

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 10-Q

November 13, 2014

[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, 2014**

**OR**

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

**Commission File No. 001-33057**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**(Exact name of registrant as specified in its charter)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>76-0837053</b> <b>(IRS Employer</b>
<b>incorporation or organization)</b>	<b>Identification No.)</b>
<b>355 Alhambra Circle</b>	
<b>Suite 1500</b>	
<b>Coral Gables, Florida</b>	<b>33134</b>
<b>(Address of principal executive offices)</b>	<b>(Zip Code)</b>
<b>Registrant's telephone number, including area code: (305) 529-2522</b>	

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 <input type="checkbox"/>	Accelerated Filer <input type="checkbox"/>
Non-Accelerated Filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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 69,119,092 shares of common stock, \$0.001 par value per share, were outstanding as of November 7, 2014.

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**INDEX**

**PART I. FINANCIAL INFORMATION**

Item 1.	<b>CONDENSED FINANCIAL STATEMENTS</b>	
	<u>Condensed balance sheets at September 30, 2014 (unaudited) and December 31, 2013</u>	3
	<u>Condensed statements of operations for the three and nine months ended September 30, 2014 and 2013 (unaudited)</u>	4
	<u>Condensed statement of stockholders' equity for the nine months ended September 30, 2014 (unaudited)</u>	5
	<u>Condensed statements of cash flows for the nine months ended September 30, 2014 and 2013 (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>	18
Item 3.	<b><u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u></b>	29
Item 4.	<b><u>CONTROLS AND PROCEDURES</u></b>	29

**PART II. OTHER INFORMATION**

Item 1.	<b><u>LEGAL PROCEEDINGS</u></b>	30
Item 1A.	<b><u>RISK FACTORS</u></b>	30
Item 2.	<b><u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u></b>	30
Item 3.	<b><u>DEFAULTS UPON SENIOR SECURITIES</u></b>	30
Item 4.	<b><u>MINE SAFETY DISCLOSURE</u></b>	30
Item 5.	<b><u>OTHER INFORMATION</u></b>	30
Item 6.	<b><u>EXHIBITS</u></b>	30

**Table of Contents****CATALYST PHARMACEUTICAL PARTNERS, INC.****CONDENSED BALANCE SHEETS**

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
	(unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 11,263,677	\$ 2,215,958
Certificates of deposit	3,714,634	4,011,576
Short-term investments	26,468,664	17,483,062
Prepaid expenses and other current assets	4,317,358	1,609,442
<b>Total current assets</b>	<b>45,764,333</b>	<b>25,320,038</b>
Property and equipment, net	71,280	40,628
Deposits	8,888	8,888
<b>Total assets</b>	<b>\$ 45,844,501</b>	<b>\$ 25,369,554</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 524,795	\$ 850,789
Accrued expenses and other liabilities	5,414,301	1,288,820
<b>Total current liabilities</b>	<b>5,939,096</b>	<b>2,139,609</b>
Accrued expenses and other liabilities, non-current	15,770	19,131
Warrants liability, at fair value	3,266,917	1,819,562
<b>Total liabilities</b>	<b>9,221,783</b>	<b>3,978,302</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; 67,169,383 shares and 54,132,937 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	67,170	54,133
Additional paid-in capital	102,908,178	75,670,718
Accumulated deficit	(66,352,630)	(54,333,599)
<b>Total stockholders' equity</b>	<b>36,622,718</b>	<b>21,391,252</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 45,844,501</b>	<b>\$ 25,369,554</b>

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

**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS (unaudited)**

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Operating costs and expenses:				
Research and development	\$ 2,885,892	\$ 2,804,352	\$ 7,733,533	\$ 6,028,691
General and administrative	1,223,137	441,424	2,874,034	1,576,044
Total operating costs and expenses	4,109,029	3,245,776	10,607,567	7,604,735
Loss from operations	(4,109,029)	(3,245,776)	(10,607,567)	(7,604,735)
Interest income	5,924	10,318	54,428	25,311
Change in fair value of warrants liability	(906,787)	(2,676,601)	(1,465,892)	(3,220,514)
Loss before income taxes	(5,009,892)	(5,912,059)	(12,019,031)	(10,799,938)
Provision for income taxes				
Net loss	\$ (5,009,892)	\$ (5,912,059)	\$ (12,019,031)	\$ (10,799,938)
Net loss per share basic and diluted	\$ (0.07)	\$ (0.13)	\$ (0.19)	\$ (0.25)
Weighted average shares outstanding basic and diluted	67,169,383	44,686,310	62,539,571	42,529,432

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

Table of Contents**CATALYST PHARMACEUTICAL PARTNERS, INC.****CONDENSED STATEMENT OF STOCKHOLDERS EQUITY (unaudited)****For the nine months ended September 30, 2014**

	<b>Preferred Stock</b>	<b>Common Stock</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Total</b>
<b>Balance at December 31, 2013</b>	\$	\$ 54,133	\$ 75,670,718	\$ (54,333,599)	\$ 21,391,252
Issuance of common stock, net		13,024	26,712,106		26,725,130
Issuance of stock options for services			490,326		490,326
Exercise of warrants for common stock		13	35,028		35,041
Net loss				(12,019,031)	(12,019,031)
<b>Balance at September 30, 2014</b>	\$	\$ 67,170	\$ 102,908,178	\$ (66,352,630)	\$ 36,622,718

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

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

	<b>For the Nine Months Ended, September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Operating Activities:</b>		
Net loss	\$ (12,019,031)	\$ (10,799,938)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	18,603	16,777
Stock-based compensation	490,326	133,305
Change in fair value of warrants liability	1,465,892	3,220,514
(Increase) decrease in:		
Prepaid expenses and other current assets and deposits	(2,707,916)	320,769
Increase (decrease) in:		
Accounts payable	(325,994)	107,678
Accrued expenses and other liabilities	4,116,292	1,255,480
Net cash used in operating activities	(8,961,828)	(5,745,415)
<b>Investing Activities:</b>		
Capital expenditures	(43,427)	(9,432)
Purchase of short-term investments	(8,985,602)	(3,173,484)
Proceeds from certificates of deposit	296,942	2,492,665
Net cash used in investing activities	(8,732,087)	(690,251)
<b>Financing Activities:</b>		
Proceeds from issuance of common stock and warrants, net	26,725,130	14,071,694
Proceeds from exercise of warrants	16,504	3,893,499
Proceeds from exercise of options	0	23,500
Net cash provided by financing activities	26,741,634	17,988,693
Net increase (decrease) in cash	9,047,719	11,553,027
Cash and cash equivalents at beginning of period	2,215,958	1,409,939
Cash and cash equivalents at end of period	\$ 11,263,677	\$ 12,962,966
<b>Supplemental disclosures of non-cash investing and financing activity</b>		
Exercise of liability classified warrants for common stock	\$ 18,537	\$ 174,900

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



**Table of Contents**

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**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 rare (orphan) neurological diseases and disorders, including Lambert-Eaton Myasthenic Syndrome (LEMS) and infantile spasms.

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. The Company's primary focus is on the development and commercialization of its drug candidates. The Company has incurred operating losses in each period from inception through September 30, 2014. The Company has been able to fund its cash needs to date through several public and private offerings of its common stock and warrants, through government grants, and through an investment by a strategic purchaser. See Note 9.

***Capital Resources***

On January 31, 2014, the Company filed a Shelf Registration Statement on Form S-3 (the 2014 Shelf Registration Statement) with the U.S. Securities and Exchange Commission (SEC) to sell up to \$100 million of common stock. This registration statement (file No. 333-193699) was declared effective by the SEC on March 19, 2014. On April 3, 2014, the Company sold 13,023,750 shares of its common stock in an underwritten public offering under the 2014 Shelf Registration Statement, raising net proceeds of approximately \$26.7 million. While there can be no assurance, based on currently available information, the Company estimates that it currently has sufficient working capital to support its operations through the end of 2015. The Company will require additional capital to support its operations in periods after 2015.

