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): March 1, 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 March 1, 2023, Catalyst Pharmaceuticals, Inc. (the "Company") and its licensing partner SERB SA ("SERB"), initiated litigation against each of (i) Annora Pharma Private Limited, Grave Consulting Services, Inc., Hetero Labs Limited, and Hetero USA, Inc. (collectively, "Hetero"), (ii) Lupin Ltd., Lupin, Inc. and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), and (iii) Teva Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Limited (collectively, "Teva", and together with Hetero and Lupin, the "Defendants") for infringement of six patents covering FIRDAPSE® (amifampridine) tablets 10mg for the treatment of Lambert-Eaton Myasthenic Syndrome ("LEMS") for adults and children aged six and up. The litigation involves United States patent nos. 10,626,088, 10,793,893, 11,060,128, 11,268,128, 11,274,331 and 11,274,332 (collectively, the "Patents") related to FIRDAPSE®. The Patents will begin to expire in April 2034. The Company licenses the Patents from SERB. As an orphan drug, FIRDAPSE® is under a seven year exclusivity period with the United States Food and Drug Administration ("FDA") that expires in November 2025.

The lawsuits, each of which were filed in the United States District Court for the District of New Jersey, allege that the Defendants infringed the Patents by submitting to the FDA Abbreviated New Drug Applications (ANDAs) seeking to market a generic version of FIRDAPSE® prior to the expiration of the Patents. Filing the lawsuits within 45 days of receiving each of the Defendants' Paragraph IV notice letters triggers an automatic stay precluding the FDA from approving any ANDA for FIRDAPSE® until the earlier of May 2026 or entry of a judgment holding the patents invalid, unenforceable, or not infringed, whichever first occurs.

Although there can be no assurance, the Company believes that its patent estate will protect FIRDAPSE® from generic competition for the life of its patents.

The Company plans to provide updates on any additional Paragraph IV certification notices that it may receive from ANDA filers seeking approval of a generic version of FIRDAPSE® in its Quarterly Reports on Form 10-Q and its Annual Reports on Form 10-K filed with the Securities and Exchange Commission.

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: March 7, 2023