CATALYST PHARMACEUTICALS, INC.
Form 8-K
April 26, 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): April 26, 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

Suite 1250

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 April 26, 2016, the Company issued a press release providing an update on the content of the planned resubmission of a New Drug Application (NDA) for Firdapse® (amifampridine phosphate). The Company recently met with the Food and Drug Administration (FDA) to obtain greater clarity regarding what will be required by the FDA to accept the Firdapse® NDA for filing. The FDA has stated that, in addition to the results of the Company s previously submitted multi-center, randomized, placebo-controlled Phase 3 trial, the Company will need to submit positive results from an additional adequate and well-controlled study in patients with Lambert-Eaton Myasthenic Syndrome (LEMS). The FDA has stated that it is open to discuss a study design that could effectively accomplish the requirement with a small, short-term study, and the Company is currently in discussions with the FDA, and with the Company s clinical experts, regarding the protocol and logistics for this confirmatory study. Additionally, there is a requirement for several more short-term toxicology studies, which are expected to start soon.

The Company also reported that at March 31, 2016, it had approximately $52 million in cash and cash equivalents, certificates of deposit and short term investments, and that it believes it has the cash resources required to complete the additional studies, as well as funding operations.

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 April 26, 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: April 26, 2016