CATALYST PHARMACEUTICAL PARTNERS, INC.
Form 8-K
January 12, 2015

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	**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 CFR240.14d-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