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): August 9, 2016

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))

Item 8.01 Other Events

On August 9, 2016, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2016 and providing a product development 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 August 9, 2016.

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: August 9, 2016

Exhibit 99.1

Catalyst Pharmaceuticals Announces Second Quarter 2016 Financial Results and Provides Product Development Update

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

CORAL GABLES, Fla., August 9, 2016 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today reported financial results for the second quarter and six months ended June 30, 2016 and provided a product development update.

"We were pleased to have reached agreement with the FDA during the quarter on the clinical trial protocol for our second pivotal Phase 3 trial for Firdapse® in the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS)", said Patrick J. McEnany, Chief Executive Officer of Catalyst. "We expect to initiate a small, efficient short term study with Firdapse during the second half of 2016, as we continue to expend additional research dollars studying other potential neuromuscular indications for Firdapse. As stated previously, we believe that our existing capital resources are adequate to get us to an accepted NDA submission without the need for additional financing."

Q2 and Recent Highlights

- Agreement with FDA on a second Phase 3 Study Protocol for Firdapse in LEMS
- Publication of detailed results from the LMS-002 Phase 3 study of Firdapse in patients with LEMS in the May 2016 issue of *Muscle & Nerve* authored by Dr. Shin Oh, et al.
- Operating expense management plan to align resources is now complete
- Ended June 30, 2016 with approximately $48 million in cash and investments and no debt

PRODUCT DEVELOPMENT UPDATE

Firdapse for LEMS NDA resubmission plan

- Finalizing logistics to launch a small, efficient short-term second Phase 3 trial in the fourth quarter 2016
- Have met with most of our key opinion leaders and they are fully supportive of our plan for the second Phase 3 trial
- Anticipate having two clinical trial sites, one each on the east and west coasts of the U.S.
- Anticipate enrolling up to 24 subjects, utilizing a cross-over design that we believe will be adequately powered
- The trial will have the same co-primary endpoints as the first Phase 3 trial (LMS-002)
- FDA is permitting us to enroll subjects currently participating in our Expanded Access Program
- Expect top-line data and an NDA resubmission (assuming favorable data) in the second half of 2017

Firdapse for Congenital Myasthenic Syndromes (CMS)

- Phase 3 trial currently underway and continues to identify and recruit patients at four sites

- Based on discussions with the FDA, the study is being expanded to include adult CMS patients in addition to the pediatric population and to expand the total subjects in this trial to approximately 20 patients
- FDA is currently reviewing amended protocol and statistical analysis plan
- Expect top-line data in the second half of 2017
- Assuming favorable data, we plan to include CMS in our NDA resubmission or as a supplement to the NDA
- Patients will be eligible to enroll in our Expanded Access Program at the completion of the study

Firdapse for MuSK antibody positive Myasthenia Gravis

- Approximately 5-8% of the Myasthenia Gravis patient population is estimated to be MuSK antibody positive
- Small phase 3 investigator-sponsored study currently underway at the Carlo Besta Neurological Institute in Milan, Italy
- Anticipate top line data in early 2017
- Assuming positive data from current study, we plan to initiate a registration-quality trial in the U.S.
- We have submitted a Special Protocol Assessment request to the FDA for the proposed U.S. based trial

CPP-115 (next generation GABA-AT inhibitor)

- Additional dose optimization studies are required
- Other studies required to make CPP-115 “Phase 2 ready” include: long-term toxicology studies in two species; development and reproductive toxicology; and additional ADME studies
- Current cash resources are devoted to advancing Firdapse, as a result we are in discussions with several potential partners for the continued development of CPP-115

Generic Sabril® (generic ingredient vigabatrin)

- Sabril marketed in U.S. by Lundbeck, and all Hatch-Waxman exclusivities expire by April 2017
- Indicated for the treatment of refractory complex partial seizures and infantile spasms
- As of July 21, 2016 FDA has relaxed the requirements under the REMS program for physicians to prescribe Sabril
- U.S. Sabril sales in 2015 as reported were approximately $144 million up 15% from 2014
- Based on currently available information, Catalyst is hopeful that any ANDA submission that it makes for this product will be one of the first ANDA’s submitted for a generic version of Sabril

Financial Results

For the quarter ended June 30, 2016, Catalyst reported a GAAP net loss of $4,568,914 or 6 cents per basic and diluted share, as compared to a GAAP net loss of $4,558,503 or 6 cents per basic and diluted share, for the same period in 2015. Excluding non-cash gain of $152,783 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $4,721,697 or 6 cents per basic and diluted share for the second quarter of 2016. In comparison, Non-GAAP[1] net loss for the second quarter of 2015 was $4,892,459 or 6 cents per basic and diluted share, which excludes non-cash gain of $333,956 attributable to the change in fair value of liability-classified warrants.

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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.

