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): March 29, 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		**33134**
(Address of principal executive offices)		**(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 CFR240.14d-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 March 29, 2018, the Company announced its resubmission of a New Drug Application to the U.S. Food and Drug Administration for Firdapse® for the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome.

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 March 29, 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: March 29, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Announces Submission of New Drug Application for Firdapse® for Treatment of Lambert-Eaton Myasthenic Syndrome

CORAL GABLES, Fla., March 29, 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 its submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Firdapse® (amifampridine) for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS).

Last month, Catalyst announced the results of its recent positive Type C meeting with the FDA and reported that the minutes of the meeting received from the Agency reflect the FDA's advice to Catalyst that its proposed filing package would be sufficient for submission of an NDA for Firdapse. Last year, Catalyst reported positive top-line results from its second Phase 3 clinical trial of Firdapse for the treatment of LEMS, which was conducted under a protocol agreed to by the FDA through the Special Protocol Assessment process.

"We are pleased to reach this regulatory milestone and believe that our NDA submission contains all of the necessary information to satisfy the FDA requirements," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "This important milestone is the culmination of a strong collaboration and commitment among the patients, physicians and Catalyst employees who have worked diligently to advance Firdapse and to further expand access to an FDA-approved product to all LEMS patients. We look forward to continuing to work with the FDA during the review process and to a potential future launch of Firdapse, if it is approved."

Catalyst also reported on its decision not to include in this FDA submission those limited types of congenital myasthenic syndromes (CMS) that are considered mechanistically similar to LEMS. Catalyst reported that while it considered adding these indications to this NDA submission, after discussion with the FDA at its Type C meeting and further consideration, it decided not to overcomplicate the review of its NDA submission for LEMS with this second indication. Catalyst is currently conducting a Phase 3 trial evaluating Firdapse for the treatment of CMS, and expects to complete enrollment in this trial before the end of the year (and to report top-line results for its trial in the first quarter of 2019). Assuming the trial is successful, Catalyst plans to seek to add CMS to its label for Firdapse for a much broader population of CMS patients.

The NDA submission announced today addressed the two issues raised in the 2016 Refusal to File letter for the previous Firdapse NDA submission and included all additional information requested by the FDA. Once an NDA is submitted, the FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing, after which time the Agency will notify the company submitting the NDA of its decision. Catalyst plans to communicate the Agency's decision once Catalyst has been notified.

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 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, spinal muscular atrophy (SMA) type 3 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 the 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 the NDA submitted for Firdapse will be accepted by the FDA, and the timing of any such 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 2017 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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