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 8, 2024

CATALYST PHARMACEUTICALS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

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

355 Alhambra Circle **Suite 801** **Coral Gables, Florida**	**33134**
(Address of principal executive offices)	**(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 CFR240.14d-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 8, 2024, the Company issued a press release announcing its results of operations for the three months ended March 31, 2024 and providing a business 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 8, 2024.
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/ Michael Kalb
Michael Kalb
Executive Vice President and CFO

Dated: May 8, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Reports Solid First Quarter 2024 Financial Results and Provides Business Update

Achieved Total Q1 2024 Revenues of $98.5 Million, a 15.4% YoY Increase, Underscored by Exceptional Execution and Continued Demand for Commercial Products

FIRDAPSE® Q1 2024 Net Product Revenues of $66.8 Million, a 16.2% YoY Increase

Robust Revenue Momentum for FIRDAPSE®

Successfully Commenced the U.S. Launch of AGAMREE® on March 13, 2024

Reported AGAMREE® Q1 2024 Net Product Revenues of $1.2 Million for the First Two Weeks of Commercial Availability

Early AGAMREE® Launch Indicators Highlight Promising Product Uptake Surpassing Initial Expectations

Q1 2024 GAAP Net Income of $23.3 Million, $0.19 Per Share Diluted

Q1 2024 Non-GAAP Net Income of $46.8 Million, $0.38 Per Share Diluted

Reaffirm Full Year 2024 Total Revenue Guidance Between $455 Million and $475 Million

Conference Call and Webcast to be Held on May 9, 2024, at 8:30 AM ET

CORAL GABLES, Fla., May 8, 2024 - Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today reported financial results for the first quarter of 2024 and provided a business update.

"Our strong performance in the first quarter provides us with the momentum for continued growth throughout the year," stated Richard Daly, President and Chief Executive Officer of Catalyst. "The successful U.S. launch of AGAMREE and sustained double-digit growth of FIRDAPSE are a testament to our team's commitment to serving patients through innovative products and outstanding execution. Building on the positive indicators observed during the initial phase of AGAMREE's launch further strengthens our confidence for accelerated growth of this critically important product."

Financial Highlights

For the Three Months Ended March 31, *(In thousands, except per share data)*	**2024**	**2023**	**% Change**
Product Revenue, net	$ 98,441	$ 85,304	15.4%
FIRDAPSE Product Revenue, net	$ 66,842	$ 57,526	16.2%
FYCOMPA Product Revenue, net**	$ 30,425	$ 27,778	9.5%
AGAMREE Product Revenue, net	$ 1,174	N/A	N/A
GAAP Net Income	$ 23,275	$ 29,568	(21.3%)
Non-GAAP Net Income ***	$ 46,767	$ 46,805	(0.1%)
GAAP Net Income Per Share - Basic	$ 0.20	$ 0.28	(28.6%)
Non-GAAP Net Income Per Share – Basic***	$ 0.40	$ 0.44	(9.1%)
GAAP Net Income Per Share – Diluted	$ 0.19	$ 0.26	(26.9%)
Non-GAAP Net Income Per Share – Diluted***	$ 0.38	$ 0.41	(7.3%)
As of March 31, 2024 and December 31, 2023 *(In thousands)*			
Cash and Cash Equivalents	$310,411	$137,636	125.5%

** For Q1 2023, represents product revenue, net from the date of acquisition of the product rights.

*** 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.

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 net income per share is calculated by dividing non-GAAP net income by the weighted average shares outstanding. See the "Reconciliation of Non-GAAP Metrics" table below.

Recent Business Highlights

- Achieved solid performance with Q1 2024 total revenues of $98.5 million, reflecting a 15.4% increase compared to Q1 2023, driven by the persistent demand for the Company's innovative commercial products.
- Promptly implemented measures to ensure uninterrupted patient access to treatment amidst external third-party prescription processing disruptions while sustaining the compelling product growth momentum.
- Delivered outstanding growth performance for FIRDAPSE, achieving net product revenues of $66.8 million for Q1 2024, representing growth of 16.2% compared to Q1 2023, despite transient revenue impact by external disruptions in prescription processing during the period.
- Achieved FYCOMPA net product revenues of $30.4 million for Q1 2024, representing growth of 9.5% compared to Q1 2023. Revenue growth reflects the full quarter for Q1 2024, compared to the partial Q1 2023 period, due to the timing of the acquisition.
- Successfully commenced the U.S. AGAMREE commercial launch, an innovative corticosteroid for the treatment of Duchenne muscular dystrophy in patients aged two years and older, on March 13, 2024.
- Early indicators for the AGAMREE U.S. launch show strong demand exceeding initial expectations.
- Reported AGAMREE net product revenues of $1.2 million for Q1 2024, reflecting approximately the first two weeks of U.S. commercial availability.
- Endorsed the inaugural Lambert-Eaton myasthenic syndrome ("LEMS") Awareness Day, now officially observed annually on March 30th, marking a significant milestone for the LEMS community.
- Strong cash position of $310.4 million as of March 31, 2024, fortified by the approximately $140.7 million in net proceeds yielded from the 10 million shares of common stock offering in January 2024.
- Reaffirm the 2024 full-year total revenue guidance in the range of $455 million and $475 million.

First Quarter 2024 Financial Results

Total revenues: In the first quarter of 2024, total revenues were $98.5 million, compared to $85.4 million for the first quarter of 2023, representing an increase of approximately 15.4%.

Product revenue, net: Product revenue, net for the first quarter of 2024 was $98.4 million, compared to $85.3 million for the first quarter of 2023, representing an increase of approximately 15.4%.

