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 29, 2020

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) 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 29, 2020, Catalyst issued a press release reporting that the District Judge considering the Company's lawsuit against the FDA has adopted the Report and Recommendation of the Magistrate Judge, granted the FDA's and Jacobus' motions for summary judgement, and dismissed Catalyst's case. Catalyst is currently reviewing the District Judge's decision, which it believes to be erroneous, and intends to appeal the result to the Eleventh Circuit Court of Appeals.

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 29, 2020.
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 29, 2020

Catalyst Pharmaceuticals Announces Ruling on Lawsuit against the FDA and Intent to Appeal

CORAL GABLES, Fla., September 29, 2020 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), today reported that the federal judge handling Catalyst's case against the FDA has adopted the previously reported Report and Recommendation of the Magistrate Judge, granted summary judgment in favor of the FDA and Jacobus, and dismissed Catalyst's case. Catalyst is currently reviewing the District Judge's decision, which it believes to be erroneous, and intends to appeal the result to the Eleventh Circuit Court of Appeals.

In the order, the District Judge found that Catalyst's interpretation of the Orphan Drug Act "is not necessarily wrong, but it is not the only reasonable way to interpret the plain language of the statute." The District Judge found that the relevant statutory language was ambiguous and adopted FDA's interpretation rather than Catalyst's. The District Judge also rejected Catalyst's argument that the approved labeling for Ruzurgi® is false and misleading. As a result of the District Judge's decision, Ruzurgi® remains approved for the treatment of pediatric LEMS patients in the United States.

Patrick J. McEnany, the Company's Chairman and CEO, stated: "We are of course disappointed with Judge Bloom's decision to accept the Magistrate's Report and Recommendation in our lawsuit challenging the FDA's decision to approve Ruzurgi® for the treatment of pediatric patients with Lambert-Eaton Myasthenic Syndrome (LEMS). This decision in no way affects our *Catalyst Pathways™* patient services programs, market access for Firdapse® or our ongoing marketing efforts for Firdapse® to adult LEMS patients, which represent about 99% of the LEMS patient community."

Mr. McEnany continued: "Judge Bloom's decision also does not alter the fact that Jacobus Pharmaceuticals is not permitted to market Ruzurgi® to adult LEMS patients in the United States, and Catalyst intends to continue to aggressively take all steps necessary to protect Firdapse®'s exclusivity under the Orphan Drug Act."

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-MuSK antibody positive myasthenia gravis (MuSK-MG) and spinal muscular atrophy (SMA) Type 3. Catalyst's new drug application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in November 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is now commercially available in the United States. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of adult patients with LEMS in Canada.

Firdapse® is currently being evaluated in clinical trials for the treatment of MuSK-MG and SMA Type 3 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) whether Catalyst can successfully overturn the decision of the District Judge in the 11th Circuit Court of Appeals, (ii) whether Catalyst can continue to successfully market its product despite the lower price charged by Jacobus for its amifampridine drug, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2019 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.

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