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 2, 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 2, 2022, the Company issued a press release announcing that the United States Patent and Trademark Office (USPTO) has notified the Company that an additional patent covering FIRDAPSE® (amifampridine) Tablets 10 mg, the Company's proprietary formulation of amifampridine, will issue on March 8, 2022, and that two additional patents will issue on March 15, 2022. The new patents are directed to the treatment of patients suffering from LEMS who have two N-acetyl transferase 2 (NAT2) fast alleles, one fast and one slow allele, or two slow alleles. Along with Catalyst's two current patents, the new patents cover the treatment of all amifampridine metabolizer types within the LEMS patient population.

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 March 2, 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 2, 2022

Catalyst Pharmaceuticals Further Strengthens FIRDAPSE® U.S. Patent Portfolio

Three New Patents Covering Additional Patient Amifampridine Metabolizer Types have been Allowed and will Issue in March 2022

Reinforces and Diversifies FIRDAPSE Long-Term Patent Portfolio

Patent Portfolio Provides Intellectual Property Protection Until 2034

CORAL GABLES, Fla., March 02, 2022 (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 notified Catalyst that an additional patent covering FIRDAPSE® (amifampridine) Tablets 10 mg, the Company's proprietary formulation of amifampridine, will issue on March 8, 2022, and that two additional patents will issue on March 15, 2022. FIRDAPSE is currently the only approved treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS") in the U.S.

The new patents are directed to the treatment of patients suffering from LEMS who have two N-acetyl transferase 2 (NAT2) fast alleles, one fast and one slow allele, or two slow alleles. Along with Catalyst's two current patents, the new patents cover the treatment of all amifampridine metabolizer types within the LEMS patient population.

"We are pleased to have been notified about these new U.S. patents that will further fortify our intellectual property estate to provide lasting durability for our flagship product," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "As part of our portfolio strategy, we will continue to execute on our key initiatives to strengthen and protect the long-term commercial potential of FIRDAPSE, which currently has patent exclusivity protection in the U.S. until 2034."

"The claims in these three new patents, combined with our two previously issued patents, provide comprehensive protection for the FIRDAPSE franchise, regardless of the NAT2 metabolizer status of the patients," commented Steven Miller, Ph.D., Chief Operating Officer and Chief Scientific Officer of Catalyst. "The issuance of these new patents will further extend FIRDAPSE's growing intellectual property portfolio. Plans are underway to submit these additional patents for inclusion in the FDA Orange Book after their issuances on March 8 and March 15, 2022, respectively. Along with the two patents currently listed, this will bring the total number to five patents listed."

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 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 at www.catalystpharma.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) the scope of protection from competition provided by Catalyst's patent portfolio, (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.