

Catalyst Pharmaceutical Partners, Inc.

Form 10-Q

August 12, 2010

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

[Mark One]

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended June 30, 2010

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission File No. 001-33057

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

(Exact name of registrant as specified in its charter)

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

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

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

**355 Alhambra Circle**

**Suite 1370**

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

**33134**  
(Zip Code)

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

Indicate by checkmark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such report(s), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 19,394,737 shares of common stock, \$0.001 par value per share, were outstanding as of August 10, 2010.

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC. INDEX**

**INDEX**

**PART I. FINANCIAL INFORMATION**

Item 1.	<b>CONDENSED FINANCIAL STATEMENTS</b>	
	<u>Condensed balance sheets at June 30, 2010 (unaudited) and December 31, 2009</u>	3
	<u>Condensed statements of operations for the three and six months ended June 30, 2010 and 2009 and from January 4, 2002 (date of inception) to June 30, 2010 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the six months ended June 30, 2010 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the six months ended June 30, 2010 and 2009 and from January 4, 2002 (date of inception) through June 30, 2010 (unaudited)</u>	6
	<u>Notes to unaudited condensed financial statements</u>	7
Item 2.	<b><u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u></b>	14
Item 3.	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>	23
Item 4.	<b><u>CONTROLS AND PROCEDURES</u></b>	23

**PART II. OTHER INFORMATION**

Item 1.	<b><u>LEGAL PROCEEDINGS</u></b>	24
Item 1A.	<b><u>RISK FACTORS</u></b>	24
Item 2.	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	24
Item 3.	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	24
Item 4.	<b><u>REMOVED AND RESERVED</u></b>	24
Item 5.	<b><u>OTHER INFORMATION</u></b>	24
Item 6.	<b><u>EXHIBITS</u></b>	24

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

	June 30, 2010 (unaudited)	December 31, 2009
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 5,608,368	\$ 7,779,277
Prepaid expenses	236,728	108,147
<b>Total current assets</b>	<b>5,845,096</b>	<b>7,887,424</b>
Property and equipment, net	55,367	68,447
Deposits	10,511	10,511
<b>Total assets</b>	<b>\$ 5,910,974</b>	<b>\$ 7,966,382</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 251,969	\$ 249,635
Accrued expenses and other liabilities	199,224	44,517
<b>Total current liabilities</b>	<b>451,193</b>	<b>294,152</b>
Accrued expenses and other liabilities, non-current	47,370	54,370
<b>Total liabilities</b>	<b>498,563</b>	<b>348,522</b>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized: none issued and outstanding		
Common stock, \$0.001 par value, 100,000,000 shares authorized; 18,043,385 shares and 18,038,385 shares, respectively, issued and outstanding at June 30, 2010 and December 31, 2009	18,043	18,038
Additional paid-in capital	35,473,184	35,305,054
Deficit accumulated during the development stage	(30,078,816)	(27,705,232)
<b>Total stockholders' equity</b>	<b>5,412,411</b>	<b>7,617,860</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 5,910,974</b>	<b>\$ 7,966,382</b>

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,		Cumulative Period from January 4, 2002 (date of inception) to June 30, 2010
	2010	2009	2010	2009	
Revenues	\$	\$	\$	\$	\$
Operating costs and expenses:					
Research and development	797,935	1,238,253	1,237,522	3,698,885	21,328,484
General and administrative	535,197	530,559	1,146,022	1,114,470	10,209,238
Total operating costs and expenses	1,333,132	1,768,812	2,383,544	4,813,355	31,537,722
Loss from operations	(1,333,132)	(1,768,812)	(2,383,544)	(4,813,355)	(31,537,722)
Interest income	4,591	6,925	9,960	20,267	1,458,906
Loss before income taxes	(1,328,541)	(1,761,887)	(2,373,584)	(4,793,088)	(30,078,816)
Provision for income taxes					
Net loss	\$ (1,328,541)	\$ (1,761,887)	\$ (2,373,584)	\$ (4,793,088)	\$ (30,078,816)
Loss per share basic and diluted	\$ (0.07)	\$ (0.13)	\$ (0.13)	\$ (0.34)	
Weighted average shares outstanding basic and diluted	18,043,385	14,065,385	18,043,385	14,065,385	

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

Table of Contents**CATALYST PHARMACEUTICAL PARTNERS, INC.****(a development stage company)****CONDENSED STATEMENT OF STOCKHOLDERS EQUITY (unaudited)****For the six months ended June 30, 2010**