The Company may raise required funds in the future 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 drug candidates or grant sublicenses on terms that are not favorable to the Company. If the Company is not able to secure additional funding when needed, the Company may have to delay, reduce the scope of, or eliminate one or more research and development programs, which could have an adverse effect on the Company's business.

**2. Basis of Presentation and Significant Accounting Policies.**

- a. INTERIM FINANCIAL STATEMENTS.** The accompanying unaudited interim financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP), and pursuant to the rules and regulations of the 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 U.S. GAAP have been condensed or omitted. The balance sheet as of December 31, 2013 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

In the opinion of management, the accompanying unaudited interim 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, 2013 included in the 2013 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, 2014 are not necessarily indicative of the results to be expected for any future period or for the full 2014 fiscal year.

**Table of Contents**

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

- b. 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.
- c. CASH AND CASH EQUIVALENTS.** The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist of money market funds. The Company has substantially all of its cash and cash equivalents deposited with one financial institution.
- d. CERTIFICATES OF DEPOSIT.** The certificates of deposit are issued by a banking institution and are recorded at cost plus accrued interest. The original maturity is greater than three months but does not exceed one year. Interest income is recorded in the statement of operations as it is earned. Carrying value at September 30, 2014 and December 31, 2013 approximates fair value.
- e. SHORT-TERM INVESTMENTS.** The Company invests in short-term investments in high credit-quality funds in order to obtain higher yields on its cash available for investments. As of September 30, 2014 and December 31, 2013 short-term investments consisted of a short-term bond fund. Such investments are not insured by the Federal Deposit Insurance Corporation. Short-term investments at September 30, 2014 and December 31, 2013 were considered trading securities. Trading securities are recorded at fair value based on the closing market price of the security. For trading securities, the Company recognizes realized gains and losses and unrealized gains and losses to earnings. Realized and unrealized losses for the three and nine months ended September 30, 2014 were \$29,430 and \$18,316, respectively. Realized and unrealized gains (losses) for the three and nine months ended September 30, 2013 were nominal.
- f. PREPAID EXPENSES AND OTHER CURRENT ASSETS.** Prepaid expenses and other current assets consist primarily of insurance recoverable, prepaid research fees, prepaid insurance and prepaid subscription fees. Insurance recoverable relates to the securities class action lawsuit proposed settlement to be paid by the Company's insurance carrier. Prepaid research fees consists of advances for the Company's product development activities, including drug manufacturing, contracts for pre-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.
- g. FAIR VALUE OF FINANCIAL INSTRUMENTS.** The Company's financial instruments consist of cash and cash equivalents, certificates of deposit, short-term investments, accounts payables, accrued expenses and other liabilities, and warrants liability. At September 30, 2014 and December 31, 2013, the fair value of these instruments approximated their carrying value.
- h.**

**FAIR VALUE MEASUREMENTS.** Current Financial Accounting Standards Board (FASB) fair value guidance emphasizes that fair value is a market-based measurement, not an entity-specific measurement. Therefore, a fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability. As a basis for considering market participant assumptions in fair value measurements, current FASB guidance establishes a fair value hierarchy that distinguishes between market participant assumptions based on market data obtained from sources independent of the reporting entity (observable inputs that are classified within Levels 1 and 2 of the hierarchy) and the reporting entity's own assumptions that market participants would use in pricing assets or liabilities (unobservable inputs classified within Level 3 of the hierarchy).

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

Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date. Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs may include quoted prices for similar assets and liabilities in active markets, as well as inputs that are observable for the asset or liability (other than quoted prices), such as interest rates, foreign exchange rates, and yield curves that are observable at commonly quoted intervals. Level 3 inputs are unobservable inputs for the asset or liability, which is typically based on an entity's own assumptions, as there is little, if any, related market activity. In instances where the determination of the fair value measurement is based on inputs from different levels of the fair value hierarchy, the level in the fair value hierarchy within which the entire fair value measurement falls is based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

**Fair Value Measurements at Reporting Date Using**

	Balances as of September 30, 2014	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 10,030,873	\$ 10,030,873	\$	\$
Certificates of deposit	\$ 3,714,634	\$	\$ 3,714,634	\$
Short-term investments	\$ 26,468,664	\$ 26,468,664	\$	\$
Warrants liability	\$ 3,266,917	\$	\$	\$ 3,266,917

**Fair Value Measurements at Reporting Date Using**

	Balances as of December 31, 2013	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	\$ 25,693	\$ 25,693	\$	\$
Certificates of deposit	\$ 4,011,576	\$	\$ 4,011,576	\$
Short-term investments	\$ 17,483,062	\$ 17,483,062	\$	\$
Warrants liability	\$ 1,819,562	\$	\$	\$ 1,819,562

- i. **WARRANTS LIABILITY.** In October 2011, the Company issued 1,523,370 warrants (the 2011 warrants) to purchase shares of the Company's common stock in connection with a registered direct offering under the 2010 Shelf Registration Statement. The Company accounted for these warrants as a liability measured at fair value due to a provision included in the warrants agreement that provides the warrants holders with an option to require the Company (or its successor) to purchase their warrants for cash in an amount equal to their Black-Scholes Option Pricing Model (the Black-Scholes Model) value, in the event that certain fundamental transactions, as defined, occur. The fair value of the warrants liability is estimated using the Black-Scholes Model which requires inputs such as the expected term of the warrants, share price volatility and risk-free interest rate. These assumptions are reviewed on a quarterly basis and changes in the estimated fair value of the outstanding warrants are recognized each reporting period in the Change in fair value of warrants liability line in the statement of operations. As of September 30, 2014 and December 31, 2013, 1,242,174 and 1,254,870, respectively, of the 2011 warrants remained outstanding.

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

- j. STOCK-BASED COMPENSATION.** 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, the single-option award approach, and the 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 seven years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

As of September 30, 2014, there were outstanding stock options to purchase 4,624,610 shares of common stock, of which stock options to purchase 3,227,942 shares of common stock were exercisable as of September 30, 2014.

For the three and nine month periods ended September 30, 2014 and 2013, the Company recorded stock-based compensation expense as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 35,704	\$ 23,133	\$ 59,583	\$ 63,508
General and administrative	408,922	23,532	430,743	69,797
Total stock-based compensation	\$ 444,626	\$ 46,665	\$ 490,326	\$ 133,305

- k. 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. For all periods presented, the Company's net loss equals comprehensive loss, since the Company has no items which are considered other comprehensive income (loss).
- l. NET LOSS PER SHARE.** Basic loss per share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. The calculation of basic and diluted net loss per share is the same for all periods presented, as the effect of potential common stock equivalents is anti-dilutive due to the Company's net loss position for all periods presented. The potential shares, which are excluded from the determination of basic and diluted net loss per share as their effect is anti-dilutive, are as follows:

	September 30,	
	2014	2013
Options to purchase common stock	4,624,610	3,488,906
Warrants to purchase common stock	4,835,924	4,994,620

Potential equivalent common stock excluded	9,460,534	8,483,526
--	-----------	-----------

Potentially dilutive options to purchase common stock as of September 30, 2014 and 2013 have exercise prices per share ranging from \$0.47 to \$3.12 and \$0.47 to \$6.00, respectively. Potentially dilutive warrants to purchase common stock as of September 30, 2014 and 2013 have exercise prices ranging from \$1.04 to \$2.08 per share.



