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): May 30, 2024

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 CFR240.14d-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 May 30, 2024, the Company issued a press release announcing that the U.S. Food and Drug Administration has approved its supplemental New Drug Application increasing the indicated maximum daily dose of FIRDAPSE® (amifampridine) for adults and pediatric patients weighing more than 45 kg from 80 mg to 100 mg for the treatment of Lambert-Eaton myasthenic syndrome.

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 May 30, 2024.
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/ Michael W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

Dated: May 30, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Receives U.S. FDA Approval For Increased Maximum Daily Dose For FIRDAPSE®

CORAL GABLES, Fla., May 30, 2024 — 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 and difficult-to-treat diseases, today announced that the U.S. Food and Drug Administration ("FDA") has approved its supplemental New Drug Application ("sNDA") increasing the indicated maximum daily dose of FIRDAPSE® (amifampridine) for adults and pediatric patients weighing more than 45 kg from 80 mg to 100 mg for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS"). The increased maximum daily dose offers healthcare providers and patients greater flexibility in treatment regimens for the management of LEMS.

LEMS is a rare autoimmune disorder characterized by muscle weakness and fatigue. FIRDAPSE is a potassium channel blocker indicated for the treatment of LEMS in adults and pediatric patients six years of age and older and works by increasing the release of acetylcholine, a neurotransmitter, at the neuromuscular junction, which helps improve muscle function in people with LEMS. FIRDAPSE is currently the only U.S. approved treatment for LEMS and this approval broadens the approved dosing options for prescribers treating LEMS.

"We are pleased to receive the approval for the increased maximum daily dose of FIRDAPSE," said Richard J. Daly, President and CEO of Catalyst. "This pivotal achievement further underscores our dedication to meeting the evolving needs of LEMS patients and their healthcare providers. We believe that this milestone will have a meaningful impact on the lives of LEMS patients, offering a new level of flexibility in treatment while aligning with our overarching mission to optimize LEMS patient outcomes."

Patients in the U.S. can access FIRDAPSE by prescription through their healthcare providers. For those seeking more information, the Catalyst Pathways® Patient Assistance Program for FIRDAPSE® offers comprehensive support, including a dedicated team to assist families throughout the treatment journey for eligible patients. Caregivers and healthcare professionals may call 1-833-422-8259 or visit www.yourcatalystpathways.com for further details.

For additional information, please visit the company website at Catalyst Pharmaceuticals.

About Catalyst Pharmaceuticals, Inc.

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare and difficult-to-treat 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. 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 approved by the FDA for commercialization in the U.S. on October 26, 2023. AGAMREE became commercially available by prescription in the U.S. on March 13, 2024.

For more information about Catalyst Pharmaceuticals, Inc., please visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, please 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, as that term is defined in the Private Securities Litigation Reform Act of 1995. 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 those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2023 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, Inc.

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