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 March 31, 2016

OR

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

Commission File No. 001-33057

CATALYST PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**76-0837053**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
355 Alhambra Circle Suite 1250 Coral Gables, Florida	**33134**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

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

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

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

Large Accelerated Filer	☐	Accelerated Filer	☒
Non-Accelerated Filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practicable date 82,870,649 shares of common stock, $0.001 par value per share, were outstanding as of May 6, 2016.

CATALYST PHARMACEUTICALS, INC.

INDEX

PART I. FINANCIAL INFORMATION

CATALYST PHARMACEUTICALS, INC.
BALANCE SHEETS

	March, 31 2016 (unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 22,227,962	$ 28,235,016
Certificates of deposit	3,717,599	3,717,229
Short-term investments	26,509,351	26,444,150
Prepaid expenses and other current assets	1,023,892	1,504,738
Total current assets	53,478,804	59,901,133
Property and equipment, net	178,351	191,549
Deposits	8,888	8,888
Total assets	$ 53,666,043	$ 60,101,570
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,251,473	$ 1,794,127
Accrued expenses and other liabilities	1,412,314	1,646,476
Total current liabilities	2,663,787	3,440,603
Accrued expenses and other liabilities, non-current	190,471	176,293
Warrants liability, at fair value	275,007	1,008,363
Total liabilities	3,129,265	4,625,259
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, 150,000,000 shares authorized; 82,870,649 shares and 82,850,619 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	82,871	82,851
Additional paid-in capital	145,915,762	145,469,078
Accumulated deficit	(95,461,855)	(90,075,618)
Total stockholders' equity	50,536,778	55,476,311
Total liabilities and stockholders' equity	$ 53,666,043	$ 60,101,570

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

CATALYST PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Revenues	$ —	$ —
Operating costs and expenses:		
Research and development	3,546,391	2,349,552
General and administrative	2,691,145	1,942,363
Total operating costs and expenses	6,237,536	4,291,915
Loss from operations	(6,237,536)	(4,291,915)
Other income, net	117,943	61,934
Change in fair value of warrants liability	733,356	(1,180,278)
Loss before income taxes	(5,386,237)	(5,410,259)
Provision for income taxes	—	—
Net loss	$ (5,386,237)	$ (5,410,259)
Net loss per share – basic and diluted	$ (0.07)	$ (0.07)
Weighted average shares outstanding – basic and diluted	82,860,083	76,039,220

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

CATALYST PHARMACEUTICALS, INC.
STATEMENT OF STOCKHOLDERS' EQUITY (unaudited)
For the three months ended March 31, 2016

	Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2015	$ —	$82,851	$145,469,078	$(90,075,618)	$55,476,311
Issuance of stock options for services	—	—	439,206	—	439,206
Amortization of restricted stock for services	—	—	18,763	—	18,763
Exercise of stock options for common stock	—	20	(11,285)	—	(11,265)
Net loss	—	—	—	(5,386,237)	(5,386,237)
Balance at March 31, 2016	$ —	$82,871	$145,915,762	$(95,461,855)	$50,536,778

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

CATALYST PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS (unaudited)

	For the Three Months Ended, March 31,	
	2016	2015
Operating Activities:		
Net loss	$ (5,386,237)	$ (5,410,259)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	13,198	8,148
Stock-based compensation	457,969	314,451
Change in fair value of warrants liability	(733,356)	1,180,278
(Increase) decrease in:		
Prepaid expenses and other current assets and deposits	480,846	120,124
Increase (decrease) in:		
Accounts payable	(542,654)	(763,695)
Accrued expenses and other liabilities	(219,984)	755,984
Net cash used in operating activities	(5,930,218)	(3,794,969)
Investing Activities:		
Capital expenditures	—	(7,910)
Purchase of short-term investments	(65,201)	(34,807)
Purchase of certificates of deposit	(370)	(552)
Net cash used in investing activities	(65,571)	(43,269)
Financing Activities:		
Proceeds from issuance of common stock, net	—	34,873,869
Payment of employee withholding tax related to stock-based compensation	(11,265)	—
Proceeds from exercise of warrants	—	1,191,026
Net cash (used in) provided by financing activities	(11,265)	36,064,895
Net (decrease) increase in cash and cash equivalents	(6,007,054)	32,226,657
Cash and cash equivalents - beginning of period	28,235,016	9,096,778
Cash and cash equivalents - end of period	$22,227,962	$41,323,435
Supplemental disclosures of non-cash investing and financing activity		
Exercise of liability classified warrants for common stock	$ —	$ 410,870

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

CATALYST PHARMACEUTICALS, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. Organization and Description of Business.

