

**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): August 11, 2014

**CATALYST PHARMACEUTICAL PARTNERS, 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 1500  
Coral Gables, Florida

33134

(Address of principal executive offices)

(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))

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**Item 8.01 Other Events**

On August 11, 2014, the Company issued a press release announcing that the final patient in its Phase 3 study of Firdapse™ (amifampridine phosphate) for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) has completed the blinded portion of the study, and that top-line results from the study are on track to be reported later this quarter. In addition, the Company announced that all patients who were randomized into the study elected to continue in the two-year open label follow-up study.

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 August 11, 2014.

**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: August 11, 2014



**FOR IMMEDIATE RELEASE**

**Catalyst Pharmaceutical Partners Provides Updates on Progress of Phase 3 Firdapse Study in Patients with Lambert-Eaton Myasthenic Syndrome (LEMS)**

*Last Patient Completes 2-Week, Blinded Primary Treatment Period - Top-Line Data on Track to Report in 3Q14*

*100% of Patients Elected to Continue in 2-Year Open Label Follow-up Period*

**Coral Gables, FL, August 11, 2014** (GLOBE NEWSWIRE) — Catalyst Pharmaceutical Partners, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today provided an update on the progress of its Phase 3 study of Firdapse™ (amifampridine phosphate) for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS). The last patient has completed the blinded portion of the study and top-line data remains on track to be reported later this quarter. A total of 38 patients completed the 3 month treatment period and were successfully randomized to either receive Firdapse™ or placebo. All patients who were randomized elected to continue in 2-year open label follow-up.

If the company obtains positive results from its Phase 3 study, the company intends to submit a request to the FDA for a pre-NDA meeting and to initiate the steps necessary to seek regulatory approval of Firdapse™. This would likely include the initiation of a rolling NDA submission to the FDA by early-2015.

The Firdapse™ Phase 3 trial utilizes a randomized, double-blind, placebo-controlled, discontinuation design. The trial is being conducted at sites in the United States and Europe. Following enrollment, patients were treated with open label drug for a minimum of 91 days, and then randomized to either continue on Firdapse™ or be discontinued to placebo over a 2-week period. Following the randomization phase of the trial, patients were then eligible to receive open label Firdapse™ treatment for a two-year follow-up period, to obtain additional long term safety data.

**LMS-002 Patient Disposition Highlights**

- Thirty eight (38) patients were successfully randomized into the 2-week, randomized, double-blind, placebo-controlled, discontinuation part of the study. The original target was to randomize 36 patients.

- All 38 randomized subjects elected to continue to receive Firdapse™ treatment in the 2-year, open label follow-up part of the trial.

Patrick J. McEnany, Chief Executive Officer of Catalyst Pharmaceutical Partners, Inc., stated, “We are very pleased to be nearing completion of the Phase 3 Firdapse™ pivotal trial for patients diagnosed with LEMS, a rare neuromuscular disease, and remain on track to report data later this quarter. We were very pleased to see 100% of the patients in the randomized portion of the trial elect to continue into the open-label 2-year safety study. Assuming we receive positive data from this study, we plan to meet with the FDA in the fourth quarter to determine the fastest U.S. registration pathway. We remain committed to the LEMS patient population and are pleased to see positive feedback from our expanded access program initiated earlier this year. We hope to see Firdapse™ become the first FDA-approved, safe and effective drug for the treatment of this debilitating disease.”

### **About Firdapse™**

Firdapse™, amifampridine phosphate or 3,4-diaminopyridine (3,4-DAP) phosphate, is a potassium channel inhibitor. By blocking this ion channel, Firdapse™ increases the nerve repolarization time, which causes an increase in the influx of calcium, thereby causing more acetylcholine to be released, which restores muscle fiber contraction, thus relieving muscle weakness caused by LEMS. In addition to LEMS, other potential orphan neuromuscular indications for Firdapse™ include certain types of Myasthenia Gravis and Congenital Myasthenic Syndrome, among others.

Firdapse™ has been granted orphan drug and breakthrough therapy designations by the FDA, and orphan medicinal product designation in the European Union for the treatment of LEMS. It is approved and commercialized in the E.U. by BioMarin Pharmaceutical. Upon completion of the Phase 3 trial, assuming the data from the trial is positive, Catalyst expects to begin submitting a rolling new drug application to the FDA in 2015.

### **About the Phase 3 Trial of Firdapse™**

The primary endpoint of the Phase 3 trial is a comparison of changes in patients randomized to continue Firdapse™ versus those who transition to placebo that occur in both the QMG score, which measures muscle strength, and subject global impression score, on which the subject rates their global impression of the effects of a study treatment during a 14-day double-blind efficacy evaluation period. The secondary endpoints are change in the investigator’s assessment of worsening of disease symptoms and changes in walking speed (Timed 25-foot walking test) during the two-week, double-blind testing period. Further details regarding the Phase 3 trial and its design can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01377922).

### **About Catalyst Pharmaceutical Partners**

Catalyst Pharmaceutical Partners, Inc. is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, including Lambert-Eaton Myasthenic Syndrome (LEMS), infantile spasms, and Tourette Syndrome. Catalyst’s lead candidate, Firdapse™ for the treatment of LEMS, is currently undergoing testing in a global, multi-center, pivotal Phase 3 trial and has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA). In 2012, Catalyst licensed Firdapse™ from BioMarin, and Catalyst assumed management of the Phase 3 pivotal trial (which had originally been initiated by BioMarin). Firdapse™ is the first and only European approved drug for symptomatic treatment in adults with LEMS. For more information, please visit [www.catalystpharma.com](http://www.catalystpharma.com).

Catalyst is also developing a potentially safer and more potent vigabatrin analog (designated CPP-115) to treat infantile spasms, and epilepsy, as well as 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 the anticipated timing of the receipt of top-line results from the double-blind, placebo-controlled portion of the Phase 3 trial of Firdapse™, whether the Phase 3 trial will be successful, 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, 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 an approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, 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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