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 9, 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 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 9, 2023, the Company issued a press release reporting that it has recently concluded a Type C meeting with the U.S. Food and Drug Administration regarding its plans to file a supplemental New Drug Application to increase the maximum daily dosage of FIRDAPSE® from 80mg to 100mg 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 9, 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: May 9, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Advances sNDA Submission Plans To Increase Indicated Maximum Dose For FIRDAPSE® From 80 mg Per Day To 100 mg Per Day

Concluded Positive FDA Type-C Meeting in Early May 2023

Company On Track to Submit an sNDA Early in the Third Quarter of 2023

Coral Gables, Fla., May 9, 2023 — Catalyst Pharmaceuticals, Inc. ("Catalyst") (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases, today reported that it recently concluded a Type C meeting with the U.S. Food and Drug Administration ("FDA" or "Agency") regarding its plans to file a supplemental New Drug Application ("sNDA") to increase the maximum daily dosage of FIRDAPSE® (amifampridine) from 80mg to 100mg for the treatment of Lambert Eaton myasthenic syndrome ("LEMS"). Based on the feedback received from the meeting, Catalyst believes it now has the information necessary to complete the submission of its sNDA for marketing approval in the U.S. early in the third quarter of 2023.

"The meeting was held for alignment of our strategy to support a proposed maximum 100-milligram daily dose indication of FIRDAPSE," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "We thank the Agency for their collaboration in reviewing our submitted materials and providing their feedback. Based on the positive outcome of the meeting, we remain on track to file an sNDA submission early in the third quarter of 2023. If approved, we believe this change will address an important need for LEMS patients, caregivers, and physicians who may benefit from an optimized therapy."

FIRDAPSE® (amifampridine) Tablets 10mg is currently approved in the U.S. for the treatment of LEMS in adults and for children ages six to seventeen with an indicated maximum daily dose of 80 milligrams.

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 ("SCLC"), 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.

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 Catalyst can submit an sNDA to increase the indicated maximum dose of FIRDAPSE® from 80 mg per day to 100 mg per day, and the timing of that submission, (ii) whether any such sNDA submission will be accepted for filing by the FDA, (iii) whether any sNDA accepted for filing will be approved, and the timing of any such approval, and (iv) 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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