Catalyst Pharmaceuticals, Inc. (the Company) is a development-stage biopharmaceutical company focused on developing and commercializing innovating therapies for people with rare debilitating diseases, including Lambert-Eaton Myasthenic Syndrome (LEMS), Congenital Myasthenic Syndromes (CMS), infantile spasms and Tourette's Disorder.

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, 2016. 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 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 for at least the next year.

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 note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been omitted. The balance sheet as of December 31, 2015 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

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, 2015 included in the 2015 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results to be expected for any future period or for the full 2016 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, 2016 and December 31, 2015 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, 2016 and December 31, 2015, short-term investments consisted of short-term bond fund. Such investments are not insured by the Federal Deposit Insurance Corporation. Short-term investments at March 31, 2016 and December 31, 2015 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 for the three months ended March 31, 2016 and 2015 were $58,861 and $29,430 respectively, 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 prepaid research fees, prepaid pre-commercialization expenses, prepaid insurance and prepaid subscription fees. Prepaid research fees consist 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, 2016 and December 31, 2015, the fair value of these instruments approximated their carrying value.

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 it believes 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, 2016	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	$21,206,232	$ 21,206,232	$ —	$ —
Certificates of deposit	$ 3,717,599	$ —	$3,717,599	$ —
Short-term investments	$26,509,351	$ 26,509,351	$ —	$ —
Warrants liability	$ 275,007	$ —	$ —	$ 275,007

		Fair Value Measurements at Reporting Date Using		
	Balances as of December 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	$25,157,601	$ 25,157,601	$ —	$ —
Certificates of deposit	$ 3,717,229	$ —	$3,717,229	$ —
Short-term investments	$26,444,150	$ 26,444,150	$ —	$ —
Warrants liability	$ 1,008,363	$ —	$ —	$1,008,363

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 both March 31, 2016 and December 31, 2015, 763,913 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 to seven years. The Company estimates forfeitures and adjusts this estimate periodically based on actual forfeitures.

As of March 31, 2016, there were outstanding stock options to purchase 4,345,000 shares of common stock, of which stock options to purchase 2,033,328 shares of common stock were exercisable as of March 31, 2016.

For the three month periods ended March 31, 2016 and 2015, the Company recorded stock-based compensation expense as follows:

	Three months ended March 31,	
	2016	2015
Research and development	$ 93,783	$ 66,941
General and administrative	364,186	247,510
Total stock-based compensation	$ 457,969	$ 314,451

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).

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:

	March 31,	
	2016	2015
Options to purchase common stock	4,345,000	3,240,000
Warrants to purchase common stock	2,407,663	2,868,750
Unvested restricted stock	53,334	80,000
Potential equivalent common stock excluded	6,805,997	6,188,750

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

Potentially dilutive options to purchase common stock as of March 31, 2016 and 2015 have exercise prices ranging from $0.47 to $4.64 and $0.47 to $4.44, respectively. Potentially dilutive warrants to purchase common stock as of both March 31, 2016 and 2015 have exercise prices ranging from $1.04 to $2.08 and expire in periods between May 2017 and August 2017.

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.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact this accounting standard will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation* (Topic 718): *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for employee share-based payment transactions for both public and nonpublic entities, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. For public companies, the changes are effective for reporting periods (annual and interim) beginning after December 15, 2016. Early adoption is permitted. However, if early adoption is elected in an interim period, any adjustments should be reflected as of the beginning of the annual period that includes that interim period. The Company is currently evaluating the effect this standard will have 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.

3. Warrants Liability, at Fair Value (continued).

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.