	Preferred Stock	Common Stock	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
<b>Balance at December 31, 2009</b>	\$	\$ 18,038	\$ 35,305,054	\$ (27,705,232)	\$ 7,617,860
Issuance of stock options for services			168,135		168,135
Vesting of restricted stock units		5	(5)		
Net loss				(2,373,584)	(2,373,584)
<b>Balance at June 30, 2010</b>	\$	\$ 18,043	\$ 35,473,184	\$ (30,078,816)	\$ 5,412,411

**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 Six Months Ended		Cumulative Period from January 4, 2002 (date of inception) through June 30, 2010
	2010	June 30, 2009	
<b>Operating Activities:</b>			
Net loss	\$ (2,373,584)	\$ (4,793,088)	\$ (30,078,816)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	13,080	15,839	98,493
Stock-based compensation	168,135	206,806	4,923,472
Changes in assets and liabilities:			
Decrease in interest receivable		12,153	
Decrease (increase) in prepaid expenses and deposits	(128,581)	22,626	(247,239)
Increase (decrease) in accounts payable	2,334	(57,044)	251,969
Increase (decrease) in accrued expenses and other liabilities	147,707	(908,344)	189,070
Net cash used in operating activities	(2,170,909)	(5,501,052)	(24,863,051)
<b>Investing Activities:</b>			
Capital expenditures			(96,339)
Net cash used in investing activities			(96,339)
<b>Financing Activities:</b>			
Proceeds from issuance of common stock			26,575,571
Proceeds from issuance of preferred stock			3,895,597
Payment of employee withholding tax related to RSUs			(3,410)
Net cash provided by financing activities			30,467,758
Net (decrease) increase in cash	(2,170,909)	(5,501,052)	5,508,368
Cash and cash equivalents at beginning of period	7,779,277	11,766,629	100,000
Cash and cash equivalents at end of period	\$ 5,608,368	\$ 6,265,577	\$ 5,608,368
<b>Supplemental disclosure of non-cash operating activity:</b>			
Non-cash incentive received from lessor	\$	\$	\$ 52,320

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

---

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(a development stage company)**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

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

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

The Company has incurred operating losses in each period from inception through June 30, 2010. The Company has been able to fund its cash needs to date through an initial funding from its founders, four private placements, an initial public offering (IPO), and registered direct offerings via a shelf registration statement to institutional investors in 2008, 2009 and 2010. See below and Note 8.

***Capital Resources***

In June 2008, the Company filed a registration statement on Form S-3 to sell up to \$30,000,000 of its authorized, but unissued common stock through future offerings. Subsequent to quarter end, on August 9, 2010 the Company sold 1,351,352 shares of its common stock under its shelf registration statement at a price of \$1.11 per share and received gross proceeds of approximately \$1.5 million before incurred expenses of approximately \$50,000. As of August 10, 2010, the Company had approximately \$20 million of authorized, but unissued common stock available for future offerings under its shelf registration statement. See Note 8.

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

The Company will require additional capital to fund many of the clinical and non-clinical studies of CPP-109 and CPP-115 that it expects will be required to file New Drug Applications (NDA) with the U.S. Food and Drug Administration (FDA). The Company will also require additional working capital to support its operations in periods after the first quarter of 2012.

In addition to the filing of the shelf registration statement described above, the Company may raise the additional funds required through public or private equity offerings, debt financings, corporate or government collaborations, governmental research grants or other means. The Company may also seek to raise new capital to fund additional product development efforts, even if it has sufficient funds for its planned operations. Any sale by the Company of additional equity or convertible debt securities could result in dilution to the Company's current stockholders. There can be no assurance that any such required additional funding will be available to the Company at all or available on terms acceptable to the Company. Further, to the extent that the Company raises additional funds through collaborative arrangements, it may be necessary to relinquish some rights to the Company's technologies or grant sublicenses on terms that are not favorable to the Company. If the Company is not able to secure additional funding when needed, the Company may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on the Company's business.



---

**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 U.S. generally accepted accounting principles applicable to a development stage company. The Company's primary focus is on the development and commercialization of its product candidates, CPP-109 and CPP-115.

b. **INTERIM FINANCIAL STATEMENTS.** The accompanying unaudited interim condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the U.S. have been condensed or omitted. In the opinion of management, the accompanying unaudited interim condensed financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of the dates and for the periods presented. Accordingly, these statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2009 included in the Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the six months ended June 30, 2010 are not necessarily indicative of the results to be expected for any future period or for the full 2010 fiscal year.

c. **USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

d. **COMPREHENSIVE INCOME (LOSS).** U.S. generally accepted accounting principles require that all components of comprehensive income (loss) be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is net income (loss), plus certain other items that are recorded directly into stockholders' equity. The Company has reported comprehensive income (loss) in the statement of stockholders' equity as net income (loss).

e. **EARNINGS (LOSS) PER SHARE.** Basic earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed by dividing net earnings (loss) for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common stock equivalents, such as unvested restricted common stock and stock options. Due to the net loss for all periods presented, all common stock equivalents were excluded because their inclusion would have been anti-dilutive.

