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): February 7, 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 8.01 Other Events

On February 7, 2023, the Company issued a press release providing preliminary 2022 fourth quarter and full year revenue estimates, a forecast of 2023 total revenue expectations, and a corporate update. 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 February 7, 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: February 7, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Reports Preliminary Fourth Quarter and Full Year 2022 Total Revenues and Provides Full Year 2023 Revenue Guidance

2022 Total Revenues Estimated at $214 Million, Representing 52% YoY Growth

Forecast 2023 Total Revenues of Between $375 Million and $385 Million Including FYCOMPA®, Representing YoY Growth of 75%—80%

2023 FIRDAPSE® Net Revenues Estimated at $245 Million to $255 Million

2023 FYCOMPA Net Revenues Estimated at $130 Million - 11 Months

FYCOMPA Business Unit Integration Expected to be Completed by Mid-Year 2023

Ended 2022 with Approximately $298 Million in Cash and Cash Equivalents

CORAL GABLES, Fla., Feb. 7, 2023 — 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 provided preliminary 2022 fourth quarter and full year total revenues estimates, a forecast of 2023 total revenue expectations, and a corporate update.

"2022 was an exceptional year for Catalyst, as we delivered record performance driven by consecutive quarterly revenue growth. The robust results capped an important year for our company, as we successfully executed our strategic initiatives across the business, adding further confidence in the long-term growth of the company," stated Patrick J. McEnany, Chairman and CEO of Catalyst. "We entered 2023 well positioned to capitalize on our expanded product portfolio, with a clear objective to fuel the continued growth of our highly complementary products, FIRDAPSE® and FYCOMPA®. We look forward to welcoming and onboarding to the Catalyst team many of the Eisai employees responsible for the success of the FYCOMPA epilepsy program. In doing so, we remain dedicated to serving our patient communities and enhancing access, as we leverage our proven competencies and our expanded U.S. presence in neuroscience. We expect to continue to deliver a sustained performance in 2023 and anticipate a meaningful increase in revenues as we build upon our momentum to maximize value for all our stakeholders. The Catalyst team is incredibly proud of what we accomplished in 2022 and excited about the prospects for the year ahead."

The information in this press release is based on preliminary unaudited information and management estimates for the full year 2022 and is subject to the completion of Catalyst's financial closing procedures. Catalyst expects to report its 2022 fourth quarter and full year results of operations on or about March 15, 2023.

CORPORATE HIGHLIGHTS

Preliminary Unaudited 2022 Fourth Quarter and Full Year Revenue and Year End Cash Position

Total 2022 Revenue

- Fourth quarter 2022 total revenues are estimated to be approximately $61 million, compared to total revenues of approximately $38 million in the fourth quarter of 2021, representing an increase of approximately 61% year-over-year.
- Full year 2022 total revenues are estimated to be approximately $214 million, compared to total revenues of $141 million for 2021, representing an increase of approximately 52% year-over-year.

Total 2022 Cash and Investments

- Year end 2022 cash and cash equivalents are expected to be approximately $298 million.

2023 Financial Guidance

- The Company forecasts 2023 full year total revenues to be in the range of between $375 million and $385 million, representing a range of between 75% - 80% increase in total revenues as compared to 2022.
- FIRDAPSE net revenues for 2023 are forecasted to be between $245 million to $255 million.
- FYCOMPA net revenues for 2023 are forecasted to be $130 million for approximately 11 months of sales. The Company's acquisition of this asset closed on January 24, 2023.

Key guidance assumptions included in these projections reflect a continued recovery in macroeconomic and healthcare activity throughout 2023 as it relates to the current COVID-19 environment.

2023 Strategic Priorities

- Sustain "patient first" commitment through established assistance programs to all patients seeking access to treatment with FIRDAPSE for LEMS and FYCOMPA for epilepsy.
- Expect to complete the full integration of the FYCOMPA business unit by mid-year. Currently extending offers to individuals on the Eisai teams responsible for FYCOMPA sales, marketing, and medical affairs.
- Continue to vigorously defend all our intellectual property rights.
- Grow U.S. revenues for FIRDAPSE through awareness and education to patients and healthcare professionals, with an expanded focus on small-cell lung cancer patients who are comorbid with LEMS.
- Capitalize on proven commercial capabilities to enhance the growth potential of FYCOMPA, an established, first-in-class, commercial-stage epilepsy asset.
- Continue to leverage data from the FIRDAPSE NDA and additional data via third-party relationships to further expand FIRDAPSE regulatory approvals internationally, with current focus on Japan and potentially other territories in Asia.
- Continue to execute our focused strategic plan to expand and diversify our rare disease neuroscience portfolio of product offerings and late-stage pipeline opportunities to drive long-term sustainable growth.

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 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.

For full prescribing and safety information on FIRDAPSE, please visit www.firdapse.com, and for full prescribing and safety information on FYCOMPA, please visit www.fycompa.com. For more information about Catalyst Pharmaceuticals, Inc., visit the Company'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) the effect of the COVID-19 pandemic on Catalyst's business and results of operations, (ii) Catalyst's ability to successfully sell its current products, (iii) Catalyst's ability to locate and acquire new product candidates through acquisition or in-licensing, (iv) Catalyst's ability to sell products acquired that are already approved and to successfully develop any new product candidates acquired or in-licensed, (v) whether Catalyst's fourth quarter and full year 2022 total revenue forecast will prove to be accurate, (vi) whether Catalyst's total revenue forecast for 2023 and its net revenue forecasts for FIRDAPSE® and FYCOMPA® for 2023 will prove to be accurate, (vii) whether Catalyst's patents listed in the Orange Book will be sufficient to eliminate generic competition for FIRDAPSE after Catalyst's orphan drug exclusivity for FIRDAPSE for LEMS expires in late November 2025, (viii) whether legislative changes currently being considered by Congress that are intended to reduce the cost of prescription drug products will adversely affect Catalyst, and (ix) 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.

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