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 3, 2022

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

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**

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))

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 3, 2022, Catalyst issued a press release reporting the District Court which heard Catalyst's lawsuit against the United States Food and Drug Administration ("FDA") has entered summary judgment in favor of Catalyst. The District Court's order implements the prior decision of the U.S. Court of Appeals for the 11th Circuit, which ruled that the FDA's approval of Ruzurgi® (Jacobus Pharmaceutical Company, Inc.'s amifampridine product) for the treatment of pediatric patients with Lambert-Eaton myasthenic syndrome ("LEMS") violated Catalyst's exclusivity for FIRDAPSE® (amifampridine) Tablets 10 mg under the Orphan Drug Act. As a result of the District Court's order, the FDA marketing approval previously granted for Ruzurgi® is no longer valid.

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 3, 2022.
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: February 3, 2022

Exhibit 99.1

Catalyst Pharmaceuticals Reports that the FDA Marketing Approval Previously Granted for Ruzurgi® is No Longer Valid

Earlier this Week the District Court Granted Summary Judgement to Catalyst in Its Lawsuit Against the FDA and this FDA Action is the Result of that Decision

CORAL GABLES, Fla., Feb. 03, 2022 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (“Catalyst”) (Nasdaq: CPRX), a commercial-stage, patient- centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases, today reported that the District Court which heard Catalyst’s Lawsuit against the FDA has entered summary judgment in favor of Catalyst. The District Court’s order implements the prior decision of the U.S. Court of Appeals for the 11th Circuit, which ruled that the United States Food and Drug Administration’s (“FDA”) approval of Ruzurgi® (Jacobus Pharmaceutical Company, Inc.’s amifampridine product) for the treatment of pediatric patients with Lambert-Eaton myasthenic syndrome (“LEMS”) violated Catalyst’s exclusivity for FIRDAPSE® (amifampridine) Tablets 10 mg under the Orphan Drug Act. As a result of the District Court’s order, the FDA marketing approval previously granted for Ruzurgi® is no longer valid.

Patrick J. McEnany, Catalyst’s Chairman and CEO stated, “The entire Catalyst patient assistance team has been preparing for this likely outcome since the decision of the U.S. Circuit Court of Appeals for the 11th Circuit was reported. We have added additional care coordinators to our Catalyst Pathways® team, and our entire patient- focused team is ready to assist LEMS patients that are currently being treated with Ruzurgi® to provide a smooth, uninterrupted transition to FIRDAPSE.”

Information for Prescribers and Patients on the options available to determine how to transition patients from Ruzurgi® are available at 1-833-422-8259 or **www.yourcatalystpathways.com**.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best- in-class medicines for other 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 (“FDA”), and FIRDAPSE is commercially available in the United States as a treatment for adults 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.

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 (i) whether Jacobus Pharmaceutical Company, Inc. will appeal the ruling of the U.S. Court of Appeals for the 11th Circuit to the U.S. Supreme Court, whether the U.S Supreme Court will agree to hear the appeal, and, if the U.S. Supreme Court agrees to hear the appeal, whether the U.S. Supreme Court will overturn the decision of the 11th Circuit, and (ii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2020 and Catalyst's 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.

Source: Catalyst Pharmaceuticals, Inc.

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Source: Catalyst Pharmaceuticals, Inc.