

CATALYST PHARMACEUTICALS, INC.

Form 8-K

August 30, 2017

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 30, 2017

CATALYST PHARMACEUTICALS, 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

33134

Suite 1250

Coral Gables, Florida

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (305) 420-3200

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this Chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

On August 30, 2017, the Company issued a press release updating the status of its amifampridine phosphate (Firdapse®) development activities. The Company reported that it has reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment for the trial design, clinical endpoints and statistical analysis approach of the Company's planned Phase 3 clinical trial evaluating Firdapse® for the treatment of MuSK antibody positive Myasthenia Gravis (MuSK-MG). The Company also reported that, based on currently available information, it now expects to submit its new drug application (NDA) for Firdapse® for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) during the first quarter of 2018 rather than before the end of the year (as previously reported).

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 30, 2017.

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 Pharmaceuticals, Inc.

By: /s/ Alicia Grande
Alicia Grande
Vice President, Treasurer and CFO

Dated: August 30, 2017