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 6, 2021

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

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**

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))

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 6, 2021, the Company issued a press release announcing that its Japanese collaboration partner, DyDo Pharma, has initiated a Phase 3 registrational study in Japan to evaluate the efficacy and safety of Firdapse® (amifampridine) 10 mg tablets for the treatment of Lambert-Eaton Myasthenic Syndrome. 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 December 6, 2021.

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 6, 2021

Catalyst Pharmaceuticals Announces DyDo Pharma Initiation of a Phase 3 Study for FIRDAPSE® (amifampridine) in Japan

CORAL GABLES, Fla., Dec. 06, 2021 (GLOBE NEWSWIRE) — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases, today announced that its collaboration partner DyDo Pharma ("DyDo") has initiated a Phase 3 registrational study in Japan to evaluate the efficacy and safety of Catalyst's FIRDAPSE® (amifampridine) 10 mg tablets for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS").

"We are pleased with the important progress being made by DyDo as we advance on our shared commitment of bringing a novel treatment option to LEMS patients in Japan," said Patrick McEnany, CEO and Chairman of Catalyst. "The initiation of this Phase 3 program marks an important milestone towards our goal to expand the global footprint of FIRDAPSE for the treatment of LEMS. Currently, there are no approved treatments for this rare autoimmune neuromuscular disorder in Japan, and we believe FIRDAPSE has the potential to provide a meaningful new therapy option to patients living with this disease. We appreciate the collaborative effort of our partnership and look forward to continuing to support DyDo in the clinical advancement of FIRDAPSE."

Catalyst entered into a sub-license agreement with DyDo to develop and commercialize FIRDAPSE in Japan in June 2021. Under the terms of the agreement, Catalyst will provide clinical and commercial supply to DyDo and technical support to obtain regulatory approval for the product from the Japanese regulatory authorities. DyDo is responsible for the development and commercialization of the product in Japan pending regulatory approval, and Catalyst will be entitled to development and sales milestones and revenue for clinical and commercial supply of the product.

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. FIRDAPSE was granted orphan drug designation by the Ministry of Health, Labour and Welfare in Japan and has previously been approved for use in the United States, Europe, and Canada for the treatment of adults with LEMS.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best-in-class medicines for other rare diseases. Catalyst's New Drug Application for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS") was approved in 2018 by the U.S. Food & Drug Administration ("FDA"), and FIRDAPSE is commercially available in the United States as a treatment for adults with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, approved the use of FIRDAPSE for the treatment of adult patients in Canada 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.

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 2020 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.

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