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): October 6, 2020

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 1250** **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 October 6, 2020, 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. 10,793,893. The patent, "Methods of Administering 3,4-Diaminopyridine", claims methods of determining NAT acetylation status of a subject with a 3,4-DAP-sensitive disease, methods of selecting a dose of 3,4-DAP or a pharmaceutically acceptable salt thereof adjusted to a subject's acetylation status, methods of administering 3,4-diaminopyridine or a pharmaceutically acceptable salt thereof to a patient in need thereof, and methods of treating 3,4-DAP sensitive diseases. The patent will expire on April 7, 2034.

The Company had previously announced the USPTO's issuance of a Notice of Allowance for this patent on August 11, 2020. The patent is available on the USPTO's public website.

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 October 6, 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: October 6, 2020

Catalyst Pharmaceuticals Announces Issuance of U.S. Patent for Firdapse®

- Issued Patent is the First Covering Firdapse®

CORAL GABLES, Fla., October 06, 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, today announced that the United States Patent and Trademark Office (USPTO) has issued a new U.S. patent to Catalyst Pharmaceuticals for Firdapse® (amifampridine), U.S. Patent No. 10,793,893, Methods of Administering 3,4-Diaminopyridine, expiring April 7, 2034.

“We are pleased that our patent for Firdapse® (amifampridine) has issued and believe that it will create significant barriers to therapeutically equivalent generic competition from entering the market for approximately nine years beyond orphan drug exclusivity,” 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 investigator-sponsored trials that, if positive, will strengthen the value proposition for the use of Firdapse®.”

“This patent is directed to innovative methods of administering amifampridine to slow metabolizers of amifampridine,” commented Steven Miller, Ph.D., Chief Operating Officer and Chief Scientific Officer of Catalyst. Dr. Miller added, “Within the next few days, we intend to 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.”

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, regardless of the therapeutic indication, that are slow metabolizers of amifampridine. Any drug product containing amifampridine with a label that states the patented dosing regimens and doses in the Dosing and Administration section prior to 4/7/2034 could possibly infringe this patent. Generic drug product labels would necessarily have to do this, and Catalyst would take appropriate action to protect its intellectual property.

About Firdapse®

Firdapse® (amifampridine) 10 mg tablets 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 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.

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 the patent, and (ii) those factors described in Catalyst's Annual Report on Form 10-K for fiscal year 2019 and its 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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