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 13, 2024

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 March 13, 2024, the Company issued a press release announcing the U.S. commercial launch of AGAMREE® (vamorolone) oral suspension 40 mg/mL for the treatment of Duchenne Muscular Dystrophy in patients aged two years and older. Following the U.S. Food and Drug Administration approval on October 26, 2023, AGAMREE® is now available by prescription and dispensed throughout the United States through a specialty pharmacy network.

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 March 13, 2024.
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: March 13, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Announces AGAMREE® Now Commercially Available in the U.S. for the Treatment of Duchenne Muscular Dystrophy (DMD)

AGAMREE® (vamorolone) a Novel Alternative Corticosteroid with Demonstrated Properties in Maintaining Efficacy and a Well-Tolerated Side Effect Profile

Available in the U.S. by Prescription for Patients Aged Two Years and Older

Catalyst Pathways® Program will Support AGAMREE Patients and Available to Help Ensure DMD Patients Affordable Access and Product Education

CORAL GABLES, Fla., Mar. 13, 2024—Catalyst Pharmaceuticals, Inc. ("Catalyst") (Nasdaq: CPRX), a commercial-stage biopharmaceutical company, today announced the U.S. commercial launch of AGAMREE® (vamorolone) oral suspension 40 mg/mL for the treatment of Duchenne Muscular Dystrophy ("DMD") in patients aged two years and older. Following the U.S. Food and Drug Administration ("FDA") approval on October 26, 2023, AGAMREE is now available by prescription and dispensed throughout the United States through a specialty pharmacy network.

"Today, we proudly announced the U.S. commercial availability of AGAMREE, an innovative alternative steroid treatment for Duchenne Muscular Dystrophy. This significant milestone offers hope for improved quality of life for individuals living with this devastating rare disease, as current steroid treatment options often involve a significant side effect burden," stated Richard J. Daly, CEO of Catalyst. "With the potential to extend ambulation and mobility for patients, AGAMREE marks an important therapeutic advancement with the prospect of reshaping the treatment paradigm for this life-threatening condition. We are firmly positioned to leverage our well-established commercial capabilities for a successful U.S. launch and remain resolute in our mission to help ensure that all patients have access to this novel therapy. Our Catalyst Pathways, a personalized program, is readily available to assist Duchenne Muscular Dystrophy patients and their families with the one-on-one education and financial support they need, thereby enhancing the access and affordability of AGAMREE for every patient. We eagerly look forward to collaborating with healthcare providers to facilitate patient access, reinforcing our unwavering dedication to serving our patient communities."

Catalyst Pathways® Patient Assistance Program for AGAMREE® is a comprehensive patient support program that includes a dedicated, personalized support team that assists families throughout the AGAMREE treatment journey for eligible patients. For more information, caregivers and healthcare professionals can call 1-833-422-8259 or visit the Catalyst Pathways® website at www.yourcatalystpathways.com.

Duchenne Muscular Dystrophy, 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 a corticosteroid treatment. Steroids are expected to remain the backbone of therapy for DMD patients and dosed concomitantly with other therapies.

The 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 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 improved behavior.

About AGAMREE® (vamorolone)

AGAMREE's unique mode of action is based on differential effects on glucocorticoid and mineralocorticoid receptors and modifying further downstream activity. As such, it is considered a novel corticosteroid with dissociative properties in maintaining efficacy that we hope has the potential to demonstrate comparable efficacy to steroids, with the potential for a better-tolerated side effect profile. This mechanism of action may allow AGAMREE 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, AGAMREE 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, psychiatric disorders, vomiting, weight increases, 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 has been granted Orphan Drug Exclusivity (ODE) for DMD and New Chemical Entity Exclusivity (NCE) in the U.S., conferring seven years and 5 years of exclusivity, respectively, from the date of approval. AGAMREE also has granted pending patents that could provide protection until 2040. In Europe, it has received Promising Innovative Medicine (PIM) status from the UK MHRA for DMD.

References:

[1] Dang UJ et al. (2024) Neurology 024;102:e208112. doi.org/10.1212/WNL.0000000000208112. Link.

[2] Guglieri M et al (2022). JAMA Neurol. 2022;79(10):1005-1014. doi:10.1001/jamaneurol.2022.2480. Link.

[3] Liu X et al. (2020). Proc Natl Acad Sci USA 117:24285-24293

[4] Heier CR et al (2019). Life Science Alliance DOI: 10.26508

[5] Ward et al., WMS 2022, FP.27 - Poster 71. Link.

[6] Hasham et al., MDA 2022 Poster presentation. Link.

[7] Applicable drug labeling: Summary of Product Characteristics (SmPC). Link

About Catalyst Pharmaceuticals

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare and difficult-to-treat 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 by the FDA for commercialization in the U.S. on October 26, 2023.

For more information about Catalyst Pharmaceuticals, Inc., please visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, please visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com. For Full Prescribing Information for AGAMREE®, please visit www.agamree.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 its Licensor Santhera Pharmaceuticals, AG 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, as AGAMREE is commercialized by Catalyst, the drug will be successfully integrated into Catalyst's business activities, and (iv) those factors described in Catalyst's those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2023 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.

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