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): February 8, 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 February 8, 2016, the Company issued a press release announcing the initiation of an investigator-sponsored adequate and well-controlled clinical trial evaluating safety, tolerability and potential efficacy of Firdapse® as a symptomatic treatment for patients with MuSK-antibody positive myasthenia gravis (MuSK-MG).

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 February 8, 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: February 8, 2016

Catalyst Pharmaceuticals Announces Initiation of Investigator-Sponsored Study of Firdapse in Patients with MuSK-Antibody Positive Myasthenia Gravis

CORAL GABLES, Fla., February 8, 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 announced the initiation of an investigator-sponsored, adequate and well-controlled clinical trial evaluating safety, tolerability and efficacy of Firdapse® (amifampridine phosphate) as a symptomatic treatment for patients with MuSK-antibody positive myasthenia gravis (MuSK-MG).

The study will be conducted by a team of researchers led by Renato Mantegazza, MD, Director, Department of Neuroimmunology and Neuromuscular Diseases, Fondazione Istituto Neurologico Carlo Besta in Milan, Italy, a major referral center for MuSK-MG patients. The study is designed as a randomized (1:1), double-blind, placebo-controlled, crossover, outpatient study to evaluate the safety, tolerability and potential efficacy of amifampridine in patients diagnosed with MuSK-MG. The study is planned to include approximately 20 male and female patients, and Catalyst anticipates reporting top-line results from the study in about a year. Catalyst is providing study drug and financial support for the study.

Patrick J. McEnany, Chief Executive Officer of Catalyst, said, “We are very pleased to provide support to Dr. Mantegazza and his team at Istituto Neurologico Carlo Besta for this study of Firdapse in patients diagnosed with MuSK-antibody positive myasthenia gravis. Unapproved or off-label treatments for patients with this disease have limited efficacy and significant side effects. If the results from this trial support the safety and efficacy of Firdapse as a treatment for MuSK-MG, we intend to submit an application for orphan drug designation and pursue approval of this product for this indication.”

The rationale for this trial comes from published positive results obtained with 3,4-DAP (amifampridine) in two preclinical studies conducted in animal models of MuSK antibody positive myasthenia gravis by research teams in Australia (Morsch et al., 2013[1]) and Japan (Mori et al., 2012[2]).

About MuSK Antibody-Positive Myasthenia Gravis

MuSK-MG is a rare disease that is estimated to inflict 5-8% of all myasthenia gravis patients (equating to an estimate of approximately 4,500 patients in the United States). MuSK antibodies identify a clinically distinguishable, more severe form of MG. The disease is characterized by a predominance in females, prominent bulbar involvement, more severe clinical condition and resistance to treatment. Although many patients with MuSK-MG are presently treated with anticholinesterase inhibitors or immunosuppressants, such patients do not generally respond adequately to these treatments.

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1 Morsch M, Reddel SW, Ghazanfari N, et al. Pyridostigime, but not 3,4-diaminopyridine exacerbates ACh receptor loss and myasthenia induced in mice by muscle-specific kinase autoantibody. J Physiol 591[10], 2747-2762. 2013.

2 Mori S, Kishi M, Kubo S, et al. 3,4-diaminopyridine improves neuromuscular transmission in a MuSK antibody-induced mouse model of myasthenia gravis. J Neuroimmunol 245, 75-78. 2012.

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, has completed testing in a global, multi-center, double-blinded randomized pivotal Phase 3 trial resulting in positive top-line data and Catalyst has recently filed an NDA for this product seeking approval for its use as a treatment of LEMS and CMS. 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. 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 obtain approval of an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether Catalyst's previously filed NDA for Firdapse will ever be accepted for filing by the FDA, the timing of any such NDA 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 the investigator-sponsored study evaluating Firdapse for the treatment of MuSK-MG will be successful, 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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