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

Potentially dilutive common stock equivalents as of June 30, 2009 include (i) stock options to purchase up to 2,781,149 shares of common stock at exercise prices ranging from \$0.69 to \$6.00 per share and (ii) 5,000 unvested 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 consist primarily of prepaid insurance and advances for our research and product development activities, including drug manufacturing, contracts for non-clinical studies, clinical trials, regulatory affairs and consulting. Such advances are recorded as expense as the related goods are received or the related services are performed.
- h. **FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company's financial instruments consist of cash and cash equivalents, accounts payables and accrued expenses and other liabilities. At June 30, 2010, the fair value of these instruments approximated their carrying value.
- i. **STOCK COMPENSATION PLANS.** The Company recognizes expense in the statement of operations for the fair value of all share-based payments to employees, directors, consultants and scientific advisors, including grants of stock options and other share-based awards. For stock options, the Company uses the Black-Scholes option valuation model and the single-option award approach and straight-line attribution method. Using this approach, compensation cost is amortized on a straight-line basis over the vesting period of each respective stock option, generally three to five years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

As of June 30, 2010, there were outstanding stock options to purchase 2,670,619 shares of common stock (including options to purchase 1,474,372 shares granted under the 2006 Stock Incentive Plan), of which stock options to purchase 2,167,286 shares of common stock were exercisable as of June 30, 2010.

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

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Research and development	\$ 61,963	\$ 48,440	\$ 122,431	\$ 120,140
General and administrative	23,825	16,092	45,704	86,666
<b>Total stock-based compensation</b>	<b>\$ 85,788</b>	<b>\$ 64,532</b>	<b>\$ 168,135</b>	<b>\$ 206,806</b>

j. **RECENT ACCOUNTING PRONOUNCEMENTS**

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

**Table of Contents****3. Prepaid Expenses.**

Prepaid expenses consist of the following:

	June 30, 2010	December 31, 2009
Prepaid insurance	\$ 101,034	\$ 82,145
Prepaid research fees	114,079	7,283
Prepaid rent		8,035
Other	21,615	10,684
<b>Total prepaid expenses</b>	<b>\$ 236,728</b>	<b>\$ 108,147</b>

**4. Property and Equipment.**

Property and equipment, net consists of the following:

	June 30, 2010	December 31, 2009
Computer equipment	\$ 29,509	\$ 29,509
Furniture and equipment	44,175	44,175
Leasehold improvements	80,176	80,176
	153,860	153,860
Less: Accumulated depreciation	(98,493)	(85,413)
<b>Total property and equipment, net</b>	<b>\$ 55,367</b>	<b>\$ 68,447</b>

Depreciation expense was \$6,329 and \$13,080, and \$7,799 and \$15,839, respectively, for the three and six month periods ended June 30, 2010 and 2009.

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

Accrued expenses and other liabilities consist of the following:

	June 30, 2010	December 31, 2009
Accrued non-clinical and clinical trial expenses	\$ 78,425	\$ 273
Deferred rent and lease incentive	13,935	13,037
Accrued license fees	21,436	18,936
Accrued compensation and benefits	52,790	
Accrued professional fees	29,500	10,000
Other	3,138	2,271
<b>Current accrued expenses and other liabilities</b>	<b>199,224</b>	<b>44,517</b>
Accrued license fees- non-current	24,886	24,770
Deferred rent and lease incentive- non-current	22,484	29,600
<b>Non-current accrued expenses and other liabilities</b>	<b>47,370</b>	<b>54,370</b>

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

Total accrued expenses and other liabilities	\$ 246,594	\$ 98,887
--	------------	-----------

**Table of Contents**

**6. Commitments.**

- a. LICENSE AGREEMENT WITH BROOKHAVEN.** The Company has entered into a license agreement with Brookhaven Science Associates, LLC, as operator of Brookhaven National Laboratory under contract with the United States Department of Energy ( Brookhaven ), whereby the Company has obtained an exclusive license for several patents and patent applications in the U.S. and outside the U.S. relating to the use of vigabatrin as a treatment for cocaine, other substance addictions and obsessive-compulsive disorders. This license agreement runs concurrently with the term of the last to expire of the licensed patents, the last of which currently expires in 2023. Under the license agreement, the Company has agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval of CPP-109, \$250,000 in each of the second and third years following approval and \$500,000 per year thereafter until the license agreement expires. The Company is also obligated to reimburse Brookhaven for certain of their patent related expenses. At June 30, 2010 and December 31, 2009, the Company believes it had a contingent liability of approximately \$166,000, relating to this obligation, a portion of which will become payable in six equal monthly installments at the time the Company submits an NDA to the U.S. Food and Drug Administration ( FDA ), and the balance of which will be due commencing within 60 days of obtaining FDA regulatory approval to sell any product. The Company also has the right to enter into sub-license agreements, and if it does, a royalty of 20% of any sub-license fees will be payable to Brookhaven.

