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): October 6, 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 CFR 240.14d-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 October 6, 2015, the Company issued a press release announcing the initiation of a clinical trial with Firdapse® in pediatric patients with congenital myasthenic syndromes (CMS). Firdapse has received Breakthrough Therapy Designation from the FDA for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS), as well as orphan drug designations for LEMS and CMS.

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 October 6, 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: October 6, 2015

Exhibit 99.1

Catalyst Pharmaceuticals Announces a Clinical Trial for Pediatric Patients with Congenital Myasthenic Syndromes

CORAL GABLES, Fla., Oct. 06, 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 announced a clinical trial with Firdapse® (amifampridine phosphate) in pediatric patients with congenital myasthenic syndromes (CMS). Firdapse has received Breakthrough Therapy Designation from the FDA for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS), as well as orphan drug designations for LEMS and CMS.

Patrick J. McEnany, Catalyst's Chief Executive Officer said, "We continue to work towards the completion of our rolling submission of the NDA for Firdapse, which, as previously announced, we expect to complete during the fourth quarter of 2015. Our initial NDA submission will include data and information on the benefits of Firdapse for certain types of CMS and will request that CMS be included in our label for Firdapse. Our initial NDA submission will also include the positive results seen to date in children with CMS who are currently being treated with Firdapse under an investigator treatment IND."

Dr. Steven Miller, Catalyst's Chief Operating Officer and Chief Scientific Officer said, "With regard to our development plan for CMS, in addition to an investigator sponsored IND, we have initiated a small blinded clinical trial in the pediatric CMS population, ages 2 to 17. When the data from this new study is available, we intend to amend our NDA filing with these data. The design of this new study is based on the guidance that the FDA provided to us during our pre-NDA meeting in early 2015. Several academic institutions have been recruited for this new trial. We expect to complete this study by April of next year and at that time participants in this study may continue to receive Firdapse through our Expanded Access Program."

Additional information about this trial (NCT02562066) can be found on www.clinicaltrials.gov.

About Congenital Myasthenic Syndromes

Congenital myasthenic syndromes, or CMS, is a rare neuromuscular disease comprising a spectrum of genetic defects and is characterized by fatigable weakness of skeletal muscles with onset at or shortly after birth or early childhood; in rare cases symptoms may not manifest themselves until later in childhood. The severity and course of the disease are variable, ranging from minor symptoms to progressive disabling weakness; symptoms may be mild, but sudden severe exacerbations of weakness or even sudden episodes of respiratory insufficiency also occur.

Congenital myasthenic syndrome(s) is rare, estimated at one-tenth that of myasthenia gravis, which in itself is rare. Based on currently available information, we estimate that there are between 1,000 and 1,500 CMS patients in the United States.

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 designation 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.

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.

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