---

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

- m. RECENTLY ISSUED ACCOUNTING STANDARDS.** In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The amendments in this ASU include: i) eliminating the requirement to present inception-to-date information on the statements of income, cash flows, and shareholders' equity, ii) eliminating the need to label the financial statements as those of a development stage entity, iii) eliminating the need to disclose a description of the development stage activities in which the entity is engaged, and iv) eliminating the requirement to disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments in ASU No. 2014-10 are effective for public companies for annual and interim reporting periods beginning after December 15, 2014. Early adoption is permitted. The Company has early adopted ASU No. 2014-10, beginning with the interim period ended June 30, 2014.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this ASU, require management to assess a company's ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The guidance will be effective for the annual period ending after December 15, 2016 and subsequent interim and annual periods thereafter. The Company is currently evaluating the impact of this accounting standard update on its financial statements.

**3. Warrants Liability, at Fair Value.***2011 Warrants*

The Company allocated approximately \$1.3 million of proceeds from its October 2011 registered direct offering to the fair value of common stock purchase warrants issued in connection with the offering that are classified as a liability (the 2011 warrants). The 2011 warrants are classified as a liability because of provisions in such warrants that allow for the net cash settlement of such warrants in the event of certain fundamental transactions (as defined in the warrant agreement). The valuation of the 2011 warrants is determined using the Black-Scholes Model. This model uses inputs such as the underlying price of the shares issued when the warrant is exercised, volatility, risk free interest rate and expected life of the instrument. The Company has determined that the 2011 warrants liability should be classified within Level 3 of the fair value hierarchy by evaluating each input for the Black-Scholes Model against the fair value hierarchy criteria and using the lowest level of input as the basis for the fair value classification. There are six inputs: closing price of the Company's common stock on the day of evaluation; the exercise price of the warrants; the remaining term of the warrants; the volatility of the Company's common stock; annual rate of dividends; forfeiture rate; and the risk free rate of return. Of those inputs, the exercise price of the warrants and the remaining term are readily observable in the warrants agreement. The annual rate of dividends is based on the Company's historical practice of not granting dividends. The closing price of the Company's common stock would fall under Level 1 of the fair value hierarchy as it is a quoted price in an active market. The risk free rate of return is a Level 2 input, while the historical volatility is a Level 3 input in accordance with the fair value accounting guidance. Since the lowest level input is a Level 3, the Company determined the warrants liability is most appropriately classified within Level 3 of the fair value hierarchy. This liability is subject to fair value mark-to-market adjustment each reporting period.

The calculated value of the 2011 warrants liability was determined using the Black-Scholes Model with the following assumptions:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Risk free interest rate	0.87%	0.94%
Expected term	2.59 years	3.34 years
Expected volatility	114%	108%
Expected dividend yield	0%	0%
Expected forfeiture rate	0%	0%

**Table of Contents****3. Warrants Liability, at Fair Value (continued).**

The following table rolls forward the fair value of the Company's warrants liability activity for the three and nine month periods ended September 30, 2014 and 2013:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Fair value, beginning of period	\$ 2,360,130	\$ 1,042,500	\$ 1,819,562	\$ 498,587
Issuance of warrants				
Exercise of warrants		(174,900)	(18,537)	(174,900)
Change in fair value	906,787	2,676,601	1,465,892	3,220,514
Fair value, end of period	\$ 3,266,917	\$ 3,544,201	\$ 3,266,917	\$ 3,544,201

No warrants were exercised during the three months ended September 30, 2014. During the nine month period ended September 30, 2014, 12,696 of the 2011 warrants were exercised, with proceeds to the Company of \$16,504. The Company recognizes the change in the fair value of the warrants liability as a non-operating income or loss in the accompanying statements of operations.

**4. Prepaid Expenses and Other Current Assets.**

Prepaid expenses consist of the following:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Insurance recoverable	\$ 3,500,000	\$
Prepaid research fees	514,923	1,334,149
Prepaid marketing fees	134,091	
Prepaid insurance	71,916	219,651
Prepaid subscription fees	32,452	24,643
Prepaid offering costs	18,160	
Prepaid rent	770	7,848
Other	45,046	23,151
Total prepaid expenses and other current assets	\$ 4,317,358	\$ 1,609,442

**5. Property and Equipment.**

Property and equipment, net consists of the following:

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
Computer equipment	\$ 92,498	\$ 81,551
Furniture and equipment	84,003	51,523
	176,501	133,074
Less: Accumulated depreciation	(105,221)	(92,446)
<b>Total property and equipment, net</b>	<b>\$ 71,280</b>	<b>\$ 40,628</b>

Depreciation expense was \$7,235 and \$18,603 for the three and nine month periods ended September 30, 2014, and \$5,707 and \$16,777, for the three and nine month periods ended September 30, 2013, respectively. The Company has executed a noncancellable operating lease agreement for its corporate offices. During February 2014, the Company entered into the second amendment of the lease for an additional contiguous space under substantially the same terms.

**Table of Contents****6. Accrued Expenses and Other Liabilities.**

Accrued expenses and other liabilities consist of the following:

	September 30, 2014	December 31, 2013
Accrued settlement liability	\$ 3,500,000	\$
Accrued pre-clinical and clinical trial expenses	1,506,668	1,083,749
Accrued professional fees	201,290	117,240
Accrued compensation and benefits	92,292	14,539
Accrued license fees	101,250	65,000
Deferred rent	4,270	2,746
Other	8,531	5,546
Current accrued expenses and other liabilities	5,414,301	1,288,820
Deferred rent- non-current	15,770	19,131
Non-current accrued expenses and other liabilities	15,770	19,131
Total accrued expenses and other liabilities	\$ 5,430,071	\$ 1,307,951

The accrued settlement liability of \$3,500,000 as of September 30, 2014 is related to the securities class action lawsuit proposed settlement, as disclosed in Note 7. The proposed settlement amount is expected to be paid for and covered by the Company's insurance carrier; therefore, there is a corresponding insurance recoverable recorded in Prepaid Expenses and Other Current Assets in the accompanying condensed balance sheet as of September 30, 2014.

**7. Commitments and Contingencies.**

- a. 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 license agreement with Northwestern, the Company is responsible for continued research and development of any resulting product candidates. As of September 30, 2014, the Company has paid \$251,590 in connection with the license and has accrued license fees of \$101,250 in the accompanying September 30, 2014 condensed balance sheet for 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 next milestone payment of \$150,000 is due on the earlier of successful completion of the first Phase 2 clinical trial of CPP-115 or August 27, 2015.

- b. LICENSE AGREEMENT WITH NEW YORK UNIVERSITY AND THE FEINSTEIN INSTITUTE FOR MEDICAL RESEARCH.** On December 13, 2011, the Company entered into a license agreement with New York University (NYU) and the Feinstein Institute for Medical Research (FIMR) under which it acquired worldwide rights to commercialize GABA aminotransferase inhibitors in the treatment for Tourette Syndrome. The Company is obligated to pay certain milestone payments in future years relating to clinical development activities and royalties on any products resulting from the license agreement.

---

**Table of Contents****7. Commitments and Contingencies (continued).**

- c. **LICENSE AGREEMENT WITH BIOMARIN.** On October 26, 2012, the Company entered into a strategic collaboration with BioMarin Pharmaceutical, Inc. (BioMarin) for Firdapse . The key components of the collaboration include: (i) the Company licensed the exclusive North American rights to Firdapse pursuant to a License Agreement, dated as of October 26, 2012 (the License Agreement) between the Company and BioMarin, and (ii) BioMarin made a \$5,000,000 investment in the Company pursuant to the terms of a Convertible Promissory Note and Note Purchase Agreement, dated as of October 26, 2012 (the Investment Agreement). The Investment Agreement provides that the Company will use the \$5 million solely for the purpose of developing Firdapse .

