CATALYST PHARMACEUTICALS, INC.
Form 8-K
February 17, 2016

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 17, 2016

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		**33134**

Suite 1500

Coral Gables, Florida
(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 February 17, 2016, the Company issued a press release reporting that it has received a Refusal to File letter from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for Firdapse® (amifampridine phosphate). The Refusal to File letter states that, after a preliminary review, the FDA has found that the Company s application, which was filed in December 2015, was not sufficiently complete, and requests additional supporting information. The letter does not provide comment on the acceptability of the submitted clinical data, and no judgment is made in the letter on the efficacy or safety of Firdapse®.

The Company plans to request a meeting with the FDA as soon as possible to discuss the FDA s comments on the Company s NDA submission and to hopefully reach an understanding as to what will be required for the Firdapse® NDA to be filed by FDA for review.

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 February 17, 2016.

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 17, 2016