Brookhaven has formally advised the Company that they believe that the amount potentially due from the Company to Brookhaven for reimbursement of patent related expenses is approximately \$1.2 million. The Company has advised Brookhaven that it disputes their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by the Company of an NDA for CPP-109. As the Company has not yet filed an NDA for CPP-109, no amounts relating to this matter are accrued in the accompanying June 30, 2010 and December 31, 2009 balance sheets.

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

Under the Northwestern license agreement, the Company will be responsible for continued research and development of any resulting product candidates. As of June 30, 2010, the Company had paid \$43,218 in connection with the license. In addition, the Company had current and long-term accrued license fees totaling \$46,322 and \$43,706 as of June 30, 2010 and December 31, 2009, respectively, in connection with license expenses, maintenance fees and milestones. In addition, the Company is obligated to pay certain milestone payments in future years relating to clinical development activities with respect to CPP-115, and royalties on any products resulting from the license agreement. The first such milestone payment of \$50,000 is due on or before August 27, 2012.

---

**Table of Contents**

**6. Commitments (continued).**

- c. **AGREEMENTS FOR DRUG DEVELOPMENT, NON-CLINICAL AND CLINICAL STUDIES.** The Company has contracted with various consultants, drug manufacturers, and other vendors to assist in drug development work, clinical and non-clinical studies, data analysis and the preparation of material necessary for the filing of Investigational New Drug Applications ( INDs ) and NDAs with the FDA. The contracts are cancelable at any time, but obligate the Company to reimburse the providers for any costs incurred through the date of termination. The Company currently estimates that it will pay an aggregate of approximately \$965,000 under these agreements. As of June 30, 2010, the Company had paid approximately \$625,000 of this amount. In addition, the Company had approximately \$114,000 in prepaid expenses, \$85,000 in accounts payable and \$78,000 in accrued expenses in the accompanying balance sheet as of June 30, 2010 relating to these contracts.

**7. Income Taxes.**

The Company is subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. The Company is not subject to U.S. federal, state and local tax examinations by tax authorities for years before 2003. If the Company were to subsequently record an unrecognized tax benefit, associated penalties and tax related interest expense would be reported as a component of income tax expense.

**8. Stockholders Equity.**

On November 13, 2009, the Company received a staff deficiency letter from The Nasdaq Stock Market ( Nasdaq ) notifying the Company that it was not in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market. The Nasdaq Listing Rules (the Rules ) require listed securities to maintain a minimum bid price of \$1.00 per share and, based on the then closing bid prices for the last 30 consecutive business days, the Company no longer met that requirement. Under the Rules, the Company had a grace period of 180 days to regain compliance, and on April 26, 2010, the Company received notice from Nasdaq confirming that the Company had regained compliance as a result of the Company s common stock having closed with a bid price of at least \$1.00 for at least ten consecutive trading days.

On June 2, 2008, the Company filed a shelf registration statement with the SEC to sell up to \$30 million of common stock. This shelf registration was declared effective by the SEC on June 26, 2008. Under this registration statement, the Company may sell common stock periodically pursuant to a Prospectus Supplement to provide additional funds for its operations. The number of shares that the Company can sell and the amount of the gross proceeds that the Company can raise are limited to 20% of the number of shares of outstanding common stock and 33% of the Company s public float, respectively, pursuant to applicable NASDAQ marketplace and SEC rules. In September 2008, the Company 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 from that sale of approximately \$4.5 million, before commissions and incurred expenses of approximately \$377,000. During October 2009, the Company sold an additional 3,973,000 shares of its common stock under its shelf registration statement at a price of \$1.00 per share and received gross proceeds of approximately \$4.0 million, before commissions and incurred expenses of approximately \$275,000. Subsequent to quarter end, on August 9, 2010 the Company sold an additional 1,351,352 shares of its common stock under its shelf registration statement at a price of \$1.11 per share and received gross proceeds of approximately \$1.5 million, before incurred expenses of approximately \$50,000 (no commissions were paid in connection with this offering).

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

No stock options were granted during the three months ended June 30, 2010 and 2009 and the six months ended June 30, 2010. During the six months ended June 30, 2009, the Company granted 34,000 common stock options to employees, officers, directors and consultants, generally at exercise prices equal to the market value of the stock at the date of grant. The Company recorded stock-based compensation related to stock options totaling \$85,788 and \$168,135 during the three and six month ended June 30, 2010 and \$59,494 and \$196,730 during the three and six month ended June 30, 2009, respectively. The weighted-average grant date fair value of stock options granted during the six month period ended June 30, 2009 was \$1.66. The total fair value of vested stock options was \$6,103 and \$9,483 during the three and six month periods ended June 30, 2010 and \$85,325 and \$211,494 during the three and six month periods ended June 30, 2009, respectively.

