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): July 22, 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 July 22, 2015, the Company issued a press release reporting that it has initiated a rolling New Drug Application with the United States Food and Drug Administration for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome.

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 July 22, 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: July 22, 2015

Catalyst Pharmaceuticals Initiates Rolling NDA Submission for Firdapse for the Treatment of Lambert-Eaton Myasthenic Syndrome (LEMS)

Expects to complete full NDA submission in the fourth quarter of 2015

CORAL GABLES, Fla., July 22, 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 the initiation of a rolling submission of a New Drug Application (NDA) to the United States (U.S.) Food and Drug Administration (FDA) for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS). Firdapse® has received Breakthrough Therapy Designation from the FDA for the treatment of LEMS, as well as orphan drug designations for LEMS and congenital myasthenic syndromes (CMS).

“Our start of the NDA submission for Firdapse® marks an important step forward in our efforts to provide a safe and effective, FDA approved, treatment option for patients in the U.S. who develop LEMS, a rare, debilitating disease,” said Patrick J. McEnany, Chief Executive Officer of Catalyst. “We expect to complete the submission of the NDA in the fourth quarter of 2015, at which time we will be requesting a Priority Review of our application. We will continue to work closely with the FDA as we seek approval of the NDA. As part of our commitment to ensure that eligible patients have access to Firdapse® as we pursue U.S. approval, we will continue to provide access to Firdapse® through an expanded access program.”

The Breakthrough Therapy Designation is designed to convey all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program. The Fast Track Designation is designed to facilitate the development and expedite the review of drugs that treat serious, life-threatening conditions and that address unmet medical needs. The Fast Track process allows a company to submit individual modules of its NDA for review by the FDA as they are completed.

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 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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