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): November 2, 2023

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

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))

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

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 November 2, 2023, the Company issued a press release reporting that the United States Patent and Trademark Office has notified the Company that two additional patents covering FIRDAPSE® (amifampridine) Tablets 10 mg, were allowed and will be granted within the next two months. These new patents are for claims associated with the unique and novel, previously unknown, bioavailability of FIRDAPSE under fasting and fed conditions of dosing. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by the Company on November 2, 2023.
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: November 3, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Receives Two New U.S. Patent Allowances For FIRDAPSE®

New Patents Further Reinforce the FIRDAPSE® (amifampridine) Intellectual Patent Portfolio

CORAL GABLES, Fla., November 2, 2023 - Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases, today announced that the Company has received notification by the United States Patent and Trademark Office ("USPTO") that two additional patents covering FIRDAPSE® (amifampridine) Tablets 10 mg, were allowed and will be granted within the next two months. These new patents are for claims associated with the unique and novel, previously unknown, bioavailability of FIRDAPSE under fasting and fed conditions of dosing. FIRDAPSE is the only approved treatment available in the U.S. for Lambert-Eaton myasthenic syndrome.

"We are very pleased to receive these patent notifications from the USPTO. This milestone reaffirms our unwavering dedication to advancing our core objectives, which are crucial in strengthening and maintaining the ongoing commercial success of our flagship product, FIRDAPSE," stated Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "Aligned with our portfolio strategy, we remain committed to advancing our core objectives to reinforce and safeguard the sustained commercial viability of FIRDAPSE, which currently benefits from patent exclusivity protection in the United States until 2037."

"These patent allowances strengthen our cumulative understanding of the uniqueness of FIRDAPSE and bolster its strong intellectual property estate offering enhanced patent protection," stated Dr. Steven Miller, Chief Operating Officer and Chief Scientific Officer of Catalyst. "These two new patents, with expiry dates out to mid-2032, cover claims related to the product's novel and unique bioavailability when administered under fasting and fed dosing conditions, further strengthening our NAT2 family of patents. We expect these patents to be granted within two months. Preparations are already in motion to include these additional FIRDAPSE patents in the FDA Orange Book post-grant, bringing the total listed patent count to eight."

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

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare neurological and epileptic diseases. Catalyst's flagship U.S. commercial product is FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") for adults and for children ages six to seventeen. In January 2023, Catalyst acquired the U.S. commercial rights to FYCOMPA® (perampanel) CIII, a prescription medicine approved in people with epilepsy aged four and older alone or with other medicines to treat partial-onset seizures with or without secondarily generalized seizures and with other medicines to treat primary generalized tonic-clonic seizures for people with epilepsy aged 12 and older. 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. Finally, on July 18, 2023, Catalyst acquired an exclusive license for North America for AGAMREE® (vamorolone) oral suspension 40 mg/mL, a novel corticosteroid treatment for Duchenne Muscular Dystrophy. AGAMREE® previously received FDA Orphan Drug and Fast Track designations and was recently approved for commercialization in the U.S. on October 26, 2023.

For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com. For Full Prescribing Information for AGAMREE®, please visit www.agamree.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 these new patents will withstand challenge by generic drug companies, (ii) whether Catalyst can successfully protect FIRDAPSE® from generic competitors until the expiration of its patent estate, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2022 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.

Source: Catalyst Pharmaceuticals

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