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): July 24, 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 July 24, 2024, the Company issued a press release announcing that it has entered into a License, Supply and Commercialization Agreement with Kye Pharmaceuticals, Inc. ("Kye"), granting Kye the exclusive Canadian commercial rights to AGAMREE® (vamorolone), a novel corticosteroid for the treatment of Duchenne Muscular Dystrophy ("DMD") and potentially other indications. Under the terms of the agreement, the Company will supply the product to Kye, which will assume full responsibility for obtaining regulatory approval for AGAMREE® for the treatment of DMD from Health Canada and all future aspects of commercialization of the product within Canada. Kye currently markets FIRDAPSE®, the Company's flagship product for the treatment of Lambert Eaton Myasthenic Syndrome, in Canada.

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 July 24, 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: July 26, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Enters Into an Exclusive License, Supply and Commercialization Agreement with Kye Pharmaceuticals for AGAMREE® in Canada

CORAL GABLES, Fla., July 24, 2024 — 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 it has entered into a License, Supply, and Commercialization Agreement with Kye Pharmaceuticals Inc., ("Kye" or "Kye Pharmaceuticals") granting Kye the exclusive Canadian commercial rights to AGAMREE® (vamorolone), a novel corticosteroid for the treatment of Duchenne Muscular Dystrophy ("DMD") and potentially other indications. Under the terms of the agreement, Catalyst will supply the product to Kye, which will assume full responsibility for obtaining regulatory approval for AGAMREE for the treatment of DMD from Health Canada and all future aspects of commercialization of the product within Canada. Kye currently markets FIRDAPSE®, Catalyst's flagship product for the treatment of Lambert Eaton myasthenic syndrome, in Canada.

"We are pleased to enter into this agreement with Kye Pharmaceuticals for AGAMREE, marking a pivotal milestone in our strategic initiative to expand the product's footprint in North America. This collaboration leverages our combined expertise, fortifies our alliance by licensing our second therapeutic rare disease product for Canada, and demonstrates our sustained commitment to patient care," stated Richard J. Daly, CEO and President of Catalyst. "Building upon the U.S. approval of AGAMREE, we are committed to helping facilitate access to this novel corticosteroid treatment to DMD patients and their healthcare providers in Canada. We look forward to working closely with our partner, who will spearhead the regulatory approval process for AGAMREE, with application submission to Health Canada anticipated by early 2025."

"Our expanded partnership with Catalyst highlights the intrinsic value of our collaboration in developing innovative treatments for rare diseases, including DMD, and exemplifies our shared dedication to improving health outcomes across the U.S. and Canada. Together, we are committed to delivering novel therapies and bridging clinically significant treatment gaps," stated John McKendry, CEO and President of Kye Pharmaceuticals.

Under the terms of the agreement, Kye Pharmaceuticals, Inc. will have the exclusive Canadian rights to commercialize AGAMREE (vamorolone) oral suspension and will be responsible for funding all regulatory, marketing, and commercialization activities in Canada. Catalyst will be responsible for clinical and commercial supply and provide support to Kye Pharmaceuticals in its efforts to obtain regulatory approval for the product from Health Canada. Subject to the satisfaction of terms and conditions set forth in the License, Supply, and Commercialization Agreement, Catalyst will receive an upfront payment and be eligible to receive further reimbursement and sales milestones and sales royalties for AGAMREE.

About Duchenne Muscular Dystrophy

Duchenne Muscular Dystrophy (DMD) is a genetic disorder characterized by progressive muscle degeneration and weakness. It primarily affects males, with symptoms typically appearing in early childhood, around ages 3 to 5. DMD is caused by mutations in the gene that encodes dystrophin, a protein that plays a crucial role in maintaining the structure and function of muscle fibers. Without dystrophin, muscle cells become fragile and easily damaged, leading to progressive muscle degeneration. Symptoms of DMD usually begin with difficulty in walking, frequent falls, and muscle weakness, particularly in the legs and pelvis. As the disease progresses, individuals may experience difficulty standing, climbing stairs, and eventually, complete loss of mobility. Other complications can include respiratory and cardiac issues due to muscle weakness.

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 designed to achieve dissociative properties while maintaining efficacy that 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.

About Kye Pharmaceuticals

Kye Pharmaceuticals is a growth-stage Canadian specialty pharmaceutical company committed to bringing value to Canadians by identifying, licensing, and commercializing novel prescription medicines that may not otherwise be available to patients across Canada. Fueled by courage and agility, our corporate philosophy is rooted in the pursuit of innovation and driven by our entrepreneurial spirit. With a growing pipeline of novel medicines, Kye's portfolio spans a range of therapeutic areas, including cardiology, psychiatry, pediatrics, rare diseases, hematology, and neurology. Kye Pharmaceuticals is a private company headquartered in Toronto focused on bringing medications to the Canadian market which fulfill clinically significant unmet needs. Kye is committed to licensing and launching medicines that matter by delivering better outcomes to our partners, Canadian healthcare professionals, and, most importantly, patients across Canada. For more information, please visit www.kyepharma.com.

About Catalyst Pharmaceuticals, Inc.

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") in adults and pediatric patients 6 years of age and older. 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. 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. AGAMREE became commercially available by prescription in the U.S. on March 13, 2024.

For more information about Catalyst, 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 Catalyst's Licensee, Kye Pharmaceuticals, Inc., will successfully obtain the approvals required to commercialize the AGAMREE® product in the licensed Canadian territory, (ii) if approved, whether AGAMREE will be successfully commercialized by Kye Pharmaceuticals in the licensed territory, and (iii) 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 first quarter of 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 Relations Contact:
Mary Coleman, Catalyst Pharmaceuticals
(305) 420-3200
mcoleman@catalystpharma.com

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