

**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): May 10, 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

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

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))

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 May 10, 2022, the Company issued a press release reporting its results of operations for the three months ended March 31, 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 May 10, 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: May 10, 2022

Catalyst Pharmaceuticals Reports Record First Quarter 2022 Financial Results And Provides Corporate Update

Achieved Record Revenues of more than \$43 Million, a 42.7% Increase YoY

Three New Patents Issued; Now Five Orange-Book Listed Patents for FIRDAPSE®

Significant Cash Position of \$198 Million and No Funded Debt

Advanced Plans to Diversify and Invest in Innovative Rare Disease Opportunities

Reaffirms FY 2022 Total Revenue Guidance of \$195 Million to \$205 Million

Company to Host a Conference Call and Webcast on May 11, 2022, at 8:30 AM ET

CORAL GABLES, Fla., May 10, 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 first quarter 2022 and provided a corporate update.

“I am proud of Catalyst’s solid progress in the first quarter of 2022, where we delivered record revenues, driven in part, by new patients converting to FIRDAPSE® following the removal of Ruzurgi® from the U. S. market in February 2022. Our accomplishments exemplify our exceptional commercial and patient services capabilities and steadfast commitment to the LEMS patient community that we serve,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. “We also achieved several meaningful milestones during the quarter, including the issuance of three new patents that we believe position us to deliver sustainable long-term growth for FIRDAPSE. We anticipate this to be a transformative year for Catalyst, as we work with increased momentum to diversify and invest in innovative therapeutic opportunities for rare diseases. We approach these objectives from a position of strength and look forward to enhancing our growth potential near-term, as well as adding long-term value for all of our stakeholders.”

RECENT BUSINESS HIGHLIGHTS

- Reported record total revenue of \$43.1 million for the first quarter of 2022, compared to \$30.2 million in the comparable 2021 period, a 42.7% increase, reflecting steady growth for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of Lambert-Eaton myasthenic syndrome (“LEMS”) in adults.
- Recently completed the seamless transition of numerous LEMS patients who were former Ruzurgi patients converting to FIRDAPSE treatment, with the support provided by our Catalyst Pathways® assistance program.
- Organic growth in new FIRDAPSE patients continues to be strong, due to improved diagnosis rates, expanded reach to thoracic oncologists, and continued low patient discontinuations.
- Strengthened FIRDAPSE patent protection and long-term commercial potential with three new patents listed in the Orange Book covering additional patient amifampridine metabolizer types.

- Received favorable Canadian Federal Court ruling enforcing FIRDAPSE (amifampridine) Innovative Drug data protection. Currently, FIRDAPSE® is the only approved product in Canada for adult LEMS patients.
- Submitted a supplemental New Drug Application to the FDA to support the approved use of FIRDAPSE for the treatment of pediatric LEMS patients.
- Continued momentum in advancing strategic initiatives to diversify the business and invest in innovative opportunities for rare diseases.
- On Global Rare Disease Day in February, partnered with rare disease patients and advocacy groups to help raise awareness of the need for new treatments.

First Quarter 2022 Financial Results

Total revenue: Total revenue in the first quarter of 2022 was \$43.1 million, compared to \$30.2 million for the first quarter of 2021, representing an increase of 42.7% year-over-year.

Research and development expenses: R&D expenses in the first quarter of 2022 were \$3.4 million, compared to R&D expenses of \$3.0 million in the first quarter of 2021.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the first quarter of 2022 were \$16.4 million, compared to \$12.7 million in the first quarter of 2021.

Operating income: Operating income for the first quarter of 2022 was \$17.4 million, compared to \$9.8 million in the first quarter of 2021, representing an increase of 77.2% year-over-year.

GAAP Net Income for the first quarter of 2022 was \$13.2 million (\$0.13 per basic and \$0.12 per diluted share), compared to \$7.7 million (\$0.07 per basic and diluted share) for the first quarter of 2021, representing a year-over-year increase of 72.8%.

