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): September 30, 2021

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 September 30, 2021, Catalyst issued a press release reporting that it has received a positive decision from the 11th Circuit Court of Appeals in its appeal to overturn a District Court decision upholding the U.S. Food and Drug Administration's (FDA) approval of another amifampridine product, Ruzurgi®, for pediatric patients with Lambert-Eaton myasthenic syndrome (LEMS) despite existing Orphan Drug exclusivity for Catalyst's Firdapse® (amifampridine) Tablets 10 mg.

With this ruling, the 11th Circuit Court panel has reversed the District Court's decision and remanded the matter to the District Court with instructions to enter summary judgment for Catalyst. The Court's decision adopted Catalyst's core argument that the FDA's approval of Ruzurgi® violated Catalyst's rights to Orphan Drug Exclusivity.

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 September 30, 2021.
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: September 30, 2021

Exhibit 99.1

Catalyst Pharmaceuticals Receives Positive Decision from Appeals Court That Supports Orphan Drug Exclusivity for Firdapse® for LEMS

CORAL GABLES, Fla., September 30, 2021 (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 it has received a positive decision from the 11th Circuit Court of Appeals in its appeal to overturn a District Court decision upholding the U.S. Food and Drug Administration's (FDA) approval of another amifampridine product, Ruzurgi®, for pediatric patients with Lambert-Eaton myasthenic syndrome (LEMS) despite existing Orphan Drug exclusivity for Catalyst's Firdapse® (amifampridine) Tablets 10 mg.

With this ruling, the 11th Circuit Court panel has reversed the District Court's decision and remanded the matter to the District Court with instructions to enter summary judgment for Catalyst. The Court's decision adopted Catalyst's core argument that the FDA's approval of Ruzurgi® violated Catalyst's rights to Orphan Drug Exclusivity.

"We are extremely pleased with the 11th Circuit Court's decision and are hopeful that it brings to a close this case that is not just important for Catalyst, but for all patients living with rare diseases who depend on medicines that would not be available if not for the efforts and investment of pharmaceutical companies willing to pursue these indications," said Patrick J. McEnany, Catalyst's Chairman and CEO. "The purpose of the Orphan Drug Act is to encourage pharmaceutical companies to make the R&D investments necessary to bring FDA-approved therapies to patient populations living with very rare diseases, and the biggest incentive the Orphan Drug Act provides is the ability to have an exclusive market within that rare disease for their drug for seven years once they obtain approval. The Orphan Drug Act has proven successful for the more than 350 rare diseases that now have an FDA-approved treatment, but there still remains about 6,500 rare diseases that do not have an approved therapy – and the incentives to develop drugs to treat these rare diseases need to remain intact. This decision increases the hope for the patients living with these diseases that one day soon an approved drug for their rare disease might be a reality. This is a goal that we feel we share with the FDA despite this dispute, and we look forward to working with the FDA in the future on these issues.**"**

Mr. McEnany continued: "Now that the Circuit Court has ruled, we are aware that this will create questions and concerns among patients currently on Ruzurgi® as well as the physicians treating them. Our priority has always been, and will continue to be, to treat patients needs first, and so we are prepared to address their questions and do everything we can to ensure that ALL patients will have uninterrupted access to amifampridine for treating their LEMS condition. 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®. Please find below information on how to reach a Catalyst Pathways® team member to assist you with this transition."

Transitioning to Firdapse® – Information for Prescribers and Patients Available at 1-833-422-8259 and www.yourcatalystpathways.com

Catalyst Pathways®, as Catalyst's patient services program, is only open for adults LEMS patients to enroll, but its staff is available to answer questions from the parents of pediatric LEMS patients and the physicians treating them on available access for pediatric LEMS patients to obtain Firdapse®. These include:

- Catalyst's Expanded Access Program which can provide investigational product to pediatric LEMS patients.
- Catalyst will provide support if a prescriber wishes to file an investigator initiated Investigational New Drug Application (IND) with the FDA, including Catalyst providing investigational product once the physician's IND is active.
- In addition, Catalyst will approach FDA to discuss expanding the Firdapse® approval to include pediatric LEMS, though any effort to do so will take time and is not guaranteed.

For the larger number of adult LEMS patients who have been receiving Ruzurgi® off-label, prescribers should call 1-833-422-8259 in order to obtain information on transitioning those patients to Firdapse® and the steps to enroll them in Catalyst Pathways®.

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 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, in July 2020 Canada's national healthcare regulatory agency, Health Canada, approved the use of Firdapse® (amifampridine) for the treatment of adult patients in Canada with LEMS.

Firdapse® is currently being evaluated in clinical trials for the treatment of MuSK-MG and has received Orphan Drug Designation from the FDA for myasthenia gravis.

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) the extent to which this decision will affect the use of Firdapse® by LEMS patients, (ii) whether the FDA and/or Jacobus exercises their opportunities to appeal this decision, 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.

Media Contact
David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

Company Contact
Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

###