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): March 11, 2022

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 March 11, 2022, Catalyst issued a press release announcing receipt of a favorable decision from the Federal Court of Canada ("Court") setting aside, for the second time, the decision of Canada's national healthcare regulatory agency, Health Canada, approving Ruzurgi® (amifampridine) for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS") patients. This decision sets aside the Notice of Compliance ("NOC") issued by Health Canada for Ruzurgi due to the inclusion of data developed for FIRDAPSE®, which is protected from such use by FIRDAPSE's status as an Innovative Drug in Canada. Drugs that qualify as Innovative Drugs are protected by regulation from other parties using their data as part of their submissions seeking an NOC for eight years from approval of the Innovative Drug. The Court determined that the Minister's approach to evaluating whether FIRDAPSE data deserved such protection was legally flawed and not supported by the evidence.

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 March 11, 2022.
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: March 11, 2022

Exhibit 99.1

Catalyst Pharmaceuticals and KYE Pharmaceuticals Announce a Second Favorable Canadian Federal Court Ruling Setting Aside Approval of Ruzurgi®

CORAL GABLES, Fla., March 11, 2022— 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 focused on bringing medications that fulfill clinically significant and unmet needs to the Canadian market, today announced receipt of a favorable decision from the Federal Court of Canada ("Court") setting aside for the second time the decision of Canada's national healthcare regulatory agency, Health Canada, to approve Ruzurgi® (amifampridine) for Lambert-Eaton Myasthenic Syndrome ("LEMS") patients.

This decision sets aside the Notice of Compliance ("NOC") issued by Health Canada for Ruzurgi due to the inclusion of data developed for FIRDAPSE®, which is protected from such use due to FIRDAPSE's status as an Innovative Drug in Canada. Drugs that qualify as Innovative Drugs are protected by regulation from other parties using that data as part of their submissions seeking an NOC for eight years from approval of the Innovative Drug. The Court determined that the Minister's approach to evaluating whether FIRDAPSE data deserved such protection was legally flawed and not supported by the evidence.

"We are very pleased by the Canadian Federal Court's decision, once again, that the data submitted to support FIRDAPSE's NOC in Canada was not adequately protected by the Minister due to its status as Innovative Drug. This is welcome news for our company and shareholders," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "Together with our partner KYE Pharmaceuticals who share our passion for addressing the needs of LEMS patients in Canada, we are well prepared to help eligible patients obtain access to this important medicine. This milestone further demonstrates our continued commitment to help ensure that all LEMS patients have access to this innovative medicine both in the U.S. and Canada."

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, its patients. For more information, please visit www.kyepharma.com.

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 Lambert-Eaton myasthenic syndrome ("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, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS. For more information, visit the Company's website.

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 Pharmaceuticals 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.

Source: Catalyst Pharmaceuticals

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