

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 10-Q

May 11, 2015

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**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 March 31, 2015**

**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 checked="" type="checkbox"/>
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Non-Accelerated Filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>
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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 82,009,849 shares of common stock, \$0.001 par value per share, were outstanding as of May 7, 2015.

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

	<b>March, 31 2015 (unaudited)</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 41,323,435	\$ 9,096,778
Certificates of deposit	3,715,935	3,715,383
Short-term investments	26,497,769	26,462,962
Prepaid expenses and other current assets	4,432,574	4,552,698
Total current assets	75,969,713	43,827,821
Property and equipment, net	71,139	71,377
Deposits	8,888	8,888
Total assets	\$ 76,049,740	\$ 43,908,086
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,050,515	\$ 1,814,210
Accrued expenses and other liabilities	4,798,494	4,040,816
Total current liabilities	5,849,009	5,855,026
Accrued expenses and other liabilities, non-current	14,145	15,839
Warrants liability, at fair value	3,564,299	2,794,891
Total liabilities	9,427,453	8,665,756
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; 82,009,849 shares and 69,119,092 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	82,010	69,119
Additional paid-in capital	141,793,196	105,015,871
Accumulated deficit	(75,252,919)	(69,842,660)
Total stockholders' equity	66,622,287	35,242,330
Total liabilities and stockholders' equity	\$ 76,049,740	\$ 43,908,086

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



**Table of Contents****CATALYST PHARMACEUTICAL PARTNERS, INC.****STATEMENTS OF OPERATIONS (unaudited)**

	<b>For the Three Months Ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Revenues	\$	\$
Operating costs and expenses:		
Research and development	2,349,552	2,748,683
General and administrative	1,942,363	759,682
Total operating costs and expenses	4,291,915	3,508,365
Loss from operations	(4,291,915)	(3,508,365)
Other income, net	61,934	32,760
Change in fair value of warrants liability	(1,180,278)	(335,514)
Loss before income taxes	(5,410,259)	(3,811,119)
Provision for income taxes		
Net loss	\$ (5,410,259)	\$ (3,811,119)
Net loss per share    basic and diluted	\$        (0.07)	\$        (0.07)
Weighted average shares outstanding    basic and diluted	76,039,220	54,138,580

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

Table of Contents**CATALYST PHARMACEUTICAL PARTNERS, INC.****STATEMENT OF STOCKHOLDERS' EQUITY (unaudited)****For the three months ended March 31, 2015**

	<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, 2014</b>	\$	\$ 69,119	\$ 105,015,871	\$ (69,842,660)	\$ 35,242,330
Issuance of common stock, net		11,500	34,862,369		34,873,869
Issuance of stock options for services			295,842		295,842
Amortization of restricted stock for services			18,609		18,609
Exercise of warrants for common stock		717	1,601,179		1,601,896
Exercise of stock options for common stock		674	(674)		
Net loss				(5,410,259)	(5,410,259)
<b>Balance at March 31, 2015</b>	\$	\$ 82,010	\$ 141,793,196	\$ (75,252,919)	\$ 66,622,287

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

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## CATALYST PHARMACEUTICAL PARTNERS, INC.

## STATEMENTS OF CASH FLOWS (unaudited)

	For the Three Months Ended, March 31,	
	2015	2014
<b>Operating Activities:</b>		
Net loss	\$ (5,410,259)	\$ (3,811,119)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	8,148	5,285
Stock-based compensation	314,451	23,130
Change in fair value of warrants liability	1,180,278	335,514
(Increase) decrease in:		
Prepaid expenses and other current assets and deposits	120,124	726,149
Increase (decrease) in:		
Accounts payable	(763,695)	81,316
Accrued expenses and other liabilities	755,984	214,681
Net cash used in operating activities	(3,794,969)	(2,425,044)
<b>Investing Activities:</b>		
Capital expenditures	(7,910)	(17,306)
Redemption (purchase) of short-term investments	(34,807)	983,738
Redemption (purchase) of certificates of deposit	(552)	298,615
Net cash provided by (used in) investing activities	(43,269)	1,265,047
<b>Financing Activities:</b>		
Proceeds from issuance of common stock, net	34,873,869	
Proceeds from exercise of warrants	1,191,026	16,504
Net cash provided by financing activities	36,064,895	16,504
Net increase (decrease) in cash	32,226,657	(1,143,493)
Cash and cash equivalents at beginning of period	9,096,778	2,215,958
Cash and cash equivalents at end of period	\$ 41,323,435	\$ 1,072,465
<b>Supplemental disclosures of non-cash investing and financing activity</b>		
Exercise of liability classified warrants for common stock	\$ 410,870	\$ 18,537

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



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**CATALYST PHARMACEUTICAL PARTNERS, INC.**

**NOTES TO UNAUDITED 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) neuromuscular and 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 March 31, 2015. 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. The Company has conducted two registered direct offerings under the 2014 Shelf Registration Statement. See Note 9.

