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): April 26, 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) 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 April 26, 2016, the Company issued a press release providing an update on the content of the planned resubmission of a New Drug Application (NDA) for Firdapse® (amifampridine phosphate). The Company recently met with the Food and Drug Administration (FDA) to obtain greater clarity regarding what will be required by the FDA to accept the Firdapse® NDA for filing. The FDA has stated that, in addition to the results of the Company's previously submitted multi-center, randomized, placebo-controlled Phase 3 trial, the Company will need to submit positive results from an additional adequate and well-controlled study in patients with Lambert-Eaton Myasthenic Syndrome (LEMS). The FDA has stated that it is open to discuss a study design that could effectively accomplish the requirement with a small, short-term study, and the Company is currently in discussions with the FDA, and with the Company's clinical experts, regarding the protocol and logistics for this confirmatory study. Additionally, there is a requirement for several more short-term toxicology studies, which are expected to start soon.

The Company also reported that at March 31, 2016, it had approximately $52 million in cash and cash equivalents, certificates of deposit and short term investments, and that it believes it has the cash resources required to complete the additional studies, as well as funding operations.

A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on April 26, 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: April 26, 2016

Exhibit 99.1

Catalyst Pharmaceuticals Provides Regulatory Update on Firdapse

CORAL GABLES, Fla., April 26, 2016 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today provided an update on the content of the planned resubmission of the New Drug Application ("NDA") for Firdapse® (amifampridine phosphate), which currently has Breakthrough Therapy and Orphan Drug designations for Lambert-Eaton myasthenic syndrome (LEMS). Catalyst recently met with the Food and Drug Administration ("FDA") to obtain greater clarity regarding what will be required by the FDA to accept the Firdapse NDA for filing.

The FDA has stated that in addition to the results of the submitted multi-center, randomized, placebo-controlled, Phase 3 LMS-002 trial, the Company will need to submit positive results from an additional adequate and well-controlled study in patients with LEMS. The FDA has stated that it is open to discuss a study design that could efficiently accomplish the requirement with a small, short-term study. Additionally, there is a requirement for several more short-term toxicology studies, which are expected to start soon.

"While we are very disappointed by this delay, Catalyst and our employees remain committed to working with the FDA and bringing Firdapse to market for patients suffering with LEMS and congenital myasthenic syndromes (CMS). We are surprised with the FDA's request for an additional clinical study for Firdapse, but are encouraged that the agency is open to an efficient, small short-term study design. We are currently in discussions with the FDA, and our clinical experts regarding the protocol and logistics for this confirmatory study," stated Patrick J, McEnany, Chief Executive Officer of Catalyst. "As always, we remain committed to LEMS and CMS patients with our continued research and our expanded access program, which continues to enroll new patients and provide Firdapse at no charge to eligible patients."

Catalyst is also continuing the development of Firdapse for additional indications and has recently initiated an investigator-sponsored study of Firdapse in patients with MuSK-Antibody Positive Myasthenia Gravis. This year the company also expects to complete a clinical trial of Firdapse for pediatric patients with CMS.

As of March 31, 2016 the company had approximately $52 million in cash and investments. The Company believes that it has the cash resources required to complete the additional studies, as well as funding operations. Catalyst will announce first quarter financial results and provide further updates by conference call on May 10, 2016.

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 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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