

**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 5, 2015

**CATALYST PHARMACEUTICAL PARTNERS, INC.**

(Exact Name Of Registrant As Specified In Its Charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-33057**

(Commission File Number)

**76-0837053**

(I.R.S. Employer  
Identification No.)

**355 Alhambra Circle  
Suite 1500  
Coral Gables, Florida**

(Address of principal executive offices)

**33134**

(Zip Code)

Registrant's telephone number, including area code:

(305) 529-2522

**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))

**Item 8.01 Other Events**

On March 5, 2015, the Company issued a press release reporting that the U.S. Food and Drug Administration (FDA) has granted the Company orphan drug designation for Firdapse™ for the treatment of Congenital Myasthenic Syndromes.

Additionally, the Company announced that it has received the official minutes from the FDA reporting on the discussions at its formal pre-new drug application (NDA) meeting held earlier this year, and that the minutes confirm the information about the results of the meeting previously reported by the Company in its Form 8-K filed on February 2, 2015.

A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K 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 5, 2015.

**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 Pharmaceutical Partners, Inc.**

By: /s/ Alicia Grande

Alicia Grande

Vice President, Treasurer and CFO

Dated: March 5, 2015



FOR IMMEDIATE RELEASE

## **Catalyst Pharmaceuticals Announces FDA Orphan Drug Designation of Firdapse for Treatment of Congenital Myasthenic Syndromes**

*Catalyst confirms information previously reported about results of recent pre-NDA meeting*

**CORAL GABLES, Fla., March 5, 2015** — **Catalyst Pharmaceutical Partners, Inc. (Nasdaq:CPRX)**, (Catalyst Pharmaceuticals), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted the company orphan drug designation for Firdapse™ for treatment of patients with Congenital Myasthenic Syndromes (CMS).

CMS is a rare neuromuscular disease comprising a spectrum of genetic defects and is 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 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.

“We are pleased with the FDA’s decision to grant Orphan Drug designation to Firdapse™ for CMS as it provides Catalyst with a number of benefits through development and commercialization,” noted Patrick J. McEnany, Chief Executive Officer of Catalyst. He continued, “CMS is a disabling and frequently severe disease with few effective treatment options. The orphan drug designation recognizes the significant unmet medical need that exists among individuals living with this disease.”

Catalyst also confirmed that it has received the formal minutes from the FDA reporting on the discussions at its pre-new drug application (NDA) meeting held earlier this year and that the minutes of the meeting confirm the information about the results of the meeting previously reported by Catalyst. On February 2, 2015, Catalyst reported that it had held a productive pre-NDA meeting with the FDA regarding Firdapse™ for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and that, based on the discussions at that meeting, Catalyst believes that its Phase 3 clinical program will provide acceptable support for submission of an NDA for Firdapse™ for LEMS. Catalyst also reported that potential paths forward for one type of congenital myasthenic syndromes were also discussed at the meeting.

### **About Orphan Drug Designation**

Orphan Drug designation is granted by the FDA’s Office of Orphan Products Development for drugs that are expected to provide significant therapeutic advantage over existing treatments and that target conditions affecting 200,000 or fewer U.S. patients annually. Orphan Drug designation qualifies a company for several benefits under the Orphan Drug Act of 1983. The benefits apply across all stages of drug development and include an accelerated approval process; seven years of market exclusivity following marketing approval; tax credits on U.S. clinical trials; eligibility for Orphan Drug grants; and waiver of Prescription Drug User Fee Act (PDUFA) and certain other administrative fees.

## **About Catalyst Pharmaceuticals**

Catalyst Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, including Lambert-Eaton Myasthenic Syndrome (LEMS), congenital myasthenic syndrome (CMS), infantile spasms, and Tourette Syndrome. Catalyst's lead candidate, Firdapse™ for the treatment of LEMS, recently completed testing in a global, multi-center, pivotal Phase 3 trial resulting in positive top-line data. Firdapse™ for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA). Firdapse™ is the first and only European approved drug for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and Tourette Syndrome. 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.

## **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 whether the receipt of breakthrough therapy designation for Firdapse™ for the treatment of LEMS 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, what clinical trials and studies will be required before Catalyst can submit an NDA for Firdapse™ for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether an NDA for Firdapse™ will ever be accepted for filing by the FDA, the timing of any such NDA filing or acceptance, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, whether CPP-115 will be determined to be effective for the treatment of infantile spasm, post-traumatic stress disorder, Tourette Syndrome or any other indications, whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2013 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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