While there can be no assurance, based on currently available information, the Company estimates that it has sufficient resources to support its operations through the end of 2016. The Company will require additional funding to support the Company's operations in periods after 2016.

The Company may raise required funds 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 Securities and Exchange Commission (SEC) for reporting of interim

financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The balance sheet as of December 31, 2014 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

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

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, 2014 included in the 2014 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the three months ended March 31, 2015 are not necessarily indicative of the results to be expected for any future period or for the full 2015 fiscal year.

- b. USE OF ESTIMATES.** The preparation of financial statements in conformity with U.S. GAAP 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 mainly 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 March 31, 2015 and December 31, 2014 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 March 31, 2015 and December 31, 2014, short-term investments consisted of short-term bond funds. Such investments are not insured by the Federal Deposit Insurance Corporation. Short-term investments at March 31, 2015 and December 31, 2014 are 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. Unrealized and realized gains (losses) for the three months ended March 31, 2015 and 2014 were nominal, and are included in other income, net in the accompanying statements of operations.
  
- 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 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 preclinical studies, clinical trials and studies, 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 March 31, 2015 and December 31, 2014, the fair value of these instruments approximated their carrying value.

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

- 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).

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 are 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 March 31, 2015	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	\$ 40,076,603	\$ 40,076,603	\$	\$
Certificates of deposit	\$ 3,715,935	\$	\$ 3,715,935	\$
Short-term investments	\$ 26,497,769	\$ 26,497,769	\$	\$
Warrants liability	\$ 3,564,299	\$	\$	\$ 3,564,299

**Fair Value Measurements at Reporting Date Using**

	Balances as of December 31, 2014	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
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Money market funds	\$ 7,053,310	\$ 7,053,310	\$	\$
Certificates of deposit	\$ 3,715,383	\$	\$ 3,715,383	\$
Short-term investments	\$ 26,462,962	\$ 26,462,962	\$	\$
Warrants liability	\$ 2,794,891	\$	\$	\$ 2,794,891

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

- 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 March 31, 2015 and December 31, 2014, 1,090,000 and 1,242,174, respectively, of the 2011 warrants remained outstanding.
- j. **STOCK-BASED COMPENSATION.** The Company recognizes expense in the statement of operations for the fair value of all stock-based payments to employees, directors, scientific advisors and consultants, 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 years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

As of March 31, 2015, there were outstanding stock options to purchase 3,240,000 shares of common stock, of which stock options to purchase 1,883,333 shares of common stock were exercisable as of March 31, 2015.

For the three month periods ended March 31, 2015 and 2014, the Company recorded stock-based compensation expense as follows:

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Research and development	\$ 66,941	\$ 11,873
General and administrative	247,510	11,257
<b>Total stock-based compensation</b>	<b>\$ 314,451</b>	<b>\$ 23,130</b>

- k. **COMPREHENSIVE INCOME (LOSS).** U.S. GAAP 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).





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

- 1. 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:

	<b>March 31,</b>	
	<b>2015</b>	<b>2014</b>
Options to purchase common stock	3,240,000	3,426,906
Warrants to purchase common stock	2,868,750	4,835,924
Unvested restricted stock	80,000	
Potential equivalent common stock excluded	6,188,750	8,262,830

Potentially dilutive options to purchase common stock as of March 31, 2015 and 2014 have exercise prices ranging from \$0.47 to \$4.44 and \$0.47 to \$6.00, respectively. Potentially dilutive warrants to purchase common stock as of March 31, 2015 and 2014 have exercise prices ranging from \$1.04 to \$2.08.

