

CATALYST PHARMACEUTICALS, INC.

Form 10-Q

November 07, 2018

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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, 2018**

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)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>76-0837053</b> <b>(IRS Employer</b>
<b>incorporation or organization)</b>	<b>Identification No.)</b>
<b>355 Alhambra Circle</b>	
<b>Suite 1250</b>	
<b>Coral Gables, Florida</b>	<b>33134</b>
<b>(Address of principal executive offices)</b>	<b>(Zip Code)</b>
<b>Registrant's telephone number, including area code: <u>(305) 420-3200</u></b>	

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	Accelerated Filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act.

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 102,739,257 shares of common stock, \$0.001 par value per share, were outstanding as of November 2, 2018.



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	<b>September 30, 2018</b>	<b>December 31, 2017</b>
	(unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 10,616,313	\$ 57,496,702
Short-term investments	51,047,842	26,516,711
Prepaid expenses and other current assets	816,820	1,173,744
Total current assets	62,480,975	85,187,157
Investments	5,018,857	
Property and equipment, net	201,093	191,385
Deposits	8,888	8,888
Total assets	\$ 67,709,813	\$ 85,387,430
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,340,984	\$ 1,945,575
Accrued expenses and other liabilities	2,127,450	2,320,587
Total current liabilities	3,468,434	4,266,162
Accrued expenses and other liabilities, non-current	164,781	157,456
Total liabilities	3,633,215	4,423,618
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized: none issued and outstanding at September 30, 2018 and December 31, 2017		
Common stock, \$0.001 par value, 150,000,000 shares authorized; 102,689,257 shares and 102,549,498 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	102,689	102,549
Additional paid-in capital	210,084,209	207,421,710
Accumulated deficit	(146,064,352)	(126,560,447)
Accumulated other comprehensive loss	(45,948)	
Total stockholders' equity	64,076,598	80,963,812
Total liabilities and stockholders' equity	\$ 67,709,813	\$ 85,387,430

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

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## CATALYST PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating costs and expenses:				
Research and development	\$ 4,538,369	\$ 2,704,923	\$ 11,502,235	\$ 7,970,603
General and administrative	3,644,234	1,601,785	8,949,663	5,197,247
Total operating costs and expenses	8,182,603	4,306,708	20,451,898	13,167,850
Loss from operations	(8,182,603)	(4,306,708)	(20,451,898)	(13,167,850)
Other income, net	343,730	129,059	947,993	330,075
Change in fair value of warrants liability				(186,904)
Loss before income taxes	(7,838,873)	(4,177,649)	(19,503,905)	(13,024,679)
Provision for income taxes				
Net loss	\$ (7,838,873)	\$ (4,177,649)	\$ (19,503,905)	\$ (13,024,679)
Net loss per share basic and diluted	\$ (0.08)	\$ (0.05)	\$ (0.19)	\$ (0.16)
Weighted average shares outstanding basic and diluted	102,641,504	84,797,969	102,598,740	83,898,724
Net loss	\$ (7,838,873)	\$ (4,177,649)	\$ (19,503,905)	\$ (13,024,679)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	(9,450)		(45,948)	
Comprehensive loss	\$ (7,848,323)	\$ (4,177,649)	\$ (19,549,853)	\$ (13,024,679)

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

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## CATALYST PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (unaudited)

For the nine months ended September 30, 2018

	Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
<b>Balance at December 31, 2017</b>	\$	\$ 102,549	\$ 207,421,710	\$ (126,560,447)	\$	\$ 80,963,812
Issuance of common stock, net		3	10,546			10,549
Issuance of stock options for services			2,506,026			2,506,026
Exercise of stock options for common stock		137	145,927			146,064
Other comprehensive loss					(45,948)	(45,948)
Net loss				(19,503,905)		(19,503,905)
<b>Balance at September 30, 2018</b>	\$	\$ 102,689	\$ 210,084,209	\$ (146,064,352)	\$ (45,948)	\$ 64,076,598

