

**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): August 9, 2022**

**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

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.

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**Item 8.01 Other Events**

On August 9, 2022, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2022 and providing 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 August 9, 2022.](#)

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: August 9, 2022

**Catalyst Pharmaceuticals Delivers Strong Second Quarter 2022  
Financial Results with Record FIRDAPSE® Revenues and  
Provides Corporate Update**

*Achieved Record Q2 2022 FIRDAPSE® Net Product Revenues of \$53.0 Million, a 57.7% YoY Increase*

*Cash and Short-Term Investments at June 30, 2022 were \$220.8 Million, with No Funded Debt*

*Completed Acquisition of Ruzurgi® U.S. and Mexico Commercial Rights*

*Advanced Plans to Diversify Portfolio and Invest in Innovative Rare Disease Opportunities*

*Provides Guidance that Full-Year 2022 Adjusted EBITDA to be Between \$100-105 Million*

*Listing New Orange Book Patent Potentially Extends FIRDAPSE Patent Protection to 2037*

*Company to Host a Conference Call and Webcast on August 10, 2022, at 8:30 AM EDT*

**CORAL GABLES, Fla. August 9, 2022**—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 reported financial results for the second quarter 2022 and provided a corporate update. These results marked a quarter of record revenues from FIRDAPSE net sales and reflect the 5<sup>th</sup> period of consecutive quarter-over-quarter growth for Catalyst.

“Catalyst’s performance in the first half of the year and into the third quarter continues to be on a strong footing, and we have gained great momentum toward achieving our key strategic objectives for the year,” stated Patrick J. McEnany, Chairman and CEO of Catalyst. “We are pleased with the continued uptake of FIRDAPSE and patient demand, partially resulting from the favorable Appellate Court ruling that removed Ruzurgi from the market on February 1, 2022, as well as robust organic growth, which is providing strong operational growth in line with our total revenue guidance for 2022. In fact, at this time we are comfortable stating that our revenue guidance for the year is expected to be at the upper end of our previous total revenue forecast.”

McEnany continued, “We intend to build on our momentum with a clear priority to diversify our product portfolio with innovative therapies that address unmet medical needs in other rare diseases. Looking ahead, we are optimistic about our future as we remain committed to the patient community we serve and confident in our full-year outlook to drive sustainable growth and create long-term value for our various stakeholders. These efforts along with our continued fiscal discipline, uniquely position Catalyst to deliver sustainable value for our stockholders while supporting our mission for people living with rare diseases.”

## RECENT BUSINESS HIGHLIGHTS

- Achieved record net product revenue of \$53.0 million for Q2 2022, representing a significant 57.7% year-over-year increase and a 23.3% increase compared to Q1 2022, driven by the transition of Ruzurgi patients converting to FIRDAPSE treatment and robust organic growth.
- Settled our U.S. disputes with Jacobus Pharmaceuticals, which included a settlement of our U.S. patent infringement litigation against Jacobus and a resolution of our litigation challenging the Ruzurgi approval. As part of the settlement, we acquired the U.S. and Mexico rights to develop and commercialize Ruzurgi, the existing inventory of Ruzurgi, and certain know-how and intellectual property, including two U.S. patents. We intend to list one of these patents in the FDA's Orange Book to add to our patent protection for FIRDAPSE, potentially extending our patent protection for FIRDAPSE until February 25, 2037, and bringing the total number of U.S. patents that we have listed in the Orange Book seeking to protect FIRDAPSE to six.
- FDA accepted for review our supplemental New Drug Application seeking approval for the use of FIRDAPSE as a treatment for pediatric LEMS patients.
- Continued to advance on strategic growth initiatives to diversify our product portfolio with innovative therapies that address unmet needs in other rare diseases.
- Established a framework for our initial Environmental, Social, and Governance report.

## Second Quarter 2022 Financial Results

**Revenue:** Product revenue, net in the second quarter of 2022 was \$53.0 million, compared to \$33.6 million for the second quarter of 2021, representing an increase of 57.7% year-over-year. Total revenue for the second quarter of 2022 was \$53.1 million, compared to \$36.4 million for the second quarter of 2021, representing an increase of 46.1% year-over-year.

**Research and development expenses:** R&D expenses in the second quarter of 2022 were \$4.0 million, compared to R&D expenses of \$4.5 million in the second quarter of 2021.

**Selling, general, and administrative expenses:** Selling, general, and administrative expenses for the second quarter of 2022 were \$12.9 million, compared to \$11.5 million in the second quarter of 2021.