- m. RECENTLY ISSUED ACCOUNTING STANDARDS.** 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 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; 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 2011 warrants liability is most appropriately classified within Level 3 of the fair value hierarchy. This liability is subject to a fair value mark-to-market adjustment each reporting period.

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

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

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Risk free interest rate	0.59%	0.81%
Expected term	2.09 years	2.34 years
Expected volatility	86%	112%
Expected dividend yield	0%	0%
Expected forfeiture rate	0%	0%

The following table rolls forward the fair value of the Company's warrants liability activity for the three month periods ended March 31, 2015 and 2014:

	<b>Three months ended March 31,</b>	
	<b>2015</b>	<b>2014</b>
Fair value, beginning of period	\$ 2,794,891	\$ 1,819,562
Issuance of warrants		
Exercise of warrants	(410,870)	(18,537)
Change in fair value	1,180,278	335,514
Fair value, end of period	\$ 3,564,299	\$ 2,136,539

During the three month periods ended March 31, 2015 and 2014, 152,174 and 12,696 of the 2011 warrants were exercised, with proceeds to the Company of \$197,826 and \$16,504, respectively. 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 and other current assets consist of the following:

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Insurance recoverable (see Notes 6, 7 and 11)	\$ 3,500,000	\$ 3,500,000
Prepaid research fees	462,505	571,428
Prepaid insurance	277,723	385,496
Prepaid subscription fees	82,163	30,495
Prepaid offering costs		20,029
Prepaid rent	867	10,870

Other	109,316	34,380
Total prepaid expenses and other current assets	\$ 4,432,574	\$ 4,552,698

## 5. Property and Equipment.

Property and equipment, net consists of the following:

	March 31, 2015	December 31, 2014
Computer equipment	\$ 103,664	\$ 95,754
Furniture and equipment	88,816	88,816
	192,480	184,570
Less: Accumulated depreciation	(121,341)	(113,193)
Total property and equipment, net	\$ 71,139	\$ 71,377

**Table of Contents****5. Property and Equipment (continued).**

Depreciation expense was \$8,148 and \$5,285, respectively, for the three month periods ended March 31, 2015 and 2014. The Company has executed a non-cancellable operating lease agreement for its corporate offices. During March 2015, the Company entered into the third amendment of the corporate office lease for additional space within the same building under substantially the same terms, in order to accommodate the Company's expanding operations.

**6. Accrued Expenses and Other Liabilities.**

Accrued expenses and other liabilities consist of the following:

	<b>March 31, 2015</b>	<b>December 31, 2014</b>
Accrued settlement liability (see Note 7)	\$ 3,500,000	\$ 3,500,000
Accrued preclinical and clinical trial expenses	735,773	333,928
Accrued professional fees	149,142	43,973
Accrued compensation and benefits	238,842	31,956
Accrued license fees	128,750	115,000
Deferred rent	4,930	4,158
Other	41,057	11,801
 Current accrued expenses and other liabilities	 4,798,494	 4,040,816
Deferred rent- non-current	14,145	15,839
 Non-current accrued expenses and other liabilities	 14,145	 15,839
 Total accrued expenses and other liabilities	 \$ 4,812,639	 \$ 4,056,655

The accrued settlement liability of \$3,500,000 as of March 31, 2015 and December 31, 2014 is related to the securities class action lawsuit proposed settlement, as disclosed with more particularity in Note 7. The proposed settlement amount is 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 balance sheets as of March 31, 2015 and December 31, 2014. See Note 11.

**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 will be responsible for continued research and development of any resulting product candidates. As of March 31, 2015, the Company has paid \$251,590 in connection with the license and has accrued license fees of \$128,750 in the accompanying March 31, 2015 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.

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

- 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.
- 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).

As part of the License Agreement, the Company took over a Phase 3 Trial previously being conducted by BioMarin and is 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), which condition has been satisfied during the third quarter of 2014. 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 part of the License Agreement, the Company agreed: (i) to pay BioMarin royalties for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the license agreement) in North America for any calendar year for sales up to \$100 million, and 10% of net sales in North America in any calendar year in excess of \$100 million; (ii) to pay to the third-party licensor of the rights sublicensed to us royalty payments for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the license agreement between BioMarin and the third-party licensor) in any calendar year; and (iii) to pay certain milestone payments that BioMarin is obligated to pay (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, and, as of March 31, 2015, the Company had paid BioMarin \$3.6 million related to expenses in connection with Firdapse® studies and trials.

