

**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, 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

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 May 10, 2023, the Company issued a press release reporting its results of operations for the three months ended March 31, 2023 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, 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: May 10, 2023

**Catalyst Pharmaceuticals Reports Record First Quarter 2023 Results, Achieving
98% Total Revenue Growth Year-over-Year**

- *Reports Record Total Revenues of \$85.4 Million for Q1 2023*
- *Delivers Revenue Growth of 98%, a Record Increase YoY*
- *GAAP EPS Diluted of \$0.26 Per Share; a 117% Increase YoY*
- *Non-GAAP EPS Diluted of \$0.41 Per Share, an Increase of 128% YoY*
- *Affirms Full Year Total Revenue Guidance of Between \$375 Million and \$385 Million*
- *Forecasts Full-Year 2023 Non-GAAP Net Income of Between \$195 Million and \$205 Million*
- *FYCOMPA® Commercial and Medical Affairs Teams Onboard and Fully Engaged*
- *Recently Reported Positive Feedback From the FDA on Submission to Seek Approval of sNDA to Increase the Maximum Daily Dose of FIRDAPSE® From 80mg to 100mg*
- *Continuing Efforts to Acquire One or More Commercial or Late-Stage Products Through a Product or Company Acquisition*

CORAL GABLES, Fla. - May 10, 2023 - Catalyst Pharmaceuticals, Inc. (“Catalyst or the Company”) (Nasdaq: CPRX) today reported financial results for the first quarter of 2023 and provided a corporate update.

“Catalyst had an excellent start to the year driven by the sustained organic growth of FIRDAPSE® and compelling revenues from the newly acquired product, FYCOMPA®. The acquisition of FYCOMPA® was strategically transformational, serving as a differentiating impetus and meaningful contributor to our company’s long-term growth and exemplary revenue performance,” stated Patrick J. McEnany, Chairman and CEO of Catalyst. “The integration of the FYCOMPA commercial and medical affairs teams is now broadly complete with a talented team that is fully trained and engaged. The seamless integration, coupled with the strong quarterly revenue performance, is a testament to the exceptional execution capabilities of the entire Catalyst team.”

Mr. McEnany continued: “As significant progress is being made across all fronts, business development remains a high priority. Our team continues to make substantial advancements through vigorous evaluation of a robust number of opportunities in pursuit of innovative assets that strategically align and complement our portfolio expansion approach. We remain confident that we are well positioned to fully leverage our accomplishments and further deliver on key initiatives to enhance the long-term value for all of our stakeholders, with an ongoing commitment to our patient communities.”

Financial Highlights (in Millions of U.S. dollars, except per share data, unaudited)

For the Three Months Ended March 31,	2023	2022	% Change
Total Revenues	\$ 85.4	\$ 43.1	98%
FIRDAPSE® Net Product Revenues	\$ 57.5	\$ 43.0	34%
FYCOMPA® Net Product Revenues*	\$ 27.8	\$ —	100%
GAAP Net Income**	\$ 29.6	\$ 13.2	123%
Non-GAAP Net Income**	\$ 46.8	\$ 19.4	141%
Earnings per share Diluted – GAAP**	\$ 0.26	\$ 0.12	117%
Earnings per share Diluted - Non-GAAP**	\$ 0.41	\$ 0.18	128%

* FYCOMPA® revenues are for the approximately 2 months that we owned the U.S. rights to the product.

** Non-GAAP financial measures refer to reconciliations of non-GAAP financial measures to GAAP financial measures included in the accompanying schedules. Non-GAAP financial measures exclude from GAAP financial measures stock-based compensation, depreciation and amortization, and income taxes. See the “Reconciliation of Non-GAAP Metrics” table below.

BUSINESS HIGHLIGHTS

- Achieved all-time high total revenues of \$85.4 Million for Q1 2023, an 98% YoY increase and a 41% increase compared to Q4-2022, bolstered by the addition of FYCOMPA® net product revenues.
- Completed the FYCOMPA® acquisition; reported robust net product revenues of \$27.8 Million for the approximately two months following the close of the product acquisition on January 24, 2023.
- Achieved Q1 2023 FIRDAPSE® net product revenue of \$57.5 Million, representing a substantial 34% YoY increase.
- On track to achieve forecast total revenues of between \$375 Million and \$385 Million.
- Completed a seamless U.S. FYCOMPA® commercial team integration, with the full integration of operations expected to be completed by the end of Q2 2023.
- Expect to file a supplemental New Drug Application (“sNDA”) to increase the maximum daily dosage of FIRDAPSE® (amifampridine) from 80mg to 100mg for the treatment of Lambert-Eaton myasthenic syndrome (“LEMS”) early in the third quarter of 2023.
- Anticipate FIRDAPSE® Phase 3 LEMS registrational study completion in Japan by late 2023, and assuming the study is successful, an expected NDA filing with the PMDA (Pharmaceuticals and Medical Devices Agency) in the second quarter of 2024 (by DyDo Pharma).

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- Continue to vigorously pursue innovative rare neurological assets in alignment with our portfolio expansion strategy.
 - Launched our inaugural Environmental, Social, and Governance (“ESG”) Report on May 1, 2023, highlighting the Company’s ESG strategy, areas of focus, and meaningful progress in key areas.

Financial Results for First Quarter 2023

Product Revenues, Net: Product revenues, net in the first quarter of 2023, were \$85.3 Million, compared to \$43.0 Million for the first quarter of 2022, representing an increase of 98% year-over-year.

Research and Development Expenses: Research and development expenses in the first quarter of 2023 were \$3.6 Million, compared to \$3.4 Million in the first quarter of 2022.

