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 8, 2017

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 8, 2017, the Company issued a press release announcing its results of operations for the three and nine months ended September 30, 2017 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 8, 2017.

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 8, 2017

Exhibit 99.1

Catalyst Pharmaceuticals Announces Third Quarter 2017 Financial Results and Provides Corporate Update

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

CORAL GABLES, Fla., November 8, 2017 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (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, 2017 and provided a corporate update.

“We have made significant progress over the past three months across our clinical programs for Firdapse®, including completing enrollment in LMS-003, our second Phase 3 study in Lambert-Eaton myasthenic syndrome (LEMS) patients, adding additional sites for our Phase 3 study in patients with congenital myasthenic syndromes (CMS), as well as preparation for the launch of the antibody positive MuSK myasthenia gravis (MuSK-MG) study that is expected to commence in early 2018,” said Patrick J. McEnany, Chief Executive Officer of Catalyst Pharmaceuticals, Inc. “We look forward to announcing top-line results for the LMS-003 study in early December of this year, and we remain focused on preparing our NDA resubmission for Firdapse as well as refining our pre-commercial launch activities for Firdapse.”

Q3 and Recent Highlights

- Announced completion of enrollment in second Phase 3 trial in LEMS
- Announced successful completion of required Abuse Liability Studies for Firdapse
- FDA granted Special Protocol Assessment agreement for Phase 3 MuSK-MG trial
- Restarted pre-commercialization activities for a potential late 2018/early 2019 launch of Firdapse
- Ended the third quarter with $33.9 million in cash and investments and no debt

Upcoming Milestones

- Expect top-line results from second Phase 3 trial for LEMS in early December 2017
- Initiate MuSK-MG Phase 3 trial in the first quarter of 2018 (www.clinicaltrials.gov)
- NDA resubmission for Firdapse expected in the first quarter of 2018
- Complete enrollment in CMS-001 clinical trial for CMS patients
- Expect top-line results from CMS-001 trial in the first half of 2018

Third Quarter 2017 Financial Results

For the quarter ended September 30, 2017, Catalyst reported a GAAP net loss of $4,177,649, or $0.05 per basic and diluted share, compared to a GAAP net loss of $3,953,981, or $0.05 per basic and diluted share, for the same period in 2016. Non-GAAP[1] net loss was the same as GAAP net loss for the quarter ended September 30, 2017, as there were no Non-GAAP[1] adjustments in the third quarter of 2017. Non-GAAP[1] net loss for the third quarter of 2016 was $3,847,033, or $0.05 per basic and diluted share, which excludes a non-cash loss of $106,948 attributable to the change in fair value of liability-classified warrants.

For the nine months ended September 30, 2017, Catalyst reported a GAAP net loss of $13,024,679, or $0.16 per basic and diluted share, as compared to a GAAP net loss of $13,909,132, or $0.17 per basic and diluted share, for the same period in 2016. Excluding non-cash expense of $186,904 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss for the first nine months of 2017 was $12,837,775 or $0.15 per basic and diluted share. In comparison, Non-GAAP[1] net loss for the first nine months of 2016 was $14,688,323, or $0.18 per basic and diluted share, which excludes a non-cash gain of $779,191 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the third quarter of 2017 were $2,704,923 compared to $2,493,999 in the third quarter of 2016. For the nine months ended September 30, 2017, research and development expenses were $7,970,603 as compared to $8,549,287 in the same period in 2016. Research and development expenses for the first nine months of 2017 continued to be substantial as the Company continued its ongoing trials evaluating Firdapse for the treatment of LEMS and CMS. The Company expects that costs related to research and development activities will continue to be substantial throughout the balance of 2017 and into 2018 as it continues its clinical studies and trials and works to resubmit an NDA for Firdapse.

General and administrative (G&A) expenses for the third quarter of 2017 totaled $1,601,785 as compared to $1,420,015 in the third quarter of 2016. For the nine months ended September 30, 2017, general and administrative expenses were $5,197,247 as compared to $6,416,715 in the same period in 2016. The 2017 decrease when compared to the same period in 2016 is primarily due to decreased employee costs resulting from a reduction in headcount, and a decrease in recruiting expenses and consulting costs for pre-commercialization activities, as part of our initiatives to conserve cash. The Company expects general and administrative expenses, excluding pre-commercialization expenses, to remain consistent for the balance of 2017. The Company also expects pre-commercialization expenses (which are reported in G&A) to increase in the fourth quarter of 2017 now that the Company has recommenced its efforts to develop a commercialization plan for Firdapse.