Non-GAAP Financial Measures

Non-GAAP¹ net income for the first quarter of 2022 was \$19.4 million (\$0.19 per basic and \$0.18 per diluted share), which excludes from GAAP net income of \$13.2 million (i) stock-based compensation expense of \$1.9 million, (ii) depreciation of \$34 thousand, and (iii) the provision for income taxes of \$4.2 million. This compares to non-GAAP¹ net income for the first quarter of 2021 of \$11.6 million (\$0.11 per

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) 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.

basic and diluted share), which excludes from GAAP net income of \$7.7 million (i) stock-based compensation expense of \$1.6 million, (ii) depreciation of \$97 thousand, and (iii) a provision for income taxes of \$2.2 million. A tabular presentation of non-GAAP¹ net income for the three months ended March 31, 2022 and 2021 is included below.

More detailed financial information and analysis can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which was filed with the Securities and Exchange Commission ("SEC") on May 10, 2022.

Cash and investments were \$198 million as of March 31, 2022, with no funded debt.

Share repurchase program: The Company implemented a share repurchase program in March 2021. As of March 31, 2022, the Company had repurchased 2.6 million shares of Catalyst common stock in the open market, at an average price of \$5.61 per share, for a total purchase price of \$14.6 million.

2022 Financial Guidance: The Company continues to forecast full year 2022 total revenues to be in the range of between \$195 million and \$205 million, representing a 38% - 45% increase in total revenues as compared to 2021, with cash operating expenses for the full year 2022 expected to be in the range of \$65 million to \$70 million. Key guidance assumptions included in these forecasts reflect a continued recovery in macroeconomic and healthcare activity throughout 2022 as it relates to the current COVID-19 environment.

Conference Call & Webcast Details

The Company will host a conference call and webcast on Wednesday, May 11, 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. A replay of the webcast 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 continuing 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 and cash operating expenses forecasts for 2022 will prove to be accurate, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2021 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.

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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except share data)

	For the Three Months Ended	
	2022	2021
Revenues:		
Product revenue, net	\$ 43,033	\$ 30,205
License and other revenue	56	—
Total revenues	<u>43,089</u>	<u>30,205</u>
Operating costs and expenses:		
Cost of sales	5,890	4,681
Research and development	3,403	3,007
Selling, general and administrative	16,430	12,716
Total operating costs and expenses	<u>25,723</u>	<u>20,404</u>
Operating income	17,366	9,801
Other income, net	93	81
Net income before income taxes	17,459	9,882
Income tax provision	4,218	2,219
Net income	<u>\$ 13,241</u>	<u>\$ 7,663</u>
Net income per share:		
Basic	<u>\$ 0.13</u>	<u>\$ 0.07</u>
Diluted	<u>\$ 0.12</u>	<u>\$ 0.07</u>
Weighted average shares outstanding:		
Basic	<u>102,781,771</u>	<u>103,814,725</u>
Diluted	<u>109,041,096</u>	<u>106,680,344</u>

CATALYST PHARMACEUTICALS, INC.

RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	For the Three Months Ended	
	March 31,	
	2022	2021
GAAP net income	\$ 13,241	\$ 7,663
Non-GAAP adjustments:		
Stock-based compensation expense	1,903	1,571
Depreciation	34	97
Income tax provision	4,218	2,219
Non-GAAP net income	\$ 19,396	\$ 11,550
Non-GAAP net income per share:		
Basic	\$ 0.19	\$ 0.11
Diluted	\$ 0.18	\$ 0.11
Weighted average shares outstanding:		
Basic	102,781,771	103,814,725
Diluted	109,041,096	106,680,344

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 178,372	\$ 171,445
Short-term investments	19,424	19,821
Accounts receivable, net	10,552	6,619
Inventory	7,827	7,870
Prepaid expenses and other current assets	5,016	4,351
Total current assets	<u>221,191</u>	<u>210,106</u>
Operating lease right-of-use asset	2,957	3,017
Property and equipment, net	925	959
Deferred tax assets, net	21,890	23,697
Deposits	9	9
Total assets	<u>\$ 246,972</u>	<u>\$ 237,788</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 5,139	\$ 2,768
Accrued expenses and other liabilities	17,799	24,295
Total current liabilities	<u>22,938</u>	<u>27,063</u>
Operating lease liability, net of current portion	3,813	3,894
Total liabilities	<u>26,751</u>	<u>30,957</u>
Total stockholders' equity	<u>220,221</u>	<u>206,831</u>
Total liabilities and stockholders' equity	<u>\$ 246,972</u>	<u>\$ 237,788</u>