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): November 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 November 29, 2018, the Company issued a press release announcing that the U.S. Food & Drug Administration has approved Firdapse® (amifampridine) for the treatment of Lambert-Eaton Myasthenic Syndrome. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on November 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: November 29, 2018

FDA Approves Firdapse® (amifampridine) for the Treatment of Lambert-Eaton Myasthenic Syndrome (LEMS)

- ***First evidenced-based medicine approved to treat LEMS***
- ***Catalyst Pathways™ designed to facilitate access to Firdapse® and provide dedicated patient support***
- ***Launch early in the first quarter of 2019***
- ***Catalyst to hold conference call on December 13, 2018 at 8:30 AM ET to discuss launch details***

CORAL GABLES, Fla., November 29, 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 U.S. Food and Drug Administration (FDA) has approved Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with Lambert-Eaton Myasthenic Syndrome (LEMS). Firdapse is expected to be commercially available early in the first quarter of 2019. For full prescribing information, please click here.

“The FDA’s approval of Firdapse is a potentially transformative milestone in the lives of patients in the U.S. suffering with LEMS, as it now gives adult LEMS patients access to a new first-in-class-therapy,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “The approval of Firdapse is a crowning achievement for our company and an important step forward in our transition into a premier neurological rare disease company. We continue to prepare for what we hope will be a successful launch based on productive discussions with payers, our efforts in patient identification and our development of a field-based commercial infrastructure. Our *Catalyst Pathways*™ patient services program is designed to assist patients and physicians with education, clinical diagnostic tools and assistance in navigating the reimbursement landscape.”

“I am pleased that the FDA has recognized the comprehensive clinical data supporting the benefits of Firdapse for patients with LEMS,” said Perry B. Shieh, M.D., Ph.D., Department of Neurology at UCLA Medical Center. “It’s important that patients living with this debilitating disease now have access to an FDA-approved treatment that has shown clinically meaningful benefits.”

LEMS is a rare autoimmune disease that affects approximately 1 in 100,000 people in the United States. The most common symptoms of LEMS are proximal muscle weakness and fatigue. Symptoms can be life threatening when the weakness involves respiratory muscles. Approximately 50% of LEMS patients have an underlying malignancy, typically small cell lung cancer.

“At the National Organization for Rare Diseases (NORD), it’s a great day for patients when we learn of FDA approval of a much-needed treatment for a rare disease. We’d like to congratulate the entire team at Catalyst for its commitment to providing LEMS patients and their doctors with access to an FDA-approved medicine,” said Peter Saltonstall, President and CEO of NORD. “With 95% of rare diseases still without an FDA-approved treatment, continued research and new products remain of vital importance to the rare disease community.”

The submission of the Firdapse NDA came following positive results from two Phase 3 studies where patients treated with Firdapse experienced rapid, significant and sustained improvements in muscle function, and reduced weakness and fatigability compared to patients receiving placebo. These benefits were observed by both patients and physicians. Please see below for Important Safety Information. Firdapse had previously received Orphan Drug designation and Breakthrough Therapy designation, as well as Priority Review from the FDA. Firdapse is the first and only approved drug in Europe for treatment of LEMS.

“This FDA approval marks the arrival of a first-in-class therapy for a rare and devastating condition with limited treatment options,” said Gary Ingenito, M.D., Ph.D., Chief Medical Officer and Head of Regulatory Affairs at Catalyst. “We extend our deepest gratitude to the patients who participated in the Firdapse clinical trials and their families and caregivers who supported them. We are also grateful for the tireless efforts of the investigators and study staff, without whom this important milestone would not have been possible. We also look forward to continuing to work with the FDA to evaluate other potential indications for Firdapse.”

Catalyst Pathways™

Catalyst Pathways™ is an optional, free, personalized program that offers patients and their families one-on-one support throughout their treatment journey with a dedicated team of specialists to help them manage their unique challenges. The support team for each enrolled patient at Catalyst Pathways includes a Care Coordinator, with extensive experience in health care; an Insurance Navigator, to help them understand their insurance coverage and the prescription drug benefit process; a Patient Assistance Liaison, to assist them in understanding their disease and their prescription, and a specialty pharmacy experienced in supporting rare disease patients to provide direct-to-patient delivery of prescriptions. The Catalyst Pathways support team also helps enrolled patients understand and access financial assistance options for qualifying patients, including a copay support program designed to minimize the patient’s burden of out-of-pocket costs. For more information on Catalyst Pathways click here.

Conference Call

Catalyst will host a conference call and webcast to discuss its commercialization plan for Firdapse, including the cost of therapy, on December 13, 2018 at 8:30 AM ET. Investors who wish to participate in the conference call may do so by dialing (877) 407-8912 for domestic and Canadian callers or (201) 689-8059 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the company’s website at www.catalystpharma.com and clicking on the webcast link on the Investors home page. A webcast replay will be available on the Catalyst website following the call by visiting the Investor page of the company’s website at https://www.catalystpharma.com.

About Lambert-Eaton Myasthenic Syndrome (LEMS)

LEMS, is a rare autoimmune disorder, most often characterized by fatigable limb muscle weakness. The disease is caused by autoantibodies against voltage-gated calcium channels located in the nerve-muscle junction, resulting in improper nerve-muscle communication, leading to progressive muscle weakness, when left untreated. 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. In early course of the disease,

muscles closest to the trunk are affected, which are manifested as difficulties with climbing stairs or rising from a sitting position. 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, with symptoms of dry mouth, dry skin, constipation, blurred vision, impaired sweating, and/or inappropriate blood pressure variations.

About Firdapse® (amifampridine)

Firdapse® (amifampridine) 10 mg tablets is an oral, nonspecific, voltage-dependent, potassium (K+) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca2+) channels, allowing for a subsequent influx of Ca2+. In turn, it induces the exocytosis of synaptic vesicles containing Acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission, and providing for improved muscle function. Firdapse is approved in the U.S. and the European Union for use by patients with LEMS.

Important Safety Information

CONTRAINDICATIONS

FIRDAPSE is contraindicated in patients with:

- A history of seizures
- Hypersensitivity to amifampridine phosphate or another aminopyridine

WARNINGS AND PRECAUTIONS

Seizures: FIRDAPSE can cause seizures. Consider discontinuation or dose reduction of FIRDAPSE in patients who have a seizure while on treatment. FIRDAPSE is contraindicated in patients with a history of seizures.

Hypersensitivity: If a hypersensitivity reaction such as anaphylaxis occurs, FIRDAPSE should be discontinued and appropriate therapy initiated.

ADVERSE REACTIONS

The most common (> 10%) adverse reactions are: paresthesia, upper respiratory tract infection, abdominal pain, nausea, diarrhea, headache, elevated liver enzymes, back pain, hypertension, and muscle spasms.

To report SUSPECTED ADVERSE REACTIONS, contact Catalyst Pharmaceuticals at 1-844-347-3277 (1-844-FIRDAPSE) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 LEMS, congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis (MuSK-MG), and spinal muscular atrophy (SMA) type 3. Amifampridine phosphate has received Orphan Drug Designation from the United States FDA for CMS and myasthenia gravis. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing a generic version of 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 Catalyst will be successful in commercializing Firdapse (ii) whether, even if Catalyst is successful in commercializing Firdapse, Catalyst will become profitable, (iii) whether Firdapse will ever be approved for the treatment of CMS, MuSK-MG, SMA type 3, or any other disease, and (iv) 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.

Investor Contact
Brian Korb
Solebury Trout
(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

###