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

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Risk free interest rate	1.52 to 2.31%	2.60%	1.52 to 2.44%	1.26 to 2.60%
Expected term	4 to 5 years	5 years	4 to 5 years	4 to 5 years
Expected volatility	100%	90%	100%	90%
Expected dividend yield		%		%
Expected forfeiture rate		%		%

As of June 30, 2010, there was approximately \$175,000 of unrecognized compensation expense related to non-vested stock compensation awards granted under the Plan. The cost is expected to be recognized over a weighted average period of approximately 1.30 years.

*Restricted Stock Units*

No restricted stock units were granted during the three and six month periods ended June 30, 2010 and 2009. There was no stock-based compensation related to restricted stock units during 2010, as all such units had vested as of January 1, 2010. The Company recorded stock-based compensation related to restricted stock units totaling \$5,038 and \$10,076, respectively, during the three month and six month periods ended June 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 six month periods ended June 30, 2010 and 2009, the Company paid approximately \$20,000 and \$14,000 and \$39,000 and \$28,000, respectively, in consulting fees to related parties.

**11. Reclassifications.**

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

---

**Table of Contents**

**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, 2009 describes a number of significant risks associated with our business. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**Overview**

We are a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting addiction and diseases of the central nervous system, such as epilepsy and neuropathic pain. We have two products in development. We are currently evaluating our lead product candidate, CPP-109 (our version of vigabatrin, a GABA aminotransferase inhibitor) for the treatment of cocaine addiction. CPP-109 has been granted Fast Track status by the U.S. Food & Drug Administration (FDA) for the treatment of cocaine addiction, which indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective pharmacological treatment and which demonstrates the potential to address unmet medical needs. We also hope to evaluate CPP-109 for the treatment of other addictions and obsessive-compulsive disorders. Further we are in the early stages of developing CPP-115, which is another GABA aminotransferase inhibitor that we believe is more potent than vigabatrin, but may have reduced side effects (e.g., visual field defects, or VFDs) from those associated with vigabatrin. We are planning to develop CPP-115 for several indications, including drug addiction, epilepsy and neuropathic pain. We believe that we control all current intellectual property for drugs that have a mechanism of action related to inhibition of GABA aminotransferase.

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

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



## **Table of Contents**

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

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

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**

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

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

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

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

We are currently advancing the development of CPP-115 by undertaking the following non-clinical studies designed to demonstrate critical safety and efficacy characteristics of CPP-115:

CPP-115 is being evaluated through the Anticonvulsant Screening Program at the U.S. National Institutes of Health using a variety of recognized and widely accepted animal models for the evaluation of the effectiveness of potential anti-epileptic drugs.

The visual safety of CPP-115 is being evaluated and compared to the only FDA approved GABA aminotransferase inhibitor drug, vigabatrin. We hope to demonstrate that CPP-115's enhanced mechanism of enzyme inactivation results in reduced or eliminated visual field defects compared to vigabatrin.

Genotoxicity and cardiac safety evaluations are on-going.

Through our CPP-109 collaborator, Stephen Dewey, Ph.D. at The North Shore Long Island Jewish Health System (LIJ) Hospital, we are conducting studies to demonstrate CPP-115's effectiveness in extinguishing the reinstatement of addictive behavior. Dr. Dewey will also conduct a PET imaging study to establish the minimum effective dose of CPP-115 required to modulate cocaine-induced dopamine surges. These studies, including an already completed conditioned place preference study, are considered the most predictive studies of a drug's potential utility as a treatment for stimulant addiction. Vigabatrin performed well when previously evaluated in these same studies. The results of the CPP-115 conditioned place preference study referred to above have already been submitted to a peer-reviewed journal for publication.



## **Table of Contents**

Most of the studies of CPP-115 described above are expected to be completed by the end of the third quarter of 2010. We expect to spend approximately \$800,000 to complete all the non-clinical studies of CPP-115 described herein.

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

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

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

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

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

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

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

### ***NASDAQ Listing***

Our common stock currently trades on the Nasdaq Capital Market. On November 13, 2009, we were informed by the Nasdaq Stock Market that, as a result of our common stock no longer meeting the requirement that it trade at a bid price of at least \$1.00 per share, our common stock would be delisted from the Nasdaq Capital Market if, by May 12, 2010, we did not regain compliance with the requirement by our common stock trading at a bid price of at least \$1.00 per share for a period of at least ten consecutive trading days. On April 26, 2010, we received notice from The Nasdaq Stock Market ( "Nasdaq" ) confirming that we had regained compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as a result of our common stock closing with a bid price of at least \$1.00 for at least ten consecutive trading days. Further, we were informed that since we were back in compliance with the rule, the matter had been closed.

