CATALYST PHARMACEUTICALS, INC.
Form 8-K
February 12, 2018

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 12, 2018

CATALYST PHARMACEUTICALS, 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 1250

Coral Gables, Florida **33134**
(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 February 12, 2018, the Company announced the results of its recent Type C meeting with the U.S. Food and Drug Administration (FDA). Prior to the meeting, the Company had provided the FDA with its preliminary data package for the proposed NDA resubmission for Firdapse®, including clinical, non-clinical, regulatory and abuse liability elements, along with the recently reported positive top-line results from a second, confirmatory Phase 3 clinical trial of Firdapse® for the symptomatic treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and the recently completed FDA-required abuse liability studies demonstrating that Firdapse® does not have abuse potential. The minutes of the meeting received from the FDA reflect the FDA s advice to the Company that its proposed filing package will be sufficient for resubmission of an NDA for Firdapse®, and the Company currently anticipates resubmitting its NDA for Firdapse® for LEMS to the FDA by the end of the first quarter of 2018.

The Company also announced that it expects to report top-line results from its Phase 3 double-blind placebo-controlled study evaluating Firdapse® for the treatment of congenital myasthenic syndromes (CMS) in the second half of this year, and that it is evaluating its options for the most appropriate and efficient path forward to include CMS in any approved labeling of Firdapse®.

The Company s 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) Exhibits

99.1 Press release issued by the Company on February 12, 2018.

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: February 12, 2018