For the six months ended June 30, 2016, Catalyst reported a GAAP net loss of $9,955,151, or 12 cents per basic and diluted share, as compared to a GAAP net loss of $9,968,762, or 13 cents per basic and diluted share, for the same period in 2015. Excluding non-cash gain of $886,139 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $10,841,290 or 13 cents per basic and diluted share for the first six months of 2016. In comparison, Non-GAAP[1] net loss for the first six months of 2015 was $9,122,440, or 12 cents per basic and diluted share, which excludes non-cash expense of $846,322 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the second quarter of 2016 were $2,508,897 as compared to $2,577,508 in the second quarter of 2015. For the six months ended June 30, 2016, research and development expenses were $6,055,288 as compared to $4,927,060 in the same period in 2015. Research and development expenses for the first six months of 2016 increased when compared to the same period in 2015, due primarily to consulting fees relating to regulatory matters, activities related to the Firdapse expanded access program, including manufacturing of related drug, and increased activities in ongoing studies and trials. We expect that costs related to research and development activities will continue to be substantial throughout the balance of 2016 and into 2017.

General and administrative expenses for the second quarter of 2016 totaled $2,305,555 as compared to $2,319,822 in the second quarter of 2015. For the six months ended June 30, 2016, general and administrative expenses were $4,996,700 as compared to $4,262,185 in the same period in 2015. The increase when compared to the same period in 2015 is primarily due to increases in pre-commercialization expenses, payroll and benefits expenses during the first half of 2016, including approximately $600,000 for severance costs related to the reduction in force that occurred in May 2016, partly offset by our initiatives to conserve resources. We expect general and administrative expenses to decrease during the remainder of 2016 as we continue taking steps to conserve our available resources.

As a development-stage biopharmaceutical company, Catalyst had no revenues in the second quarter of 2016 and 2015 or the first six months of 2016 and 2015.

At June 30, 2016, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of $48.0 million and no debt. Catalyst believes that these resources give it sufficient runway for at least the next year. However, until Catalyst finalizes the details and logistics of its required confirmatory study evaluating Firdapse for the treatment of LEMS, it will be difficult for Catalyst to provide more details regarding how far its existing resources will take it. Notwithstanding, and while there can be no assurance, Catalyst continues to believe that its currently available resources will be sufficient to complete the development of Firdapse and get to an accepted NDA submission for Firdapse without the need for additional financing.

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), August 9th, 2016

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET on Wednesday, August 10, 2016 to discuss the financial results and provide a product development 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. Firdapse for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and orphan drug designation for LEMS and CMS. 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 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 study design for a second trial evaluation Firdapse for the treatment of LEMS will be acceptable to the FDA, the timing of such trial, and whether it will be successful, whether Catalyst's assumptions in its updated business plan will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements and on Catalyst's ability to get to an accepted NDA submission for Firdapse without the need for additional funding, 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 the investigator-sponsored study evaluating Firdapse for the treatment of MuSK-MG 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 Firdapse will ever be approved for commercialization, 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, 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 infantile spasms, 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 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 2015 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.

STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2016	2015	2016	2015
Operating costs and expenses:				
Research and development	$ 2,508,897	$ 2,577,508	$ 6,055,288	$ 4,927,060
General and administrative	2,305,555	2,319,822	4,996,700	4,262,185
Total operating costs and expenses	4,814,452	4,897,330	11,051,988	9,189,245
Loss from operations	(4,814,452)	(4,897,330)	(11,051,988)	(9,189,245)
Other income, net	92,755	4,871	210,698	66,805
Change in fair value of warrants liability	152,783	333,956	886,139	(846,322)
Loss before income taxes	(4,568,914)	(4,558,503)	(9,955,151)	(9,968,762)
Provision for income taxes	—	—	—	—
Net loss	$ (4,568,914)	$ (4,558,503)	$ (9,955,151)	$ (9,968,762)
Net loss per share – basic and diluted	$ (0.06)	$ (0.06)	$ (0.12)	$ (0.13)
Weighted average shares outstanding – basic and diluted	82,870,649	82,037,560	82,865,366	79,054,960

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$18,717,104	$28,235,016
Certificates of deposit	2,767,946	3,717,229
Short-term investments	26,537,413	26,444,150
Prepaid expenses and other current assets	650,977	1,504,738
Total current assets	48,673,440	59,901,133
Property and equipment, net	258,518	191,549
Deposits	8,888	8,888
Total assets	$48,940,846	$60,101,570
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 707,292	$ 1,794,127
Accrued expenses and other liabilities	1,598,165	1,646,476
Total current liabilities	2,305,457	3,440,603
Accrued expenses and other liabilities, non-current	188,032	176,293
Warrants liability, at fair value	122,224	1,008,363
Total liabilities	2,615,713	4,625,259
Total stockholders' equity	46,325,133	55,476,311
Total liabilities and stockholders' equity	$48,940,846	$60,101,570