# 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 24, 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 CFR 240.14d-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 2.01 Completion of Acquisition or Disposition of Assets**

On January 24, 2023, Catalyst Pharmaceuticals, Inc. (the "Company") completed its previously announced purchase of the U.S. Rights for FYCOMPA® (perampanel) CIII from Eisai Co., Ltd. ("Eisai") pursuant to the terms of that certain Asset Purchase Agreement (the "Purchase Agreement") between the Company and Eisai. Under the terms of the Purchase Agreement, the Company paid an upfront payment to Eisai of $160 million.

Also at the closing of the asset purchase, the parties entered into two related agreements: (i) a short term Transition Services Agreement (the "Transition Services Agreement") and (ii) a longer term Supply Agreement (the "Supply Agreement"). Under the Transition Services Agreement, a U.S. subsidiary of Eisai will provide commercial and manufacturing services to the Company for a period of 180 days following the closing of the asset purchase (or such longer period as is set forth in the Transition Services Agreement), for which it will be paid service and other amounts in return for such services, all as more particularly set forth in the Transition Services Agreement. Further, under the Supply Agreement, Eisai will manufacture FYCOMPA® for the Company for a period of seven years (or such longer period as is set forth in the Supply Agreement) following the closing of the asset purchase in return for a purchase price for the product determined under the terms of the Supply Agreement.

Pursuant to Rule 3-05(b)(4)(i)(B) promulgated under Regulation S-X, the Company will file financial statements related to the asset purchase transaction no later than 74 days after January 24, 2023, the date of consummation of the asset purchase transaction.

The foregoing descriptions of the Purchase Agreement, the Transition Services Agreement, and the Supply Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which were attached as **Exhibit 2.1**, **Exhibit 10.1**, and **Exhibit 10.2**, respectively, to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on December 22, 2022.

***Forward-Looking Statements***

This Current Report on Form 8-K includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, including any statements containing the words "believes," expects," "anticipates," "plans," "estimates," and similar expressions, are forward-looking statements. These forward-looking statements are based on the Company's current intentions, beliefs and expectations regarding future events. The Company cannot guarantee that any forward-looking statement will be accurate. The reader should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from expectations. The reader is, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this Form 8-K, and, except as required by law, the Company does not undertake to update any forward-looking statement to reflect new information, events or circumstances.

**Item 8.01 Other Events**

On January 25, 2023, the Company issued a press release announcing the closing of the Purchase Agreement and related transactions. A copy of the press release is attached as **Exhibit 99.1** to this Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| | |
|---|---|
| 2.1 | Asset Purchase Agreement by and between Eisai and the Company, dated as of December 17, 2022 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on December 22, 2022). |
| 10.1 | Form of Transition Services Agreement between Eisai, Inc., a subsidiary of Eisai, and the Company (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 22, 2022). |
| 10.2 | Form of Supply Agreement between Eisai and the Company (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 22, 2022). |
| 99.1 | Press release issued by the Company on January 25, 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: January 30, 2023

**Exhibit 99.1**

**Catalyst Pharmaceuticals Completes the Acquisition of U.S. Rights to FYCOMPA® (Perampanel) CIII**

*Strengthens its Commercial Portfolio with the First and Only AMPA Receptor Antagonist Marketed Product for Epilepsy*

*Bolsters Presence in Neuroscience*

*Expected to be Accretive in 2023*

CORAL GABLES, Fla., Jan. 25, 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 it has successfully completed the acquisition of the U.S. rights for FYCOMPA® (perampanel) CIII, from Eisai Co., Ltd, ("Eisai"). The closing of the acquisition provides Catalyst with an increased U.S. commercial presence in neurology and an expanded product portfolio with an established, first-in-class, commercial stage epilepsy asset.

"The completion of the acquisition of U.S. rights to FYCOMPA marks an important step in the expansion and diversification of our portfolio of marketed products, adds a second complementary commercial product that will further strengthen Catalyst's financial position through increased revenue scale, and is expected to be accretive to EBITDA and EPS in 2023," said Patrick J. McEnany, Chairman and CEO of Catalyst. "Coupled with the continued growth of FIRDAPSE®, our flagship product, we look forward to leveraging our proven capabilities and expanded U.S. presence in neuroscience to drive organic growth for both FYCOMPA and FIRDAPSE. While we are focused on a seamless transition of FYCOMPA, we will also continue to execute our growth strategy into other rare neurological and epileptic diseases. We remain committed to enhancing our portfolio with innovative medicines that address critical unmet medical needs for patients with a continued disciplined approach to our capital allocation."