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

	March 31, 2016	December 31, 2015
Risk free interest rate	0.60%	0.79%
Expected term	1.09 years	1.34 years
Expected volatility	85%	68%
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, 2016 and 2015:

	Three months ended March 31,	
	2016	2015
Fair value, beginning of period	$ 1,008,363	$ 2,794,891
Issuance of warrants	—	—
Exercise of warrants	—	(410,870)
Change in fair value	(733,356)	1,180,278
Fair value, end of period	$ 275,007	$ 3,564,299

During the three months ended March 31, 2016 none of the 2011 warrants were exercised. During the three months ended March 31, 2015, 152,174 of the 2011 warrants were exercised, with proceeds to the Company of $197,826. 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:

	March 31, 2016	December 31, 2015
Prepaid research fees	$ 457,591	$ 915,194
Prepaid insurance	347,510	436,726
Prepaid pre-commercialization fees	87,166	90,248
Prepaid subscription fees	76,209	26,602
Prepaid rent	19,319	1,252
Other	36,097	34,716
Total prepaid expenses and other current assets	$ 1,023,892	$ 1,504,738

5. Property and Equipment.

Property and equipment, net consists of the following:

	March 31, 2016	December 31, 2015
Computer equipment	$ 27,915	$ 27,915
Furniture and equipment	102,533	102,533
Leasehold improvements	131,175	131,175
	261,623	261,623
Less: Accumulated depreciation	(83,272)	(70,074)
Total property and equipment, net	$ 178,351	$ 191,549

Depreciation expense was $13,198 and $8,148, respectively, for the three month periods ended March 31, 2016 and 2015.

6. Accrued Expenses and Other Liabilities.

Accrued expenses and other liabilities consist of the following:

	March 31, 2016	December 31, 2015
Accrued preclinical and clinical trial expenses	$ 295,640	$ 332,905
Accrued professional fees	467,317	330,490
Accrued compensation and benefits	535,919	894,846
Accrued license fees	78,750	52,500
Deferred rent and lease incentive	18,093	18,093
Other	16,595	17,642
Current accrued expenses and other liabilities	1,412,314	1,646,476
Deferred rent and lease incentive - non-current	190,471	176,293
Non-current accrued expenses and other liabilities	190,471	176,293
Total accrued expenses and other liabilities	$ 1,602,785	$ 1,822,769

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 March 31, 2016, the Company has paid $406,590 in connection with the license and has accrued license fees of $78,750 in the accompanying March 31, 2016 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 $300,000 is due on the earlier of successful completion of the first Phase 3 clinical trial for CPP-115 or August 27, 2018.

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's Disorder. 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® under which: (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 to further the development of Firdapse®.

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, 2016, the Company had paid BioMarin $3.8 million related to expenses in connection with Firdapse® studies and trials.

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.

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 2012. 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.

(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

No warrants were exercised during the three months ended March 31, 2016. During the three months 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 periods ended March 31, 2016 and 2015, the Company granted seven-year options to purchase an aggregate of 155,000 and 185,000 shares of the Company's common stock to employees and directors. The Company recorded stock-based compensation related to stock options totaling $439,206 and $295,842 respectively, during the three month periods ended March 31, 2016 and 2015. During the three month periods ended March 31, 2016 and 2015, respectively, 56,665 and 25,000 options vested.

During the three month periods ended March 31, 2016 and 2015, options to purchase 50,000 and 829,608 shares of the Company's common stock were exercised on a "cashless" basis, resulting in the issuance of an aggregate 20,030 and 673,583 shares of the Company's common stock, respectively.

As of March 31, 2016, there was approximately $3,921,000 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 2.18 years.

Restricted Stock Units

No restricted stock units were granted during the three months ended March 31, 2016 and 2015. The Company recorded stock-based compensation related to restricted stock units totaling $18,763 and $18,609, respectively, during the three month periods ended March 31, 2016 and 2015. As of March 31, 2016, there was $122,000 of total restricted stock unit compensation expense related to non-vested awards not yet recognized, which is expected to be recognized over a weighted average period of 1.62 years.

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 2016.
- *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 months ended March 31, 2016 as compared to the same period ended March 31, 2015.
- *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). In August 2013, we were granted "breakthrough therapy designation" by the U.S. Food & Drug Administration (FDA) for Firdapse® for the treatment of patients with Lambert-Eaton Myasthenic Syndrome, or LEMS, a rare and sometimes fatal autoimmune disease characterized by muscle weakness, and, in March 2015, we were granted Orphan Drug Designation for Firdapse® for the treatment of patients with Congenital Myasthenic Syndromes, or CMS.

  The chemical entity, amifampridine (3,4-diaminopyridine or 3,4-DAP), has never been approved by the FDA for any indication. Because Firdapse® has been granted Orphan Drug Designation for the treatment of LEMS and CMS by the FDA, the product is also eligible to receive seven years of marketing exclusivity for either or both indications. Further, if we are the first pharmaceutical company to obtain approval for an amifampridine product, of which there can be no assurance, we will be eligible to receive five years of marketing exclusivity with respect to the use of this product for any indication, running concurrently with the seven years of orphan marketing exclusivity described above if both exclusivities are granted.