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

- d. AGREEMENTS FOR DRUG DEVELOPMENT, PRECLINICAL 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.

***Securities Class Action Lawsuit***

The Company has settled its previously disclosed securities class action lawsuit. For historic information about the securities class action lawsuit that was filed against the Company in late 2013, see Note 7 to the Notes to Financial Statements in the Company's financial statements for the year ended December 31, 2014. In connection with the settlement, which became effective on April 16, 2015, the Company paid \$3.5 million to settle this matter, all of which was paid by the Company's insurance carrier. Under the settlement, the defendants, and various of their related persons and entities, received 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 settlement contains no admission of any liability or wrongdoing on the part of the defendants, each of whom continue to deny all of the allegations against each of them and believe that the claims were without merit. Because the full amount of the settlement payment was paid by the Company's insurance carrier, the settlement did not have a material adverse effect on the Company's financial position or results of operations. There were no opt outs from the settlement. See Note 11.

**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.

**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 common stock. This registration statement (file No. 333-193699) was declared effective by the SEC on March 19, 2014. The Company has to date conducted the following sales under the 2014 Shelf Registration Statement:



- (a) 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.

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**9. Stockholders Equity (continued).**

- (b) On February 4, 2015, the Company filed a prospectus supplement and offered for sale 11,500,000 shares of its common stock at a price of \$3.25 per share in an underwritten public offering. The Company received gross proceeds in the public offering of approximately \$37.4 million before underwriting commission and incurred expenses of approximately \$2.5 million.

***Warrant Exercises***

During the three month period ended March 31, 2015, the Company issued an aggregate of 717,174 shares of its authorized but unissued common stock upon the exercise of previously issued common stock purchase warrants, raising gross proceeds of \$1,191,026.

**10. Stock Compensation.**

***Stock Options***

During the three month period ended March 31, 2015, the Company granted seven-year options to purchase an aggregate of 185,000 shares of the Company's common stock to employees and directors. The options vest over a period of 3 years. During the three month period ended March 31, 2014, the Company granted five-year options to purchase an aggregate of 25,000 shares of the Company's common stock to a consultant. The Company recorded stock-based compensation related to stock options totaling \$295,842 and \$23,130 respectively, during the three month periods ended March 31, 2015 and 2014. During the three month periods ended March 31, 2015 and 2014, respectively, 25,000 and 25,000 options vested.

During the three month period ended March 31, 2015, options to purchase 829,608 shares of the Company's common stock were exercised on a cashless basis, resulting in the issuance of an aggregate of 673,583 shares of the Company's common stock.

As of March 31, 2015, there was approximately \$2,600,000 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 2.42 years.

***Restricted Stock Units***

No restricted stock units were granted during the three months ended March 31, 2015 and 2014. The Company recorded stock-based compensation related to restricted stock units totaling \$18,609 and \$0, respectively, during the three month periods ended March 31, 2015 and 2014. As of March 31, 2015, there was \$197,660 of total restricted stock unit compensation expense related to non-vested awards not yet recognized, which is expected to be recognized over a weighted average period of 2.62 years.

**11. Subsequent Events.**

Subsequent to quarter-end, the Company's securities class action lawsuit settlement became effective and the Company paid \$3.5 million to settle this matter, all of which was paid by the Company's insurance carrier. For additional information about the securities class action lawsuit settlement payment, see Note 7.



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# **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 and information about our business that we believe is important in understanding our financial condition and results of operations.

*Basis of Presentation.* This section provides information about key accounting estimates and policies that we followed in preparing our financial statements for the first quarter of fiscal 2015.

*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 fiscal quarter ended March 31, 2015 as compared to the first quarter of fiscal year 2014.

*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 biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases. We currently have three drug candidates 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 neuromuscular orphan indications such as certain forms of Congenital Myasthenic Syndromes (CMS) and Myasthenia Gravis (MuSK myasthenia gravis). In August 2013, we were granted breakthrough therapy designation by the U.S. Food & Drug Administration (FDA) for Firdapse® for the treatment of LEMS and, in March 2015, we were granted Orphan Drug Designation for Firdapse® for the treatment of patients with CMS.

The chemical entity 3,4-diaminopyridine (3,4-DAP) 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, because 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 if both exclusivities are granted.

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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.