**Strategic Rationale**

- The addition of FYCOMPA serves as a complementary growth driver and a strategic market adjacency within neuroscience that establishes a potential gateway for Catalyst to expand into rare epileptic diseases.
- Strengthens and diversifies revenues and cash flow generation with the addition of a successfully U.S. marketed asset, by building upon the company's organic revenue growth of FIRDAPSE.
- The acquisition of FYCOMPA is expected to be accretive to EBITDA and EPS in 2023 and provides synergies to build on the company's proven operational and commercial execution in neurology.

- Strategically aligns with Catalyst's growth plans to optimize the FIRDAPSE franchise and invest in portfolio expansion opportunities.
- Physician call point for FYCOMPA overlaps about 45% with FIRDAPSE call points.
- Net FYCOMPA revenues for the 2022 fiscal year ending March 31, 2023, are expected to be approximately $136 million. FYCOMPA has gross profit margins similar to FIRDAPSE.

**Additional Transaction Details**

As previously disclosed, Catalyst made a total all-cash purchase payment of $160 million to Eisai. Under certain conditions, Catalyst may be obligated to pay a milestone payment and royalty. The completion of the acquisition does not impact Catalyst's previously reported 2022 full-year FIRDAPSE total net revenue guidance of $205 million to $210 million.

**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 U.S. commercial product portfolio consists of FIRDAPSE® (amifampridine) Tablets 10 mg, approved for the treatment of Lambert-Eaton myasthenic syndrome ("LEMS") for adults and children ages six to seventeen. In January 2023, Catalyst acquired the U.S. commercial rights of 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.

For more information, visit the Company's website at **www.catalystpharma.com**.

**About FYCOMPA**

FYCOMPA is a prescription medicine used in people with epilepsy aged 4 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.

FYCOMPA, an oral medication, is a selective non-competitive AMPA (alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid) receptor antagonist. The precise mechanism by which FYCOMPA exerts its antiepileptic effects in humans is unknown.

FYCOMPA is supplied as 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg film-coated tablets, and as a 0.5 mg/mL oral suspension formulation. FYCOMPA has been designated by the U.S. Drug Enforcement Administration as a federally-controlled substance (CIII). To date, FYCOMPA has been prescribed to over 500,000 patients globally.

FYCOMPA is expected to have patent protection through at least May 23, 2025, with possible patent protection into June 2026.

**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 expectation that the acquisition transaction will prove to be accretive to EBITDA and EPS during 2023 will prove to be accurate, (ii) whether Catalyst can successfully integrate the FYCOMPA business into its business activities, and (iii) those factors described in Catalyst's Annual Report on Form 10-K for the 2021 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the third quarter of 2022, and Catalyst's other filings with the 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.

**Important Safety Information: INDICATION FOR FYCOMPA**

FYCOMPA® (perampanel) is indicated in patients with epilepsy aged 4 years and older for partial-onset seizures (POS) with or without secondarily generalized seizures and adjunctive therapy for patients aged 12 years and older for primary generalized tonic-clonic (PGTC) seizures.

**IMPORTANT SAFETY INFORMATION FOR FYCOMPA**

**WARNING: SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS**

- Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, irritability, anger, and homicidal ideation and threats have been reported in patients taking FYCOMPA
- These reactions occurred in patients with and without prior psychiatric history, prior aggressive behavior, or concomitant use of medications associated with hostility and aggression
- Advise patients and caregivers to contact a healthcare provider immediately if any of these reactions or changes in mood, behavior, or personality that are not typical for the patient are observed while taking FYCOMPA or after discontinuing FYCOMPA
- Closely monitor patients particularly during the titration period and at higher doses
- FYCOMPA should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening

**SERIOUS PSYCHIATRIC AND BEHAVIORAL REACTIONS**

In the partial-onset seizures clinical trials, hostility- and aggression-related adverse reactions occurred in 12% and 20% of patients randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 6% of patients in the placebo group. These effects were dose-related and generally appeared within the first 6 weeks of treatment, although new events continued to be observed through more than 37 weeks. These effects in FYCOMPA-treated patients led to dose reduction, interruption, and discontinuation more frequently than placebo-treated patients. Homicidal ideation and/or threat have also been reported postmarketing in patients treated with FYCOMPA. The combination of alcohol and FYCOMPA significantly worsened mood and increased anger. Patients taking FYCOMPA should avoid the use of alcohol. Patients, their caregivers, and families should be informed that FYCOMPA may increase the risk of psychiatric events. Patients should be monitored during treatment and for at least one month after the last dose of FYCOMPA, and especially when taking higher doses and during the initial few weeks of drug therapy (titration period) or at other times of dose increases. Similar serious psychiatric and behavioral events were observed in the primary generalized tonic-clonic (PGTC) seizure clinical trial.