  As part of our 2012 agreement with BioMarin, we took over the sponsorship of an ongoing Phase 3 clinical trial evaluating Firdapse® for the treatment of LEMS. The Phase 3 trial was designed as a double blind, randomized

"withdrawal trial" in which all patients were initially treated with Firdapse® during a 7 to 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 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 versus 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 (approximately 10% of patients withdrew during this part of the study due to adverse events). 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 paresthesias 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, 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, should we receive such approval (of which there can be no assurance). We are informing neuromuscular physicians on the availability of the Firdapse® EAP and working with various rare disease advocacy organizations to inform patients and physicians about the program.

On July 22, 2015, we announced that we had initiated a rolling submission of an NDA for Firdapse® for the treatment of LEMS and CMS, and on December 17, 2015 we announced the completion of this submission. On February 17, 2016, we announced that we had received a "refusal to file" letter from the FDA regarding our NDA submission. The "refusal to file" letter stated that after a preliminary review, the FDA had found that our application was not sufficiently complete for review.

In early April 2016, we met with the FDA to obtain greater clarity regarding what will be required by the FDA to accept the Firdapse® NDA for filing. Following the receipt of the formal minutes of that meeting, on April 26, 2016, we issued a press release reporting that the FDA has stated that in addition to the results of the Company's previously submitted multi-center, randomized, placebo-controlled Phase 3 trial, we will need to submit positive results from an additional adequate and well-controlled study in patients with Lambert-Eaton Myasthenic Syndrome (LEMS). The FDA has stated that it is open to discuss a study design that could efficiently accomplish the requirement with a small, short-term study, and we are currently in discussions with the FDA, and with our clinical experts, regarding the protocol and logistics for this confirmatory study. Additionally, there is a requirement for several more short-term toxicology studies, which are expected to start soon. There can be no assurance that any of the trials and studies we are required to conduct will be successful.

We expect to update our guidance as additional facts become available, and there can be no assurance as to the timing or requirements of this confirmatory study, whether this additional study will be sufficient for the FDA to accept for filing any NDA that we might refile in the future for Firdapse®, or whether Firdapse® will ever be approved for commercialization.

Our original NDA submission for Firdapse® included data and information (including data from a currently ongoing investigator treatment IND) providing evidence supporting the benefits of Firdapse® for treating certain types of CMS, and requested that CMS be included in our initial label for Firdapse®. To provide additional support for our submission of an NDA for Firdapse® for the treatment of CMS, in October 2015 we initiated a small blinded clinical trial in the pediatric CMS population, ages 2 to 17, to further evaluate the use of Firdapse® for the treatment of CMS. There can be no assurance that this trial will be successful, whether other trials will be required before the FDA considers any NDA for Firdapse® for the treatment of CMS, or whether any NDA that we may submit for Firdapse® for the treatment of CMS will be filed by the FDA for review and approved.

Firdapse® is also currently being evaluated as a treatment for MuSK-antibody positive myasthenia gravis. In February 2016, we announced the initiation of an investigator-sponsored, randomized, double-blind, placebo-controlled, crossover Phase 2/3 clinical trial evaluating the safety, tolerability and potential efficacy of Firdapse® as a symptomatic treatment for patients with MuSK-antibody positive myasthenia gravis (MuSK-MG). The study is planned to include approximately 20 patients and we anticipate the investigator reporting top-line results from the study in 2017. We are providing study drug and financial support for this trial. If this trial is successful, we will consider pursuing approval of Firdapse® for this indication. There can no assurance that this trial will be successful, or, even if this trial is successful, whether other clinical trials will be required before we may seek approval of an NDA for Firdapse® for the treatment of MuSK-MG.

Finally, we may seek to evaluate Firdapse® for the treatment of other treatment-refractory types of Myasthenia Gravis or other rare, similar neuromuscular diseases, although we have not yet begun to develop clinical programs for these indications. There can be no assurance that Firdapse® will be an effective treatment for other treatment-refractory types of myasthenia gravis or for any other rare, similar neuromuscular diseases.

