

**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): November 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 November 9, 2022, the Company issued a press release announcing its results of operations for the three and nine months ended September 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 November 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: November 9, 2022

**Catalyst Pharmaceuticals Reports Record Third Quarter 2022 Financial Results and Provides a Corporate Update**

*Achieved Record Q3 2022 FIRDAPSE® Net Revenue of \$57.2 Million, a 59.3% YoY Increase*

*Company Increases Full Year 2022 Total Revenue Guidance to \$205-210 Million*

*Q3 2022 GAAP Net Income of \$22.7 Million (\$0.22 per basic and \$0.20 per diluted share), which Includes a One Time Charge of \$4.1 Million Related to the Acquisition of Ruzurgi®*

*Cash and Short-Term Investments Increased in Q3 2022 by \$35.3 Million to \$256.1 Million*

*Non-GAAP Net Income for Q3 2022 of \$28.6 Million (\$0.28 per basic share and \$0.26 per diluted share)*

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

**CORAL GABLES, Fla. – November 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 and provided a corporate update for the third quarter of 2022.

“Catalyst delivered another solid quarter driven by record net revenues that exceeded expectations, marking this as another strong quarter of sequential growth of our FIRDAPSE® brand. These results reflect our exceptional commercial execution and continued commitment to the patient community that we serve,” said Patrick J. McEnany, Chairman and CEO of Catalyst. “Coupled with sustained organic growth, several significant milestones were achieved during the quarter that further enhance the commercial runway and long-term growth potential for FIRDAPSE®. The extraordinary execution across all segments of our business underscores our core competencies and adds further confidence that we are on the right path to achieving our long-term goals. With robust year-to-date performance and continued momentum going into the fourth quarter, we are raising our 2022 full year total revenue guidance to \$205-210 million.”

McEnany continued, “During the quarter, our priorities continued to be focused on commercial execution, preparing for the launch of our thoracic oncology programs to reach small-cell lung cancer patients with LEMS and diversifying our product portfolio with the acquisition of innovative therapies that address unmet medical needs in rare diseases. Moving ahead, we are well positioned to continue to drive organic growth as we look to strengthen our business with strategic opportunities that translate into added long-term value creation for all of our stakeholders.”

## RECENT BUSINESS HIGHLIGHTS

- Achieved all-time high net FIRDAPSE® product revenue of \$57.2 million for Q3 2022, representing robust growth of 59.3% year-over-year increase and a 7.8% increase compared to Q2 2022.
- In July 2022, completed the acquisition of Ruzurgi®, including the acquisition of intellectual property and inventory and a license for commercial rights in the U.S. and Mexico, which settled U.S. patent litigation and pending disputes in the U.S. between Catalyst and Jacobus Pharmaceutical Company, Inc.
- In September 2022, received FDA approval of the supplemental New Drug Application for FIRDAPSE®, expanding the indicated age range to include pediatric patients six years of age and older for the treatment of Lambert-Eaton myasthenic syndrome (“LEMS”).
- Enhanced intellectual property portfolio with an additional patent listed in the Orange Book with an expiry date of February 25, 2037, bringing the total number of U.S. patents listed to six.
- Advanced Environmental, Social, and Governance (“ESG”) initiatives through the launch of a comprehensive assessment of key ESG topics to identify appreciable targets for sustainability activities. Expect inaugural ESG Report in the first half of next year.
- On September 15<sup>th</sup> Catalyst was added to the S&P SmallCap 600 Index. For inclusion in the index, a stock must have a market cap that ranges from \$850 million to \$3.7 billion.
- In the third quarter of 2022 we were ranked #39 in the 2022 Fortune 100 Fastest Growing Companies List.
- Recently awarded the BioFlorida 2022 “David J. Gury Company of the Year” for the achievement of significant milestones and contributions to the growth of Florida’s life science industry.
- Advanced strategic growth initiatives to diversify our product portfolio with innovative therapies that address unmet needs in rare diseases.

### Third Quarter 2022 Financial Results

**Revenue:** Product revenue, net in the third quarter of 2022, was \$57.2 million, compared to \$35.9 million for the third quarter of 2021, representing an increase of 59.3% year-over-year. Total revenue for the third quarter of 2022 was \$57.2 million, compared to \$36.0 million for the third quarter of 2021, representing an increase of 59.2% year-over-year.

**Research and development expenses:** Research and development expenses in the third quarter of 2022 were \$8.3 million, compared to \$4.5 million in the third quarter of 2021. In connection with the Q3-22 Ruzurgi® acquisition, a one-time expense of \$4.1 million related to the write-off of acquired inventory was included in R&D.

**Selling, general, and administrative expenses:** Selling, general, and administrative expenses for the third quarter of 2022 were \$14.2 million, compared to \$12.2 million in the third quarter of 2021.

**Operating income:** Operating income for the third quarter of 2022 was \$25.1 million, compared to \$14.0 million in the third quarter of 2021, representing an increase of 79.2% year-over-year.

**GAAP net income:** GAAP net income for the third quarter of 2022 was \$22.7 million (\$0.22 per basic and \$0.20 per diluted share), compared to \$10.3 million (\$0.10 per basic and diluted share) for the third quarter of 2021.