Selling, General, and Administrative Expenses: Selling, general, and administrative expenses for the first quarter of 2023 were \$29.7 Million, compared to \$16.4 Million in the first quarter of 2022.

Amortization of Intangible Assets: Amortization of intangible assets was \$6.5 Million in the first quarter of 2023, compared to \$0.00 in the first quarter of 2022. Intangible assets acquired subsequent to the first quarter of 2022 relate to the FYCOMPA® rights acquired in the first quarter of 2023 and the RUZURGI® rights acquired in the third quarter of 2022.

Operating Income: Operating income for the first quarter of 2023 was \$35.6 Million, compared to \$17.4 Million in the first quarter of 2022, representing an increase of 105% year-over-year.

GAAP Net Income: GAAP net income for the first quarter of 2023 was \$29.6 Million (\$0.28 per basic share and \$0.26 per diluted share), compared to \$13.2 Million (\$0.13 per basic share and \$0.12 per diluted share) for the first quarter of 2022, representing a 123% increase YoY.

Non-GAAP Net Income¹: Non-GAAP net income for the first quarter of 2023 was \$46.8 Million (\$0.44 per basic share and \$0.41 per diluted share), compared to \$19.4 Million (\$0.19 per basic share and \$0.18 per diluted share) for the first quarter of 2022, representing a 132% increase YoY for each basic share and a 128% increase YoY for each diluted share.

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 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.

Cash and Equivalents: Cash and equivalents were \$148.2 Million as of March 31, 2023.

2023 Financial Guidance: The Company forecasts full-year 2023 total revenues, including FYCOMPA[®], to be between \$375 Million and \$385 Million, representing a 75% - 80% increase in total revenues compared to 2022. Key guidance assumptions in this forecast reflect a continued recovery in macroeconomic and healthcare activity throughout 2023 related to the current COVID-19 environment.

More detailed financial information and analysis regarding the Company's financial position on March 31, 2023, and its results of operations for the three months ended on that date can be found in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, filed with the U.S. Securities and Exchange Commission ("SEC") on March 10, 2023.

Conference Call & Webcast Details

The Company will host a conference call and webcast on Thursday, May 11, 2023, at 8:30 AM ET to discuss the financial results and provide a business update.

U.S./Canada Dial-in Number: (877) 407-8912

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

A webcast will be accessible under the investor section on the Company's website at www.catalystpharma.com. A webcast replay will be available on the Catalyst website for 30 days after the event.

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 www.catalystpharma.com.

The non-GAAP financial measure included 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 expense, (iii) non-cash amortization of intangible assets expense, and (iv) the provision for income taxes. Non-GAAP income per share is calculated by dividing non-GAAP income by the weighted average common shares outstanding.

For Full Prescribing and Safety Information for FIRDAPSE[®], please visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for 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) 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 total revenue forecast 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 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.

CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

(in thousands, except share data)

	For the Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenue, net	\$ 85,304	\$ 43,033
License and other revenue	62	56
Total revenues	<u>85,366</u>	<u>43,089</u>
Operating costs and expenses:		
Cost of sales (a)	9,946	5,890
Research and development	3,562	3,403
Selling, general and administrative (a)	29,718	16,430
Amortization of intangible assets	6,531	—
Total operating costs and expenses	<u>49,757</u>	<u>25,723</u>
Operating income	35,609	17,366
Other income, net	1,704	93
Net income before income taxes	37,313	17,459
Income tax provision	7,745	4,218
Net income	<u>\$ 29,568</u>	<u>\$ 13,241</u>
Net income per share:		
Basic	<u>\$ 0.28</u>	<u>\$ 0.13</u>
Diluted	<u>\$ 0.26</u>	<u>\$ 0.12</u>
Weighted average shares outstanding:		
Basic	<u>105,561,229</u>	<u>102,781,771</u>
Diluted	<u>113,986,129</u>	<u>109,041,096</u>

(a) Exclusive of amortization of intangible assets

CATALYST PHARMACEUTICALS, INC.

RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	<u>For the Three Months Ended March 31,</u>	
	<u>2023</u>	<u>2022</u>
GAAP net income	\$ 29,568	\$ 13,241
Non-GAAP adjustments:		
Stock-based compensation expense	2,892	1,903
Depreciation	69	34
Amortization of intangible assets	6,531	—
Income tax provision	7,745	4,218
Non-GAAP net income	\$ 46,805	\$ 19,396
Non-GAAP net income per share:		
Basic	\$ 0.44	\$ 0.19
Diluted	\$ 0.41	\$ 0.18
Weighted average shares outstanding:		
Basic	105,561,229	102,781,771
Diluted	113,986,129	109,041,096

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2023 <u>(unaudited)</u>	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 148,247	\$ 298,395
Accounts receivable, net	33,402	10,439
Inventory	10,328	6,805
Prepaid expenses and other current assets	6,934	5,167
Total current assets	<u>198,911</u>	<u>320,806</u>
Operating lease right-of-use asset	2,706	2,770
Property and equipment, net	1,285	847
License and acquired intangibles, net	184,083	32,471
Deferred tax assets, net	20,242	18,736
Total assets	<u>\$ 407,227</u>	<u>\$ 375,630</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,391	\$ 3,975
Accrued expenses and other liabilities	53,318	53,613
Total current liabilities	<u>56,709</u>	<u>57,588</u>
Operating lease liability, net of current portion	3,468	3,557
Other non-current liabilities	13,389	14,064
Total liabilities	<u>73,566</u>	<u>75,209</u>
Total stockholders' equity	<u>333,661</u>	<u>300,421</u>
Total liabilities and stockholders' equity	<u>\$ 407,227</u>	<u>\$ 375,630</u>

Source: Catalyst Pharmaceuticals, Inc.

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