As part of the License Agreement, the Company took over a Phase 3 Trial previously being conducted by BioMarin and was obligated to use its diligent efforts to seek to obtain regulatory approval for and to commercialize Firdapse in the United States. The Company was obligated to use diligent efforts to complete the double-blind treatment phase of the Phase 3 trial within 24 months of entering into the License Agreement, and BioMarin had the right to terminate the License Agreement if such treatment phase had not been completed in such 24-month period (unless the Company was using diligent effort to pursue the completion of such treatment phase and had spent at least \$5 million in connection with the conduct of the Phase 3 Trial during such 24 month period). On September 29, 2014, the Company announced positive top-line results from its Phase 3 Trial of Firdapse for the symptomatic treatment of LEMS. Both co-primary endpoints, quantitative myasthenia gravis score (QMG) and subject global impression (SGI) demonstrated statistical significance, as did a secondary endpoint for the physician s clinical global impression of improvement (CGI-I). As of September 30, 2014, the Company had disbursed more than \$5 million in connection with expenses related to the Phase 3 trial.

As part of the License Agreement, the Company agreed: (i) to pay BioMarin certain royalty payments based on net sales in North America; (ii) to pay to a third-party licensor of the rights sublicensed certain royalty payments based on net sales in North America, and (iii) to pay certain milestone payments that BioMarin is obligated to make (approximately \$2.6 million of which will be due upon acceptance by the FDA of a filing of an NDA for Firdapse for the treatment of LEMS, and approximately \$7.2 million of which will be due on the unconditional approval by the FDA of an NDA for Firdapse for the treatment of LEMS). The Company also agreed to share in the cost of certain post-marketing studies being conducted by BioMarin. As of September 30, 2014, the Company has paid BioMarin \$3.1 million related to expenses in connection with Firdapse studies and trial. On April 15, 2014, effective as of April 8, 2014, the Company and BioMarin entered into Amendment No. 1 to the License Agreement, amending in certain respects the License Agreement, dated October 26, 2012, between the Company and BioMarin. The amendment related to purchases of additional product by the Company from BioMarin, the sharing of data between the parties with respect to clinical trials and studies undertaken by each party and the payment terms for certain joint studies.

- d. **AGREEMENTS FOR DRUG DEVELOPMENT, PRE-CLINICAL AND CLINICAL STUDIES.** The Company has entered into agreements with contract manufacturers for the manufacture of drug and study placebo for the Company s trials and studies, with contract research organizations (CRO) to conduct and monitor the Company s trials and studies and with various entities for laboratories and other testing related to the Company s trials and studies. The contractual terms of the agreements vary, but most require certain advances as well as payments based on the achievement of milestones. Further, these agreements are cancellable at any time, but obligate the Company to reimburse the providers for any time or costs incurred through the date of termination.





**Table of Contents**

**7. Commitments and Contingencies (continued).**

***Securities Class Action Lawsuit***

In October 2013 and November 2013, three securities class action lawsuits were filed against the Company and certain of its executive officers and directors seeking unspecified damages in the U.S. District Court for the Southern District of Florida (the Court). These complaints, which were substantially identical, purported to state a claim for violation of federal securities laws on behalf of a class of those who purchased the Company's common stock between October 31, 2012 and October 18, 2013. Two of the cases were voluntarily dismissed by the plaintiffs and the Court granted the Company's motion to dismiss on the third case on January 3, 2014. However, the Court granted leave to the plaintiffs to file an amended complaint within 20 days.

On January 23, 2014, the plaintiffs filed an amended complaint against the Company and one of its executive officers seeking unspecified damages. The amended complaint purports to state a claim for alleged misrepresentations regarding the development of Firdapse on behalf of a class of those who purchased shares of the Company's common stock between August 27, 2013 and October 18, 2013. In February 2014, the Company filed a motion to dismiss the amended complaint, which was granted in part and denied in part by the Court. Subsequently, on September 29, 2014, the Court certified a class consisting of all persons or entities that purchased shares of the Company's common stock during the period from August 27, 2013, through October 18, 2013 (the Class Period), and who did not sell such securities prior to October 18, 2013 (excluding: defendants; any entities affiliated with the Company, the present and former officers and directors of the Company or any subsidiary or affiliate thereof; members of such excluded persons immediate families and their legal representatives, heirs, successors or assigns; and any entity in which any excluded person has or had a controlling interest).

Following a mediation in mid-October conducted by an independent mediator, the Company entered into a memorandum of understanding (MOU) with the lead plaintiffs in the class action lawsuit to settle the lawsuit. The settlement is subject to the execution of a formal stipulation of settlement between the parties to the lawsuit and approval of the settlement by the Court. The Court has ordered that the formal stipulation of settlement be filed with the Court on or before November 21, 2014.

Under the MOU, the Company will pay \$3.5 million in return for a dismissal and release of all claims against the defendants. The settlement amount is expected to be paid by the Company's insurance carrier. Under the proposed settlement, the defendants, and various of their related persons and entities, will receive a full release of all claims that were or could have been brought in the action, as well as all claims that arise out of, are based upon, or relate to the allegations, transactions, facts, representations, omissions or other matters involved in the action related in any way to the purchase or acquisition of the Company's securities by class members during the class period.

The proposed settlement contains no admission of any liability or wrongdoing on the part of the defendants, each of whom continues to deny all of the allegations against each of them and believes that the claims are without merit. Because the full amount of the proposed settlement payment is expected to be paid by the Company's insurance carrier, the settlement is not expected to have a material adverse effect on the Company's financial position or results of operations. There can be no assurance that the settlement will be formally documented and approved by the Court.

**8. 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 any years before 2010. 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.

## **Table of Contents**

### **9. Stockholders Equity.**

#### ***2014 Shelf Registration Statement***

On January 31, 2014, the Company filed a Shelf Registration Statement on Form S-3 (the 2014 Shelf Registration Statement) with the SEC to sell up to \$100 million of shares of common stock. This registration statement (file No. 333-193699) was declared effective by the SEC on March 19, 2014.

On April 3, 2014, the Company filed a prospectus supplement and offered for sale 13,023,750 shares of its common stock at a price of \$2.21 per share in an underwritten public offering. The Company received gross proceeds in the public offering of approximately \$28.8 million before underwriting commission and incurred expenses of approximately \$2.1 million.

At September 30, 2014, there is approximately \$71.2 million available for future sale under the 2014 Shelf Registration Statement. If the Company's public float (the market value of its common stock held by non-affiliate stockholders) falls below \$75 million, the Company will be subject to a further limitation under which it can sell no more than one-third (1/3) of its public float during any 12-month period. Further, the number of shares that the Company can sell at any one time may be limited under certain circumstances to 20% of the outstanding common stock under applicable NASDAQ marketplace rules.

#### ***Warrant Exercises***

No warrants were exercised during the three months ended September 30, 2014. During the nine month period ended September 30, 2014, the Company issued an aggregate of 12,696 shares of its authorized but unissued common stock upon the exercise of previously issued common stock purchase warrants, raising gross proceeds of \$16,504.

### **10. Stock Compensation.**

#### ***Stock Options***

During the three and nine month periods ended September 30, 2014, the Company granted options to purchase an aggregate of 1,210,000 shares and 1,255,000 shares, respectively, of the Company's common stock to employees, directors and consultants. Stock option terms ranged from 5 to 7 years. During the nine month period ended September 30, 2013, the Company granted five-year options to purchase an aggregate of 115,000 shares of the Company's common stock to certain employees. No options were granted during the three month period ended September 30, 2013. The Company recorded stock-based compensation related to stock options totaling \$444,626 and \$490,326 during the three and nine month periods ending September 30, 2014, respectively. The Company recorded stock-based compensation related to stock options totaling \$46,665 and \$133,305, during the three and nine month periods ended September 30, 2013, respectively. During the three and nine month periods ended September 30, 2014, 135,000 and 173,333 options vested. No options vested during the three and nine month periods ended September 30, 2013.

As of September 30, 2014, there was approximately \$2.6 million of unrecognized compensation expense related to non-vested stock compensation awards granted under the 2006 and 2014 Stock Incentive Plans. The cost is expected to be recognized over a weighted average period of approximately 2.66 years.

