The adoption of this pronouncement 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.

**Table of Contents**

**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, 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**

None.

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

- 10.1 Second Amendment to Employment Agreement between the Company and Patrick J. McEnany, dated as of November 8, 2009.
- 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: November 11, 2009

**Table of Contents**

**Exhibit Index**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.1	Second Amendment to Employment Agreement between the Company and Patrick J. McEnany, dated as of November 8, 2009
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