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 9, 2015

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) 529-2522

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))

Item 8.01 Other Events

On November 9, 2015, the Company issued a press release announcing its results of operations for the three and nine months ended September 30, 2015. 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 9, 2015.

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 9, 2015

Exhibit 99.1

Catalyst Pharmaceuticals Announces Third Quarter 2015 Financial Results and Provides Corporate Update

- Company to host quarterly conference call at 8:30am ET tomorrow

CORAL GABLES, Fla., Nov 9, 2015 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today reported financial results for the third quarter and nine months ended September 30, 2015.

“The third quarter was a very productive period for the Catalyst team, with the initiation of the rolling submission of our New Drug Application for the use of Firdapse® in the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS)”, said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. “We expect to complete the submission this quarter and at that time will be requesting a priority review.”

Mr. McEnany added, “We continue to advance our preparations for the planned commercial launch of Firdapse to treat LEMS, and we remain focused on additional development efforts with Firdapse as a potential therapy for other neuromuscular diseases that represent unmet medical needs.”

Q3 and Recent Highlights:

- Initiated rolling NDA submission for Firdapse for the treatment of LEMS
- Appointed Paul J. Merrigan as Chief Commercial Officer
- Development and advancement of comprehensive commercialization and pre-launch plan for Firdapse
- Announced intent to develop generic equivalent of Sabril® (vigabatrin)
- Announced a blinded clinical trial for pediatric patients with congenital myasthenic syndromes (CMS)
- Announced notice of allowance of a U.S. patent application for the method of treating Tourette’s Disorder with GABA aminotransferase inactivators
- Announced poster presentation on results from the Tourette’s investigator sponsored study at 62nd Annual Meeting of the American Academy of Child and Adolescent Psychiatry

Upcoming 2015 Milestones:

- Expected completion of NDA submission of Firdapse for the treatment of LEMS during this quarter
- Announcement of topline results from a Phase 1(b) multiple dose safety and tolerance study for CPP-115 during this quarter
- Developing additional data to support use of Firdapse in the treatment of certain types of CMS
- Exploration of additional indications for Firdapse including a subset of Myasthenia Gravis (antibody positive MuSK)

Financial Results

For the quarter ended September 30, 2015, Catalyst reported a GAAP net loss of $4,449,038, or 5 cents per basic and diluted share, compared to a GAAP net loss of $5,009,892, or 7 cents per basic and diluted share, for the same period in 2014. Excluding a non-cash gain of $521,731 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $4,970,769 or 6 cents per basic and diluted share for the third quarter of 2015. In comparison, Non-GAAP[1] net loss for the third quarter of 2014 was $4,103,105, or 6 cents per basic and diluted share, which excludes non-cash expense of $906,787 attributable to the change in fair value of liability-classified warrants.

For the nine months ended September 30, 2015, Catalyst reported a GAAP net loss of $14,417,800, or 18 cents per basic and diluted share, compared to a GAAP net loss of $12,019,031, or 19 cents per basic and diluted share, for the same period in 2014. Excluding non-cash expense of $324,591 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $14,093,209 or 18 cents per basic and diluted share for the first nine months of 2015. In comparison, Non-GAAP[1] net loss for the first nine months of 2014 was $10,553,139, or 17 cents per basic and diluted share, which excludes non-cash expense of $1,465,892 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the third quarter of 2015 were $3,042,671 compared to $2,885,892 in the third quarter of 2014. For the nine months ended September 30, 2015 research and development expenses were $7,969,731 compared to $7,733,533 in the same period in 2014. Research and development expenses increased when compared to the same period in 2014 as we increased activities related to our NDA filing for Firdapse and ongoing studies and trials and decreased activities related to our completed Phase 3 trial for Firdapse. We expect that our research and development spend for the rest of the year will increase as we prepare for and submit our NDA for Firdapse and as we increase activities in other ongoing studies and trials.

General and administrative expenses for the third quarter of 2015 totaled $1,974,757 compared to $1,223,137 in the third quarter of 2014. For the nine months ended September 30, 2015 general and administrative expenses were $6,236,942 as compared to $2,874,034 in the same period in 2014.The increase when compared to the same period in 2014 is primarily due to increases in pre-commercialization expenses and headcount, in preparation for the future commercialization of Firdapse.

As a development-stage biopharmaceutical company, Catalyst had no revenues in the third quarter of 2015 and 2014 or the first nine months of 2015 and 2014.

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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, 2015, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of $63.0 million and no debt. This includes proceeds from our February 2015 offering in which we sold 11.5 million shares of our common stock, and raised net proceeds of approximately $34.9 million, and proceeds from stock option and warrant exercises during 2015. We believe that these resources give us sufficient runway through anticipated approval and subsequent product launch of Firdapse, assuming approval in 2016.

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 9, 2015.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EST on Tuesday, November 10, 2015 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 diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), infantile spasms, and Tourette's Disorder. Catalyst's lead candidate, Firdapse for the treatment of LEMS, recently completed testing in a global, multi-center, pivotal Phase 3 trial resulting in positive top-line data. Firdapse for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and orphan drug designations for LEMS and CMS. Firdapse is the first and only European approved drug for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and 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, what clinical trials and studies will be required before Catalyst can submit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether an NDA for Firdapse will ever be accepted for filing by the FDA, 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 will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, 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 spasm, post-traumatic stress disorder, Tourette's Disorder or 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 files 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 2014 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.

Investor Contact
Brian Korb
The Trout Group LLC
(646) 378-2923
bkorb@troutgroup.com

Company Contact
Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 529-2522
pmcenany@catalystpharma.com

Media Contacts
David Schull
Matt Middleman, M.D.
Russo Partners
(212) 845-4271
(212) 845-4272
david.schull@russopartnersllc.com
matt.middleman@russopartnersllc.com

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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,	
	2015	2014	2015	2014
Operating costs and expenses:				
Research and development	$ 3,042,671	$ 2,885,892	$ 7,969,731	$ 7,733,533
General and administrative	1,974,757	1,223,137	6,236,942	2,874,034
Total operating costs and expenses	5,017,428	4,109,029	14,206,673	10,607,567
Loss from operations	(5,017,428)	(4,109,029)	(14,206,673)	(10,607,567)
Other income, net	46,659	5,924	113,464	54,428
Change in fair value of warrants liability	521,731	(906,787)	(324,591)	(1,465,892)
Loss before income taxes	(4,449,038)	(5,009,892)	(14,417,800)	(12,019,031)
Provision for income taxes	—	—	—	—
Net loss	$ (4,449,038)	$ (5,009,892)	$(14,417,800)	$(12,019,031)
Net loss per share – basic and diluted	$ (0.05)	$ (0.07)	$ (0.18)	$ (0.19)
Weighted average shares outstanding – basic and diluted	82,470,139	67,169,383	80,205,864	62,539,571

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$32,750,459	$ 9,096,778
Certificates of deposit	3,716,823	3,715,383
Short-term investments	26,495,033	26,462,962
Prepaid expenses and other current assets	1,393,918	4,552,698
Total current assets	64,356,233	43,827,821
Property and equipment, net	197,635	71,377
Deposits	8,888	8,888
Total assets	$64,562,756	$43,908,086
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 817,021	$ 1,814,210
Accrued expenses and other liabilities	1,569,166	4,040,816
Total current liabilities	2,386,187	5,855,026
Accrued expenses and other liabilities, non-current	128,885	15,839
Warrants liability, at fair value	1,397,959	2,794,891
Total liabilities	3,913,031	8,665,756
Total stockholders' equity	60,649,725	35,242,330
Total liabilities and stockholders' equity	$64,562,756	$43,908,086