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): October 30, 2019

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered	Ticker Symbol
Common Stock, par value $0.001 per share	**NASDAQ Capital Market**	**CPRX**

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 October 30, 2019, the Company issued a press release announcing top-line results from CMS-001, a Phase 3 study evaluating Firdapse® for the symptomatic treatment of genetically confirmed Congenital Myasthenic Syndromes in adults and children. A copy of the press release is attached hereto 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 October 30, 2019.

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: October 30, 2019

**Catalyst Pharmaceuticals Announces Top-Line Results of CMS-001, a Phase 3 Trial of Firdapse®
(Amifampridine Phosphate) in Patients with Congenital Myasthenic Syndromes (CMS)**

CMS-001 trial is the first and only double-blinded, placebo-controlled study ever conducted in genetically confirmed CMS patients

Results in full population across all tested subtypes of CMS did not achieve statistical significance for the primary or secondary endpoints

MuSK-Myasthenia Gravis Phase 3 trial and SMA Type-3 proof of concept study both remain on schedule

CORAL GABLES, Fla., October 30, 2019 (GLOBE NEWSWIRE) – Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a commercial-stage biopharmaceutical company focused on developing innovative therapies for people with ultra-rare debilitating, chronic neuromuscular and neurological diseases, today announced top-line results from CMS-001, a Phase 3 study evaluating amifampridine phosphate for the symptomatic treatment of genetically confirmed Congenital Myasthenic Syndromes (CMS) in adults and children aged 2 years and above. The Company's lead product, Firdapse® (amifampridine phosphate), is currently approved for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in adults, and amifampridine phosphate is being investigated for the treatment of CMS and other neuromuscular and neurological disease to support applications to FDA for these indications.

CMS-001 is the first ever double-blind, placebo-controlled, clinical trial conducted in genetically confirmed CMS patients. In the trial, 20 subjects were enrolled and 16 randomized, in a 2 period, 2 treatment crossover study designed to evaluate the efficacy and safety of amifampridine phosphate in patients (aged 2 years and above) diagnosed with certain genetic subtypes of CMS. While individual patient improvements were observed in some patient sub-groups, the trial did not meet its primary endpoint of subject global impression (SGI) or the secondary endpoint of muscle function measure (MFM) across all tested subtypes. Due to the rarity of CMS, this trial took almost 4 years to recruit.

"While we are disappointed that this trial did not reach its primary or secondary endpoints in the evaluated CMS patient subtypes, we are pleased with the new valuable clinical information that these results will provide to the medical and scientific communities as we work to develop FDA-approved treatment options for patients with this disease" said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "We also remain committed to developing FDA-approved treatment options for other rare neuromuscular disorders."

Catalyst is scheduled to meet with the FDA before the end of the year to discuss the outcome of this clinical trial, and potential paths forward to seek approval of amifampridine phosphate for the symptomatic treatment of some subset of genetic subtypes of CMS. After receiving additional guidance, Catalyst will provide future updates on its plans for this potential indication.

The Company also reports that it remains on track to complete enrollment in its clinical trial of amifampridine phosphate in patients with anti-MuSK antibody positive myasthenia gravis (MuSK-MG) before the end of this year, and to report top-line data from this trial in the first half of 2020. We also expect to report top-line results from our SMA Type-3 proof of concept study in the first half of 2020. Both of these diseases have a much more homogeneous patient population than CMS and should not present the same challenges.

"We have made significant progress in genetically testing patients who were unable to previously get diagnosed," added Steven Miller, Ph.D., Chief Operating Officer and Chief Scientific Officer of Catalyst Pharmaceuticals. "Due to the small patient prevalence, the low number of patients tested, and heterogeneity of the disease with a wide range of variation in clinical presentation across its more than 50 subtypes, it was challenging to demonstrate a statistically significant benefit across multiple subtypes."

About Congenital Myasthenic Syndromes (CMS)

Congenital myasthenic syndromes, or CMS, are rare neuromuscular disorders comprising a spectrum of more than 50 genetic defects with some of the various mutations having as few as a handful of diagnosed patients. CMS patients are 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 genetic 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.

CMS is rare. Catalyst estimates that there are between 1,000 and 1,500 CMS patients in the United States.

About MuSK Myasthenia Gravis (MuSK-MG)

About 15% of Myasthenia Gravis, or MG, patients test negative for the acetylcholine receptor antibody, and about 40-50% of these "seronegative MG" patients are test positive for the MuSK-MG antibody and are identified as MuSK-MG patients, representing about 4,500 patients in the United States. MuSK is a protein that is required for the maintenance of the neuromuscular junction. MuSK-MG is a clinically distinguishable, more severe form of MG. The disease is characterized by a predominance in females, a prevalent involvement of cranial and bulbar muscles, high incidence of respiratory crises and a resistance to treatment. Although many patients with MuSK-MG are presently treated with anticholinesterase inhibitors or immunosuppressants, such patients do not generally respond adequately to these treatments.

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), anti-MuSK antibody positive myasthenia gravis (MuSK-MG), congenital myasthenic syndromes (CMS), and spinal muscular atrophy (SMA) Type 3. Catalyst's new drug application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in November 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse is now commercially available in the United States.

Firdapse is currently being evaluated in clinical trials for the treatment of MuSK-MG, CMS, and SMA Type 3 and has received Orphan Drug Designation from the FDA for myasthenia gravis and CMS. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults with LEMS.

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 FDA will allow Catalyst to file an sNDA for certain types of CMS based on the data from the recently completed Phase 3 trial, (ii) whether Catalyst will complete enrollment in its MuSK-MG trial by the end of the year, and report top-line data from this trial in the first half of 2020; (iii) whether Catalyst will report top-line data from its SMA Type 3 proof-of-concept study in the first half of 2020, (iv) whether the MuSK-MG trial or the SMA Type 3 study will be successful, (v) whether Firdapse will ever be approved to treat CMS, MuSK-MG or SMA Type 3, and (vi) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2018 and its other filings with the U.S. Securities and Exchange Commission (SEC), all of which 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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