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): September 29, 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

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 September 29, 2022, the Company issued a press release announcing that the U.S. Food and Drug Administration has approved the supplemental New Drug application to expand the indicated age range for FIRDAPSE® (amifampridine) Tablets 10 mg to include pediatric patients, six years of age and older for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS"). FIRDAPSE® is currently approved in the U.S. and Canada for the treatment of LEMS in adult patients.

A copy of the Company's press release is attached as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by the Company on September 29, 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: September 29, 2022

Exhibit 99.1

Catalyst Pharmaceuticals Announces FDA Approval of Supplemental New Drug Application for FIRDAPSE® Expanding Patient Population to Include Pediatric Patients

FIRDAPSE is Now a Treatment Option for All LEMS Patients 6 Years of Age and Older in the U.S.

CORAL GABLES, Fla., Sept. 29, 2022 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. ("Catalyst") (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 U.S. Food and Drug Administration ("FDA") has approved the supplemental New Drug Application ("sNDA") to expand the indicated age range for FIRDAPSE® (amifampridine) Tablets 10 mg to include pediatric patients, six years of age and older for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS"). FIRDAPSE is currently approved in the U.S. and Canada for the treatment of LEMS in adult patients.

"We are very pleased to have received FDA approval for the expanded pediatric indication for FIRDAPSE. While the U.S. LEMS pediatric population is an exceptionally small number of patients, this positive outcome helps ensure that all eligible LEMS patients have access to FIRDAPSE for the treatment of this rare disease," stated Patrick J. McEnany, Chairman and CEO of Catalyst. "This milestone represents our long-standing and unwavering commitment to the LEMS patient community, and we are pleased that this medicine is now available for this important patient population. We look forward to building upon our recent achievements with a sustained focus on addressing the needs of LEMS patients. We thank the Agency for their collaboration during the review of this application and our Catalyst employees for their shared commitment to improving the lives of patients."

As part of Catalyst's efforts to help ensure those patients who can benefit from FIRDAPSE are able to obtain access, Catalyst offers a comprehensive patient access support program and patient assistance for qualifying LEMS patients through its Catalyst Pathways® program. More information is available for prescribers and patients by visiting www.yourcatalystpathways.com or by calling 1-833-422-8259.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, best-in-class medicines for 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 and children ages six to seventeen 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 additional information about the Company, please visit 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 those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2021 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.

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