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): September 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 September 24, 2024, the Company issued a press release announcing that its sub-licensee in Japan, DyDo Pharma, Inc. ("DyDo"), has reported that the Ministry of Health, Labor and Welfare of Japan has approved DyDo's New Drug Application ("NDA") to commercialize FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of patients with Lambert-Eaton myasthenic syndrome ("LEMS") in Japan. Under the sub-license agreement between the Company and DyDo, upon approval of the NDA the Company has earned a milestone payment from DyDo in the amount of JPY 300 million (approximately $2.1 million USD based on current exchange rates).

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 September 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
EVP, Treasurer and CFO

Dated: September 26, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Announces Sub-Licensee DyDo Pharma Received Approval to Commercialize FIRDAPSE® in Japan

CORAL GABLES, Fla., September 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 diseases, today announced that its sub-licensee in Japan, DyDo Pharma, Inc., ("DyDo") has reported that the Ministry of Health, Labor and Welfare of Japan has approved DyDo's New Drug Application ("NDA") to commercialize FIRDAPSE® (amifampridine) Tablets 10 mg for treatment of patients with Lambert-Eaton Myasthenic Syndrome ("LEMS") in Japan. This approval marks a pivotal advancement in the treatment of LEMS, a rare autoimmune disorder that can severely impact quality of life and represents a significant step forward in addressing the unmet needs of patients affected by LEMS in Japan.

"We are pleased that our partner, DyDo, has secured regulatory approval for FIRDAPSE in Japan. This represents a meaningful milestone, bringing renewed hope to patients and further affirming FIRDAPSE's proven effectiveness in the treatment of LEMS," said Richard J. Daly, Catalyst's President and Chief Executive Officer. "This achievement underscores our unwavering commitment to advancing patient care. We appreciate the collaborative efforts of our partner in securing this approval, and we remain focused on expanding our innovative rare disease product portfolio beyond the U.S. to make a meaningful impact on patients' lives worldwide."

FIRDAPSE (amifampridine) is a leading therapy indicated in the United States for the treatment of LEMS in adults and pediatric patients six years of age and older. LEMS is a rare autoimmune disorder characterized by muscle weakness and fatigue. About 50% of people with LEMS have underlying cancer, as LEMS is observed in approximately 3% of small-cell lung cancer patients. FIRDAPSE is the only U.S. FDA-approved, evidence-based treatment for LEMS. As a cornerstone of Catalyst's commitment to serving those with rare diseases, FIRDAPSE is supported in the U.S. by a comprehensive patient support program to help ensure accessibility and assistance for eligible U.S. patients.

About FIRDAPSE® (amifampridine) Tablets 10 mg

FIRDAPSE® (amifampridine) Tablets 10 mg is an oral, nonspecific, voltage-dependent, potassium (K+) channel blocker that causes depolarization of the presynaptic membrane and slows or inhibits repolarization. This action results in the opening of slow voltage-dependent calcium (Ca2+) channels, allowing for a subsequent influx of Ca2+. In turn, it induces the exocytosis of synaptic vesicles containing acetylcholine (ACh) to release more ACh into the synaptic cleft, enhancing neuromuscular transmission and providing for improved muscle function. Amifampridine phosphate was granted orphan drug designation by the Ministry of Health, Labor, and Welfare in Japan, and FIRDAPSE has previously been approved for use in the U.S. in adults and pediatric patients six years of age and older and in Europe and Canada for the treatment of adults with LEMS.

For Full Prescribing and Safety Information for FIRDAPSE, please visit www.firdapse.com.

About DyDo Pharma

DyDo Pharma is the rare disease pharmaceutical wholly-owned subsidiary of DyDo Group Holdings. DyDo Group Holdings, Inc. operates through the following segments: Domestic Beverage Business, International Beverage Business, Pharmaceutical-related Business, Food Business, and Other Businesses. The Domestic Beverage Business accounts for more than 70% of total sales, and beverages are sold through vending machines that are widely prevalent in Japan. The Company was founded on January 27, 1975, and is headquartered in Osaka, Japan.

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 is headquartered in Coral Gables, FL., and was recognized on the Forbes 2024 list as one of America's most successful small-cap companies. For more information, please visit Catalyst's website at www.catalystpharma.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 DyDo can successfully commercialize FIRDAPSE in Japan, (ii) whether Catalyst's revenues derived in future periods from its sub-license with DyDo will be profitable and cash flow positive to Catalyst, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for fiscal year 2023, its Quarterly Report on Form 10-Q for the second quarter of fiscal year 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.

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