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 3, 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 CFR240.13e-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 3, 2021, the Company issued a press release reporting a positive decision in its suit in Canadian Federal Court challenging Health Canada's approval of Medunik's New Drug Submission (NDS) for Ruzurgi®.

The lawsuit sought judicial review of Health Canada's decision to approve the NDS for Ruzurgi® (Jacobus Pharmaceutical's amifampridine product distributed in Canada by Medunik) and issue a Notice of Compliance (NOC) on August 10, 2020, as unreasonable due to Ruzurgi®'s product monograph and NDS explicitly referencing data included in Firdapse®'s NDS, approved by Health Canada on July 31, 2020 and given data protection as an Innovative Drug as of that date. The Judge's decision quashes the NOC previously issued for Ruzurgi® and remands the matter to the Minister of Health to redetermine its decision to grant marketing authorization to Ruzurgi® in spite of Firdapse®'s data protection rights. This leaves Ruzurgi® without marketing authorization in Canada

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 June 3, 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 3, 2021

Catalyst Pharmaceuticals, Inc.'s and KYE Pharmaceuticals' Lawsuit in Canadian Federal Court Quashes the Notice of Compliance (NOC) for Ruzurgi®

- Without an NOC, Ruzurgi® is without a Marketing Authorization in Canada

- Matter Remanded Back to Health Canada to Provide a More Transparent Record of Its Decision in Light of Firdapse®'s Data Protection

CORAL GABLES, Fla., June 03, 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, and KYE Pharmaceuticals Inc. ("KYE"), a private company headquartered in Mississauga, Ontario and focused on bringing medicines that fulfill clinically significant unmet needs to the Canadian market, today announced a positive decision in their lawsuit in Canadian Federal Court challenging Health Canada's approval of Medunik's New Drug Submission (NDS) for Ruzurgi®.

The lawsuit sought judicial review of Health Canada's decision to approve the NDS for Ruzurgi® (Jacobus Pharmaceutical's amifampridine product distributed in Canada by Medunik) and issue a Notice of Compliance ("NOC") on August 10, 2020, as unreasonable due to Ruzurgi®'s product monograph and NDS explicitly referencing data included in Firdapse®'s NDS, approved by Health Canada on July 31, 2020 and given data protection as an Innovative Drug as of that date. The Judge's decision quashes the NOC previously issued for Ruzurgi® and remands the matter to the Minister of Health to redetermine its decision to grant marketing authorization to Ruzurgi® in spite of Firdapse®'s data protection rights. This leaves Ruzurgi® without marketing authorization in Canada.

"We are very pleased that the Judge has taken seriously the need to protect Firdapse®'s data exclusivity," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "New chemical entities like Firdapse®, are required to go through a thorough drug approval process in Canada, requiring an exacting demonstration of safety and efficacy, and, in exchange for that effort, Health Canada regulations are supposed to prevent other pharmaceutical companies from being able to use the innovative drug's data in their NDS for 8 years from the date of the Notice of Compliance. In Firdapse®'s case, Health Canada allowed Medunik to use Catalyst's protected data in its application for Ruzurgi® during the data exclusivity period."

"As the company marketing Firdapse® in Canada," added Douglas Reynolds, President of KYE, "we are pleased to see that the judge is providing oversight on the Minister's decision to ignore the eight years of data protection for Firdapse® that was granted 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.

About KYE Pharmaceuticals

KYE Pharmaceuticals is a private company headquartered in Canada focused on bringing medications to the Canadian market which fulfill clinically significant and unmet needs. KYE has licensed many innovative products and was founded on an entrepreneurial spirit that optimizes our team's strengths and brings unique value to our partners, Canadian healthcare professionals, and most importantly, our patients. For more information please visit www.kyepharma.com.

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 KYE can successfully commercialize Firdapse® in Canada, (ii) whether any such commercialization of Firdapse® in Canada will be on a profitable basis, (iii) whether the decision of the court will be appealed and overturned, (iv) whether Health Canada will approve Ruzurgi® in the future without reference to Firdapse®'s protected data, (v) the impact in the United States if an amifampridine product is purchased in Canada for use in the United States, and (vi) 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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