On February 27, 2014, the Company's Board of Directors approved the adoption of the Catalyst Pharmaceutical Partners, Inc. 2014 Stock Incentive Plan (the 2014 Plan). The 2014 Plan became effective upon stockholder approval

of the 2014 Plan at the Company's 2014 Annual Meeting of Stockholders held on May 15, 2014.

**11. Subsequent Events.**

Subsequent to quarter end, during October 2014, options to purchase 580,000 shares of the Company's common stock were exercised by employees and directors with proceeds to the Company of \$522,000. In addition, options to purchase 185,000 shares of the Company's common stock were exercised on a cashless basis, resulting in the issuance of an aggregate of 119,709 shares of the Company's common stock.

In addition, subsequent to quarter end, during October 2014, the Company issued an aggregate of 1.25 million of its authorized but unissued common stock upon the exercise of previously issued common stock purchase warrants, raising gross proceeds of \$1.3 million.

**Table of Contents**

**11. Subsequent Events (continued).**

Subsequent to quarter end, the Company entered into an MOU to settle the class action lawsuit pending against the Company. The settlement is subject to the execution of a formal stipulation of settlement between the parties to the lawsuit and approval of the settlement by the Court. For information about the settlement, see Note 7.

## **Table of Contents**

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

#### **Introduction**

Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to provide an understanding of our financial condition, changes in financial condition and results of operations. The discussion and analysis is organized as follows:

*Overview.* This section provides a general description of our business, trends in our industry, as well as a discussion regarding recent developments in our business.

*Basis of Presentation.* This section provides information about key accounting estimates and policies that we followed in preparing our financial statements for the third quarter of fiscal 2014.

*Critical Accounting Policies and Estimates.* This section discusses those accounting policies that are both considered important to our financial condition and results of operations, and require significant judgment and estimates on the part of management in their application. All of our significant accounting policies, including our critical accounting policies, are also summarized in the notes to our interim financial statements that are included in this report.

*Results of Operations.* This section provides an analysis of our results of operations for the three and nine month periods ended September 30, 2014 as compared to the same periods ended September 30, 2013.

*Liquidity and Capital Resources.* This section provides an analysis of our cash flows, capital resources, off-balance sheet arrangements and our outstanding commitments, if any.

*Caution Concerning Forward-Looking Statements.* This section discusses how certain forward-looking statements made throughout this MD&A and in other sections of this report are based on management's present expectations about future events and are inherently susceptible to uncertainty and changes in circumstance.

#### **Overview**

We are a development-stage biopharmaceutical company focused on the development and commercialization of prescription drugs targeting rare (orphan) neuromuscular and neurological diseases. We have three pharmaceutical products in development:

Firdapse. In October 2012, we licensed the North American rights to Firdapse, a proprietary form of amifampridine phosphate, or chemically known as 3,4-diaminopyridine phosphate, from BioMarin

Pharmaceutical Inc. (BioMarin). As part of our agreements with BioMarin, we took over the sponsorship of an ongoing Phase 3 clinical trial evaluating Firdapse for the treatment of Lambert- Eaton Myasthenic Syndrome, or LEMS, a rare and sometimes fatal autoimmune disease characterized by muscle weakness. We also hope to evaluate Firdapse for the treatment of other orphan indications such as certain forms of Congenital Myasthenic Syndrome, refractory Myasthenia Gravis, and Downbeat Nystagmus. In August 2013, we were granted breakthrough therapy designation by the U.S. Food & Drug Administration (FDA) for Firdapse for the treatment of LEMS.

The chemical entity 3,4-diaminopyridine (3,4-DAP), or its phosphate salt, has never been approved by the FDA for any indication. If we are the first pharmaceutical company to obtain approval for an amifampridine-based product, we will be eligible to receive five years of marketing exclusivity with respect to the use of this product for any indication. Further, since Firdapse for the treatment of LEMS has previously been granted Orphan Drug Designation by the FDA, the product is also eligible to receive seven years of marketing exclusivity for this indication (running concurrently with the five years of marketing exclusivity described above).

The Phase 3 trial was designed as a double blind, randomized, withdrawal trial in which all patients were initially treated with Firdapse during a 91-day run-in period followed by treatment with either Firdapse or placebo (randomly assigned, about 1:1) during a two-week randomization period. A total of 38 patients completed the three month run-in period and subsequent two week randomization period. In a trial of this design, the clinically significant findings, when present, are worsening of symptoms in the placebo group.

**Table of Contents**

On September 29, 2014, we reported top-line results from this trial. A summary of the results is as follows:

Primary Endpoints:

The primary endpoint of change in quantitative myasthenia gravis score, or QMG, at day 14 reached statistical significance ( $p=0.0452$ ) with a clinically significant worsening of 2.2 points observed in the placebo group;

The primary endpoint of change in subject global impression, or SGI, at day 14 was highly statistically significant ( $p=0.0028$ ) with a clinically significant worsening of 2.6 points observed in the placebo group.

Secondary Endpoints:

The secondary endpoint for the physician's clinical global impression of improvement, or CGI-I, reached statistical significance ( $p=0.0267$ ) with a clinically significant observation at day 14 of 4.7 points in the placebo group.

The secondary endpoint of change in walking speed at day 14 showed a worsening of 9.7 ft/min in the placebo group. While quantitative worsening in walking speed in the placebo group was expected, the magnitude of the change relative to the variance inherent in this test prevented the change from achieving statistical significance for this endpoint.

Patient Tolerance of Firdapse :

Firdapse was generally safe and well tolerated

All subjects who were randomized into the trial elected to continue with Firdapse in the safety follow-up phase of the trial.

The Company expects to have a pre-NDA meeting with the FDA in the next few months and hopes to determine the fastest way to obtain an NDA approval for Firdapse .

During April 2014 we initiated the process required to establish an expanded access program to make Firdapse available in the United States to patients diagnosed with LEMS, Congenital Myasthenic Syndrome or Downbeat Nystagmus, that meet the program's inclusion and exclusion criteria, through their neuromuscular disease specialists. Firdapse distributed through this program will be provided at no cost until sometime after FDA approval.



CPP-115. We are in the early stages of developing CPP-115, a GABA aminotransferase inhibitor that, based on our pre-clinical studies to date, we believe is a more potent form of vigabatrin, but may have fewer side effects (e.g., visual field defects, or VFDs) than those associated with vigabatrin. We are hoping to develop CPP-115 for the treatment of epilepsy (initially infantile spasms) and for the treatment of other selected neurological indications. CPP-115 has been granted Orphan Drug Designation by the FDA for the treatment of infantile spasms and Orphan Medicinal Product Designation in the European Union, or E.U., for West's syndrome (a form of infantile spasms). During the third quarter of 2014, we began a multi-dose safety and tolerance study of CPP-115, which is on-going. We expect to have top-line results from this study in the first half of 2015.

CPP-109. An academic investigator proof-of-concept study evaluating the use of CPP-109 for the treatment of Tourette Syndrome is currently ongoing and, if the results of that study show evidence of reduced number of tics, we will likely seek to develop CPP-109 or CPP-115 (which has the same mechanism of action as CPP-109) for this indication. We do not control this proof-of-concept study and therefore have no control over its timing. However, based on currently available information, we expect to have top-line results for this academic investigator proof-of-concept study during the first half of 2015.

## Table of Contents

### Securities Class Action Lawsuit

In October 2013 and November 2013, three securities class action lawsuits were filed against us and certain of our executive officers and directors seeking unspecified damages in the U.S. District Court for the Southern District of Florida (the Court). These complaints, which were substantially identical, purported to state a claim for violation of federal securities laws on behalf of a class of those who purchased our common stock between October 31, 2012 and October 18, 2013. Two of the cases were voluntarily dismissed by the plaintiffs and the Court granted our motion to dismiss on the third case on January 3, 2014. However, the Court granted leave to the plaintiffs to file an amended complaint within 20 days.