### **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 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,



## **Table of Contents**

clinical manufacturing costs, clinical trial expenses, insurance coverage for clinical trials, consulting, scientific advisors and other third-party costs, salaries and employee benefits, stock-based compensation expense, supplies and materials and allocations of various overhead costs related to our product development efforts. To date, all of our research and development resources have been devoted to the development of CPP-109 and CPP-115, and we expect this to continue for the foreseeable future. Costs incurred in connection with research and development activities are expensed as incurred.

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

### *Selling and marketing expenses*

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

### *General and administrative expenses*

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

### *Stock-based compensation*

We recognize expense for the fair value of all stock-based awards to employees, directors, scientific advisors and consultants in accordance with U.S. generally accepted accounting principles. For stock options we use the Black-Scholes option valuation model in calculating the fair value of these awards, and recognize stock-based compensation expense ratably over the vesting period.

### *Income taxes*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of June 30, 2010 and December 31, 2009, as we believe it is more likely than not that the deferred tax asset will not be realized. If an ownership change, as defined under Internal Revenue Code Section 382, occurs, the use of any of our carry-forward tax losses may become subject to limitation.

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

---

## **Table of Contents**

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

#### *Stock-based compensation*

We recognize stock-based compensation for the fair value of all share-based payments, including grants of stock options and restricted stock units. For stock options we use the Black-Scholes option valuation model to determine the fair value of stock options on the date of grant. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield. Our expected volatility is based on the historical volatility of other publicly traded companies in the same industry. The estimated expected option life is based upon estimated employee exercise patterns and considers whether and the extent to which the options are in-the-money. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the estimated expected life of our stock option awards. For the three month periods ended June 30, 2010 and 2009, the assumptions used were an estimated annual volatility of 100% and 90%, average expected holding periods of four to five years, and risk-free interest rates of 1.52% to 2.31%, and 2.60%, respectively. For the six month periods ended June 30, 2010 and 2009, the assumptions used were an estimated annual volatility of 100% and 90%, average expected holding periods of four to five years, and risk-free interest rates of 1.52% to 2.44% and 1.26% to 2.60%, respectively.

### **Results of Operations**

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

*Research and Development Expenses.* Research and development expenses for the three and six months ended June 30, 2010 and 2009 were \$797,935 and \$1,238,253 and \$1,237,522 and \$3,698,885, respectively, including stock-based compensation expense in each of the three and six months periods of \$61,963 and \$48,440 and \$122,431 and \$120,140, respectively. Research and development expenses, in the aggregate, represented

---

**Table of Contents**

approximately 60% and 70% and 52% and 77% of total operating costs and expenses, respectively, for the three and six months ended June 30, 2010 and 2009. The stock-based compensation is non-cash and relates to the expense of stock options awards and restricted stock unit awards to our employees, officers, directors, consultants and scientific advisors. Expenses for research and development for the three and six month periods ended June 30, 2010 decreased compared to amounts expended in the same period in 2009 as we completed our Phase II clinical trial evaluating CPP-109 for use in the treatment of cocaine addiction and our proof-of-concept study evaluating CPP-109 for use in the treatment of methamphetamine addiction during the third quarter of 2009.

We expect that costs related to research and development activities will increase for the remainder of 2010, as we conduct non-clinical trials for CPP-115 and begin the NIDA/VA U.S. Phase II(b) clinical trial evaluating CPP-109 as a treatment for cocaine addiction. We estimate that we will incur an average of \$600,000 per quarter over the next six quarters for research and development expenses relating to these matters. This estimate is based on currently available information, and there can be no assurance that actual research and development expenses incurred will be in the amount estimated. Further, while we believe that our estimate of average quarterly research and development expenses over the next six quarters is accurate, the amount of research and development expenses in any particular quarter will likely be higher or lower than the quarterly estimate, depending on the timing and status of our research activities.

*Selling and Marketing Expenses.* We had no selling and marketing expenses during the three and six month periods ended June 30, 2010 and 2009. 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 six months ended June 30, 2010 and 2009 were \$535,197 and \$530,559 and \$1,146,022 and \$1,114,470, respectively, including stock-based compensation expense in each of the three and six month periods of \$23,825 and \$16,092 and \$45,704 and \$86,666, respectively. General and administrative expenses represented 40% and 30% and 48% and 23%, respectively, of total operating costs and expenses for the three and six months ended June 30, 2010 and 2009. General and administrative expenses for the three and six months periods ended June 30, 2010 were consistent with comparable periods in 2009. General and administrative expenses include among other expenses, management salaries and benefits, office expenses, legal and accounting fees and travel expenses for certain employees and consultants, directors and members of our Scientific Advisory Board. We estimate that our general and administrative expenses will average approximately \$500,000 per quarter over the next 6 quarters. This estimate is based on currently available information, and there can be no assurance that actual general and administrative expenses will not differ from the amount estimated.

