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 17, 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 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 February 17, 2016, the Company issued a press release reporting that it has received a ‘Refusal to File” letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Firdapse® (amifampridine phosphate). The “Refusal to File” letter states that, after a preliminary review, the FDA has found that the Company’s application, which was filed in December 2015, was not sufficiently complete, and requests additional supporting information. The letter does not provide comment on the acceptability of the submitted clinical data, and no judgment is made in the letter on the efficacy or safety of Firdapse®.

The Company plans to request a meeting with the FDA as soon as possible to discuss the FDA’s comments on the Company’s NDA submission and to hopefully reach an understanding as to what will be required for the Firdapse® NDA to be filed by FDA for review.

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 17, 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 17, 2016

Catalyst Pharmaceuticals Receives "Refusal to File" Letter from the FDA on its NDA for Firdapse

Coral Gables, Fla., February 17, 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 that the Company has received a "Refusal to File" letter from the US Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Firdapse® (amifampridine phosphate). Firdapse is Catalyst's investigational drug candidate for the symptomatic treatment of Lambert Eaton myasthenic syndrome (LEMS) and congenital myasthenic syndromes (CMS).

The "Refusal to File" letter states that after a preliminary review, the FDA has found that the application, which was submitted in December 2015, was not sufficiently complete, and requests additional supporting information. The letter does not provide comment on the acceptability of the submitted clinical data, and no judgment is made in the letter on the efficacy or safety of Firdapse. Catalyst plans to request a meeting with the FDA as soon as possible to discuss the FDA's comments on Catalyst's NDA submission and to hopefully reach an understanding as to what will be required for the Firdapse NDA to be filed by FDA for review.

"We expect to work closely with the FDA over the coming weeks in an effort to resolve the open issues and to define a path forward for a successful resubmission of our application at the earliest point in time," said Patrick J. McEnany, Chairman and CEO of Catalyst. "We remain focused on delivering on our promise to transform the way people living with LEMS and CMS are provided access to a safe and effective, FDA approved therapy. Additionally, our Expanded Access Program continues to enroll new patients and provide Firdapse at no cost to patients who meet the enrollment criteria."

Catalyst has previously received Orphan Drug Designation for Firdapse to treat LEMS and CMS, and Breakthrough Therapy Designation for Firdapse to treat LEMS.

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 charged calcium atoms 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 estimates 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 disorder comprising of 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 types 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 estimates that there are between 1,000 and 1,500 CMS patients in the United States, who might 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 what additional supporting information will be required before the FDA will accept an NDA filing for Firdapse, whether any additional clinical studies or trials will be required before the FDA will accept an NDA filing for Firdapse for LEMS, 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 file an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, the timing of any future 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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