# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of Earliest Event Reported): June 1, 2023

# CATALYST PHARMACEUTICALS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

Delaware (State or other jurisdiction of incorporation) 001-33057 (Commission File Number) 76-0837053 (I.R.S. Employer Identification No.)

355 Alhambra Circle Suite 801 Coral Gables, Florida (Address of principal executive offices)

33134 (Zip Code)

Registrant's telephone number, including area code: (305) 420-3200

Not Applicable
Former Name or Former address, if changed since last report

	eck the appropriate box below if the Form 8-K filin following provisions:	g is intended to simultaneously satisfy the fil	ing obligation of the registrant under any of				
	Written communications pursuant to Rule 425 u	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				
С	ommon Stock, par value \$0.001 per share	NASDAQ Capital Market	CPRX				
	cate by check mark whether the registrant is an enis Chapter) or Rule 12b-2 of the Securities Excha						
			Emerging Growth Company				
	n emerging growth company, indicate by check many new or revised financial accounting standard	•	1 1 3				

# Item 8.01 Other Events

On June 1, 2023, the Company issued a press release reaffirming its full-year 2023 total revenue guidance and its forecast for full-year 2023 non-GAAP net income. 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 June 1, 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.

/s/ Alicia Grande Alicia Grande Vice President, Treasurer and CFO

Dated: June 1, 2023

#### Catalyst Pharmaceuticals Reports Positive Momentum in Second Quarter 2023

Reaffirms Full Year 2023 Total Revenue Guidance of Between \$375 Million and \$385 Million

Forecasts FIRDAPSE® 2023 Net Product Revenue Guidance of Between \$245 Million and \$255 Million, an Increase of 17% YoY

Forecasts FYCOMPA® 2023 Net Product Revenue of Approximately \$130 Million for 11 Months

Reaffirms Full Year 2023 Non-GAAP Net Income Forecast of Between \$195 Million and \$205 Million

CORAL GABLES, Fla., June 1, 2023 — Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today reported positive momentum for the second quarter of 2023 and reaffirmed its full-year 2023 total revenue guidance of between \$375 million and \$385 million, representing a 75% to 80% increase in total revenues compared to 2022. The Company also reaffirmed its forecast for the full year 2023 non-GAAP net income to be between \$195 million and \$205 million. This guidance reflects Catalyst's confidence in sustained organic revenue growth for FIRDAPSE® combined with synergistic net product revenues derived from sales of FYCOMPA®, a second commercial product for which the Company acquired U.S. rights on January 24, 2023.

"As recently reported, the ongoing execution of our commercial strategy drove record results for the first quarter of this year as viewed against all metrics," said Patrick J. McEnany, Chairman and CEO of Catalyst. "As we advance into the second quarter of 2023 with sustained momentum, we are on track to meet our guidance which is supported by our exceptional financial performance and strategic accomplishments. Given our recent acquisition of FYCOMPA® and the related increase in amortization expenses of intangible assets, we believe that the non-GAAP financial measures that we are currently providing in our financial results press releases provide greater transparency and should assist in better understanding and assessing Catalyst's business as well as how we manage our business internally and set operational goals. We believe the benefits from our diversified and complementary product portfolio will continue to generate strong free cash flow as we continue to advance on our growth initiatives to drive sustainable growth and deliver value for our shareholders."

#### Financial Guidance for Full Year 2023

The Company's 2023 financial guidance reflects considerations reported in its Form 10-Q filed on May 10, 2023, as well as its performance to date in the 2023 second quarter. Based on these considerations, the Company believes that it is now in a position to provide more detailed financial guidance for the full year 2023 on both a GAAP and a non-GAAP basis.

- Full-year 2023 total revenues are forecasted to be in the range of between \$375 million and \$385 million, representing a 75% 80% increase in total revenues as compared to 2022.
- FIRDAPSE® net product revenues for 2023 are forecasted to be between \$245 million to \$255 million, a 17% increase from the mid-point year over year.
- FYCOMPA® net product revenues for 2023 are forecasted to be approximately \$130 million for approximately 11 months of sales. The Company's acquisition of this product closed on January 24, 2023.
- Cost of goods sold is expected to be approximately 13% of aggregate net product revenues.
- GAAP operating expenses are forecasted to be between \$175 million and \$185 million in 2023. This includes (i) approximately \$57 million of expenses directly related to our FYCOMPA program, which includes approximately \$10.3 million for one-time transition services fees (\$6.7 million in Q1-2023 and estimated \$3.6 million in Q2-2023), and (ii) amortization of intangible assets of approximately \$32 million (approximately \$8.5 million per quarter for the second, third and fourth quarter of 2023).
- GAAP net income before income tax for 2023 is forecasted to be between \$150 million and \$155 million.
- Non-GAAP net income for 2023 is forecasted to be between \$195 million and \$205 million.

This forecast does not account for the impact on the forecasted results of any future acquisition transactions that Catalyst may complete in 2023. Further, non-GAAP net income for 2023 excludes from GAAP net income stock-based compensation, depreciation, amortization, and income taxes. Finally, key guidance assumptions included in these projections reflect a continued recovery in macroeconomic and healthcare activity throughout 2023 and no change to the current COVID-19 environment.

#### **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 and up. 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 additional information about the Company, please visit <a href="https://www.catalystpharma.com">www.catalystpharma.com</a>.

For Full Prescribing and Safety Information for FIRDAPSE ®, please visit <a href="www.firdapse.com">www.firdapse.com</a>. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit <a href="www.FYCOMPA.com">www.FYCOMPA.com</a>. For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at <a href="www.catalystpharma.com">www.catalystpharma.com</a>.

#### **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) Catalyst's ability to successfully continue to sell its current products, (ii) Catalyst's ability to locate and acquire new product candidates through acquisition or in-licensing, (iii) Catalyst's ability to sell products acquired in the future that are already approved and to successfully develop any new product candidates acquired or in-licensed, (iv) whether Catalyst's forecasts of its financial results for 2023 will prove to be accurate, (v) whether Catalyst's patents will be sufficient to eliminate generic competition for FIRDAPSE® after Catalyst's orphan drug exclusivity for FIRDAPSE® for LEMS expires in late November 2025, (vi) whether legislative changes already made that are intended to reduce the cost of prescription drug products and any similar future legislative changes made by Congress will adversely affect Catalyst, and (vii) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2023, and Catalyst's 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.

#### **Contact information:**

#### **Investor Contact**

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# **Media Contact**

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