*Stock-Based Compensation.* Total stock based compensation for the three and six months ended June 30, 2010 and 2009 was \$85,788 and \$64,532 and \$168,135 and \$206,806, respectively. The reduction in expense for the six month ended June 30, 2010 from the comparable period in 2009 is due to granted awards to directors which vested immediately in 2009. There were no such grants in 2010.

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

*Income taxes.* We have incurred net operating losses since inception. For the three and six month periods ended June 30, 2010 and 2009, we have applied a 100% valuation allowance against our deferred tax asset as we believe that it is more likely than not that the deferred tax asset will not be realized.

**Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through the net proceeds of private placements, the IPO and registered direct offerings under our shelf registration statement. At June 30, 2010, we had

## **Table of Contents**

cash and cash equivalents of \$5.6 million and working capital of \$5.4 million. At December 31, 2009, we had cash and cash equivalents of \$7.8 million and working capital of \$7.6 million. At June 30, 2010, substantially all of our cash and cash equivalents were deposited with one financial institution. We had cash balances at certain financial institutions in excess of federally insured limits throughout the quarter.

We have to date incurred operating losses, and we expect these losses to continue into the future as we seek to conduct the clinical trials and non-clinical studies that will be required before we can commercialize CPP-109 and CPP-115. We anticipate using current cash on hand to finance these activities. It will likely take several years to obtain the necessary regulatory approvals to commercialize CPP-109 and CPP-115 in the United States.

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

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

the results of our non-clinical and clinical trials;

the terms and timing of any collaborative, licensing and other arrangements that we may establish;

the cost and timing of regulatory approvals;

the cost and delays in product development as a result of any changes in regulatory oversight applicable to our products;

the cost and timing of establishing sales, marketing and distribution capabilities;

the effect of competition and market developments;

the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and

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: (i) the additional clinical trials that we currently believe will be required before we are in a position to file an NDA for CPP-109 and CPP-115; and (ii) the non-clinical testing of CPP-109 and CPP-115 that we currently believe we will be required to complete before we can file an NDA for CPP-109 or CPP-115. We will also require additional working capital to support our operations in periods after the first quarter of 2012.

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



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

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

**Table of Contents**

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

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

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

Subsequent to quarter end, on August 9, 2010 we raised gross proceeds of approximately \$1.5 million from the sale of 1,351,352 shares of our common stock.

The following table sets forth our capitalization as of June 30, 2010 on an actual basis and on a pro forma basis after giving effect to our August 9, 2010 share sale and our receipt of an estimated \$1,450,000 of net proceeds therefrom (after deducting estimated offering expenses to be paid by us):

	June 30, 2010	
	Actual	Pro Forma
Cash and cash equivalents	\$ 5,608,368	\$ 7,058,369
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, 18,043,385 shares outstanding actual; 19,394,737 shares outstanding pro forma	18,043	19,395
Additional paid-in capital	35,473,184	36,921,833
Deficit accumulated during the development stage	(30,078,816)	(30,078,816)
<b>Total stockholders' equity</b>	<b>5,412,411</b>	<b>6,862,412</b>
<b>Total capitalization</b>	<b>\$ 5,412,411</b>	<b>\$ 6,862,412</b>

We expect to use the net proceeds from our recently completed offering for general corporate purposes.

Currently, we have approximately \$20.0 million of authorized but unissued common stock available for future offerings under the shelf registration. However, there can be no assurance that we will be able to sell any additional shares under our shelf registration statement.

*Cash Flows*

Net cash used in operating activities was \$2,170,909 and \$5,501,052, respectively, for the six month periods ended June 30, 2010 and 2009. During the six months ended June 30, 2010, net cash used in operating activities was primarily attributable to our net loss of \$2,373,584 and an increase of \$128,581 in prepaid expenses and deposits. This was offset in part by \$181,215 of non-cash expenses, and increases of \$147,707 in accrued expenses and other liabilities, and \$2,334 in accounts payable. During the six months ended June 30, 2009, net cash used in operating activities was primarily attributable to our net loss of \$4,793,088, and decreases of \$57,044 in accounts payables and \$908,344 in accrued expenses and other liabilities. This was offset in part by \$222,645 of non-cash expenses, decreases of \$22,626 in prepaid expenses and deposits and \$12,153 in accrued interest receivable. Non-cash expenses include depreciation and stock-based compensation expense.

