# 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 8, 2025**

# 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**<br>**Suite 801**<br>**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 January 8, 2025, the Company issued a press release announcing that it and its licensor, SERB S.A. ("SERB") have entered into a Settlement Agreement with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively "Teva"). This agreement resolves the patent litigation brought by the Company and SERB in response to Teva's Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of FIRDAPSE® (amifampridine) 10 mg tablets prior to the expiration of the applicable patents.

Pursuant to the terms of the settlement agreement, Teva has agreed not to market its generic version of FIRDAPSE® in the United States any earlier than February 25, 2035, if approved by the U.S.. Food and Drug Administration, unless certain limited circumstances customarily included in these types of settlements occur. In accordance with the Agreement, Catalyst/SERB and Teva will terminate all ongoing patent litigation between them that is currently pending in the U.S. District Court for the District of New Jersey.

The Company further reported in the press release that the pending FIRDAPSE® patent litigation against the remaining defendants, Hetero (for all of FIRDAPSE®'s Orange Book-listed patents) and Lupin (only for Catalyst's FIRDAPSE® patent expiring in 2037) is ongoing, and there can be no assurance whether such ongoing patent litigation will allow a generic version of FIRDAPSE® to be marketed in the U.S. prior to February 25, 2035.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| | |
|---|---|
| 99.1 | Press release issued by the Company on January 8, 2025. |
| 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: January 8, 2025

**Exhibit 99.1**

**Catalyst Pharmaceuticals Announces Settlement of FIRDAPSE® (amifampridine) Patent Litigation with Teva Pharmaceuticals**

*As Part of the Settlement, Teva Receives a License to Market Generic FIRDAPSE Beginning in February 2035*

**CORAL GABLES, Fla., January 8, 2025**- 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 Company and its licensor SERB S.A. ("SERB") have entered into a Settlement Agreement (Agreement) with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. (collectively Teva). This Agreement resolves the patent litigation brought by Catalyst and SERB in response to Teva's Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of FIRDAPSE® (amifampridine) 10 mg tablets prior to expiration of the applicable patents.

Pursuant to the terms of the Agreement, Teva will not market its generic version of FIRDAPSE in the United States any earlier than February 25, 2035, if approved by the U.S. Food and Drug Administration (FDA), unless certain limited circumstances customarily included in these types of agreements occur. In accordance with the Agreement, the parties will terminate all ongoing patent litigation between Catalyst/SERB and Teva regarding FIRDAPSE patents pending in the U.S. District Court for the District of New Jersey. The pending FIRDAPSE patent litigation against the remaining defendants, Hetero (for all of FIRDAPSE's Orange Book-listed patents) and Lupin (only for Catalyst's FIRDAPSE patent expiring in 2037), is ongoing.

As required by law, the companies will submit the confidential license agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

**About Catalyst Pharmaceuticals**

Catalyst Pharmaceuticals, Inc. (Nasdaq: CPRX) is a biopharmaceutical company committed to improving the lives of patients with rare diseases. With a proven track record of bringing life-changing treatments to the market, we focus on in-licensing, commercializing, and developing innovative therapies. Guided by our deep commitment to patient care, we prioritize accessibility, ensuring patients receive the care they need through a comprehensive suite of support services designed to provide seamless access and ongoing assistance. Catalyst maintains a well-established U.S. presence while actively seeking to expand its global commercial footprint through strategic partnerships. Catalyst, headquartered in Coral Gables, FL., was recognized as one of North America's Fastest-Growing Companies on the 2024 Deloitte Technology Fast 500™ List.

For more information, please visit Catalyst's website at www.catalystpharma.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 (i) whether the ongoing litigation matters referenced above between Catalyst/SERB and Hetero and Lupin with respect to FIRDAPSE®'s Orange Book listed patents will allow a generic version of FIRDAPSE to be marketed in the U.S. prior to February 25, 2035, and (ii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2023, its Quarterly Report on Form 10-Q for the fiscal quarter ending September 30, 2024, 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.

**Investor Contact**
Mary Coleman, Catalyst Pharmaceuticals, Inc.
(305) 420-3200
**mcoleman@catalystpharma.com**

**Media Contact**
David Schull, Russo Partners
(858) 717-2310
**david.schull@russopartnersllc.com**