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): October 26, 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 October 26, 2023, the Company issued a press release reporting that Santhera Pharmaceuticals ("Santhera") has obtained U.S. Food and Drug Administration approval for AGAMREE® (vamorolone) oral suspension 40 mg/mL for use in treating Duchenne Muscular Dystrophy ("DMD") in patients aged two years and older. In July 2023, the Company secured the exclusive North American license and commercial rights for AGAMREE® from Santhera for DMD and other potential indications. As part of that transaction, Santhera will promptly transfer the approved New Drug Application for AGAMREE® to the Company. 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 October 26, 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: October 27, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Reports FDA Approval of AGAMREE® (vamorolone) for Duchenne Muscular Dystrophy Granted to Santhera Pharmaceuticals

AGAMREE® Indicated for the Treatment of Duchenne Muscular Dystrophy for Patients Aged Two Years and Older

Catalyst Holds the Exclusive North American License to Commercialize AGAMREE (vamorolone) for Duchenne Muscular Dystrophy and Other Potential Indications

Novel Corticosteroid With Favorable Side Effect Profile

Catalyst Expects to Commercially Launch AGAMREE in Q1 2024

AGAMREE Comprehensive Patient Assistance Program to Help Ensure Affordable Access for All DMD Patients Upon Commercial Launch

Coral Gables, Fla, Oct. 26, 2023 — Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today reported that Santhera Pharmaceuticals ("Santhera") has obtained U.S. Food and Drug Administration ("FDA") approval for AGAMREE® (vamorolone) oral suspension 40 mg/mL for use in treating Duchenne Muscular Dystrophy ("DMD") in patients aged two years and older. AGAMREE offers a novel corticosteroid treatment option for DMD, addressing a significant unmet medical need. In July 2023, Catalyst secured the exclusive North American license and commercial rights for AGAMREE from Santhera for DMD and other potential indications, bolstering its neuroscience commercial portfolio with a highly synergistic neuromuscular asset. As part of that transaction, Santhera will promptly transfer the approved New Drug Application for AGAMREE to Catalyst.

FDA's approval of AGAMREE® was based on the data from the pivotal Phase 2b VISION-DMD study as supplemented with safety information collected from three open-label studies, including extension studies. In these trials, AGAMREE was administered at doses ranging from 2 to 6 mg/kg/day, extending for a period of up to 48 months. Compared with current standard-of-care corticosteroids, this novel corticosteroid treatment exhibited comparable efficacy, with data suggesting a reduction in adverse events, notably related to bone health, growth trajectory, and behavior.

"We strongly believe that this novel steroid has the transformational potential to make a significant difference for patients living with Duchenne Muscular Dystrophy and potentially other chronic inflammatory diseases. The approval of AGAMREE underscores the potential of reshaping the DMD treatment paradigm for this life-threatening rare disease. The addition of AGAMREE expands our rare neuromuscular disease portfolio, and we look forward to executing on our proven commercial capabilities to bolster our long-term growth potential," said Patrick J. McEnany, Chairman and CEO of Catalyst Pharmaceuticals. "Our unwavering commitment extends beyond this important milestone as we are resolute in our mission to ensure that DMD patients in the U.S. have access to this treatment option as we

believe that AGAMREE may offer the potential of increasing the duration of ambulation and mobility in these patients, thereby significantly improving their overall quality of life. We expect to launch the product in the first quarter of 2024. At that time, we will introduce a comprehensive financial assistance program aimed at helping ensure accessibility and minimizing patient co-pays and deductibles, thereby enhancing affordability for all DMD patients. We look forward to successfully commercializing this product with a continued commitment to serving our patient communities."

Upon the transfer of AGAMREE's NDA into its neuromuscular franchise, Catalyst will harness its product portfolio synergies by leveraging its well-established expertise and proven commercial capabilities. The Company plans to launch the product in Q1 2024, spearheaded by its seasoned and experienced U.S. commercial and medical affairs neuromuscular teams.

AGAMREE was granted Orphan Drug and Rare Pediatric Disease designations status for DMD in the U.S. and will be eligible for seven years of orphan drug exclusivity upon approval date and has issued pending patents that could provide protection until 2040.

About Duchenne Muscular Dystrophy (DMD)

DMD, the most common form of muscular dystrophy, is a rare and life-threatening neuromuscular disorder characterized by progressive muscle dysfunction, ultimately leading to loss of ambulation, respiratory failure, and fatality. Current standard treatment for DMD involves corticosteroids, which often come with significant side effects. It is estimated that between 11,000 and 13,000 patients in the U.S. are affected by DMD, with approximately 70% of patients currently receiving concomitant corticosteroid treatment.

About AGAMREE® (vamorolone)

AGAMREE's unique mode of action is based on differential effects on glucocorticoid and mineralocorticoid receptors and modifying further downstream activity and, as such, is considered a novel corticosteroid with dissociative properties in maintaining efficacy, with a better-tolerated side effect profile. This mechanism of action may allow vamorolone to emerge as an effective alternative to the current standard of care corticosteroids in children, adolescents, and adult patients with DMD. In the pivotal VISION-DMD study, vamorolone met the primary endpoint Time to Stand (TTSTAND) velocity versus placebo (p=0.002) at 24 weeks of treatment and showed a good safety and tolerability profile. The most commonly reported adverse events versus placebo from the VISION-DMD study were cushingoid features, vomiting, and vitamin D deficiency. Adverse events were generally of mild to moderate severity.

AGAMREE was granted U.S FDA approval on October 26, 2023, and was granted Orphan Drug and Rare Pediatric Disease designations status for DMD in the U.S. and making it eligible for seven years of orphan drug exclusivity upon approval. AGAMREE also has issued and pending patents that could provide protection until 2040. In Europe, it has received Promising Innovative Medicine (PIM) status from the UK MHRA for DMD.

About Catalyst Pathways AGAMREE® Patient Assistance Program

AGAMREE will be available in the U.S. and marketed by Catalyst, supported by its Catalyst Pathway Program®. This comprehensive patient support program includes a dedicated, personalized support team that assists families throughout the AGAMREE treatment journey, from answering questions to coordinating financial assistance programs for eligible patients. For more information, caregivers and healthcare professionals can visit www.yourcatalystpathways.com or call 1-833-422-8259.

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. Finally, on July 18, 2023, Catalyst acquired an exclusive license for North America for AGAMREE (vamorolone) oral suspension 40 mg/mL, a novel corticosteroid treatment for Duchenne Muscular Dystrophy. AGAMREE previously received FDA Orphan Drug and Fast Track designations and was approved for commercialization in the U.S. FDA on October 26, 2023.

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 AGAMREE's commercialization by Catalyst in the U.S. will prove to be accretive to Catalyst, (ii) whether Catalyst and Santhera will successfully develop additional indications for AGAMREE and obtain the approvals required to commercialize the product in the licensed territory for those additional indications, (iii) whether, if AGAMREE is commercialized by Catalyst, the drug will be successfully integrated into Catalyst's business activities, and (iv) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2023, and Catalyst's other filings with the 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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