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): January 21, 2025

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 January 21, 2025, the Company issued a press release announcing that its sub-licensee in Japan, DyDo Pharma, Inc., has launched FIRDAPSE® Tablets 10 mg in Japan for the indication of improving muscle weakness in patients living with Lambert-Eaton myasthenic syndrome, or LEMS.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release issued by the Company on January 21, 2025.
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: January 21, 2025

Exhibit 99.1

Catalyst Pharmaceuticals Announces Sub-Licensee DyDo Pharma Launched FIRDAPSE® in Japan

CORAL GABLES, Fla., January 21, 2023—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 reported that its sub-licensee in Japan, DyDo Pharma, Inc., ("DyDo") has launched FIRDAPSE® (amifampridine) Tablets 10 mg in Japan for the indication of improving muscle weakness in patients living with Lambert-Eaton myasthenic syndrome ("LEMS").

"We are pleased that our sub-licensee, DyDo, has launched FIRDAPSE in Japan. We believe in health equity, and this launch is a testament to our ongoing efforts to increase patient access to life-changing therapies worldwide." said Richard J. Daly, Catalyst's President and Chief Executive Officer. "The launch of FIRDAPSE in Japan marks another advancement in our efforts to expand the geographic footprint of our portfolio products and paves the way for healthcare providers and patients in Japan to access this therapy."

FIRDAPSE (amifampridine) is the only U.S. FDA approved, evidence-based therapy 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. 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 Pharmaceutical Business. The Domestic Beverage Business accounts for more than 60% of total sales (as of FY24, 1-3Q), 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, headquartered in Coral Gables, FL., was recognized as one of North America's Fastest-Growing Companies on the 2024 Deloitte Technology Fast 500™ List.

For more information, please visit Catalyst's website at www.catalystpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, as that term is defined in the Private Securities Litigation Reform Act of 1995. 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 material to Catalyst, 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 fiscal quarter ended September 30, 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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