As a development-stage biopharmaceutical company, Catalyst had no revenues in either the third quarter of 2017 and 2016 or the first nine months of 2017 and 2016.

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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 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.

At September 30, 2017, Catalyst had cash and cash equivalents and short-term investments of $33.9 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through at least the next 12 months.

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 8th, 2017.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EST on Thursday, November 9th, 2017 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 infantile spasms. Firdapse® 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 CPP-115 to treat refractory infantile spasms, and possibly refractory Tourette's Disorder. CPP-115 has been granted U.S. Orphan Drug Designation for the treatment of infantile spasms by the FDA and has been granted E.U. Orphan Medicinal Product Designation for the treatment of West syndrome by the European Commission. In addition, Catalyst is 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 whether the receipt of breakthrough therapy designation for Firdapse will expedite the development and review of Firdapse by the FDA or the likelihood that the product will be found to be safe and effective, the timing of Catalyst's second trial evaluating Firdapse for the treatment of LEMS and whether the trial will be successful, whether any additional abuse liability studies of Firdapse will be required by the FDA before Catalyst can resubmit an NDA for Firdapse, whether Catalyst's assumptions as to the availability of funding to meet its anticipated working capital requirements in future periods will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements, what clinical trials and studies will be required

before Catalyst can resubmit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether any NDA for Firdapse resubmitted to the FDA will ever be accepted for filing, the timing of any such NDA filing or acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether Catalyst can successfully complete a registration trial evaluating Firdapse for the treatment of MuSK-MG that is acceptable to the FDA, whether any such future trial evaluating Firdapse for the treatment of MuSK-MG will be successful, whether Catalyst has sufficient funding to complete such a trial, whether Firdapse will ever be approved for commercialization, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, what additional testing will be required before CPP-115 is "Phase 2 ready", whether CPP-115 will be determined to be effective for the treatment of refractory infantile spasms or possibly Tourette's Disorder or for any other indications, whether Catalyst can successfully design and complete a bioequivalence study of its 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 ANDA that Catalyst submits for a generic version of Sabril will be accepted for filing, whether any ANDA for Sabril accepted for filing by the FDA will be approved (and the timing of any such approval), whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2016 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,	
	2017	2016	2017	2016
Operating costs and expenses:				
Research and development	$ 2,704,923	$ 2,493,999	$ 7,970,603	$ 8,549,287
General and administrative	1,601,785	1,420,015	5,197,247	6,416,715
Total operating costs and expenses	4,306,708	3,914,014	13,167,850	14,966,002
Loss from operations	(4,306,708)	(3,914,014)	(13,167,850)	(14,966,002)
Other income, net	129,059	66,981	330,075	277,679
Change in fair value of warrants liability	—	(106,948)	(186,904)	779,191
Loss before income taxes	(4,177,649)	(3,953,981)	(13,024,679)	(13,909,132)
Provision for income taxes	—	—	—	—
Net loss	$ (4,177,649)	$ (3,953,981)	$(13,024,679)	$(13,909,132)
Net loss per share – basic and diluted	$ (0.05)	$ (0.05)	$ (0.16)	$ (0.17)
Weighted average shares outstanding – basic and diluted	84,797,969	82,870,649	83,898,724	82,867,140

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,328,984	$13,893,064
Short-term investments	26,577,501	26,512,753
Prepaid expenses and other current assets	510,492	1,047,944
Total current assets	34,416,977	41,453,761
Property and equipment, net	205,450	244,204
Deposits	8,888	8,888
Total assets	$34,631,315	$41,706,853
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,081,608	$ 933,176
Accrued expenses and other liabilities	1,655,986	1,161,359
Total current liabilities	2,737,594	2,094,535
Accrued expenses and other liabilities, non-current	164,516	181,162
Warrants liability, at fair value	—	122,226
Total liabilities	2,902,110	2,397,923
Total stockholders' equity	31,729,205	39,308,930
Total liabilities and stockholders' equity	$34,631,315	$41,706,853