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): December 17, 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 1500** **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 December 17, 2015, the Company issued a press release reporting that it has completed the rolling submission of a New Drug Application to the United States Food and Drug Administration for Firdapse® (amifampridine phosphate) for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and congenital myasthenic syndromes (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 December 17, 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: December 17, 2015

Catalyst Pharmaceuticals Completes NDA Submission to FDA for Firdapse for the Treatment of Lambert-Eaton Myasthenic Syndrome and Congenital Myasthenic Syndromes

CORAL GABLES, Fla., Dec 17, 2015 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, announced today the completion of its rolling submission of a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for Firdapse® (amifampridine phosphate) for the treatment of Lambert Eaton myasthenic syndrome (LEMS) and congenital myasthenic syndromes (CMS). Both of these diseases are ultra-rare, with prevalences in the United States believed to be approximately 3,000 and 1,000-1,500 patients, respectively.

“The completion of our NDA submission for Firdapse represents the culmination of years of effort by our employees, investigators, clinical trial sites, and most importantly the patients and families of the LEMS and CMS communities,” said Patrick J. McEnany, Chief Executive Officer of Catalyst. “Our NDA submission includes more than 60 pre-clinical and clinical studies conducted over the past 5 years by both Catalyst and BioMarin Pharmaceutical. The submission of this NDA brings us one step closer to making a treatment for LEMS and CMS available to all patients, not just a selected few fortunate enough to be treated by physicians holding INDs to treat these diseases with experimental variations of 3,4-DAP. We look forward to working with the FDA during the regulatory process in pursuit of our goal of bringing Firdapse to patients suffering with LEMS and CMS.”

The NDA submission includes a request for a Priority Review by the FDA. Previously, Firdapse has received Breakthrough Therapy designation from the FDA for the treatment of LEMS, as well as Orphan Drug designations for LEMS and CMS.

Shin Oh, M.D., Distinguished Professor Emeritus in the Department of Neurology at the University of Alabama at Birmingham School of Medicine, said, “As a clinician who treats patients with LEMS and CMS, there is a great deal of value in having an FDA approved drug that would include approved labeling and prescribing information, as well as pharmacovigilance. If Firdapse is approved by the FDA, patients currently without any access to effective drugs, which make up the vast majority, will be able to receive a treatment that has been shown to be both safe and highly effective.”

About Lambert-Eaton Myasthenic Syndrome

Lambert-Eaton myasthenic syndrome, or LEMS, is a rare, debilitating and sometimes life-threatening autoimmune, neuromuscular disorder characterized primarily by progressive muscle weakness of the limbs. The disease is caused by an autoimmune response, where antibodies are formed against voltage-gated calcium channels on nerve endings in the neuromuscular junction, which damages the channels. These calcium channels are responsible for the transport of calcium ions that activate the biochemical machinery responsible for releasing acetylcholine. Acetylcholine is the neurotransmitter responsible for causing muscles to contract, and the failure to release enough of this neurotransmitter results in muscle weakness in LEMS patients. Additionally, LEMS can be associated with an underlying malignancy, most commonly small-cell lung cancer (SCLC), and in some individuals, LEMS is the first symptom of such malignancy.

Based on currently available information, Catalyst believes that there are approximately 3,000 LEMS patients in the United States.

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.

Based on currently available information, Catalyst believes that there are between 1,000 and 1,500 CMS patients in the United States, who may benefit from treatment with Firdapse.

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, double-blinded randomized pivotal Phase 3 trial resulting in positive top-line data on both co-primary endpoints. Firdapse 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 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 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, 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 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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