**SUICIDAL BEHAVIOR AND IDEATION**

Antiepileptic drugs (AEDs), including FYCOMPA, increase the risk of suicidal thoughts or behavior in patients. Anyone considering prescribing FYCOMPA or any other AED must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients, their caregivers, and families should be informed of the risk and advised to monitor and immediately report the emergence or worsening of depression, suicidal thoughts or behavior, thoughts about self-harm and/or any unusual changes in mood or behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

**DIZZINESS AND GAIT DISTURBANCE**

FYCOMPA caused dose-related increases in events related to dizziness and disturbance in gait or coordination. Dizziness and vertigo were reported in 35% and 47% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 10% of placebo-treated patients. Gait disturbance related events were reported in 12% and 16% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 2% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial.

**SOMNOLENCE AND FATIGUE**

FYCOMPA caused dose-dependent increases in somnolence and fatigue-related events. Somnolence was reported in 16% and 18% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 7% of placebo-treated patients. Fatigue-related events were reported in 12% and 15% of patients in the partial-onset seizure trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 5% of placebo-treated patients. These adverse reactions occurred mostly during the titration phase. These adverse reactions were also observed in the PGTC seizure clinical trial. Patients should be advised against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of FYCOMPA is known. Patients should be carefully observed for signs of central nervous system (CNS) depression when FYCOMPA is used with other drugs with sedative properties because of potential additive effects.

**FALLS**

Falls were reported in 5% and 10% of patients in the partial-onset seizure clinical trials randomized to receive FYCOMPA at doses of 8 mg and 12 mg per day, respectively, compared to 3% of placebo-treated patients.

**DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS (DRESS)**

DRESS, also known as multiorgan hypersensitivity, has been reported in patients taking AEDs, including FYCOMPA. DRESS may be fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement. If signs or symptoms are present, immediately evaluate the patient and discontinue FYCOMPA if an alternative etiology for signs or symptoms cannot be established.

**WITHDRAWAL OF AEDs**

A gradual withdrawal is generally recommended with AEDs to minimize the potential of increased seizure frequency, but if withdrawal is a response to adverse events, prompt withdrawal can be considered.

**MOST COMMON ADVERSE REACTIONS**

The most common adverse reactions in patients aged 12 years and older receiving FYCOMPA (≥5% and ≥1% higher than placebo) include dizziness, somnolence, fatigue, irritability, falls, nausea, weight gain, vertigo, ataxia, headache, vomiting, contusion, abdominal pain, and anxiety. Adverse reactions in patients aged 4 to <12 years were generally similar to patients aged 12 years and older.

**DRUG INTERACTIONS**

FYCOMPA may decrease the efficacy of contraceptives containing levonorgestrel. Plasma levels of perampanel were decreased when administered with known moderate and strong CYP3A4 inducers, including, carbamazepine, phenytoin, or oxcarbazepine. Multiple dosing of FYCOMPA 12 mg per day enhanced the effects of alcohol on vigilance and alertness, and increased levels of anger, confusion, and depression. These effects may also be seen when FYCOMPA is used in combination with other CNS depressants.

**PREGNANCY AND LACTATION**

Physicians are advised to recommend that pregnant patients taking FYCOMPA enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Caution should be exercised when FYCOMPA is administered to pregnant or nursing women as there are no adequate data on the developmental risk associated with use in pregnant women, and no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

**HEPATIC AND RENAL IMPAIRMENT**

Use in patients with severe hepatic or severe renal impairment is not recommended. Dosage adjustments are recommended in patients with mild or moderate hepatic impairment. Use with caution in patients with moderate renal impairment.

**DRUG ABUSE AND DEPENDENCE**

FYCOMPA is a Schedule III controlled substance and has the potential to be abused and lead to drug dependence and withdrawal symptoms including anxiety, nervousness, irritability, fatigue, asthenia, mood swings, and insomnia.

Please see full **Prescribing Information**, including Boxed WARNING.

**Contact information:**

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

**Investor Contact**
Mary Coleman
Catalyst Pharmaceuticals, Inc.
(305) 420-3200
mcoleman@catalystpharma.com