

CATALYST PHARMACEUTICAL PARTNERS, INC.

Form 8-K

February 02, 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): February 2, 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

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))

Item 8.01 Other Events

On February 2, 2015, Catalyst Pharmaceutical Partners, Inc. (the Company) announced that it has held a productive pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA) regarding its lead product candidate, Firdapse, for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS). Based on this meeting, the Company believes that its Phase 3 clinical program will provide acceptable support for a submission of an NDA for Firdapse for LEMS. The Company plans to complete a full NDA submission during the third quarter of 2015. The Company will confirm the overall regulatory path forward upon receipt of formal meeting minutes from the FDA in the coming weeks and will provide a further update at that time.

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 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 February 2, 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: February 2, 2015