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

No cash was provided by (used in) financing activities during the six month periods ended June 30, 2010 and 2009.

## **Table of Contents**

### *Contractual Obligations*

We have entered into the following contractual arrangements:

*Payment to Brookhaven under our license agreement.* We have agreed to pay Brookhaven a fee of \$100,000 in the year of NDA approval for CPP-109, \$250,000 in each of the second and third years following approval, and \$500,000 per year thereafter until the license agreement expires. We are also obligated to reimburse Brookhaven upon the filing of an NDA for CPP-109 and upon obtaining FDA regulatory approval to sell any licensed products for certain of their patent-related expenses. We believe that such obligation is approximately \$166,000 at June 30, 2010 and December 31, 2009. See *Dispute with Brookhaven* below.

*Payment to Northwestern University under our license agreement.* We have agreed to pay Northwestern an upfront fee of \$35,000, reimbursement of approximately \$33,000 in expenses, and certain milestone payments in future years relating to clinical development activities with respect to CPP-115 or payable upon passage of time, and royalties on any products resulting from the license agreement. At June 30, 2010, we had paid \$43,218 of this amount, and had accrued license fees of \$46,322 in the accompanying condensed balance sheet.

*Payments for drug development, non-clinical and clinical studies.* We currently estimate that we will pay various consultants, drug manufacturers, and other vendors approximately \$965,000, in connection with our drug development work, including clinical and non-clinical studies, data analysis and the preparation of material necessary for the filing of NDAs with the FDA. At June 30, 2010, we have paid approximately \$625,000 of this amount, \$114,000 of which had been advanced and as such have been included in prepaid expenses. In addition, at June 30, 2010, we had approximately \$85,000 in accounts payable and \$78,000 in accrued expenses in the accompanying condensed balance sheet related to these contracts.

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

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

### *Dispute with Brookhaven*

Brookhaven has formally advised us that they believe that the amount due to them for patent related expenses is approximately \$1.2 million. We believe that we are only liable to Brookhaven for the approximately \$166,000 described above, and we have advised Brookhaven that we dispute their determination of patent-related expenses due under the license agreement. There can be no assurance as to the outcome of this matter. In any event, no patent-related expenses are due to Brookhaven under the license agreement until the submission by the Company of an NDA for CPP-109. As we have not filed an NDA for CPP-109, no amounts are accrued relating to this matter in the accompanying June 30, 2010 and December 31, 2009 balance sheets.

### *Off-Balance Sheet Arrangements*

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

## **Recent Accounting Pronouncements**

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



**Table of Contents**

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this section.

**ITEM 4. CONTROLS AND PROCEDURES**

- a. We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(c) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2010, our disclosure controls and procedures were effective to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act, was recorded, processed, summarized or reported within the time periods specified in the rules and regulations of the SEC, and include controls and procedures designed to ensure that information required to be disclosed by us in such reports was accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.
  
- b. There have been no changes in our internal controls or in other factors that could have a material effect, or are reasonably likely to have a material effect, on our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

The Company is not a party to any legal proceedings.

**ITEM 1A. RISK FACTORS**

There are many factors that affect our business, our financial condition, and the results of our operations. In addition to the information set forth in this quarterly report, you should carefully read and consider Item 1A. Risk Factors in Part I, and Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in Part II, of our Annual Report on Form 10-K for the year ended December 31, 2009, which contain a description of significant factors that might cause our actual results of operations in future periods to differ materially from those currently expected or desired.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. REMOVED AND RESERVED**

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

- 10.1 Securities Purchase Agreement, dated as of August 5, 2010, between the Company and Fidelity Select Portfolios: Biotechnology Portfolio (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 6, 2010).
- 10.2 Securities Purchase Agreement, dated as of August 5, 2010, between the Company and Fidelity Advisor Services VII: Fidelity Advisor Biotechnology Fund (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 6, 2010).
- 31.1 Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002





**Table of Contents**

**SIGNATURES**

Pursuant to the Securities Exchange Act of 1934, the Registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Catalyst Pharmaceutical Partners, Inc.**

By: /s/ Jack Weinstein  
Jack Weinstein  
Vice President, Treasurer and Chief Financial  
Officer

Date: August 12, 2010

**Table of Contents**

**Exhibit Index**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.1	Securities Purchase Agreement, dated as of August 5, 2010, between the Company and Fidelity Select Portfolios: Biotechnology Portfolio (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 6, 2010).
10.2	Securities Purchase Agreement, dated as of August 5, 2010, between the Company and Fidelity Advisor Services VII: Fidelity Advisor Biotechnology Fund (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 6, 2010).
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