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): January 23, 2023

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 801** **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))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Exchange on Which Registered**	**Ticker Symbol**
Common Stock, par value $0.001 per share	NASDAQ Capital Market	CPRX

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 January 23, 2023, the Company issued a press release commenting on the U.S. Food and Drug Administration's (FDA) notice setting forth its position on Orphan Drug Exclusivity in light of the 11th Circuit's decision in Catalyst Pharmaceuticals, Inc. v. Becerra. The FDA announcement states that while the FDA is complying with the 11th Circuit decision in the Company's favor with respect to FIRDAPSE®, the FDA intends to continue to apply its regulations tying the scope of orphan drug exclusivity to the uses or indications for which a drug is approved with respect to other orphan drugs. The Company reported that it is not affected by the FDA's newly announced position and that the FDA's announcement confirms the FDA's previous decision to set aside the approval of RUZURGI® as a result of the 11th Circuit's decision.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press release issued by the Company on January 23, 2023
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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: January 24, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Comments on FDA's Announcement of its Position on Orphan Drug Exclusivity In Light of the 11th Circuit Decision in *Catalyst Pharmaceuticals, Inc. v. Becerra*

Announced Earlier Today-Notice Received from ANDA Filer for FIRDAPSE®

CORAL GABLES, Fla., Jan. 23, 2023 — Catalyst Pharmaceuticals, Inc. ("Catalyst") (NASDAQ: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases, today commented on the FDA's notice setting forth its position on Orphan Drug Exclusivity in light of the 11th Circuit's decision in Catalyst Pharmaceuticals, Inc. v. Becerra. The FDA announcement states that while the FDA is complying with the 11th Circuit decision in Catalyst's favor with respect to FIRDAPSE®, the FDA intends to continue to apply its regulations tying the scope of orphan drug exclusivity to the uses or indications for which a drug is approved with respect to other orphan drugs. Catalyst reports that it is not affected by the FDA's newly announced position and that the FDA's announcement confirms the FDA's previous decision to set aside the approval of RUZURGI® as a result of the 11th Circuit's decision. Further, Catalyst acquired the United States rights to RUZURGI®, including all intellectual property relating thereto, in July 2022. Finally, Catalyst's supplemental New Drug Application expanding its label for FIRDAPSE® to children ages 6-17 was approved by the FDA in September 2022.

Separately, Catalyst announced this morning that an abbreviated new drug application has been filed by Teva Pharmaceuticals, Inc. seeking authorization from the FDA to manufacture, use, or sell a generic version of FIRDAPSE® in the United States. As Catalyst has previously reported, the filing of a Paragraph IV challenge to FIRDAPSE® was not unexpected, and Catalyst intends to vigorously enforce its intellectual property rights relating to FIRDAPSE®.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, best-in-class medicines for rare diseases. Catalyst's New Drug Application for FIRDAPSE (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS") was approved in 2018 by the U.S. Food & Drug Administration and FIRDAPSE is commercially available in the United States as a treatment for adults and children ages six to seventeen with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS.

For more information, visit Catalyst's website at **www.catalystpharma.com**.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including those set forth in Catalyst's Annual Report on Form 10-K for the fiscal year 2021, its Quarterly Report on Form 10-Q, and its other filings with the U.S. Securities and Exchange Commission ("SEC"), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website, or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.