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 worsening of 2.2 points observed in the placebo group and a worsening of 0.4 points observed in the treatment group.

The primary endpoint of change in subject global impression, or SGI, at day 14 was highly statistically significant ( $p=0.0028$ ), with a worsening of 2.6 points observed in the placebo group and a worsening of 0.8 points observed in the treatment 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 worsening at day 14 of 1.1 points between the placebo group and the treatment group.

The secondary endpoint of change in walking speed at day 14 showed a worsening of 9.7 feet per minute in the placebo group. The magnitude of the change relative to the variance in this test prevented the change from achieving statistical significance.

### **Patient tolerance of Firdapse®:**

Firdapse® was generally safe and well tolerated. During the 91-day open label run-in period, treatment emergent adverse events occurred more frequently in treatment-naïve patients than in previously treated patients (10% of treatment naïve patients withdrew during this part of the study). During the placebo-controlled portion of the study, side effects occurring more frequently in the Firdapse® group were benign and consisted primarily of perioral and digital paresthesia and infections. No patients withdrew during this period.

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

During 2014, we established an expanded access program (EAP) to make Firdapse® available to any patients diagnosed with LEMS, Congenital Myasthenic Syndromes (CMS) or Downbeat Nystagmus in the United States who meet the inclusion and exclusion criteria, with Firdapse® being provided to patients for free until sometime after NDA approval. We are working with various rare disease advocacy organizations to inform physicians and patients as to the availability of the Firdapse® EAP.

During January 2015, we met with the FDA to discuss our anticipated submission of an NDA for Firdapse® for the treatment of LEMS. Based on our discussions with the FDA, we believe that our Phase 3 clinical program will provide acceptable support for submission of an NDA for Firdapse® for LEMS. We currently expect to complete a rolling submission NDA for Firdapse® during the fourth quarter of 2015. Although there can be no assurance, we anticipate that under those circumstances we may obtain approval from the FDA of such NDA in third quarter of 2016. If approved on this timeline, we would hope to commercially launch Firdapse® for the treatment of LEMS shortly after its approval.

In anticipation of the commercialization of Firdapse®, we have begun to prepare for the marketing of Firdapse® in the United States. This has included the appointment of a Chief Commercial Officer, the hiring of a Vice President of Patient Advocacy and Reimbursement and the hiring of several rare disease clinical liaisons. We are currently working with several rare disease advocacy organizations to help increase awareness of LEMS and CMS and to provide education for the physicians who treat these rare diseases and the patients they treat. We anticipate developing a sales force of 15-20 representatives experienced in selling drugs that treat rare diseases. This sales force will market Firdapse® to the approximately 900 neuromuscular and oncology specialists who we believe most often diagnosis and treat neuromuscular diseases such as LEMS and CMS.

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CPP-115. We are currently developing CPP-115, a GABA aminotransferase inhibitor that, based on our preclinical 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 such as complex partial seizures and Tourette Syndrome. 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 syndrome (a form of infantile spasms). We are currently evaluating CPP-115 in a Phase 1(b) multi-dose safety and tolerance study. We expect to report the results of this study during the third quarter of 2015.

CPP-109. An academic investigator proof-of-concept study evaluating the use of CPP-109 (our formulation of vigabatrin, another GABA aminotransferase inhibitor) for the treatment of Tourette Syndrome is currently ongoing and, if the results of this study show evidence of reduced number of tics, we will likely seek to develop CPP-115 (which has the same mechanism of action as CPP-109) for this indication. Although we have provided drug and financial support, we do not control this study and therefore have no control over the timing of its completion. However, based on currently available information, we expect to have top-line results for this study during the second quarter of 2015.

## Securities Class Action Lawsuit

We have settled our previously disclosed securities class action lawsuit. For historic information about the securities class action lawsuit that was filed against us in late 2013, see Note 7 to the Notes to Financial Statements in our financial statements for the year ended December 31, 2014. In connection with the settlement, which became effective on April 16, 2015, we paid \$3.5 million to settle this matter, all of which was paid by our insurance carrier. Under the settlement, the defendants, and various of their related persons and entities, received 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 settlement contains no admission of any liability or wrongdoing on the part of the defendants, each of whom continue to deny all of the allegations against each of them and believe that the claims were without merit. Because the full amount of the settlement payment was paid by our insurance carrier, the settlement did not have a material adverse effect on our financial position or results of operations. There were no opt outs from the settlement.

