# 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): January 18, 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 January 18, 2023, Catalyst Pharmaceuticals, Inc. (the "Company") received a Paragraph IV Certification Notice Letter (the "Notice Letter") from Teva Pharmaceuticals, Inc. ("Teva") advising that Teva had submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the United States.

In the Notice Letter, Teva states that it intends to market a generic version of FIRDAPSE® before the expiration of the Company's patents listed in the FDA Orange Book covering FIRDAPSE®: U.S. Patent Numbers 10,626,088 (expiring February 2037); 10,793,893 (expiring May 2034); 11,060,128 (expiring June 2032); 11,268,128 (expiring June 2032); 11,274,331 (expiring June 2032); and 11,274,332 (expiring June 2032). Teva's Notice Letter states that its ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Teva's ANDA submission.

Under the Food and Drug Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, after receipt of a valid Paragraph IV notice, the Company may bring a patent infringement suit in a federal district court against Teva within 45 days from the receipt of the Notice Letter. If such a suit is commenced within the 45-day period, the Company is entitled to a 30 month stay on the FDA's ability to give final approval to any proposed products that reference FIRDAPSE®. In the present case, the 30-month stay is expected to preempt any final approval by the FDA on Teva's ANDA until at least May 2026.

The Company is currently assessing the Notice Letter and intends to vigorously defend its intellectual property rights relating to FIRDAPSE®.

On January 23, 2023, the Company issued a press release announcing the receipt of the Notice Letter. The press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

*Forward-Looking Statements*

This Current Report on Form 8-K contains forward-looking statements relating to, among other things, the Company's intention to vigorously enforce its intellectual property rights. Any such statements that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "potential," "may," "expects," "intends" and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward looking statements as a result of these risks and uncertainties, which include, without limitation, those risks and uncertainties relating to the Company's ability to successfully enforce its intellectual property rights and to defend its patents, the possible introduction and timing of generic competition to FIRDAPSE®, and the other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. The Company does not undertake any obligation to update any forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| | |
|---|---|
| 99.1 | Press release issued by the Company on January 23, 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: January 23, 2023

**Exhibit 99.1**

**Catalyst Pharmaceuticals Notified of Abbreviated New Drug Application Filing for FIRDAPSE®**

**CORAL GABLES, Fla., January 23, 2023** – 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 it has received a Paragraph IV Certification Notice Letter (the "Notice Letter") from Teva Pharmaceuticals, Inc. ("Teva") advising that Teva had submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking authorization from the FDA to manufacture, use or sell a generic version of FIRDAPSE® in the United States.

In the Notice Letter, Teva states that it intends to market a generic version of FIRDAPSE® before the expiration of Catalyst's patents listed in the FDA Orange Book covering FIRDAPSE®: U.S. Patent Numbers 10,626,088 (expiring February 2037); 10,793,893 (expiring May 2034); 11,060,128 (expiring June 2032); 11,268,128 (expiring June 2032); 11,274,331 (expiring June 2032); and 11,274,332 (expiring June 2032). Teva's Notice Letter states that its ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Teva's ANDA submission.

Under the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, Catalyst has 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit in a federal district court against Teva to trigger a stay precluding FDA from approving Teva's ANDA until May 2026 or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first.

Catalyst is currently assessing the Notice Letter and intends to vigorously enforce its intellectual property rights relating to FIRDAPSE®.

**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 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 more information, visit Catalyst's website at 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 (i) those risks and uncertainties relating to Catalyst's ability to successfully enforce its intellectual property rights and to defend its patents, (ii) the possible introduction and timing of generic competition to FIRDAPSE®, and (iii) 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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