

**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): August 26, 2020

CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33057
(Commission
File Number)

76-0837053
(I.R.S. Employer
Identification No.)

**355 Alhambra Circle
Suite 1250
Coral Gables, Florida**
(Address of principal executive offices)

33134
(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 CFR 240.14d-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 August 26, 2020, the Company issued a press release announcing the filing of a proceeding in Canadian Federal Court challenging Health Canada's issuance of a Notice of Compliance (NOC) on August 10, 2020 for Medunik's New Drug Submission (NDS) for the drug Ruzurgi® (amifampridine) for the treatment of Lambert-Eaton Myasthenic Syndrome despite the fact that Catalyst's Firdapse® (amifampridine phosphate) was issued an NOC on July 31, 2020 and was granted data protection as an "innovative drug" as it was the first amifampridine product to be approved in Canada.

The proceeding seeks judicial review of Health Canada's decision to issue an NOC for Ruzurgi® as incorrect and unreasonable. Data protection, per Health Canada regulations, is supposed to prevent Health Canada from issuing an NOC to a drug that directly or indirectly references an innovative drug's data, for eight years from the date of the innovative drug's approval. The Ruzurgi® Product Monograph clearly references pivotal nonclinical carcinogenicity and reproductive toxicity data for amifampridine phosphate developed by Catalyst. As such, the Catalyst data was relied upon to establish the nonclinical safety profile of Ruzurgi® needed to meet the standards of the Canadian Food and Drugs Act. Data protection had, however, been granted to Firdapse® at the time that the NOC was issued for Ruzurgi®. Contrary to the regulations, Health Canada approved Ruzurgi® even though its drug submission included carcinogenicity and reproductive toxicity data with Firdapse®. Firdapse®'s status as an innovative drug should have prevented the marketing authorization of Ruzurgi®.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.(d) Exhibits99.1 [Press release issued by the Company on August 26, 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: August 26, 2020



KYE Pharmaceuticals and Catalyst Pharmaceuticals Challenge Health Canada's Decision to Overlook Firdapse® Data Exclusivity

-Notice of Application for Judicial Review Filed Today in the Federal Court of Canada

CORAL GABLES, Fla., August 26, 2020 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological 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 the filing of a proceeding in Canadian Federal Court challenging Health Canada's issuance of a Notice of Compliance (NOC) on August 10, 2020 for Medunik's New Drug Submission (NDS) for the drug Ruzurgi® (amifampridine) for the treatment of Lambert-Eaton Myasthenic Syndrome despite the fact that Catalyst's Firdapse® (amifampridine phosphate) was issued an NOC on July 31, 2020 and was granted data protection as an "innovative drug" as it was the first amifampridine product to be approved in Canada.

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"Innovative drugs, not previously approved in Canada, go through a rigorous drug approval process in Canada. A sponsor must submit clinical and nonclinical safety, tolerability, and efficacy data, to demonstrate the safety and efficacy of the drug," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "In exchange for that effort, and as an incentive to do that, Health Canada regulations are supposed to prevent other pharmaceutical companies from being able to use the innovator's (in this case Catalyst's) data as a basis for approval for eight years from the date of the Notice of Compliance. In Firdapse®'s case, Health Canada only did so for ten days. We are compelled to bring this application to preserve the specialized regulatory framework for new chemical entities, and the future of drug innovation in Canada."

“As the marketing partner for Firdapse® in Canada,” added Douglas Reynolds, President of KYE, “it is essential that we seek to enforce the data protection for Firdapse® as the regulations have been designed to do. Without that incentive, the motivation to bring new chemical entities to Canada is significantly diminished.”

About Lambert-Eaton Myasthenic Syndrome (LEMS)

Lambert-Eaton myasthenic syndrome, or LEMS, is a rare autoimmune disorder, most often characterized by muscle weakness of the limbs. The disease is caused by an autoimmune reaction where antibodies are formed against voltage gated potassium channels in the connection between nerves and the muscles they communicate with. In approximately 50% of cases, LEMS is associated with an underlying malignancy, most commonly small-cell lung cancer, and in some individuals, LEMS is the first symptom of such malignancy. LEMS generally affects the extremities, especially the legs. As the disease most affects the parts of limbs closest to the trunk, difficulties with climbing stairs or rising from a sitting position are commonly noted. Physical exercise and high temperatures tend to worsen the symptoms. Other symptoms occasionally seen include weakness of the muscles of the mouth, throat, and eyes. Individuals affected with LEMS also may have a disruption of the autonomic nervous system, including dry mouth, constipation, blurred vision, impaired sweating, and/or hypotension.

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 patients in Canada with LEMS.

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.

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.

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) the impact of competition from Ruzurgi® on sales of Firdapse® in Canada, (iv) whether Catalyst’s action to overturn the approval of Ruzurgi® in Canada will be successful, (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 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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