# 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 27, 2013

# 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 CFR240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

# Item 8.01 Other Events

On August 27, 2013, the Company issued a press release announcing that the U.S. Food and Drug Administration has granted Breakthrough Therapy Designation to the Company's investigational product, Firdapse<sup>™</sup>, for the symptomatic treatment of patients with Lambert-Eaton Myasthenic Syndrome (LEMS). The 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) <u>Exhibits</u>
- 99.1 Press Release issued by the Company on August 27, 2013

## 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 27, 2013

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NEWS RELEASE

For Further Information Contact: Patrick J. McEnany Catalyst Pharmaceutical Partners Chief Executive Officer (305) 529-2522 <u>pmcenany@catalystpharma.com</u>

#### FOR IMMEDIATE RELEASE

Melody Carey Rx Communications Group Co-President (917) 322-2571 <u>mcarey@rxir.com</u>

## Catalyst Pharmaceutical Partners Receives Breakthrough Therapy Designation From FDA For Firdapse™ For The Treatment of LEMS

**CORAL GABLES, FL, August 27, 2013** — Catalyst Pharmaceutical Partners, Inc. (Nasdaq: CPRX), a specialty pharmaceutical company focused on the development and commercialization of novel prescription drugs targeting rare (orphan) neuromuscular and neurological diseases, today announced that its investigational product Firdapse<sup>™</sup> (amifampridine phosphate) has received "Breakthrough Therapy Designation" by the U.S. Food and Drug Administration (FDA) for the symptomatic treatment of patients with Lambert-Eaton Myasthenic Syndrome (LEMS). Firdapse<sup>™</sup> is Catalyst's investigational therapy that is being evaluated for the treatment of the debilitating symptoms associated with LEMS, including muscle weakness.

"We are very pleased to have received Breakthrough Therapy Designation for Firdapse<sup>™</sup> and we are excited by the FDA's decision to place our product in a category that may enable expedited development and review for patients with LEMS," said Patrick McEnany, President and Chief Executive Officer of Catalyst. "With no approved or effective symptomatic treatment currently available for LEMS, Firdapse<sup>™</sup> has the potential to be the first-line treatment option for patients with this rare condition."

Breakthrough Therapy Designation for Firdapse<sup>™</sup> was based on clinical data from several previously published clinical trials of amifampridine (3,4-DAP) in patients with LEMS. Firdapse<sup>™</sup> has the potential to provide significant relief of the often debilitating symptoms of the disease, including muscle weakness (e.g. difficulty walking), difficulty swallowing and talking, drooping of eyelids and facial weakness.

#### About Breakthrough Therapy Designation

Breakthrough Therapy Designation was enacted as part of the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA). FDASIA defines breakthrough therapy as a drug that is "intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development."

A breakthrough therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

#### About Firdapse<sup>™</sup>

Firdapse<sup>M</sup>, also known as amifampridine phosphate, 3,4-diaminopyridine phosphate or 3,4-DAP phosphate, is a potassium channel blocker. It delays repolarization of the pre-synaptic neuron, causing voltage gated Ca2+ channels to remain open longer. The increase Ca2+ influx causes more acetylcholine to be released, making it more likely that a muscle action potential will be initiated, thereby reducing muscle weakness. The North American rights to Firdapse<sup>M</sup> were licensed to the Company in 2012 by BioMarin Pharmaceutical. BioMarin currently markets Firdapse<sup>M</sup> in the EU for the treatment of LEMS.

In the United States, where the product has previously received orphan drug designation, Firdapse<sup>TM</sup> is in a Phase III, multicenter, double-blind, placebocontrolled, randomized discontinuation study followed by an open-label extension period to evaluate the efficacy and safety of Firdapse<sup>TM</sup> in patients with LEMS. In addition to LEMS, other potential orphan neuromuscular indications for Firdapse<sup>TM</sup> include Myasthenia Gravis and Congenital Myasthenic Syndrome, among others.

#### About LEMS

Lambert-Eaton Myasthenic Syndrome, LEMS, is a rare autoimmune disease that can be severely disabling, with the primary symptom of muscle weakness. The weakness is generally more marked in the proximal muscles, particularly of the legs and trunk. Other problems include reduced reflexes, drooping of the eyelids, facial weakness and problems with swallowing. Patients often report dry mouth, impotence, constipation and feelings of light headedness on standing. These problems can be life threatening when the weakness involves respiratory muscles. The muscle weakness in LEMS is caused by autoantibodies to voltage gated calcium channels, which cause a reduction in the amount of acetylcholine released from nerve terminals. The prevalence of LEMS is estimated at approximately 3,000 patients in the United States and



Canada. Approximately 50 percent of LEMS patients diagnosed have small cell lung cancer. Patients with LEMS typically present with fatigue, muscle pain and stiffness. A diagnosis of LEMS is generally made on the basis of clinical symptoms, electromyographic and compound muscle action potential (CMAP) testing and where available, the presence of autoantibodies against voltage gated calcium channel.

## **About Catalyst Pharmaceutical Partners**

Catalyst Pharmaceutical Partners, Inc. is a specialty pharmaceutical company focused on the development and commercialization of novel prescription drugs targeting rare (orphan) neuromuscular and neurological diseases, including Lambert-Eaton Myasthenic Syndrome (LEMS), infantile spasms, and Tourette Syndrome. Catalyst's lead candidate, Firdapse<sup>™</sup> for the treatment of LEMS, is currently undergoing testing in a global, multi-center, pivotal phase III trial. 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.

#### 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 timing of completion of Catalyst's currently ongoing Phase III trial of Firdapse<sup>TM</sup>, whether the Phase III trial will be successful, whether the receipt of breakthrough therapy designation for Firdapse<sup>TM</sup> will expedite the development and review of Firdapse<sup>TM</sup> by the FDA or the likelihood that the product will be found to be safe and effective, whether an NDA for Firdapse<sup>TM</sup> will ever be accepted for filing by the FDA, the timing of any such NDA filing or acceptance, 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 2012 and 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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