

**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): January 12, 2015

**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**

(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 January 12, 2015, the Company issued a press release announcing the Company's 2015 goals for its product portfolio. The Company announced that it expects to achieve the following key milestones during 2015:

- Conduct Pre-NDA meeting. The Company expects to hold a pre-NDA meeting with the FDA in Q1 2015.
- Submit Firdapse™ NDA to FDA. The Company expects to complete its renal safety study and full toxicology program for Firdapse™ in Q2 2015, with an anticipated completion of an NDA submission to the FDA by Q3 2015.
- Complete launch of Firdapse™ expanded access program. The Company is currently enrolling LEMS and CMS patients in the expanded access program, which will provide Firdapse™ at no charge to patients who meet the inclusion/exclusion requirements.
- Complete all pre-commercialization activities required for successful Firdapse™ launch. The Company will continue to focus on pre-commercial activities ahead of an estimated approval / launch of Firdapse™ in 1H 2016.
- CPP-109: Top-line results from Tourette's Disorder. An academic investigator sponsored study evaluating CPP-109 for the treatment of Tourette's Disorder is ongoing at Mt. Sinai, in New York, and the Company expects to announce topline results in the first half of 2015.
- CPP-115: The Company expects to announce topline results from a Phase 1 multiple dose safety and tolerance study in the first half of 2015.
- Exploration of additional indications for Firdapse™. The Company plans to continue to explore additional indications including Congenital Myasthenic Syndrome and refractory Myasthenia Gravis.

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.

This Current Report on Form 8-K contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause the Company'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™ 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 the Company 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 the Company's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in the Company'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 the Company's filings with the SEC are available from the SEC, may be found on the Company's website or may be obtained upon request from the Company. The Company does not undertake any obligation to update the information contained herein, which speaks only as of this date.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press release issued by the Company on January 12, 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: January 12, 2015



FOR IMMEDIATE RELEASE

## Catalyst Pharmaceuticals Provides an Update of 2015 Goals for its Product Portfolio

*Pre-NDA Meeting with the FDA*

*Firdapse NDA Submission*

*Developing Regulatory Strategy for Firdapse for Congenital Myasthenic Syndrome*

*Hosting 1x1 Meetings in San Francisco January 12-15*

**CORAL GABLES, FL, January 12, 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 the company's 2015 goals for its product portfolio. The Company will be hosting 1x1 meetings this week in conjunction with The Trout Group Management Access Conference in San Francisco, January 12-15. The Company's presentation materials will be available on the "Investors" section of the Company's website, [www.catalystpharma.com](http://www.catalystpharma.com).

Firdapse™ has been granted Breakthrough Therapy and Orphan Drug Designations by the FDA for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and reported positive results from its Phase 3 clinical trial evaluating Firdapse™ for the treatment of LEMS in September 2014. The Company has also initiated an expanded access program (EAP) under which patients with LEMS and Congenital Myasthenic Syndrome (CMS), who meet the inclusion/exclusion requirements, have access to Firdapse™ via the EAP, at no charge to the patients. Catalyst expects to meet with the FDA for its pre-NDA meeting in Q1 2015, to begin its rolling NDA submission for Firdapse™ for the treatment of LEMS sometime thereafter and to complete its NDA submission sometime in Q3 2015. Catalyst recently promoted David D. Muth to Chief Commercial Officer as it continues to build out its commercial team ahead of a potential launch of the product in 2016.

Catalyst is continuing to develop CPP-115, a novel GABA-aminotransferase inhibitor, for a broad range of central nervous system indications, such as infantile spasms, epilepsy, Tourette Syndrome and Post Traumatic Stress Disorder (PTSD). The Company expects initial top line results from an academic investigator sponsored proof-of-concept study evaluating another GABA-aminotransferase inhibitor, vigabatrin, for the treatment of Tourette's Disorder during the second quarter of 2015. It also expects to obtain the results of its Phase 1 MAD study of CPP-115 during the second quarter of 2015. Additionally, Catalyst plans to explore other selected diseases in which modulation of GABA levels might be beneficial.

“This year will provide significant anticipated milestones and achievements for the company and our pipeline as we move towards an NDA filing for Firdapse™ this summer,” said Patrick J. McEnany, Chief Executive Officer of Catalyst. “Along with the commencement of the expanded access program, we continue to focus on our pre-commercial activities for Firdapse™ in the LEMS community, as we prepare for an anticipated launch of the product in the first half of 2016, pending FDA approval. Finally, exploration of additional indications like Congenital Myasthenic Syndrome for Firdapse™ may provide further opportunities to expand the market and serve additional patients with unmet medical needs.”

### **Anticipated 2015 Goals**

Catalyst expects to achieve the following key milestones in the upcoming year:

- *Conduct Pre-NDA meeting.* Catalyst expects to hold a pre-NDA meeting with the FDA in Q1 2015.
- *Submit Firdapse™ NDA to FDA.* Catalyst expects to complete its renal safety study and full toxicology program for Firdapse™ in Q2 2015, with an anticipated completion of an NDA submission to the FDA by Q3 2015.
- *Complete launch of Firdapse™ expanded access program.* Catalyst is currently enrolling LEMS and CMS patients in the expanded access program, which will provide Firdapse™ at no charge to patients who meet the inclusion/exclusion requirements.
- *Complete all pre-commercialization activities required for successful Firdapse™ launch.* The Company will continue to focus on pre-commercial activities ahead of an estimated approval / launch of Firdapse™ in 1H 2016.
- *CPP-109: Top-line results from Tourette’s Disorder.* An academic investigator sponsored study evaluating CPP-109 for the treatment of Tourette’s Disorder is ongoing at Mt. Sinai, in New York, and Catalysts expects to announce topline results in the first half of 2015.
- *CPP-115: Catalyst expects to announce topline results from a Phase 1 multiple dose safety and tolerance study in the first half of 2015.*
- *Exploration of additional indications for Firdapse™.* Catalyst plans to continue to explore additional indications including Congenital Myasthenic Syndrome and refractory Myasthenia Gravis.

### **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), 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™ 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 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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