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): May 10, 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 May 10, 2016, the Company issued a press release announcing its results of operations for the quarter ended March 31, 2016 and providing a coprorate 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 May 10, 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: May 10, 2016

Catalyst Pharmaceuticals Announces First Quarter 2016 Financial Results and Provides Corporate Update

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

CORAL GABLES, Fla., May 10, 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 first quarter ended March 31, 2016.

"This past quarter has been very challenging, as we were very disappointed by the receipt of the refusal to file letter from the U.S. Food and Drug Administration (FDA) for the Firdapse® new drug application (NDA)," said Patrick J. McEnany, Chief Executive Officer of Catalyst. "While we are frustrated by the delay, our focus remains to provide the FDA with the additional studies required to file our NDA for review and to hopefully ensure that all LEMS patients have access to an FDA approved safe and effective therapy. We are currently engaged in dialogue with the FDA with regard to logistics required for our path forward and will provide an update once we have more clarity."

Q1 and Recent Highlights

- Met with the FDA to discuss and define a regulatory pathway forward for the Firdapse NDA
- Appointed Brian Elsbernd as Senior Vice President of Legal and Compliance
- Announced initiation of investigator-sponsored study of Firdapse in patients with MuSK-antibody positive Myasthenia Gravis
- Ended March 31, 2016 with $52.5 million in cash and investments and no debt

Upcoming 2016 Milestones

- Collaboratively working with the FDA to finalize a regulatory path forward for Firdapse
- Initiate the confirmatory Phase 3 trial for Firdapse to treat Lambert-Eaton myasthenic syndrome (LEMS)
- Evaluate our operating plan once the path forward to refile an NDA for Firdapse is determined, with a goal of completing the development of Firdapse and refiling an NDA using our current financial resources
- Continue to identify and recruit patients for the ongoing study evaluating Firdapse in the treatment of patients with congenital myasthenic syndromes (CMS)
- Continue to support an investigator-sponsored study evaluating Firdapse for the treatment of MuSK antibody positive Myasthenia Gravis
- Ongoing development of generic equivalent of Sabril® (vigabatrin)
- Continue to evaluate the pharmacological properties of CPP-115, subject to the availability of funding

Financial Results

For the quarter ended March 31, 2016, Catalyst reported a GAAP net loss of $5,386,237, or $0.07 per basic and diluted share, compared to a GAAP net loss of $5,410,259, or $0.07 per basic and diluted share, for the same period in 2015. Excluding the non-cash gain of $733,356 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $6,119,593 or $0.07 per basic and diluted share for the first quarter of 2016. In comparison, Non-GAAP[1] net loss for the first quarter of 2015 was $4,229,981, or $0.06 per basic and diluted share, which excludes non-cash expense of $1,180,278 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the first quarter of 2016 were $3,546,391 compared to $2,349,552 in the first quarter of 2015. Research and development expenses increased when compared to the same period in 2015 due primarily to consulting on regulatory matters, activities related to Firdapse expanded access program, including manufacturing of the related drug, and increased activities in other ongoing studies and trials.

General and administrative expenses for the first quarter of 2016 totaled $2,691,145 compared to $1,942,363 in the first quarter of 2015. The increase when compared to the same period in 2015 is primarily due to increases in pre-commercialization expenses, payroll and benefit expenses.

As a development-stage specialty pharmaceutical company, Catalyst had no revenues in either the first quarter of 2016 or the first quarter of 2015.

At March 31, 2016, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of $52.5 million and no debt. We believe that these resources give us sufficient runway for at least the next year. However, until the details and logistics of the required confirmatory study evaluating Firdapse for the treatment of LEMS are finalized, we cannot provide more details regarding how far our existing resources will take us. Notwithstanding, and while there can be no assurance, we continue to believe that our currently available resources will be sufficient to complete the development of Firdapse and refile an NDA for Firdapse.

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 May 10, 2016.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EDT on Wednesday, May 11, 2016 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. Firdpase 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 drug approved in Europe for symptomatic treatment in adults with LEMS.

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.

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 evaluating Firdapse for the treatment of LEMS will be acceptable to the FDA, the timing of such trial, and whether such trial will be successful, 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 Firdapse will 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 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 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 March 31,	
	2016	2015
Revenues	$ —	$ —
Operating costs and expenses:		
Research and development	3,546,391	2,349,552
General and administrative	2,691,145	1,942,363
Total operating costs and expenses	6,237,536	4,291,915
Loss from operations	(6,237,536)	(4,291,915)
Other income, net	117,943	61,934
Change in fair value of warrants liability	733,356	(1,180,278)
Loss before income taxes	(5,386,237)	(5,410,259)
Provision for income taxes	—	—
Net loss	$ (5,386,237)	$ (5,410,259)
Net loss per share – basic and diluted	$ (0.07)	$ (0.07)
Weighted average shares outstanding – basic and diluted	82,860,083	76,039,220

CATALYST PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$22,227,962	$28,235,016
Certificates of deposit	3,717,599	3,717,229
Short-term investments	26,509,351	26,444,150
Prepaid expenses and other current assets	1,023,892	1,504,738
Total current assets	53,478,804	59,901,133
Property and equipment, net	178,351	191,549
Deposits	8,888	8,888
Total assets	$53,666,043	$60,101,570
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,251,473	$ 1,794,127
Accrued expenses and other liabilities	1,412,314	1,646,476
Total current liabilities	2,663,787	3,440,603
Accrued expenses and other liabilities, non-current	190,471	176,293
Warrants liability, at fair value	275,007	1,008,363
Total liabilities	3,129,265	4,625,259
Total stockholders' equity	50,536,778	55,476,311
Total liabilities and stockholders' equity	$53,666,043	$60,101,570