On January 23, 2014, the plaintiffs filed an amended complaint against us and one of our executive officers seeking unspecified damages. The amended complaint purported to state a claim for alleged misrepresentations regarding the development of Firdapse on behalf of a class of those who purchased shares of our common stock between August 27, 2013 and October 18, 2013. In February 2014, we filed a motion to dismiss the amended complaint, which was granted in part and denied in part by the Court. Subsequently, on September 29, 2014, the Court certified a class consisting of all persons or entities that purchased shares of our common stock during the period from August 27, 2013, through October 18, 2013 (the Class Period), and who did not sell such securities prior to October 18, 2013 (excluding: defendants; any entities affiliated with us, our present and former officers and directors or any subsidiary or affiliate thereof; members of such excluded persons' immediate families and their legal representatives, heirs, successors or assigns; and any entity in which any excluded person has or had a controlling interest).

Following a mediation in mid-October conducted by an independent mediator, we entered into a memorandum of understanding (MOU) with the lead plaintiffs in the class action lawsuit to settle the lawsuit. The settlement is subject to the execution of a formal stipulation of settlement between the parties to the lawsuit and approval of the settlement by the Court. The Court has ordered that the formal stipulation of settlement be filed with the Court on or before November 21, 2014.

Under the MOU, we will pay \$3.5 million in return for a dismissal and release of all claims against the defendants. The settlement amount is expected to be paid by our insurance carrier. Under the proposed settlement, the defendants, and various of their related persons and entities, will receive a full release of all claims that were or could have been brought in the action, as well as all claims that arise out of, are based upon, or relate to the allegations, transactions, facts, representations, omissions or other matters involved in the action related in any way to the purchase or acquisition of our securities by class members during the class period.

The proposed settlement contains no admission of any liability or wrongdoing on the part of the defendants, each of whom continues to deny all of the allegations against each of them and believes that the claims are without merit. Because the full amount of the proposed settlement payment is expected to be paid by our insurance carrier, the settlement is not expected to have a material adverse effect on our financial position or results of operations. There can be no assurance that the settlement will be formally documented and approved by the Court.

### Risks Associated with Product Development

The successful development of our current drug candidates or any other drug candidate we may acquire, develop or license in the future 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 studies and trials, pre-clinical studies, proof-of-concept studies and other product development activities;

the results of our pre-clinical studies and clinical studies and trials, and the number of such studies and trials (and the scope of such studies and trials) that will be required for us to seek and obtain approval of our product candidates;

the risk that another pharmaceutical company will receive an approval for its formulation of amifampridine for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) before us; and

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

## **Table of Contents**

### **Available Capital Resources**

Based on an analysis of our current financial condition and forecasts of available cash, we believe that we have sufficient resources to support our operations through 2015. However, we will require additional funding to support our operations beyond 2015. There can be no assurance that we will obtain required additional funding or ever be able to commercialize any of our product candidates. See *Liquidity and Capital Resources* below.

### **Basis of presentation**

#### *Revenues*

We are a development stage company and have had no revenues from product sales to date. We will not have revenues from product sales until such time as we receive approval of our product candidates, 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, as well as occasional support for selected investigator-sponsored research. The major components of research and development costs include pre-clinical study costs, clinical manufacturing costs, clinical study and 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, CPP-115, and Firdapse , 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 studies and trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical study and trial sites and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical study and 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 or milestones, the successful enrollment of patients, the allocation of responsibilities among the parties to the agreements, and the completion of portions of the clinical study or 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 pre-clinical and clinical studies or trials are recognized based on our estimate of the degree of completion of the event or events specified in the specific study or trial contract. We monitor service provider activities to the extent possible; however, if we underestimate activity levels associated with various studies or trials at a given point in time, we could be required to record significant additional research and development expenses in future periods. Pre-clinical and clinical study and trial activities require significant up front expenditures. We anticipate paying significant portions of a study or trial s cost before such study or trial begins, and incurring additional expenditures as the study or trial progresses and reaches certain milestones.

#### *Selling and marketing expenses*

We do not currently have any selling expenses. We expect we will begin to incur costs tied to our future sales efforts during 2014 as we move closer to the potential commercialization of Firdapse . In accordance with our 2014 business

plan, during 2014 we have retained personnel that will help us develop both a sales force and a patient advocacy and assistance program so that we are in a position to commence our selling efforts immediately if we are successful in obtaining approval of any NDA that we may file for Firdapse , of which there can be no assurance. Such pre-commercialization expenses have been included in general and administrative expenses.

*General and administrative expenses*

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, certain pre-commercialization expenses (including marketing expenses), and professional fees for legal, information technology, accounting and consulting services.

## **Table of Contents**

### *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 the awards.

### *Warrants Liability*

We issued warrants to purchase shares of our common stock as part of the equity financing that we completed in October 2011. In accordance with U.S. generally accepted accounting principles, we have recorded the fair value of these warrants as a liability in the accompanying balance sheets at September 30, 2014 and December 31, 2013 using a Black-Scholes option-pricing model. We will remeasure the fair value of the warrants liability at each reporting date until the warrants are exercised or have expired. Changes in the fair value of the warrants liability are reported in the statements of operations as income or expense. The fair value of the warrants liability is subject to significant fluctuation based on changes in the inputs to the Black-Scholes option-pricing model, including our common stock price, expected volatility, expected life, the risk-free interest rate and dividend yield. The market price for our common stock has been and may continue to be volatile. Consequently, future fluctuations in the price of our common stock may cause significant increases or decreases in the fair value of these warrants.

### *Income taxes*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of September 30, 2014 and December 31, 2013, 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 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.

### *Recently Issued Accounting Standards*

For discussion of recently issued accounting standards, please see Note 2, *Basis of Presentation and Significant Accounting Policies*, in the interim financial statements included in this report.

### *Non-GAAP Financial Measures*

We prepare our financial statements and footnotes thereto which accompany this report in accordance with U.S. Generally Accepted Accounting Principles (GAAP). To supplement our financial results presented on a GAAP basis, we may use non-GAAP financial measures in our reports filed with the Commission and/or our communications with investor. Non-GAAP measures are provided as additional information and not as an alternative to our financial statements presented in accordance with GAAP. Our non-GAAP financial measures are intended to enhance an overall understanding of our current financial performance. We believe that the non-GAAP financial measures that we present provide investors and prospective investors with an alternative method for assessing our operating results in a manner that we believe is focused on the performance of ongoing operations and provide a more consistent basis for comparison between periods.

The non-GAAP financial measure that we often present excludes from the calculation of net loss the expense of (or the income associated with) the change in fair value of the liability-classified warrants.

Any non-GAAP financial measures that we report should not be considered in isolation or as a substitute for comparable GAAP accounting, and investors should read them in conjunction with our financial statements and notes thereto prepared in accordance with GAAP. Finally, the non-GAAP measures of net loss we may use may be different from, and not directly comparable to, similarly titled measures used by other companies.

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The

---

**Table of Contents**

preparation of these financial statements requires us to make judgments, estimates, and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and disclosures of contingent assets and liabilities. For a full discussion of our accounting policies, please refer to Note 2 on the Financial Statements included in our 2013 Annual Report on Form 10-K filed with the SEC. Our most critical accounting policies and estimates include: research and development expenses and stock-based compensation, measurement of fair value, fair value of warrants liability, income taxes and reserves. 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 that 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. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2013 Annual Report on Form 10-K, other than the discontinuation of accounting for development stage in accordance with ASU No. 2014-10.

**Results of Operations***Revenues.*

We had no revenues for the three and nine month periods ended September 30, 2014 and 2013.