## 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, preclinical studies, proof-of-concept studies and other product development activities;



the results of our preclinical 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.

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### **Available Capital Resources**

Based on our current financial condition and forecasts of available cash, we believe that we have sufficient resources to support our operations through the end of 2016. However, we will require additional funding to support our operations beyond the end of 2016. There can be no assurance that we will obtain additional funding or that we will ever be in a position to commercialize any of our drug candidates. See **Liquidity and Capital Resources** below for further information on our liquidity and cash flow.

### **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 drug 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 preclinical 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 (CROs). 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 preclinical 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. Preclinical 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.

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### *Selling and marketing expenses.*

We do not currently have any selling expenses. We have begun to incur costs tied to our future sales and marketing efforts, as we move closer to the potential commercialization of Firdapse®. Our plan is to put in place over the next year the 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.

### *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, and professional fees for legal, information technology, accounting and consulting services.

### *Stock-based compensation.*

We recognize expense for the fair value of all stock-based awards to employees, directors, scientific advisors and consultants in accordance with U.S. GAAP. 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. GAAP, we have recorded the fair value of the warrants as a liability in the accompanying balance sheets at March 31, 2015 and December 31, 2014 using a Black-Scholes option-pricing model. We will re-measure 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 the warrants.

### *Income taxes.*

We have incurred operating losses since inception. Our net deferred tax asset has a 100% valuation allowance as of March 31, 2015 and December 31, 2014, 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

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financial measures 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 typically present excludes from the calculation of net loss the expense (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 GAAP. The 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 2014 Annual Report on Form 10-K filed with the SEC. Our most critical accounting policies and estimates include: accounting for 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 2014 Annual Report on Form 10-K.

## **Results of Operations**

### *Revenues.*

We had no revenues for the three month periods ended March 31, 2015 and 2014.

### *Research and Development Expenses.*

Research and development expenses for the three months periods ended March 31, 2015 and 2014 were \$2,349,552 and \$2,748,683, respectively, including stock-based compensation expense in each of the three months periods of \$66,941 and \$11,873, respectively. Research and development expenses, in the aggregate, represented approximately 55% and 78%, respectively, of total operating costs and expenses for the three month periods ended March 31, 2015 and 2014. The stock-based compensation is non-cash and relates to the expense of stock options and restricted stock unit awards to certain employees.

Expenses for research and development for the three month period ended March 31, 2015, excluding stock based compensation, decreased when compared to amounts expended in the same period in 2014, as we decreased activities related to our completed Phase 3 trial for Firdapse®, and increased activities in other ongoing studies and trials.

As a result of our ongoing and projected studies and trials required for an NDA filing for Firdapse®, we expect that costs related to research and development activities will continue to be substantial in 2015, as we continue our currently planned research and development activities, including the completion of all testing required to submit an NDA for Firdapse®, costs relating to our currently anticipated rolling submission of an NDA for Firdapse®, costs relating to the operation of the Firdapse® Expanded Access Program and costs related to the Phase 1b trial for CPP-115.

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*Selling and Marketing Expenses.*

We had no selling and marketing expenses during the three month periods ended March 31, 2015 and 2014. We have begun to incur pre-commercialization costs, tied to our preparation for future sales and marketing efforts, as we move closer to the potential commercialization of Firdapse®. These costs are for personnel, and their related activities, to develop both a sales force and a patient advocacy and assistance program so that we are in a position to commence our selling efforts at such time as 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.

*General and Administrative Expenses.*

General and administrative expenses for the three months ended March 31, 2015 and 2014 were \$1,942,363 and \$759,682, respectively, including stock-based compensation expense in each of the three month periods of \$247,510 and \$11,257, respectively. General and administrative expenses represented 45% and 22%, respectively, of total operating costs and expenses for the three months ended March 31, 2015 and 2014. The increase in general and administrative expenses for the three months ended March 31, 2015 when compared to the same period in 2014 is primarily due to increases in pre-commercialization expenses, payroll and benefits expenses, investor relations expenses, and travel expenses. We expect general and administrative expenses to increase in future periods as we expand our operations and headcount in preparation for the future commercialization of Firdapse®.