Prior to the receipt of the “refusal-to-file” letter, we were actively taking steps to prepare for the commercialization of Firdapse® in the United States. In light of the determination that we will have to complete another adequate and well controlled study evaluating Firdapse® for the treatment of LEMS, we are currently placing these activities on hold in order to conserve cash. Notwithstanding, we plan to continue to work with several rare disease advocacy organizations to help increase awareness of LEMS and CMS and to provide and support education for the physicians who treat these rare diseases and the patients they treat.

- CPP-115.

We are developing CPP-115, a GABA aminotransferase inhibitor that, based on our preclinical studies to date, we believe is a more potent form of vigabatrin, and 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’s Disorder. 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 recently announced top line results from a Phase 1b double-blind, placebo controlled safety and tolerance study of CPP-115 in six normal, healthy, adult male volunteers. The results showed significant increases in brain levels of the surrogate marker for potential efficacy, gamma-aminobutyric acid (GABA), a mechanism known to effectively treat epilepsy, infantile spams, and potentially Tourette's Disorder. The main adverse effect of prolonged elevated brain GABA, somnolence, was also observed.

While the primary objective of this study was to obtain safety and tolerability data for CPP-115 administered over 14 days, brain GABA levels were measured as a surrogate marker of potential efficacy, since CPP-115 is a second generation GABA aminotransferase inhibitor. Specifically, this study examined GABA levels in both the POC (Parietal-Occipital Cortex), a grey matter rich region similar to brain regions thought to be associated with epilepsy, and which was previously studied using vigabatrin, and the SMA (Supplementary Motor Area), which is thought to be associated with Tourette's Disorder. The maximum brain GABA increases, in both brain regions, ranged from about 150% to over 200% of baseline levels, as measured by magnetic resonance spectroscopy (MRS).

We are presently evaluating the full results of this study, including additional data from laboratory safety tests and pharmacokinetic modeling of the patients in this study, and developing a plan to make CPP-115 "ready for Phase 2," including a Phase 1b dose ranging study evaluating the effects on brain GABA of CPP-115 at lower doses. We hope to commence the next study sometime in 2016, subject to the availability of funding.

- CPP-109.

Tourette's Disorder

During June 2015, we announced the top-line results of 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's Disorder. The 8-week, four subject open label study was designed as an open label trial to evaluate the potential effect of GABA-aminotransferase inhibition as a mechanism for reducing tics in patients with treatment-refractory Tourette's Disorder. The most common side-effect was daytime tiredness, and one subject experienced an increase in moodiness and obsessive-compulsive symptoms. Vigabatrin was used as a "research surrogate" in this study to demonstrate the utility of GABA-aminotransferase (GABA-AT) blockade, with the expectation that upon successfully demonstrating the utility of this mechanism, further development activities would focus on the potentially safer, more potent GABA-AT inhibitor, CPP-115.

We believe that the top-line results from this study suggest an encouraging signal of activity in adult treatment-refractory patients with Tourette's Disorder. Further, we believe that CPP-109's mechanism of action validates the potential for CPP-115 to be a candidate for the treatment of Tourette's Disorder. However, there can be no assurance that CPP-115 will be effective for the treatment of refractory patients with Tourette's Disorder.

Generic Sabril®

During September 2015, we announced the initiation of a project to develop a generic version of Sabril® (vigabatrin). Sabril® is marketed by Lundbeck Inc. ("Lundbeck") in the United States for the treatment of infantile spasms and complex partial seizures. We have substantial previous experience with our version of vigabatrin (CPP-109), which we believe will contribute to our development and submission of an abbreviated new drug application (ANDA) for a generic version of Sabril®. There can be no assurance that we will be successful in these efforts or that any ANDA that we submit for vigabatrin will be accepted for review or approved.