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



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## CATALYST PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	For the Nine Months Ended September 30,	
	2018	2017
<b>Operating Activities:</b>		
Net loss	\$ (19,503,905)	\$ (13,024,679)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	25,485	38,754
Stock-based compensation	2,521,023	1,922,451
Change in fair value of warrants liability		186,904
(Increase) decrease in:		
Prepaid expenses and other current assets and deposits	356,924	537,452
Increase (decrease) in:		
Accounts payable	(604,591)	148,432
Accrued expenses and other liabilities	(185,812)	477,981
Net cash used in operating activities	(17,390,876)	(9,712,705)
<b>Investing Activities:</b>		
Purchases of property and equipment	(35,193)	
Purchases of investments	(37,141,968)	(64,748)
Proceeds from maturities of investments	7,546,032	
Net cash provided by (used in) investing activities	(29,631,129)	(64,748)
<b>Financing Activities:</b>		
Payment of employee withholding tax related to stock-based compensation	(4,448)	
Proceeds from exercise of warrants		3,209,423
Proceeds from exercise of stock options	146,064	3,950
Net cash provided by (used in) financing activities	141,616	3,213,373
Net increase (decrease) in cash and cash equivalents	(46,880,389)	(6,564,080)
Cash and cash equivalents beginning of period	57,496,702	13,893,064
Cash and cash equivalents end of period	\$ 10,616,313	\$ 7,328,984
<b>Non-cash investing and financing activities:</b>		
Unrealized gain (loss) on available-for-sale securities	\$ (45,948)	\$
Exercise of liability classified warrants for common stock	\$	\$ 309,130

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



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**CATALYST PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED CONSOLIDATED 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, chronic neuromuscular and neurological diseases, including Lambert-Eaton Myasthenic Syndrome (LEMS), Congenital Myasthenic Syndromes (CMS), and MuSK antibody positive myasthenia gravis (MuSK-MG).

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, 2018. 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 10.

*Capital Resources*

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 12 months.

The Company may raise additional funds in the future, if required for its business, 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 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 consolidated 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 consolidated balance sheet as of December 31, 2017 included in this Form 10-Q was derived from the audited financial statements and does not include all disclosures required by U.S. GAAP.

In the opinion of management, the accompanying unaudited interim consolidated 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 consolidated statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2017 included in the 2017 Annual Report on Form 10-K filed by the Company with the SEC. The results of operations for the nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for any future period or for the full 2018 fiscal year.

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

- b. PRINCIPLES OF CONSOLIDATION.** The consolidated financial statements include the Company's accounts and those of its wholly-owned subsidiary Catalyst Pharmaceuticals Ireland, Ltd. (Catalyst Ireland). All intercompany accounts and transactions have been eliminated in consolidation. Catalyst Ireland was organized in 2017.
- c. 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.
- d. 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.
- e. INVESTMENTS.** The Company invests in high credit-quality funds in order to obtain higher yields on its cash available for investments. At September 30, 2018, investments consisted of a short-term bond fund and U.S. Treasuries. At December 31, 2017, investments consisted of a short-term bond fund. Such investments are not insured by the Federal Deposit Insurance Corporation.

*Short-term bond fund*

The short-term bond fund is classified in 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. At September 30, 2018 and December 31, 2017, the only investment classified as trading securities was the short-term bond fund. Unrealized gain (loss) on trading securities was \$0 and (\$29,430), respectively, for the three and nine months ended September 30, 2018, and \$29,431 and \$58,861 for the three and nine months ended September 30, 2017 and is included in other income, net in the accompanying consolidated statements of operations.

*U.S. Treasuries*

U.S. Treasuries are classified as available-for-sale securities. The Company classifies available-for-sale securities with stated maturities of greater than three months and less than one year from the date of purchase as short-term investments. Available-for-sale securities with stated maturities greater than one year are classified as non-current investments in the accompanying consolidated balance sheets. The Company records available-for-sale securities at fair value with unrealized gains and losses reported in accumulated other comprehensive income (loss) in stockholders equity. Realized gains and losses are included in other income, net and are derived using the specific identification method for determining the cost of securities sold. Interest income is recognized when earned and is included in other income, net in the consolidated statements of operations. The Company recognizes a charge when the declines in the fair value below the amortized cost basis of its available-for-sale securities are judged to be other-than-temporary. The Company considers various factors in determining whether to recognize an other-than-temporary charge, including

whether the Company intends to sell the security or whether it is more likely than not that the Company would be required to sell the security before recovery of the amortized cost basis. The Company has not recorded any other than temporary impairment charges on its available-for-sale securities. See Note 4.

- 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