Research and development expenses: Research and development expenses for the first quarter of 2024 were $2.6 million, compared to $3.6 million for the first quarter of 2023, representing a decrease of approximately 27.5%.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the first quarter of 2024 were $46.9 million, compared to $29.7 million for the first quarter of 2023, representing an increase of approximately 57.9% primarily relating to preparation for the launch of AGAMREE.

Amortization of intangible assets: Amortization of intangible assets was $9.3 million in the first quarter of 2024, compared to $6.5 million in the first quarter of 2023, representing an increase of approximately 43.1%.

Operating income: Operating income for the first quarter of 2024 was $27.1 million, compared to $35.6 million for the first quarter of 2023, representing a decrease of approximately 23.8%.

GAAP net income: GAAP net income for the first quarter of 2024 was $23.3 million ($0.20 per basic and $0.19 per diluted share), compared to GAAP net income of $29.6 million ($0.28 per basic and $0.26 per diluted share) for the first quarter of 2023.

Non-GAAP net income: Non-GAAP net income for the first quarter of 2024 was $46.8 million ($0.40 per basic and $0.38 per diluted share), compared to non-GAAP net income of $46.8 million ($0.44 per basic and $0.41 per diluted share) for the first quarter of 2023.

Cash and cash equivalents: Cash and cash equivalents were $310.4 million as of March 31, 2024.

Our Form 10-Q for the first quarter of 2024, filed with the U.S. Securities and Exchange Commission on May 8, 2024, provides more detailed financial information and analysis of our financial condition and results of operations.

Conference Call & Webcast Details

The Company will host a conference call and webcast on May 9, 2024, 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, Inc.

With exceptional patient focus, Catalyst is committed to developing and commercializing innovative first-in-class medicines that address rare and difficult-to-treat 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 to seventeen. 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. On July 18th, 2023, Catalyst acquired an exclusive license for North America for AGAMREE® (vamorolone) oral suspension 40 mg/mL, a novel corticosteroid treatment for Duchenne muscular dystrophy. AGAMREE previously received FDA Orphan Drug and Fast Track designations and was approved by the FDA for commercialization in the U.S. on October 26th, 2023. AGAMREE became available in the U.S. by prescription on March 13, 2024.

For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at www.catalystpharma.com. For Full Prescribing and Safety Information for FIRDAPSE®, visit www.firdapse.com. For Full Prescribing Information, including Boxed WARNING for FYCOMPA®, please visit www.fycompa.com. For Full Prescribing Information for AGAMREE®, please visit www.agamree.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) whether the launch of AGAMREE® will surpass initial expectations and exceed 2024 full-year revenue forecasts for sales of the product that were previously published by the Company (ii) whether AGAMREE's commercialization will ultimately be profitable, cash flow positive, and accretive to Catalyst, (iii) Catalyst's ability to continue to successfully sell its current products, (iv) whether Catalyst will continue to be profitable and cash flow positive, (v) whether Catalyst's total revenue forecast for 2024 included in this press release will prove to be accurate, (vi) whether Catalyst will complete additional acquisitions of products, and the timing of any such acquisitions; (vii) the impact of pending Paragraph IV litigation relating to the Company's FIRDAPSE® and FYCOMPA® products if the results of these litigation matters are adverse, and (viii) those factors described in Catalyst's Annual Report on Form 10-K for the 2023 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2024, 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.

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

	For the Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Product revenue, net	$ 98,441	$ 85,304
License and other revenue	68	62
Total revenues	98,509	85,366
Operating costs and expenses:		
Cost of sales (a)	12,520	9,946
Research and development	2,581	3,562
Selling, general and administrative (a)	46,938	29,718
Amortization of intangible assets	9,344	6,531
Total operating costs and expenses	71,383	49,757
Operating income	27,126	35,609
Other income, net	1,963	1,704
Net income before income taxes	29,089	37,313
Income tax provision	5,814	7,745
Net income	$ 23,275	$ 29,568
Net income per share:		
Basic	$ 0.20	$ 0.28
Diluted	$ 0.19	$ 0.26
Weighted average shares outstanding:		
Basic	116,806,117	105,561,229
Diluted	123,403,626	113,986,129

(a) exclusive of amortization of intangible assets

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

	For the Three Months Ended March 31,	
	2024	2023
GAAP net income	**$ 23,275**	**$ 29,568**
Non-GAAP adjustments:		
Stock-based compensation expense	8,248	2,892
Depreciation	86	69
Amortization of intangible assets	9,344	6,531
Income tax provision	5,814	7,745
Non-GAAP net income	**$ 46,767**	**$ 46,805**
Non-GAAP net income per share:		
Basic	$ 0.40	$ 0.44
Diluted	$ 0.38	$ 0.41
Weighted average shares outstanding:		
Basic	116,806,117	105,561,229
Diluted	123,403,626	113,986,129

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

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 310,411	$ 137,636
Accounts receivable, net	60,493	53,514
Inventory	19,953	15,644
Prepaid expenses and other current assets	13,745	12,535
Total current assets	404,602	219,329
Operating lease right-of-use asset	2,440	2,508
Property and equipment, net	1,308	1,195
License and acquired intangibles, net	184,705	194,049
Deferred tax assets, net	38,276	36,544
Investment in equity securities	15,345	16,489
Total assets	$ 646,676	$ 470,114
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 10,261	$ 14,795
Accrued expenses and other liabilities	69,305	61,268
Total current liabilities	79,566	76,063
Operating lease liability, net of current portion	3,091	3,188
Other non-current liabilities	2,607	2,982
Total liabilities	85,264	82,233
Total stockholders' equity	561,412	387,881
Total liabilities and stockholders' equity	$ 646,676	$ 470,114

Source: Catalyst Pharmaceuticals, Inc.

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