*Research and Development Expenses.*

Research and development expenses for the three and nine month periods ended September 30, 2014 were \$2,885,892 and \$7,733,533, respectively, including stock-based compensation expense in each of the three and nine months periods of \$35,704 and \$59,583, respectively. Research and development expenses for the three and nine month periods ended September 30, 2013 were \$2,804,352 and \$6,028,691 respectively, including stock-based compensation expense in each of the three and nine months periods of \$23,133 and \$63,508 respectively. Research and development expenses, in the aggregate, represented approximately 70% and 73% of total operating costs and expenses for the three and nine month periods ended September 30, 2014 and 86% and 79% for the three and nine month periods ended September 30, 2013, respectively. The stock-based compensation is non-cash and relates to the expense of stock options awards to certain employees.

Expenses for research and development for the nine month period September 30, 2014, excluding stock-based compensation, increased compared to amounts expended in the same period in 2013. During the first nine months of 2013, we completed the transfer of the management and oversight of the Phase 3 trial of Firdapse<sup>®</sup> for the treatment of LEMS from BioMarin. In connection with such transfer, we retained a CRO and hired additional personnel to provide day-to-day oversight of the Phase 3 trial, including identifying and contracting with additional clinical sites. Such efforts increased the number of total clinical sites and related expenses during 2013 and 2014. Expenses during the three and nine month periods ended September 30, 2014 included costs associated with our Phase 3 trial and other clinical studies and trials that we are conducting. It also included our share of the joint studies we are presently conducting with BioMarin.

As a result of our ongoing and projected studies and trials required for an NDA filing for Firdapse<sup>®</sup>, we expect that costs related to research and development activities will continue to be substantial throughout the balance of 2014, as we close out our Phase 3 trial, continue with the Phase 3 trial extension, launch our Expanded Access Program and conduct the pre-clinical activities of Firdapse<sup>®</sup> required to file an NDA for Firdapse<sup>®</sup>. We also expect to incur additional costs related to the Phase 1 study for CPP-115 that we recently commenced.



*Selling and Marketing Expenses.*

We had no selling expenses during the three and nine months periods ended September 30, 2014 and 2013. We recently began to incur pre-commercialization costs, as we move closer to the potential commercialization of Firdapse . These costs are in connection with personnel, and their related activities, to help us develop both a sales force and a patient advocacy and assistance program so that we are in a position to commence our selling efforts immediately if we are successful in obtaining an approval of any NDA that we may file for Firdapse , of which there can be no assurance. Pre-commercialization costs have been included in general and administrative expenses.

**Table of Contents**

*General and Administrative Expenses.*

General and administrative expenses for the three and nine months ended September 30, 2014 were \$1,223,137 and \$2,874,034, respectively, including stock-based compensation expense in each of the three and nine month periods ending September 30, 2014 of \$408,922 and \$430,743, respectively. General and administrative expenses for the three and nine months ended September 30, 2013 were \$441,424 and \$1,576,044, respectively, including stock-based compensation expense in each of the three and nine month periods ended September 30, 2013 of \$23,532 and \$69,797, respectively. General and administrative expenses represented 30% and 27% of total operating costs and expenses for the three and nine months ended September 30, 2014 and 14% and 21% for the three and nine months ended September 30, 2013, respectively. The increase in general and administrative expenses for the nine month periods ended September 30, 2014 when compared to the same period in 2013 is primarily due to increases in consulting and marketing fees, as we began our pre-commercial activities for Firdapse, as well as increases in legal fees and investor relations expense, and an increase in stock-based compensation expense. We expect that general and administrative costs in total will increase in 2014 and future periods, as we add headcount and continue activities required to prepare for the future commercialization of Firdapse.

*Stock-Based Compensation.*

Total stock-based compensation for the three and nine month periods ended September 30, 2014 were \$444,626 and \$490,326 and for the three and nine month periods ended September 30, 2013 were \$46,665 and \$133,305, respectively. The increase in stock-based compensation for the nine month period ended September 30, 2014 when compared to the same period in 2013, is mainly due to the timing and amount of options granted to employees and directors during the third quarter of 2014.

*Change in fair value of warrants liability.*

In connection with our October 2011 equity offering, we issued warrants to purchase an aggregate of 1,523,370 shares of common stock. The fair value of the portion of these warrants which remain outstanding is recorded in the liability section of the balance sheet and was estimated at \$3,266,917 and \$1,819,562 at September 30, 2014 and December 31, 2013, respectively. The fair value of the warrants liability is determined at the end of each reporting period with the resulting gains or losses recorded as the change in fair value of warrants liability in the statements of operations. For the three and nine months ended September 30, 2014, we recognized losses of \$906,787 and \$1,465,892 due to the change in the fair value of the warrants liability. The losses during the three and nine months ended September 30, 2014 were principally a result of the increases of our stock price between June 30, 2014 and September 30, 2014, and December 31, 2013 and September 30, 2014, respectively. We believe, future changes in the fair value of the warrants liability will be due primarily to fluctuations in the value of our common stock and the timing of warrant exercises.

*Interest Income.*

We reported interest income in all periods relating to our investment of funds received from offerings of our securities. The increase in interest income for the nine month period ended September 30, 2014 when compared to the same period in 2013 is due to higher average investment balances from the proceeds of our offerings, offset by slightly lower interest rates. These proceeds were used to fund our product-development activities and our operations. Substantially all such funds were invested in short-term interest bearing obligations and short-term bond funds.

*Income taxes.*

We have incurred net operating losses since inception. For the three and nine month periods ended September 30, 2014 and 2013, 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.

*Net Loss.*

Our net loss was \$5,009,892 and \$12,019,031, respectively, for the three and nine months ended September 30, 2014 (\$0.07 and \$0.19, respectively, per basic and diluted share) as compared to a net loss of \$5,912,059 and \$10,799,938, respectively, for the three and nine months ended September 30, 2013 (\$0.13 and \$0.25, respectively, per basic and diluted share).

*Non-GAAP Net Loss.*

Our non-GAAP net loss, which excludes for the three and nine months ended September 30, 2014 a loss of \$906,787 and \$1,465,892 associated with the change in the fair value of liability classified warrants, was \$4,103,105 and \$10,553,139 for the three and nine months ended September 30, 2014 (\$0.06 and \$0.17, respectively, per basic and diluted share). Our non-GAAP net loss, which excludes for the three and nine months ended September 30, 2013 a loss of \$2,676,601 and \$3,220,514 associated with the change in the fair value of liability classified warrants, was \$3,235,458 and \$7,579,424 for the three and nine months ended September 30, 2013 (\$0.07 and \$0.18, respectively, per basic and diluted share).

**Table of Contents**

**Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through equity issuances, government grants, and an investment by a strategic purchaser. At September 30, 2014, we had cash and cash equivalents, certificates of deposit and short-term investments aggregating \$41.4 million and working capital of \$39.8 million. At December 31, 2013, we had cash and cash equivalents, certificates of deposit and short term investments aggregating \$23.7 million and working capital of \$23.2 million. At September 30, 2014, substantially all of our cash and cash equivalents and certificates of deposit were deposited with one financial institution, and such balances were in excess of federally insured limits.

We have to date incurred operating losses, and we expect these losses to increase substantially in the future as we expand our product development programs and prepare for the commercialization of our product candidates. 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 one or more of our product candidates in the United States.

While there can be no assurance, based on currently available information, we believe that we currently have the cash resources to support our planned operations through 2015. If our costs are greater than we expect, our assumptions may not prove to be accurate.

At the present time, we believe that we will require additional working capital to support our operations beyond 2015, including obligations to make milestone payment in periods after 2015 that we may be obligated to pay. There can be no assurance as to the amount of any such funding that will be required for these purposes or whether any such funding will be available to us when it is required.

In that regard, our future funding requirements will depend on many factors, including:

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

future clinical trial results;

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

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

We hope to raise additional funds to support our future product development activities and working capital requirements 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 pre-clinical trials. We may also seek to raise 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.