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 risk that another pharmaceutical company will receive an approval for its formulation of 3,4-diaminopyridine (3,4-DAP) for the treatment of LEMS or CMS, or any other indication, before we do;
- what additional supporting information will be required before the U.S. Food and Drug Administration (FDA) will file an NDA submission for Firdapse® for the treatment of either LEMS or CMS;
- whether any NDA that we may submit for Firdapse®, if accepted for filing by the FDA, will be granted a priority review;
- the scope and timing of the clinical studies or trials that will be required before the FDA will accept an NDA submission for Firdapse® for the treatment of either LEMS or CMS;
- whether, even if the FDA accepts an NDA submission for Firdapse®, such product will be determined to be safe and effective and approved for commercialization;
- whether the receipt of breakthrough therapy designation for Firdapse® for LEMS will expedite the review of Firdapse® by the FDA or affect the likelihood that the product will be found to be safe and effective;
- whether CPP-115 will be determined to be safe for humans;
- whether CPP-115 will be determined to be effective for the treatment of infantile spasms, post-traumatic stress disorder, Tourette's Disorder or any other indication;
- whether we can successfully design and complete a bioequivalence study of our version of vigabatrin compared to Sabril® that is acceptable to the FDA;
- whether any such bioequivalence study, the design of which is acceptable to the FDA, will be successful;
- whether any abbreviated new drug application (ANDA) that we submit for a generic version of Sabril® will be accepted by the FDA for review and approved (and the timing of any such approval);
- the scope, rate of progress and expense of our clinical trials and studies, pre-clinical studies, proof-of-concept studies, and our other drug development activities;
- 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;

Available Capital Resources

Based on forecasts of available cash, we currently believe that we have sufficient resources to fund our operations for at least the next year. However, until the details and logistics of our required confirmatory study evaluating Firdapse® for the treatment of LEMS are finalized, and we can determine with certainty our path forward to refile our NDA for Firdapse®, it will be difficult for us to provide more details regarding our capital resources. Once we have a better understanding of these requirements, we expect to take steps to allocate our resources and conserve cash based on our revised plan, at which time we expect to be in a better position to report on how far our existing capital resources will take us. Notwithstanding, and while there can be no assurance, we continue to believe that our currently available resources will be sufficient to complete the development of Firdapse® and refile an NDA for Firdapse®.

If we require additional funding, there can be no assurance that we will obtain the required 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 drug 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.

Selling and marketing expenses.

We do not currently have any selling or marketing expenses. We have been incurring costs tied to our future sales and marketing efforts for Firdapse®. However, we have recently put most of these activities on hold in order to conserve cash. Pre-commercialization expenses to date 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, 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 an equity financing that we completed in October 2011. In accordance with U.S. GAAP, we have recorded the fair value of these warrants as a liability in the accompanying balance sheets at March 31, 2016 and December 31, 2015 using a Black-Scholes option-pricing model. We will re-measure the fair value of this 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 March 31, 2016 and December 31, 2015, 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 would 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 an 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 in our communications with investors. 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 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 that 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 2015 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 2015 Annual Report on Form 10-K.

Results of Operations

Revenues.

We had no revenues for the three month periods ended March 31, 2016 and 2015.

Research and Development Expenses.

Research and development expenses for the three month periods ended March 31, 2016 and 2015 were $3,546,391 and $2,349,552, respectively, including stock-based compensation expense in each of the three month periods of $93,783 and $66,941, respectively. Research and development expenses, in the aggregate, represented approximately 57% and 55% of total operating costs and expenses for the three month periods ended March 31, 2016 and 2015, 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 three months ended March 31, 2016, excluding stock based compensation, increased compared to amounts expended in the same period in 2015, due primarily to consulting on regulatory matters, activities related to the Firdapse® expanded access program, including manufacturing of related drug, and increased activities in other ongoing studies and trials. We expect that costs related to research and development activities will continue to be substantial throughout the balance of 2016.

Selling and Marketing Expenses.

We had no selling expenses during the three month periods ended March 31, 2016 and 2015. We have been incurring pre-commercialization costs for Firdapse®, but have recently put most of these activities on hold in order to conserve cash. These costs are principally for personnel, and their related activities. Pre-commercialization costs are included in general and administrative expenses.

General and Administrative Expenses.

General and administrative expenses for the three months ended March 31, 2016 and 2015 were $2,691,145 and $1,942,363, respectively, including stock-based compensation expense in each of the three month periods ending March 31, 2016 and 2015 of $364,186 and $247,510, respectively. General and administrative expenses represented 43% and 45% of total operating costs and expenses for the three months ended March 31, 2016 and 2015, respectively. The increase in general and administrative expenses for the three months ended March 31, 2016 when compared to the same period in 2015 is primarily due to increases in pre-commercialization expenses, payroll and benefits expenses. We expect general and administrative expenses to decrease in 2016 as we take steps to conserve our available resources once we have a better understanding of the timing and logistics of our development plan for Firdapse®.

Stock-Based Compensation.