**Operating income:** Operating income for the second quarter of 2022 was \$28.6 million, compared to \$15.8 million in the second quarter of 2021, representing an increase of 80.4% year-over-year.

**GAAP Net Income** for the second quarter of 2022 was \$21.6 million (\$0.21 per basic and \$0.20 per diluted share), compared to \$12.2 million (\$0.12 per basic and \$0.11 per diluted share) for the second quarter of 2021.

## Non-GAAP Financial Measures

Non-GAAP<sup>1</sup> net income for the second quarter of 2022 was \$30.3 million (\$0.29 per basic and \$0.28 per diluted share), which excludes from GAAP net income of \$21.6 million (i) stock-based compensation expense of \$2.0 million, (ii) depreciation of \$37 thousand, and (iii) the provision for income taxes of \$6.6 million. This compares to non-GAAP<sup>1</sup> net income for the second quarter of 2021 of \$17.4 million (\$0.17 per basic and \$0.16 per diluted share), which excludes from GAAP net income of \$12.2 million (i) stock-based compensation of \$1.5 million, (ii) depreciation of \$31 thousand, and (iii) the provision for income taxes of \$3.7 million.

**Cash and investments** were \$220.8 million as of June 30, 2022, with no funded debt.

**Share repurchase program:** The Company implemented a share repurchase program in March 2021. As of June 30, 2022, the Company had repurchased approximately 3.2 million shares of Catalyst common stock in the open market, at an average price of \$5.92 per share, for a total purchase price of approximately \$19.0 million.

More detailed financial information and analysis regarding the Company's financial position at June 30, 2022 and its results of operations for the three and six months ended on that date can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 that was filed with the U.S. Securities and Exchange Commission ("SEC") on August 9, 2022.

**2022 Financial Guidance:** The Company continues to forecast that its full-year 2022 total revenues will be in the range of between \$195 million and \$205 million, representing a 38% - 45% increase in total revenues compared to 2021, with cash operating expenses for the full year 2022 expected to be in the range of \$65 million to \$70 million and adjusted EBITDA (calculated in the same manner as non-GAAP net income) expected to be in the range of \$100-105 million. Key guidance assumptions included in these forecasts reflect, among other risks, continued recovery in healthcare activity throughout 2022 as it relates to the current COVID-19 environment.

<sup>1</sup> Statements made in this press release include non-GAAP financial measures. Such information is provided as additional information and not as an alternative to Catalyst's financial statements presented in accordance with the U.S. generally accepted accounting principles (GAAP). These non-GAAP financial measures are intended to enhance an overall understanding of Catalyst's current financial performance. Catalyst believes that the non-GAAP financial measures presented in this press release provide investors and prospective investors with an alternative method for assessing Catalyst's operating results in a manner that Catalyst believes is focused on the performance of ongoing operations and provides a more consistent basis for comparison between periods. Non-GAAP financial measures should not be considered in isolation or as a substitute for comparable GAAP accounting. Further, non-GAAP measures of net income used by Catalyst may be different from and not directly comparable to similarly titled measures used by other companies.

The non-GAAP financial measure in this press release excludes from the calculation of net income (i) the expense associated with non-cash, stock-based compensation, (ii) depreciation expense, and (iii) the provision for income taxes. Non-GAAP income per share is calculated by dividing non-GAAP income by the weighted average common shares outstanding.

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## Conference Call & Webcast Details

The Company will host a conference call and webcast on Wednesday, August 10, 2022, at 8:30 AM ET to discuss the financial results and provide a business update.

US/Canada Dial-in Number: (877) 407-8912

International Dial-in Number: (201) 689-8059

A webcast and accompanying materials will be accessible under the investor section on the Company's website at [www.catalystpharma.com](http://www.catalystpharma.com). A webcast replay will be available on the Catalyst website for 30 days following the date of the event.

## About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, best-in-class medicines for 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, has approved the use of FIRDAPSE for the treatment of adult patients in Canada with LEMS.

## 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 locate and acquire new product candidates through acquisition or in-licensing, (iii) Catalyst's ability to successfully develop any new product candidates acquired or in-licensed, (iv) whether Catalyst's total revenue, cash operating expense, and adjusted EBITDA forecasts for 2022 will prove to be accurate, (v) whether Catalyst's patents listed in the Orange Book will be sufficient to eliminate generic competition for FIRDAPSE after our orphan drug exclusivity for FIRDAPSE for LEMS expires in late November 2025, (vi) whether legislative changes currently being considered by Congress that are intended to reduce the cost of prescription drug products will adversely affect Catalyst, and (vii) those factors described in Catalyst's Annual Report on Form 10-K for the 2021 fiscal year 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.