## **Table of Contents**

On January 31, 2014, we filed a Shelf Registration Statement on Form S-3 (the 2014 Shelf Registration Statement) with the SEC to sell up to \$100 million of shares of common stock. This registration statement (file No. 333-193699) was declared effective by the SEC on March 19, 2014. On April 8, 2014, we issued 13,023,750 shares of our common stock in an underwritten public offering under the 2014 Shelf Registration Statement, raising gross proceeds of approximately \$28.8 million, before underwriting commission and incurred expenses of approximately \$2.1 million, for net proceeds of approximately \$26.7 million.

There is approximately \$71.2 million available for future sale under the 2014 Shelf Registration Statement. If our public float (the market value of our common stock held by non-affiliate stockholders) falls below \$75 million, we will be subject to a further limitation under which we can sell no more than one-third (1/3) of our public float during any 12-month period. Further, the number of shares that we can sell at any one time may be limited under certain circumstances to 20% of the outstanding common stock under applicable NASDAQ marketplace rules.

### *Cash Flows*

Net cash used in operating activities was \$8,961,828 and \$5,745,415, respectively, for the nine month periods ended September 30, 2014 and 2013. During the nine months ended September 30, 2014, net cash used in operating activities was primarily attributable to our net loss of \$12,019,031, an increase in prepaid expenses and other current assets and deposits of \$2,707,916 and a decrease in accounts payable of \$325,994. This was partially offset by an increase of \$4,116,292 in accrued expenses and other liabilities, \$1,465,892 of non-cash change in fair value of warrants liability and \$508,929 of other non-cash expenses. During the nine months ended September 30, 2013, net cash used in operating activities was primarily attributable to our net loss of \$10,799,938, partially offset by increases of \$1,255,480 in accrued expenses and other liabilities and \$107,678 in accounts payable, a decrease of \$320,769 in prepaid expenses and other current assets and deposits, \$3,220,514 of non-cash change in fair value of warrants liability and \$150,082 of other non-cash expenses. Other non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities during the nine months period ended September 30, 2014 was \$8,732,087, consisting primarily of purchases of short term investments of \$8,985,602 and capital expenditures of approximately \$43,427, offset by redemptions of investments of \$296,942. Net cash used in investing activities during the nine months period ended September 30, 2013 was \$690,251 consisting primarily of purchases of short term investments of \$3,173,484 offset by redemptions of investments of \$2,492,665, and purchases of furniture and computer equipment of \$9,432.

Net cash provided by financing activities during the nine month period ended September 30, 2014 was \$26,741,634, consisting of \$26,725,130 from the net proceeds from the sale of common stock under the 2014 Shelf Registration Statement, and \$16,504 of proceeds from the exercise of warrants to purchase common stock. Net cash provided by financing activities during the nine month period ended September 30, 2013 was \$17,988,693, consisting of \$14,071,694 from the net proceeds from the sale of common stock under the 2010 shelf registration statement, \$3,893,499 from proceeds of warrant exercises and \$23,500 from proceeds from the exercise of stock options.

### *Contractual Obligations*

We have entered into the following contractual arrangements:

*Payments to BioMarin and others under our license agreement.* We have agreed: (i) to pay BioMarin certain royalty payments based on our net sales in North America; (ii) to pay to a third-party licensor of the rights sublicensed to us certain royalty payments based on our net sales in North America, and (iii) to pay certain milestone payments that BioMarin is obligated to make (approximately \$2.6 million of which will be due upon acceptance by the FDA of a filing of an NDA for Firdapse for the treatment of LEMS, and approximately \$7.2 million of which will be due on the unconditional approval by the FDA of an NDA for Firdapse for the treatment of LEMS). We have also agreed to share in the cost of certain post-marketing studies that are being conducted by BioMarin.

## **Table of Contents**

*Payments for Firdapse development.* Based on current available information, we estimate that the total product development costs for Firdapse , excluding third-party milestone payments, will be approximately \$25 million. At September 30, 2014, we had paid approximately \$11.9 million of this amount and had prepaid research fees of approximately \$500,000, accounts payable of approximately \$323,000 and accrued liabilities of approximately \$1.5 million in the accompanying condensed balance sheet in connection with related agreements. Under our license agreement with BioMarin, we were obligated to spend at least \$5 million in connection with the Phase III trial of Firdapse during the two years following the date of the license agreement (October 26, 2012). By the end of the first quarter of 2014, we had spent more than \$5 million on the Phase 3 trial of Firdapse for the treatment of LEMS.

*Payments to Northwestern University under our license agreement.* Under our license agreement with Northwestern, we have paid to date \$251,590, had accrued liabilities of \$101,250, at September 30, 2014 in the accompanying condensed balance sheet, and owe certain milestone payments in future years if we do not cancel the license agreement. The next milestone payment of \$150,000 is due on the earlier of August 27, 2015 or the successful completion of the first Phase 2 trial of CPP-115.

*Employment agreements.* We have entered into an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately \$425,000 in 2014. The agreement expires in November 2016.

*Leases for office space.* We have entered into a lease agreement for our office space that requires payments of approximately \$8,000 per month.

### *Off-Balance Sheet Arrangements*

We currently have no debt. Capital lease obligations as of September 30, 2014 and December 31, 2013 were not material. We have an operating lease for our corporate office facility. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

## **Caution Concerning Forward-Looking Statements**

This Current Report on Form 10-Q contains forward-looking statements , as that term is defined in the Private Securities Litigation Reform Act of 1995. These include statements regarding our expectations, beliefs, plans or objectives for future operations and anticipated results of operations. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, believes , anticipates , proposes , plans , expects , intends , may , and other similar expressions are intended to identify forward-looking statements. Such statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. The forward-looking statements made in this report are based on current expectations that involve numerous risks and uncertainties.

The successful development of our product candidates 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 pre-clinical studies, proof-of-concept studies and clinical studies and trials and other product development activities;

our ability to complete our studies on a timely basis and within the budgets we establish for such trials;

whether our studies and trials will be successful;

the results of our pre-clinical studies and clinical studies and trials, and the number and scope of such studies and trials that will be required for us to seek and obtain approval of NDAs for our product candidates;

whether the third parties we retain to assist us in our trials and studies perform as contracted for and within the budgets established for their activities;

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

the risk that another pharmaceutical company will receive an approval for its formulation of 3,4-DAP for the treatment of LEMS before we do;

**Table of Contents**

whether others develop and commercialize products competitive to our products;

whether any of our product candidates will ever be approved for commercialization;

changes in the laws and regulations affecting our business;

whether the proposed settlement of the pending class action lawsuit will be formally documented and approved by the Court;

whether individual claimants will opt out of the class action settlement and pursue their own claims against us;

our ability to overcome objections or appeals regarding the proposed settlement of the pending class action lawsuit;

our ability to attract and retain skilled employees; and

changes in general economic conditions and interest rates.

Our current plans and objectives are based on assumptions relating to the development of our current product candidates. Although we believe that our assumptions are reasonable, any of our assumptions could prove inaccurate. In light of the significant uncertainties inherent in the forward-looking statements made herein, which reflect our views only as of the date of this report, you should not place undue reliance upon such statements. We undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

**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(e) 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, 2014, 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.** During the three months ended September 30, 2014, there were 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**

See Note 7 to Notes to Unaudited Condensed Financial Statements for information about pending litigation.

Except as disclosed in this report, the Company is not a party to any other 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 2013 Annual Report on Form 10-K filed with the SEC, 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. MINE SAFETY DISCLOSURE**

Not applicable

**ITEM 5. OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

- 31.1 Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002

Edgar Filing: CATALYST PHARMACEUTICAL PARTNERS, INC. - Form 10-Q

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
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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/ Alicia Grande  
Alicia Grande  
Vice President, Treasurer and Chief  
Financial Officer

Date: November 13, 2014

**Table of Contents**

**Exhibit Index**

Exhibit	
Number	Description
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Principal Executive Officer under Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase