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 28, 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 June 28, 2021, the Company issued a press release commenting on the recent decision by Health Canada to re-issue a Notice of Compliance (NOC) for Ruzurgi® (amifampridine tablets), once again allowing the product to be marketed in Canada for patients with Lambert-Eaton Myasthenic Syndrome (LEMS). The Company and its Canadian sublicensee, KYE Pharmaceuticals (KYE), are currently evaluating their further litigation options to challenge Health Canada's most recent decision, since such decision means that the data protection that Catalyst and KYE are entitled to under Canadian law has not been recognized by Health Canada.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release issued by the Company on June 28, 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: June 28, 2021

Exhibit 99.1

Catalyst Pharmaceuticals Comments on Recent Decision by Health Canada to Re-issue an NOC for Ruzurgi®

CORAL GABLES, Fla., June 28, 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 commented on the recent decision by Health Canada to re-issue a Notice of Compliance ("NOC") for Ruzurgi® (amifampridine tablets), once again allowing the product to be marketed in Canada for patients with Lambert-Eaton Myasthenic Syndrome (LEMS). Health Canada's original NOC for Ruzurgi® for marketing in Canada was quashed in a recent decision of the Federal Court of Canada, which sent the matter back to Health Canada to re-determine its decision to grant marketing authority to Ruzurgi® despite Firdapse's® data protection rights under Canadian law.

Patrick J. McEnany, Catalyst's Chairman and CEO commented: "We are obviously disappointed with Health Canada's decision to re-issue an NOC for Ruzurgi®. Our effort to get Firdapse® approved in Canada commenced three years ago, at a time when there was no approved therapy in Canada to treat LEMS patients. Our interest was to assure that all adult LEMS patients had access to a Health Canada approved therapy, despite recognizing that our market opportunity in Canada was always expected to be small."

Catalyst and its Canadian sublicensee, KYE Pharmaceuticals ("KYE"), are currently evaluating their further litigation options to challenge Health Canada's most recent decision, since such decision means that the data protection that Catalyst and KYE are entitled to under Canadian law has not been recognized by Health Canada.

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) 10 mg tablets 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, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of 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.

Catalyst's 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 any future legal challenge by Catalyst and KYE to the NOC recently granted for Ruzurgi® will be successful, (ii) whether commercialization of Firdapse® in Canada will be successful, (iii) the impact in the United States if an amifampridine product is purchased in Canada for use in the United States, and (iv) 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.

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