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): June 12, 2019

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 June 12, 2019, the Company announced that it has filed a suit against the U.S. Food and Drug Administration (FDA) and several related parties challenging the recent approval of a new drug application and related drug labeling for Jacobus Pharmaceutical Company's drug Ruzurgi™ for the treatment of Lambert-Eaton Myasthenic Syndrome in pediatric patients. The complaint was filed on June 12, 2019 in the United States District Court for the Southern District of Florida.

The complaint alleges that the defendants' approval of Ruzurgi violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated Catalyst's statutory rights to Orphan Drug Exclusivity and to New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit seeks an order vacating the FDA's approval of Ruzurgi.

A copy of a press release issued by the Company announcing the filing of the lawsuit is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on June 12, 2019

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: June 12, 2019

Exhibit 99.1

Catalyst Pharmaceuticals Files Federal Lawsuit Against U.S. Food and Drug Administration

- Complaint Cites Multiple Violations of Food, Drug, and Cosmetic Act

CORAL GABLES, Fla., June 12, 2019 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), today announced it has filed a suit against the U.S. Food and Drug Administration (FDA) and several related parties challenging the recent approval of a new drug application and related drug labeling for Jacobus Pharmaceutical Company's drug Ruzurgi™ for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) in pediatric patients. The complaint was filed today in the United States District Court for the Southern District of Florida.

The complaint alleges that the defendants' approval of Ruzurgi violated multiple provisions of FDA regulations regarding labeling, resulting in misbranding in violation of the Federal Food, Drug, and Cosmetic Act (FDCA); violated Catalyst's statutory rights to Orphan Drug Exclusivity and to New Chemical Entity Exclusivity under the FDCA; and was in multiple other respects arbitrary, capricious, and contrary to law, in violation of the Administrative Procedure Act. Among other remedies, the suit seeks an order vacating the FDA's approval of Ruzurgi.

"New chemical entities (drugs) are required to go through the full drug approval process which requires demonstration of safety and efficacy," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "We believe the FDA has misapplied its regulations, contradicting decades of precedent and has undercut Catalyst's orphan drug exclusivity. We are compelled to bring this action, to preserve the specialized regulatory framework provided by the Orphan Drug legislation, and the prospect of future rare disease drug development for all rare disease patients in need of an approved treatment."

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including LEMS, anti-MuSK antibody positive myasthenia gravis (MuSK-MG), congenital myasthenic syndromes (CMS), 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 recently approved by the U.S. Food & Drug Administration, and Firdapse is now commercially available in the United States. Prior to its approval, Firdapse for LEMS had received breakthrough therapy designation and orphan drug designation from the FDA.

Firdapse is currently being evaluated in clinical trials for the treatment of MuSK-MG, CMS, and SMA Type 3 and has received Orphan Drug Designation from the FDA for CMS and myasthenia gravis. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults 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 Catalyst's suit to vacate the FDA's approval of Ruzurgi, among other relief, will be successful, (ii) the impact of the approval of Ruzurgi on Catalyst's future results of operations and business, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2018 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.

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