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 12, 2018

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** **(Address of principal executive offices)**	**33134** **(Zip Code)**

Registrant's telephone number, including area code: (305) 420-3200

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this Chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On February 12, 2018, the Company announced the results of its recent Type C meeting with the U.S. Food and Drug Administration (FDA). Prior to the meeting, the Company had provided the FDA with its preliminary data package for the proposed NDA resubmission for Firdapse®, including clinical, non-clinical, regulatory and abuse liability elements, along with the recently reported positive top-line results from a second, confirmatory Phase 3 clinical trial of Firdapse® for the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and the recently completed FDA-required abuse liability studies demonstrating that Firdapse® does not have abuse potential. The minutes of the meeting received from the FDA reflect the FDA's advice to the Company that its proposed filing package will be sufficient for resubmission of an NDA for Firdapse®, and the Company currently anticipates resubmitting its NDA for Firdapse® for LEMS to the FDA by the end of the first quarter of 2018.

The Company also announced that it expects to report top-line results from its Phase 3 double-blind placebo-controlled study evaluating Firdapse® for the treatment of congenital myasthenic syndromes (CMS) in the second half of this year, and that it is evaluating its options for the most appropriate and efficient path forward to include CMS in any approved labeling of Firdapse®.

The Company's press release is attached to this Current Report on Form 8-K as Exhibit 99.1 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 12, 2018.

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 12, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Announces Plans to Resubmit New Drug Application for Firdapse®

- Positive meeting with the FDA about the resubmission of an NDA for Firdapse
- Resubmission of NDA for Firdapse on schedule for end of the first quarter

CORAL GABLES, Fla., February 12, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Nasdaq: CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today announced the results of its recent Type C meeting with the U.S. Food and Drug Administration (FDA). Prior to the meeting, Catalyst had provided the FDA with its preliminary data package for the proposed NDA resubmission, including clinical, non-clinical, regulatory and abuse liability elements. The preliminary data package included the recently reported positive top-line results from a required second, confirmatory Phase 3 clinical trial (LMS-003) of Firdapse® for the symptomatic treatment of LEMS, as well as the recently completed FDA-required abuse liability studies demonstrating that Firdapse does not have abuse potential. The minutes of the meeting received from the FDA reflect the FDA's advice to Catalyst that its proposed filing package will be sufficient for resubmission of an NDA for Firdapse, and Catalyst currently anticipates resubmitting its NDA for Firdapse® for LEMS to the FDA by the end of the first quarter of 2018.

As previously reported, Catalyst is presently conducting a Phase 3 double-blind placebo-controlled clinical trial evaluating Firdapse® for the treatment of congenital myasthenic syndromes (CMS), and Catalyst expects to report top line results from the trial in the second half of this year. Catalyst is currently evaluating its options for the most appropriate and efficient path forward to hopefully include CMS in any approved labeling for Firdapse.

"We remain on track to resubmit our NDA for Firdapse in the first quarter of this year," stated Patrick J. McEnany, President and CEO of Catalyst Pharmaceuticals. "Based on our discussions with the FDA, we believe that we have a clear regulatory pathway forward, and we will continue to work collaboratively with the FDA as we seek to bring FDA approved therapies forward for the treatment of LEMS and CMS."

About Lambert-Eaton Myasthenic Syndrome (LEMS)

Lambert-Eaton Myasthenic Syndrome, or LEMS, is a rare autoimmune disorder, most often characterized by muscle weakness of the limbs. The disease is caused by an autoimmune reaction where antibodies are formed against voltage gated potassium channels in the connection between nerves and the muscles they communicate with. In approximately 50% of cases, LEMS is associated with an underlying malignancy, most commonly small-cell lung cancer, and in some individuals, LEMS is the first symptom of such malignancy. LEMS generally affects the extremities, especially the legs. As the disease most affects the parts of limbs closest to the trunk, difficulties with climbing stairs or rising from a sitting position are commonly noted. Physical exercise and high temperatures tend to worsen the symptoms. Other symptoms occasionally seen include weakness of the muscles of the mouth, throat, and eyes. Individuals affected with LEMS also may have a disruption of the autonomic nervous system, including dry mouth, constipation, blurred vision, impaired sweating, and/or hypotension.

About Congenital Myasthenic Syndromes (CMS)

Congenital myasthenic syndromes, or CMS, are rare neuromuscular disorders comprising a spectrum of genetic defects and is characterized by fatigable weakness of skeletal muscles with usual onset at or shortly after birth or early childhood; in rare cases symptoms may not manifest themselves until later in childhood or adulthood. 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 syndromes are rare, estimated at one-tenth that of myasthenia gravis, which in itself is rare. Based on currently available information, Catalyst estimates 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, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis, and infantile spasms. Firdapse® has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LEMS and Orphan Drug Designation for LEMS, CMS and myasthenia gravis. Firdapse is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat refractory infantile spasms. 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 (i) whether the results of the LMS-003 trial, combined with the results of the Company's previous Phase 3 trial, will be acceptable to the FDA as support for an approval of Firdapse for the treatment of LEMS, (ii) whether the results of the abuse liability studies undertaken by Catalyst will be acceptable to the FDA as support for an approval of Firdapse, (iii) whether any NDA submitted for Firdapse will be accepted by the FDA, and the timing of any such submission and acceptance, (iv) 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, (v) whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, (vi) whether Firdapse will ever be approved for commercialization, (vii) whether Catalyst will be the first company to receive an approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, and (viii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2016 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.

Investor Contact
Brian Korb
The Trout Group LLC
(646) 378-2923
bkorb@troutgroup.com

Company Contact
Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

Media Contact
David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

###