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): December 18, 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 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 December 18, 2023, the Company issued a press release announcing that its collaboration partner in Japan, DyDo Pharma, Inc. ("DyDo"), reported that it has submitted a New Drug Application ("NDA") to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") seeking marketing approval for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") in Japan. The submission is based on preliminary favorable analysis results of interim data after six months into the safety phase of DyDo's registration study to evaluate the efficacy and safety of FIRDAPSE® in Japanese patients with LEMS.

Under the license agreement between the Company and DyDo, upon acceptance of filing of the NDA, the Company will be due a milestone payment from DyDo of JPY 200 million (approximately $1.4 million USD based on current exchange rates). Further, upon acceptance of the NDA submission, the Company's territorial rights to develop and market FIRDAPSE® will automatically extend to other key markets in Asia, Central and South America, and the Company is currently initiating plans to seek opportunities to expand FIRDAPSE®'s global footprint through strategic partnerships (with the current focus on the Asia Pacific and Latin America regions).

There can be no assurance whether DyDo's clinical trial in Japan will ultimately be successful, whether FIRDAPSE® will ever be approved for commercialization in Japan, or whether the Company will be able to successfully expand FIRDAPSE®'s global footprint.

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 December 18, 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: December 19, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Announces FIRDAPSE® New Drug Application Submitted in Japan by Partner DyDo Pharma

CORAL GABLES, Fla., Dec 18, 2023—Catalyst Pharmaceuticals, Inc. ("Catalyst") (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 collaboration partner, DyDo Pharma, Inc. ("DyDo"), reported that it has submitted a New Drug Application ("NDA") to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") seeking marketing approval for FIRDAPSE® (amifampridine) Tablets 10 mg (generic name: amifampridine phosphate), for the treatment of Lambert Eaton myasthenic syndrome ("LEMS") in Japan. The submission is based on preliminary favorable analysis results of interim data after six months into the safety phase of the registration study to evaluate the efficacy and safety of FIRDAPSE for the treatment of LEMS. The review period is expected to be approximately a minimum of nine months from the submission date.

"The NDA submission to the PMDA by our partner DyDo represents a pivotal milestone in our mission to broaden FIRDAPSE's access as a treatment for LEMS patients in Japan," stated Patrick J. McEnany, Catalyst's Chairman and CEO. "Given the absence of therapies available in Japan for this rare neuromuscular disorder, we believe that if approved, FIRDAPSE holds the potential to be a novel treatment option for Japanese individuals grappling with this condition. As we continue to collaborate with our partner during the review process, the submission also triggers an expansion of our territorial rights for the product and a milestone payment to Catalyst. We look forward to initiating our plans to expand the reach for FIRDAPSE into other global regions seeking a novel therapy for the treatment of LEMS."

In June 2021, Catalyst entered into a license agreement with DyDo for the development and commercialization of FIRDAPSE in Japan. Under the terms of the agreement, Catalyst is eligible to receive a regulatory milestone payment from DyDo upon submission of the NDA to the PMDA. Under the Company's license agreement with SERB S.A., upon acceptance of the NDA submission to the PMDA in Japan, Catalyst's territorial rights to develop and market the product will automatically extend to other key markets in Asia, Central, and South America. The Company is currently initiating plans to seek opportunities to expand the product's global footprint through strategic partnerships, with a current focus on the Asia Pacific and Latin American regions.

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, Labour, and Welfare in Japan, and FIRDAPSE has previously been approved for use in the United States for adults and for children ages six to seventeen and in Europe and Canada for the treatment of adults with LEMS.

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

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 recently approved for commercialization in the U.S. 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. 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 DyDo Pharma's clinical trial in Japan will be successful, (ii) whether FIRDAPSE® will ever be approved for commercialization in Japan, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for fiscal year 2022 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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