*Stock-Based Compensation.*

Total stock-based compensation for the three months ended March 31, 2015 and 2014 was \$314,451 and \$23,130, respectively. The substantial increase in stock-based compensation for the three month period ended March 31, 2015 when compared to the same period in 2014, is principally due to the 2015 amortization of grants issued in August 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 these warrants is recorded in the liability section of the balance sheet and was estimated at \$3,564,299 and \$2,794,891 at March 31, 2015 and December 31, 2014, 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 months ended March 31, 2015, we recognized a loss of \$1,180,278 due to the change in the fair value of the warrants liability. The loss during the three months ended March 31, 2015 was principally a result of the increase of our stock price between March 31, 2015 and December 31, 2014. Future changes in the fair value of the warrants liability will be due primarily to fluctuations in the value of our common stock.

*Other Income, net.*

We reported other income, net in all periods relating to our investment of funds received from offerings of our securities. The increase in other income, net in the three month period ended March 31, 2015 as compared to the same period in 2014 is due to higher average investment balances from the proceeds of our offerings, slightly offset by lower interest rates. Other income net, consists of interest income, dividend income and unrealized and realized gain (loss) on trading securities. 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 month periods ended March 31, 2015 and 2014, 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.



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### *Net Loss.*

Our net loss was \$5,410,259 for the quarter ended March 31, 2015 (\$0.07 per basic and diluted share) as compared to \$3,811,119 for the quarter ended March 31, 2014 (\$0.07 per basic and diluted share).

### *Non-GAAP Net Loss.*

Our non-GAAP net loss, which excludes for the first quarter of 2015 and 2014 a loss of \$1,180,278 and \$335,514, respectively, associated with the change in the fair value of liability classified warrants, was \$4,229,981 for the first quarter of 2015, compared to a non-GAAP net loss of \$3,475,605 for the first quarter of 2014 (\$0.06 and \$0.06, respectively, per basic and diluted share).

## **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 March 31, 2015, we had cash and cash equivalents, certificates of deposit and short-term investments aggregating \$71.5 million and working capital of \$70.1 million. At December 31, 2014, we had cash and cash equivalents, certificates of deposit and short term investments aggregating \$39.3 million and working capital of \$38.0 million. At March 31, 2015, substantially all of our cash and cash equivalents 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 be substantial 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 some time to obtain the necessary regulatory approvals to commercialize one or more of our product candidates in the United States.

We currently believe that we have the resources to support our operations through the end of 2016. These expectations are based on current information available to us. 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 funding to support our operations beyond 2016. 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.

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We plan to raise additional funds to support our 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 preclinical 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.

On January 31, 2014, we filed a shelf registration statement with the SEC to sell up to \$100 million of common stock. This shelf registration statement was declared effective on March 19, 2014. We have completed two offerings under this shelf registration statement:

On April 3, 2014, we raised net proceeds of approximately \$26.7 million from the sale of 13,023,750 shares of our common stock; and

On February 4, 2015, we raised net proceeds of approximately \$34.9 million from the sale of 11,500,000 shares of our common stock.

### *Cash Flows.*

Net cash used in operating activities was \$3,794,969 and \$2,425,044, respectively, for the three month periods ended March 31, 2015 and 2014. During the three months ended March 31, 2015, net cash used in operating activities was primarily attributable to our net loss of \$5,410,259 and a decrease of \$763,695 in accounts payable, partially offset by a decrease of \$120,124 in prepaid expenses and other current assets and deposits, and an increase of \$755,984 in accrued expenses and other liabilities, \$1,180,278 of non-cash change in fair value of warrants liability and \$322,599 of other non-cash expenses. During the three months ended March 31, 2014, net cash used in operating activities was primarily attributable to our net loss of \$3,811,119, partially offset by a decrease of \$726,149 in prepaid expenses and other current assets and deposits, and increases of \$214,681 in accrued expenses and other liabilities, and \$81,316 in accounts payable, \$335,514 of non-cash change in fair value of warrants liability and \$28,415 of other non-cash expenses. Other non-cash expenses include depreciation and stock-based compensation expense.

Net cash used in investing activities during the three month period ended March 31, 2015 was \$43,269, consisting primarily of purchases of investments. Net cash provided by investing activities during the three month period ended March 31, 2014 was \$1,265,047, consisting primarily of redemptions of investments of \$1,282,353, offset by purchases of furniture and computer equipment of \$17,306.

