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 13, 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 October 13, 2023, the Company issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted for review the Company's supplemental New Drug Application to increase the indicated maximum daily dosage of FIRDAPSE® (amifampridine) Tablets 10 mg from 80 mg to 100 mg. The FDA has assigned a Prescription Drug User Fee Act action date of June 4, 2024. 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 October 13, 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: October 13, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Announces FDA Acceptance of the Supplemental New Drug Application for FIRDAPSE®

The sNDA Seeks to Increase the Indicated Maximum Daily Dose for FIRDAPSE to 100mg for the Treatment of Lambert-Eaton Myasthenic Syndrome

U.S. FDA Assigned Target Action Date of June 4, 2024

CORAL GABLES, Fla., October 13, 2023 - Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today announced that the U.S. Food and Drug Administration ("FDA" or "Agency") has accepted for review the Company's supplemental New Drug Application ("sNDA") to increase the indicated maximum daily dosage of FIRDAPSE® (amifampridine) Tablets 10 mg from 80mg to 100mg for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS"). The Agency assigned a Prescription Drug User Fee Act ("PDUFA") action date of June 4, 2024. FIRDAPSE is currently approved in the U.S. for the treatment of LEMS for adults and for children ages six to seventeen.

"We are pleased by the Agency's acceptance of the sNDA filing for FIRDAPSE, marking yet another milestone in the advancement of our initiative to address an important need of LEMS patients and their physicians who desire an increased daily dosage," stated Patrick J. McEnany, Chairman and CEO of Catalyst. "FIRDAPSE has proven to be an important therapeutic option for individuals in the U.S. affected by LEMS, including those comorbid with small-cell lung cancer. If approved, this will offer additional indicated dosage options for LEMS patients who may benefit from a FIRDAPSE daily dosage greater than 80mg and further underscores our unwavering commitment to the patient communities we serve. We look forward to working collaboratively with the Agency during the application review process."

Lambert-Eaton myasthenic syndrome, or LEMS, is a rare autoimmune neuromuscular disorder characterized primarily by muscle weakness of the limbs. The disease is caused by an autoimmune reaction where antibodies are formed against voltage-gated calcium channels on nerve endings, which damages the channels. These calcium channels are responsible for the transport of charged calcium atoms that activate the biochemical machinery responsible for releasing acetylcholine. Acetylcholine is the neurotransmitter responsible for causing muscles to contract, and the failure to release enough of this neurotransmitter results in muscle weakness in LEMS patients.

Additionally, LEMS is often associated with an underlying malignancy, most commonly small-cell lung cancer, and in some individuals, LEMS is the first symptom of such malignancy.

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 vamorolone, a promising best-in-class dissociative anti-inflammatory steroid treatment for Duchenne Muscular Dystrophy. Vamorolone has received FDA Orphan Drug and Fast Track designations and has been granted a PDUFA action date of 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.

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 the sNDA will be approved, and (ii) 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, Inc.

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