Total stock-based compensation for the three month periods ended March 31, 2016 and 2015 were $457,969 and $314,451, respectively. The increase in stock-based compensation for the three month periods ended March 31, 2016 when compared to the same period in 2015, is primarily due to additional headcount.

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 $275,007 and $1,008,363 at March 31, 2016, and December 31, 2015, 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, 2016 and 2015, we recognized a gain of $733,356 and a loss of $1,180,278, respectively, due to the change in the fair value of the warrants liability. The gain during the three months ended March 31, 2016 was principally a result of the decrease of our stock price between December 31, 2015 and March 31, 2016. The loss during the three months ended March 31, 2015 was principally a result of the increase of our stock price between December 31, 2014 and March 31, 2015. 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.

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 for the three months ended March 31, 2016 when compared to the same period in 2015 is due to higher average investment balances from the proceeds of our offerings. Other income, net, consists of interest income, dividend income and unrealized and realized gain (loss) on trading securities. These proceeds are used to fund our drug 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, 2016 and 2015, 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 $5,386,237 for the three months ended March 31, 2016 ($0.07, per basic and diluted share) as compared to a net loss of $5,410,259, for the three months ended March 31, 2015 ($0.07 per basic and diluted share).

Non-GAAP Net Loss.

Our non-GAAP net loss, which excludes for the three months ended March 31, 2016 and 2015 a gain of $733,356 and a loss of $1,180,278, respectively, associated with the change in the fair value of liability classified warrants, was $6,119,593 and $4,229,981 for the three months ended March 31, 2016 and 2015, respectively ($0.07 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, 2016, we had cash and cash equivalents, certificates of deposit and short-term investments aggregating $52.5 million and working capital of $50.8 million. At December 31, 2015, we had cash and cash equivalents, certificates of deposit and short term investments aggregating $58.4 million and working capital of $56.5 million. At March 31, 2016, 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 drug development programs and prepare for the commercialization of our drug 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 drug candidates in the United States.

Based on forecasts of available cash, we currently believe that we have sufficient resources to fund our operations for at least the next year. However, until the details and logistics of our required confirmatory study evaluating Firdapse® for the treatment of LEMS are finalized, and we can determine with certainty our path forward to refile our NDA for Firdapse®, it will be difficult for us to provide more details regarding our capital resources. Once we have a better understanding of these requirements, we expect to take steps to allocate our resources and conserve cash based on our revised plan, at which time we expect to be in a better position to report on how far our existing capital resources will take us. Notwithstanding, and while there can be no assurance, we continue to believe that our currently available resources will be sufficient to complete the development of Firdapse® and refile an NDA for Firdapse®.

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 drug 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.

If we are required to raise additional funds to support our product development activities and working capital requirements, we would raise such funds through public or private equity offerings, corporate collaborations or other means. We also may 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 or product acquisitions, 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 $5,930,218 and $3,794,969, respectively, for the three month periods ended March 31, 2016 and 2015. During the three months ended March 31, 2016, net cash used in operating activities was primarily attributable to our net loss of $5,386,237, decreases of $542,654 in accounts payable and $219,984 in accrued expenses and other liabilities and $733,356 of non-cash change in fair value of warrants liability. This was partially offset by $480,846 decrease in prepaid expenses and other current assets and $471,167 of other non-cash expenses. 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 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.

Net cash used in investing activities during the three months ended March 31, 2016 was $65,571, consisting primarily of purchases of short-term investments. Net cash used in investing activities during the three months ended March 31, 2015 was $43,269 consisting primarily of purchases of short term investments of $34,807, and capital expenditures of $7,910.

Net cash used in financing activities during the three months ended March 31, 2016 was $11,265, for payment of employee withholding tax related to stock based compensation. Net cash provided by financing activities during the three months ended March 31, 2015 was $36,064,895, consisting of $34,873,869 from the net proceeds from the sale of common stock under the 2014 Shelf Registration Statement and $1,191,026 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 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 to Northwestern University under our license agreement.* Under our license agreement with Northwestern, we have paid to date $406,590, had accrued liabilities of $78,750, at March 31, 2016 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 $300,000 is due on the earlier of successful completion of the first Phase 3 clinical trial of CPP-115 or August 27, 2018.
- E*mployment agreements.* We have entered into an employment agreement with our Chief Executive Officer that requires us to make base salary payments of approximately $471,000 in 2016. The agreement expires in November 2016.
- *Lease for office space*. We operate our business in leased office space in Coral Gables, Florida. We currently lease approximately 5,200 square feet of office space for which we pay annual rent of approximately $200,000.

