CATALYST PHARMACEUTICALS, INC.
Form 10-Q
November 09, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

[Mark One]

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

For the Quarterly Period Ended September 30, 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	**(IRS Employer**
incorporation or organization)	**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 November 4, 2016.

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PART I. FINANCIAL INFORMATION

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CATALYST PHARMACEUTICALS, INC.

BALANCE SHEETS

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 17,638,100	$ 28,235,016
Certificates of deposit	568,031	3,717,229
Short-term investments	26,538,304	26,444,150
Prepaid expenses and other current assets	310,855	1,504,738
Total current assets	45,055,290	59,901,133
Property and equipment, net	249,038	191,549
Deposits	8,888	8,888
Total assets	$ 45,313,216	$ 60,101,570
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,055,324	$ 1,794,127
Accrued expenses and other liabilities	940,271	1,646,476
Total current liabilities	1,995,595	3,440,603
Accrued expenses and other liabilities, non-current	185,095	176,293
Warrants liability, at fair value	229,172	1,008,363
Total liabilities	2,409,862	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 September 30, 2016 and December 31, 2015, respectively	82,871	82,851
Additional paid-in capital	146,805,233	145,469,078
Accumulated deficit	(103,984,750)	(90,075,618)
Total stockholders equity	42,903,354	55,476,311
Total liabilities and stockholders equity	$ 45,313,216	$ 60,101,570

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

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CATALYST PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating costs and expenses:				
Research and development	$ 2,493,999	$ 3,042,671	$ 8,549,287	$ 7,969,731
General and administrative	1,420,015	1,974,757	6,416,715	6,236,942
Total operating costs and expenses	3,914,014	5,017,428	14,966,002	14,206,673
Loss from operations	(3,914,014)	(5,017,428)	(14,966,002)	(14,206,673)
Other income, net	66,981	46,659	277,679	113,464
Change in fair value of warrants liability	(106,948)	521,731	779,191	(324,591)
Loss before income taxes	(3,953,981)	(4,449,038)	(13,909,132)	(14,417,800)
Provision for income taxes				
Net loss	$ (3,953,981)	$ (4,449,038)	$ (13,909,132)	$ (14,417,800)
Net loss per share basic and diluted	$ (0.05)	$ (0.05)	$ (0.17)	$ (0.18)
Weighted average shares outstanding basic and diluted	82,870,649	82,470,139	82,867,140	80,205,864

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

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CATALYST PHARMACEUTICALS, INC.

STATEMENT OF STOCKHOLDERS EQUITY (unaudited)

For the nine months ended September 30, 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			1,290,943		1,290,943
Amortization of restricted stock for services			56,497		56,497
Exercise of stock options for common stock		20	(11,285)		(11,265)
Net loss				(13,909,132)	(13,909,132)
Balance at September 30, 2016	$	$ 82,871	$ 146,805,233	$ (103,984,750)	$ 42,903,354

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

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CATALYST PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS (unaudited)

	For the Nine Months Ended, September 30,	
	2016	**2015**
Operating Activities:		
Net loss	$ (13,909,132)	$ (14,417,800)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	31,442	28,382
Stock-based compensation	1,347,440	1,009,116
Change in fair value of warrants liability	(779,191)	324,591
Decrease (increase) in:		
Prepaid expenses and other current assets and deposits	1,193,883	(341,220)
(Decrease) increase in:		
Accounts payable	(738,803)	(997,189)
Accrued expenses and other liabilities	(697,403)	1,010,221
Net cash used in operating activities	(13,551,764)	(13,383,899)
Investing Activities:		
Capital expenditures	(88,931)	(23,465)
Purchase of short-term investments	(94,154)	(32,071)
Proceeds (purchase) of certificates of deposit	3,149,198	(1,440)
Net cash provided by (used in) investing activities	2,966,113	(56,976)
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		1,895,738
Proceeds from exercise of stock options		324,949
Net cash (used in) provided by financing activities	(11,265)	37,094,556
Net (decrease) increase in cash and cash equivalents	(10,596,916)	23,653,681
Cash and cash equivalents - beginning of period	28,235,016	9,096,778
Cash and cash equivalents - end of period	$ 17,638,100	$ 32,750,459
Supplemental disclosures of non-cash investing and financing activity		
Exercise of liability classified warrants for common stock	$	$ 1,721,523
Non-cash incentive received from lessor	$	$ 131,175

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

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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 September 30, 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 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.

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

In the opinion of management, the accompanying unaudited interim financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of the dates and for the periods presented. Accordingly, these statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 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 and nine months ended September 30, 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. These amounts at times may exceed federally insured limits.

d. **CERTIFICATES OF DEPOSIT.** The certificates of deposit are issued by a banking institution and are recorded at cost plus accrued interest. The original maturity is greater than three months but does not exceed one year. Interest income is recorded in the statement of operations as it is earned. Carrying value at September 30, 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 September 30, 2016 and December 31, 2015, short-term investments consisted of a short-term bond fund. Such investments are not insured by the Federal Deposit Insurance Corporation. Short-term investments at September 30, 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 gain (loss) for the three and nine months ended September 30, 2016 were $0 and $88,291, respectively. Unrealized gain (loss) for the three and nine months ended September 30, 2015 were $29,430 and $29,430 respectively. Unrealized gain (loss) for each period is 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 September 30, 2016 and December 31, 2015, the fair value of these instruments approximated their carrying value.

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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 September 30, 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	$ 17,329,687	$ 17,329,687	$	$
Certificates of deposit	$ 568,031	$	$ 568,031	$
Short-term investments	$ 26,538,304	$ 26,538,304	$	$
Warrants liability	$ 229,172	$	$	$ 229,172

	Fair Value Measurements at Reporting Date Using			
	Balances as of December 31,	Quoted Prices in Active Markets	Significant Other Observable	Significant Unobservable Inputs

	2015	for Identical Assets/Liabilities (Level 1)	Inputs (Level 2)	(Level 3)
Money market funds	$ 25,157,601	$ 25,157,601	$	$