Net cash provided by financing activities during the three month period ended March 31, 2015 was \$36,064,895, consisting mainly of \$34,873,869 net proceeds from the sale of shares of common stock in an underwritten public offering under our registration statement and \$1,191,026 from exercise of warrants to purchase common stock. Net cash provided by financing activities during the three month period ended March 31, 2014 consisted of \$16,504 of proceeds from the exercise of warrants to purchase common stock.

*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 royalties for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in our license agreement) in North America for any calendar year for sales up to \$100 million, and 10% of net sales in North America in any calendar year in excess of \$100 million; (ii) to pay to the third-party licensor of the rights sublicensed to us royalty payments for seven years from the first commercial sale of Firdapse® equal to 7% of net sales (as defined in the license agreement between BioMarin and the third-party licensor) in any calendar year; and (iii) to pay certain milestone payments that BioMarin is obligated to pay (approximately \$2.6 million

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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.

*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 March 31, 2015, we had paid approximately \$15.8 million of this amount and had prepaid research fees of approximately \$471,000, accounts payable of approximately \$752,000 and accrued liabilities of approximately \$783,000 in the accompanying balance sheet in connection with related agreements. Under our license agreement with BioMarin, we were obligated to complete our Phase 3 trial of Firdapse® during the two years following the date of the license agreement (October 26, 2012), which condition was satisfied during the third quarter of 2014.

*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 \$128,750, at March 31, 2015 in the accompanying 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 \$453,000 in 2015. The agreement expires in November 2016.

*Lease for office space.* We currently operate our business in leased office space in Coral Gables, Florida. We currently lease approximately 2,600 square feet of office space for which we pay annual rent of approximately \$96,000.

### *Off-Balance Sheet Arrangements.*

We currently have no debt or capital leases. We have operating leases for our office facilities. We do not have any off-balance sheet arrangements as such term is defined in rules promulgated by the SEC.

## **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:

our estimates regarding anticipated capital requirements and our need for additional financing;

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

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

whether our trials and studies will be successful;

the results of our clinical studies and trials, preclinical studies, proof-of-concept studies and our other development activities, and the number of such studies and trials that will be required for us to seek and obtain approval of NDAs for our drug candidates;

whether the third parties that assist us in our trials and studies perform as anticipated and within the budgets established for their activities;

the ability of our third-party suppliers and contract manufacturers to maintain compliance with current Good Manufacturing Processes (cGMP);

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

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;

even if one or more of our drug candidates is approved for commercialization, whether we will be able to successfully commercialize those products;

whether we will ever be able to achieve sustained profitability;

our estimates of the pricing of our drug candidates if approved and the size of the market for such drug candidates;

third-party payor reimbursement for any of our drug candidates that are commercialized;

the market adoption of any of our drug candidates approved for commercialization by physicians and patients;

our ability to obtain a sufficient commercial supply of our products;

our ability to successfully obtain additional indications for our drug candidates beyond those which may initially be approved;

the impact on sales of our products by others that are competitive to our products;

if one or more of our products are approved for commercialization, the costs, timing or estimated completion of any post-marketing studies that we are obligated to complete;

our expectations regarding licensing, acquisitions or strategic relationships;

changes in the laws and regulations affecting our business;

whether we can successfully protect any of our drug candidates under intellectual property laws;

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



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our ability to develop a sales force to commercialize any products as to which we may obtain the right to commercialize;

our ability to attract and retain skilled employees;

security breaches of our computer systems, or the computer systems of our contractors and/or vendors;

the impact of employee or consultant misconduct; 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 drug 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.

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

Our market risks during the three months ended March 31, 2015 have not materially changed from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014.

## **ITEM 4. CONTROLS AND PROCEDURES**

- a.** We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(c) and 15d-15(e)) of the Securities Exchange Act of 1934, as amended (the Exchange Act ). Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2015, 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 March 31, 2015, 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.



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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

See Notes 7 and 11 to Notes to Unaudited Financial Statements for information about the settlement of the securities class action litigation.

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 2014 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**

10.1	Third Amendment to Lease, dated effective March 16, 2015, between the Company and CPT 355 Alhambra Circle, LLC (filed by reference to our current Report on Form 8-K filed on March 27, 2015)
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

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**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: May 11, 2015

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**Exhibit Index**

Exhibit Number	Description
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