Source: Catalyst Pharmaceuticals, Inc.

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**FOR FURTHER INFORMATION, CONTACT:**

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**CATALYST PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)**  
*(in thousands, except share data)*

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue, net	\$ 53,049	\$ 33,636	\$ 96,082	\$ 63,841
License and other revenue	64	2,729	120	2,729
Total revenues	<u>53,113</u>	<u>36,365</u>	<u>96,202</u>	<u>66,570</u>
Operating costs and expenses:				
Cost of sales	7,643	4,545	13,533	9,226
Research and development	3,983	4,450	7,386	7,457
Selling, general and administrative	12,918	11,532	29,348	24,248
Total operating costs and expenses	<u>24,544</u>	<u>20,527</u>	<u>50,267</u>	<u>40,931</u>
Operating income	28,569	15,838	45,935	25,639
Other income (expense), net	(324)	62	(231)	143
Net income before income taxes	28,245	15,900	45,704	25,782
Income tax provision	6,626	3,719	10,844	5,938
Net income	<u>\$ 21,619</u>	<u>\$ 12,181</u>	<u>\$ 34,860</u>	<u>\$ 19,844</u>
Net income per share:				
Basic	<u>\$ 0.21</u>	<u>\$ 0.12</u>	<u>\$ 0.34</u>	<u>\$ 0.19</u>
Diluted	<u>\$ 0.20</u>	<u>\$ 0.11</u>	<u>\$ 0.32</u>	<u>\$ 0.18</u>
Weighted average shares outstanding:				
Basic	<u>102,795,600</u>	<u>103,407,803</u>	<u>102,788,719</u>	<u>103,610,138</u>
Diluted	<u>109,264,730</u>	<u>107,734,924</u>	<u>109,149,185</u>	<u>107,299,262</u>

**CATALYST PHARMACEUTICALS, INC.**  
**RECONCILIATION OF NON-GAAP METRICS (unaudited)**  
*(in thousands, except share data)*

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<b>GAAP net income</b>	<b>\$ 21,619</b>	<b>\$ 12,181</b>	<b>\$ 34,860</b>	<b>\$ 19,844</b>
Non-GAAP adjustments:				
Stock-based compensation expense	2,023	1,518	3,926	3,089
Depreciation	37	31	71	128
Income tax provision	6,626	3,719	10,844	5,938
Non-GAAP net income	<u>\$ 30,305</u>	<u>\$ 17,449</u>	<u>\$ 49,701</u>	<u>\$ 28,999</u>
Non-GAAP net income per share:				
Basic	<u>\$ 0.29</u>	<u>\$ 0.17</u>	<u>\$ 0.48</u>	<u>\$ 0.28</u>
Diluted	<u>\$ 0.28</u>	<u>\$ 0.16</u>	<u>\$ 0.46</u>	<u>\$ 0.27</u>
Weighted average shares outstanding:				
Basic	<u>102,795,600</u>	<u>103,407,803</u>	<u>102,788,719</u>	<u>103,610,138</u>
Diluted	<u>109,264,730</u>	<u>107,734,924</u>	<u>109,149,185</u>	<u>107,299,262</u>

**CATALYST PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(in thousands)*

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	<u>(unaudited)</u>	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 210,912	\$ 171,445
Short-term investments	9,876	19,821
Accounts receivable, net	9,587	6,619
Inventory	7,850	7,870
Prepaid expenses and other current assets	4,333	4,351
Total current assets	<u>242,558</u>	<u>210,106</u>
Operating lease right-of-use asset	2,895	3,017
Property and equipment, net	917	959
Deferred tax assets, net	20,930	23,697
Deposits	9	9
Total assets	<u>\$ 267,309</u>	<u>\$ 237,788</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 2,315	\$ 2,768
Accrued expenses and other liabilities	<u>20,173</u>	<u>24,295</u>
Total current liabilities	22,488	27,063
Operating lease liability, net of current portion	<u>3,729</u>	<u>3,894</u>
Total liabilities	26,217	30,957
Total stockholders' equity	<u>241,092</u>	<u>206,831</u>
Total liabilities and stockholders' equity	<u>\$ 267,309</u>	<u>\$ 237,788</u>