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): July 19, 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 July 19, 2021, the Company issued a press release announcing that the United States Patent and Trademark Office (USPTO) has issued a new U.S. patent to the Company for Firdapse®, U.S. Patent No. 11,060,128. The patent, “Methods of Administering 3,4-Diaminopyridine”, is directed to the use of suitable doses of amifampridine to treat patients with Lambert-Eaton myasthenic syndrome, or LEMS, that are slow metabolizers of amifampridine. Any drug product containing amifampridine with a label for the treatment of LEMS that states the patented dosing regimens and doses in the Dosing and Administration section of a product label could possibly infringe this patent.

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) Exhibits

99.1	Press release issued by the Company on July 19, 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: July 19, 2021

Catalyst Pharmaceuticals Announces Issuance of U.S. Patent 11,060,128 a Method of Use Patent with Claims Covering Firdapse®

- *New patent bolsters intellectual property protection for Firdapse®*
- *First in a family of four pending patents for Firdapse® to issue*

CORAL GABLES, Fla., July 19, 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 announced that the United States Patent and Trademark Office (USPTO) has issued a new U.S. patent to Catalyst Pharmaceuticals for Firdapse® (amifampridine) Tablets 10mg, U.S. Patent No. 11,060,128, Methods of Administering 3,4-diaminopyridine.

"We are pleased that this second patent for Firdapse® has been issued and believe that it further enhances our intellectual property protection for Firdapse®", said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. Mr. McEnany added, "We remain committed to serving the neuromuscular community by continuing to investigate Firdapse® for other rare neurodegenerative diseases. We also look forward to results from various studies, that if positive, could strengthen the value proposition for the Firdapse® brand."

"This patent is directed to innovative methods of administering amifampridine to slow metabolizers of amifampridine for the treatment of LEMS," commented Steven Miller, Ph.D., Chief Operating Officer and Chief Scientific Officer of Catalyst. Dr. Miller added, "We will submit a request to the FDA that this patent be listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the FDA's Orange Book), which is published by the United States Food and Drug Administration. This new patent is the first in a group of four pending patents to issue, and we are cautiously optimistic that the U.S. Patent and Trademark Office will find the other pending patents allowable as well."

Amifampridine is extensively metabolized by N-Acetyl Transferase, type 2 (or NAT2) and the rate of this metabolism can be quite variable in patients. The patent is directed to the use of suitable doses of amifampridine to treat patients suffering with Lambert-Eaton myasthenic syndrome (LEMS), that are slow metabolizers of amifampridine. Any drug product containing amifampridine with a label for the treatment of LEMS, that states the patented dosing regimens and doses in the Dosing and Administration section of a product label could possibly infringe this patent.

About Firdapse®

Firdapse® (amifampridine) Tablets 10 mg is an oral, nonspecific, voltage-dependent, potassium (K+) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca2+) channels, allowing for a subsequent influx of Ca2+. In turn, it induces the exocytosis of synaptic vesicles containing Acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission, and providing for improved muscle function.

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 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, in July 2020 Canada's national healthcare regulatory agency, Health Canada, approved the use of Firdapse® (amifampridine) for the treatment of adult 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.

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) the scope of protection from competition provided by this patent, (ii) whether any of Catalyst's other pending patents for Firdapse® will be issued, and (iii) 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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