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 and commercialization of our current drug 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 risk that another pharmaceutical company will receive an approval for its formulation of 3,4-diaminopyridine (3,4-DAP) for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS), Congenital Myasthenic Syndromes (CMS), or any other indication, before we do;
- what additional supporting information will be required before the U.S. Food and Drug Administration (FDA) will file a new drug application (NDA) submission for Firdapse® for the treatment of either LEMS or CMS;
- whether any NDA that we may submit for Firdapse®, if accepted for filing by the FDA, will be granted a priority review;
- whether any additional clinical studies or trials will be required before the FDA will accept an NDA submission for Firdapse® for the treatment of either LEMS or CMS;
- whether any clinical studies or trials that may be required before the FDA will accept an NDA submission for Firdapse® for the treatment of either LEMS or CMS will be successful;
- whether, even if the FDA accepts an NDA submission for Firdapse®, such product will be determined to be safe and effective and approved for commercialization;
- whether the receipt of breakthrough therapy designation for Firdapse® for LEMS will expedite the review of Firdapse® by the FDA or affect the likelihood that the product will be found to be safe and effective;
- whether as part of the FDA review of any NDA that we may submit for filing for Firdapse®, the tradename Firdapse®, which is the tradename used for the same product in Europe, will be approved for use for the product in the United States;
- whether, assuming Firdapse® is approved for commercialization, we will be able to develop a sales and marketing organization that can successfully market Firdapse® while maintaining full compliance with applicable federal and state laws, rules and regulations;

- whether CPP-115 will be determined to be safe for humans;
- whether CPP-115 will be determined to be effective for the treatment of infantile spasms, post-traumatic stress disorder, Tourette's Disorder or any other indication;
- whether we can successfully design and complete a bioequivalence study of our version of vigabatrin compared to Sabril® that is acceptable to the FDA;
- whether any such bioequivalence study, the design of which is acceptable to the FDA, will be successful;
- whether any abbreviated new drug application (ANDA) that we submit for a generic version of Sabril® will be accepted by the FDA for review and approved (and the timing of any such approval);
- the scope, rate of progress and expense of our clinical trials and studies, pre-clinical studies, proof-of-concept studies, and our other drug development activities;
- 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, pre-clinical 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 new drug applications, or 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 Practices (cGMP);
- whether any of our drug candidates will ever be approved for commercialization;
- even if one or more of our drug candidates is approved for commercialization, whether we will be able to successfully commercialize those products and achieve sustained profitability;
- our estimates of the pricing of our drug candidates, if approved, and the size of the market for our drug candidates;
- third-party payor reimbursement for any of our drug candidates that are commercialized;
- what pricing we will be able to achieve with respect to our drug products and the impact of public scrutiny on the pricing of drug products generally and our products and orphan drugs in particular;
- changes in the laws and regulations and regulatory guidance affecting our business;
- 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;
- if one or more of our products are approved for commercialization, the costs, timing or estimated completion of any post-marketing studies that we may be obligated to complete;

- our expectations regarding licensing, acquisitions or strategic relationships;
- 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 we may have for our drug candidates;
- 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 potential employee, vendor 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 we have 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, 2016 have not materially changed from those discussed in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015.

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 March 31, 2016, 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, 2016, 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 7 to the Financial Statements in our financial statements for the year ended December 31, 2015 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 2015 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
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

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 Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and Chief Financial Officer

Date: May 10, 2016

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

Exhibit 31.1

Certification of Principal Executive Officer

I, Patrick J. McEnany, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Patrick J. McEnany

Patrick J. McEnany
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer

I, Alicia Grande, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Catalyst Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2016

/s/ Alicia Grande

Alicia Grande
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Patrick J. McEnany as Principal Executive Officer of Catalyst Pharmaceuticals, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1. the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2016 (the "Report"), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

/s/ Patrick J. McEnany
Patrick J. McEnany
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification Required by 18 U.S.C. Section 1350
(as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)

I, Alicia Grande as Principal Financial Officer of Catalyst Pharmaceuticals, Inc. (the "Company"), certify, pursuant to 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002), that to my knowledge:

1. the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 2016 (the "Report"), filed with the U.S. Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2016

/s/ Alicia Grande

Alicia Grande
Chief Financial Officer
(Principal Financial Officer)