UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of Earliest Event Reported): November 7, 2018

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware	**001-33057**	**76-0837053**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. 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

Not Applicable
Former Name or Former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this Chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On November 7, 2018, the Company issued a press release announcing its results of operations for the three and nine months ended September 30, 2018 and providing a corporate update. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on November 7, 2018.

SIGNATURES

Pursuant to the requirements of 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 CFO

Dated: November 7, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Announces Third Quarter 2018 Financial Results and Provides Corporate Update

—Company to Host Quarterly Conference Call at 8:30 am ET Tomorrow

CORAL GABLES, Fla., November 7, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today reported financial results for the third quarter ended September 30, 2018 and provided a corporate update.

"We are extremely focused on executing on our launch-readiness plan as we prepare for the potential commercial launch of Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) early next year," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "We were also pleased to announce the expansion of our clinical leadership team with the hiring of Stanley Iyadurai, M.D., Ph.D., as our Vice President of Clinical Development, to assist us in accelerating and managing our clinical programs as we continue to evaluate Firdapse in the treatment of other potential neuromuscular indications. We believe we are well positioned to achieve our vision of positively impacting lives of patients living with rare neuromuscular diseases as we continue to build our rare disease company."

Q3-18 and Other Recent Highlights

- Continued progress with pre-commercialization activities for a potential launch of Firdapse in early 2019
- Appointed Dr. Stanley Iyadurai as VP of Clinical Development
- Recently added three additional medical science liaisons to our medical affairs team
- Number of current FTEs is 37 as compared to 18 at the beginning of this year
- FDA Acceptance of NDA and Priority Review Status for Firdapse for LEMS
- Ended the third quarter with $66.7 million in cash and investments and no debt

Upcoming Milestones

- Prescription Drug User Fee Act (PDUFA) goal date of November 28, 2018 for Firdapse for LEMS
- Potential launch of Firdapse for LEMS in early 2019
- Enroll first patients in SMA Type 3 proof of concept study
- Complete enrollment in CMS Phase 3 trial
- Expect top-line results from Phase 3 CMS (CMS-001) trial in the second half of 2019
- Expect top-line results from Phase 3 trial for MuSK-MG in the second half of 2019

Financial Results

For the quarter ended September 30, 2018, Catalyst reported a GAAP net loss of $7,838,873, or $0.08 per basic and diluted share, compared to a GAAP net loss of $4,177,649, or $0.05 per basic and diluted share, for the same period in 2017. For the third quarter of 2018 and 2017, Non-GAAP[1] net loss was the same as GAAP net loss as there were no Non-GAAP[1] adjustments.

For the nine months ended September 30, 2018, Catalyst reported a GAAP net loss of $19,503,905, or $0.19 per basic and diluted share, as compared to a GAAP net loss of $13,024,679, or $0.16 per basic and diluted share, for the same period in 2017. For the nine months ended September 30, 2018, Non- GAAP[1] net loss was the same as GAAP net loss, as there were no Non-GAAP[1] adjustments. In comparison, Non-GAAP[1] net loss for the first nine months of 2017 was $12,837,775, or $0.15 per basic and diluted share, which excludes non-cash loss of $186,904 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the third quarter of 2018 were $4,538,369 compared to $2,704,923 in the third quarter of 2017. For the nine months ended September 30, 2018, research and development expenses were $11,502,235 as compared to $7,970,603 in the same period in 2017. The increase in research and development expenses for the nine months ended September 30, 2018 when compared to the same period in 2017 is primarily due to increases in consulting expenses as Catalyst prepared to submit its NDA for Firdapse during the first quarter of 2018, milestone expenses relating to the acceptance of Catalyst's NDA submission in May 2018, expenses from Catalyst's medical affairs program, and compensation and related personnel costs as Catalyst expands its headcount to support its currently ongoing trials and programs. Catalyst expects that costs related to research and development activities will continue to be substantial during the balance of 2018 as Catalyst works towards completing trials evaluating Firdapse for the treatment of CMS, MuSK-MG and SMA Type 3, continues its Expanded Access Program for Firdapse and its other development programs, and prosecutes its NDA submission for Firdapse for LEMS.

General and administrative expenses for the third quarter of 2018 totaled $3,644,234 as compared to $1,601,785 in the third quarter of 2017. For the nine months ended September 30, 2018, general and administrative expenses were $8,949,663 as compared to $5,197,247 in the same period in 2017. The increase when compared to the same period in 2017 is primarily due to increases in pre-commercialization expenses and headcount, and corporate expenses as Catalyst builds up its infrastructure and commercial programs in preparation for a potential launch of Firdapse in 2019. Catalyst expects general and administrative expenses, including pre-commercialization expenses, to continue to increase in 2018 as Catalyst continues to expand its operations in preparation for a potential launch of Firdapse in 2019.

As a development-stage biopharmaceutical company, Catalyst had no revenues in either the third quarter of 2018 and 2017 or the first nine months of 2018 and 2017.

At September 30, 2018, Catalyst had cash and investments of $66.7 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through 2019 (without considering revenues and cash receipts that may be received in 2019 if Catalyst is successful in obtaining an approval of Firdapse and launching the product in 2019, of which there can be no assurance).

More detailed financial information and analysis may be found in the Company's Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on November 7, 2018.

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[1] Statements made in this press release include a non-GAAP financial measure. Such information is provided as additional information and not as an alternative to Catalyst's financial statements presented in accordance with U.S. generally accepted accounting principles (GAAP). This non-GAAP financial measure is intended to enhance an overall understanding of Catalyst's current financial performance. Catalyst believes that the non-GAAP financial measure presented in this press release provides investors and prospective investors with an alternative method for assessing Catalyst's operating results in a manner that Catalyst believes is focused on the performance of ongoing operations and provides a more consistent basis for comparison between periods. The non-GAAP financial measure in this press release excludes from the calculation of net loss the expense (or the income) associated with the change in fair value of the liability-classified warrants. Non-GAAP net loss per share is calculated by dividing non-GAAP net loss by the weighted average common shares outstanding.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Thursday, November 8, 2018 to discuss the financial results and provide a corporate update. Investors who wish to participate in the conference call may do so by dialing (877) 407-8912 for domestic and Canadian callers or (201) 689-8059 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the company's website at www.catalystpharma.com and clicking on the webcast link on the Investors home page. A webcast replay will be available on the Catalyst website for 30 days following the call by visiting the Investor page of the company's website at www.catalystpharma.com.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis and spinal muscular atrophy (SMA) type 3. Firdapse® (amifampridine phosphate) has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LEMS and Orphan Drug Designation for LEMS, CMS and myasthenia gravis. Firdapse is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing a generic version of Sabril® (vigabatrin).

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including (i) whether Firdapse will ever be approved for commercialization, (ii) whether, even if Firdapse is approved for commercialization, Catalyst will be successful in commercializing Firdapse, (iii) whether Catalyst will be the first company to receive an approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, and (iv) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2017 and its other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (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

CATALYST PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (unaudited)	December 31, 2017
ASSETS		
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
LIABILITIES AND STOCKHOLDERS' EQUITY		
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
Total stockholders' equity	64,076,598	80,963,812
Total liabilities and stockholders' equity	$67,709,813	$85,387,430