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): April 19, 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 April 19, 2018, the Company announced that the first patient has been enrolled into its Phase 3 clinical trial to evaluate the efficacy and safety of Firdapse® in patients with MuSK antibody positive Myasthenia Gravis (MuSK-MG).

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 April 19, 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: April 19, 2018

Exhibit 99.1

Catalyst Pharmaceuticals Announces Enrollment of First Patient in Phase 3 Trial of Firdapse® in MuSK Antibody Positive Myasthenia Gravis

Pivotal Study sites in U.S. and Italy

CORAL GABLES, Fla., April 19, 2018 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today announced that the first patient has been enrolled into its Phase 3 clinical trial (designated as MSK-002) to evaluate the efficacy and safety of Firdapse® (amifampridine phosphate) in patients with MuSK antibody positive Myasthenia Gravis (MuSK-MG).

“By conducting this Phase 3 study in patients with MuSK-MG, we hope to provide a potential treatment option for people suffering from this rare condition,” said Patrick J. McEnany, Chairman and CEO of Catalyst. “Catalyst continues to build a leadership position in developing therapies to treat rare neuromuscular diseases with this next step for an important investigational product to potentially treat the symptoms of MuSK-MG.”

In August 2017, Catalyst announced that it had reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the protocol design, clinical endpoints, and statistical analysis approach in the Phase 3 trial. Catalyst has also received Orphan Drug designation for Firdapse for the treatment of Myasthenia Gravis.

“There is a significant unmet medical need to treat the symptoms of MuSK-MG, and these patients are eagerly awaiting a new treatment option,” said Gary Ingenito, M.D., Ph.D., Chief Medical Officer of Catalyst. “The previous Catalyst supported, proof-of-concept investigator-sponsored study in MuSK-MG patients showed impressive clinical improvement in multiple measures. We’re pleased to have begun enrolling patients in this study and look forward to working closely with the MG community to advance Firdapse through this Phase 3 trial.”

About the MSK-002 Clinical Trial

Catalyst previously announced that it had reached agreement with the FDA on a special protocol assessment for its Phase 3 trial (designated as MSK-002) of Firdapse in patients with MuSK-MG. This is a particularly severe form of myasthenia gravis that affects about 3,000 to 4,800 patients in the U.S., for which there are no approved effective therapies and is therefore an unmet medical need. The double-blind, placebo-controlled withdrawal trial will be conducted at clinical trial sites in the U.S. and Italy and is targeted to enroll about 60 subjects diagnosed with MuSK-MG. The trial will employ a primary endpoint of Myasthenia Gravis Activities of Daily Living (MG-ADL) and a secondary endpoint of Quantitative Myasthenia Gravis Score (QMG). At the FDA’s request, the trial will also enroll up to 10 generalized myasthenia gravis patients who will be assessed with the same clinical endpoints, but achieving statistical significance in this subgroup of patients is not required and only summary statistics will be provided. We anticipate that it will take about 12 months to complete the enrollment for the trial.

Additional information about MSK-002 can be found on www.clinicaltrials.gov (NCT03304054).

About myasthenia gravis and MuSK-MG

Myasthenia gravis (MG) is a rare, debilitating, autoimmune disease that affects the neuromuscular junction—the place where nerve cells and muscle cells communicate. In MG, the body attacks special receptors on nerve cells that are sensitive to an important chemical called acetylcholine (ACh). ACh is an important chemical because it helps send messages from nerves across the neuromuscular junction to muscles, where these special receptors interpret the message. These special receptors are called acetylcholine receptors (AChR). There is a second chemical that is needed for proper nerve-muscle communication and it is called muscle-specific kinase (MuSK). MuSK also helps nerve-muscle communication across the neuromuscular junction. Unlike AChR-MG, in which the body attacks the receptor, in patients with MuSK-MG, their bodies attack cells that produce the MuSK chemical. It's estimated that up to 8% of all people with MG (or about 3,000-4,800 total patients in the U.S.) have the MuSK-MG type.

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® (amifampridine phosphate) 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 MSK-002 study will be successful, (ii) the timing of the enrollment of the MSK-002 study, (iii) whether the NDA recently submitted for Firdapse for LEMS 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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