

**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 10, 2022

CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

**355 Alhambra Circle
Suite 801
Coral Gables, Florida**
(Address of principal executive offices)

33134
(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 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 January 10, 2022, the Company issued a press release reporting that the 11th Circuit Court of Appeals has denied Jacobus Pharmaceutical Company Inc.'s petition for rehearing of the 11th Circuit's prior ruling to overturn the U.S. Food and Drug Administration (FDA) approval of Ruzurgi® for pediatric patients with Lambert-Eaton myasthenic syndrome (LEMS) based on the orphan drug exclusivity of FIRDAPSE®. The Company expects that the mandate to the District Court with instructions to enter summary judgment for the Company will be issued in the near future.

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 January 10, 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: January 10, 2022

Catalyst Pharmaceuticals Announces 11th Circuit Court of Appeals Denial of Jacobus Pharmaceutical Company Inc.'s Petition for Rehearing

CORAL GABLES, Fla., January 10, 2022 — 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 11th Circuit Court of Appeals has denied Jacobus Pharmaceutical Company Inc.'s petition for rehearing of the 11th Circuit's prior ruling to overturn the U.S. Food and Drug Administration (FDA) approval of Ruzurgi® for pediatric patients with Lambert-Eaton myasthenic syndrome (LEMS) based on the orphan drug exclusivity of FIRDAPSE®. Catalyst expects that the mandate to the District Court with instructions to enter summary judgment for Catalyst will be issued in the near future.

Patrick J. McEnany, Catalyst's Chairman and CEO stated: "Catalyst's priority has always been, and will continue to be, to put patients' needs first, and we are well prepared to address their questions and do everything we can to ensure that ALL LEMS patients continue with uninterrupted access to amifampridine for treating their LEMS condition, whether through commercial access or compassionate use access for those who qualify. Our patient-focused Catalyst Pathways® team stands ready to provide information to patients currently being treated with Ruzurgi on how best to transition to FIRDAPSE."

Information for Prescribers and Patients is available at 1-833-422-8259 and 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 will appeal the ruling of the 11th Circuit to the U.S. Supreme Court, (ii) the timing as to when the mandate will issue, and the timing, following the issuance of the mandate, when the District Court will enter summary judgment in favor of Catalyst in its lawsuit against the FDA, and (iii) 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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