#### **Non-GAAP Financial Measures**

Non-GAAP<sup>1</sup> net income for the third quarter of 2022 was \$28.6 million (\$0.28 per basic and \$0.26 per diluted share), which excludes from GAAP net income of \$22.7 million (i) stock-based compensation expense of \$2.1 million, (ii) depreciation of \$35 thousand, (iii) amortization of \$518 thousand, and (iv) the provision for income taxes of \$3.3 million. This compares to Non-GAAP<sup>1</sup> net income for the third quarter of 2021 of \$15.6 million (\$0.15 per basic and \$0.14 per diluted share), which excludes from GAAP net income of \$10.3 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:** Cash and investments were \$256.1 million as of September 30, 2022.

**Share repurchase program:** The Company implemented a share repurchase program in March 2021. As of September 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. As of now the Company has suspended share repurchases to conserve cash for business development activities.

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

**2022 Financial Guidance:** The Company has increased its forecast for the full year 2022 total revenues to be in the range of between \$205 million and \$210 million, representing a 46% - 49% 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 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.

1 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) non-cash depreciation and amortization 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 Thursday, November 10, 2022, at 8:30 AM ET to discuss the financial results and provide a business update.

US/Canada Dial-in Number: (866) 682-6100

International Dial-in Number: (862) 298-0702

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 and children ages six to seventeen 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.

For additional information about the Company, please visit [www.catalystpharma.com](http://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 locate and acquire new product candidates through acquisition or in-licensing, (iii) Catalyst's ability to sell products acquired that are already approved and to successfully develop any new product candidates acquired or in-licensed, (iv) whether Catalyst's total revenue, cash operating expense, and non-GAAP net income 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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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Product revenue, net	\$ 57,173	\$ 35,890	\$ 153,255	\$ 99,731
License and other revenue	71	64	191	2,793
Total revenues	57,244	35,954	153,446	102,524
Operating costs and expenses:				
Cost of sales	9,665	5,310	23,198	14,536
Research and development	8,310	4,487	15,696	11,944
Selling, general and administrative	14,167	12,153	43,515	36,401
Total operating costs and expenses	32,142	21,950	82,409	62,881
Operating income	25,102	14,004	71,037	39,643
Other income (expense), net	905	68	674	211
Net income before income taxes	26,007	14,072	71,711	39,854
Income tax provision	3,259	3,743	14,103	9,681
Net income	\$ 22,748	\$ 10,329	\$ 57,608	\$ 30,173
Net income per share:				
Basic	\$ 0.22	\$ 0.10	\$ 0.56	\$ 0.29
Diluted	\$ 0.20	\$ 0.10	\$ 0.52	\$ 0.28
Weighted average shares outstanding:				
Basic	103,318,572	103,196,550	102,967,280	103,470,762
Diluted	111,986,025	107,843,196	110,352,214	107,476,175

CATALYST PHARMACEUTICALS, INC.

RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
<b>GAAP net income</b>	<b>\$ 22,748</b>	<b>\$ 10,329</b>	<b>\$ 57,608</b>	<b>\$ 30,173</b>
Non-GAAP adjustments:				
Stock-based compensation expense	2,055	1,512	5,981	4,601
Depreciation	35	31	106	159
Amortization	518	—	518	—
Income tax provision	3,259	3,743	14,103	9,681
Non-GAAP net income	<u>\$ 28,615</u>	<u>\$ 15,615</u>	<u>\$ 78,316</u>	<u>\$ 44,614</u>
Non-GAAP net income per share:				
Basic	<u>\$ 0.28</u>	<u>\$ 0.15</u>	<u>\$ 0.76</u>	<u>\$ 0.43</u>
Diluted	<u>\$ 0.26</u>	<u>\$ 0.14</u>	<u>\$ 0.71</u>	<u>\$ 0.42</u>
Weighted average shares outstanding:				
Basic	<u>103,318,572</u>	<u>103,196,550</u>	<u>102,967,280</u>	<u>103,470,762</u>
Diluted	<u>111,986,025</u>	<u>107,843,196</u>	<u>110,352,214</u>	<u>107,476,175</u>

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

	September 30, 2022 (unaudited)	December 31, 2021
<b>ASSETS</b>		
<b>Current Assets:</b>		
Cash and cash equivalents	\$ 256,065	\$ 171,445
Short-term investments	—	19,821
Accounts receivable, net	9,337	6,619
Inventory	7,132	7,870
Prepaid expenses and other current assets	3,776	4,351
<b>Total current assets</b>	<b>276,310</b>	<b>210,106</b>
Operating lease right-of-use asset	2,833	3,017
Property and equipment, net	882	959
License and acquired intangibles, net	33,051	—
Deferred tax assets, net	20,029	23,697
Deposits	9	9
<b>Total assets</b>	<b>\$ 333,114</b>	<b>\$ 237,788</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities:</b>		
Accounts payable	\$ 2,529	\$ 2,768
Accrued expenses and other liabilities	42,152	24,295
<b>Total current liabilities</b>	<b>44,681</b>	<b>27,063</b>
Operating lease liability, net of current portion	3,643	3,894
Other non-current liabilities	14,749	—
<b>Total liabilities</b>	<b>63,073</b>	<b>30,957</b>
Total stockholders' equity	270,041	206,831
<b>Total liabilities and stockholders' equity</b>	<b>\$ 333,114</b>	<b>\$ 237,788</b>