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 7, 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 August 7, 2024, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 2024 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 7, 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: August 7, 2024

Exhibit 99.1

Catalyst Pharmaceuticals Reports Strong Second Quarter 2024 Financial Results and Provides Corporate Update

Delivered Robust Revenue Performance, Fueled by Exceptional Commercial Execution and Early Success of the U.S. AGAMREE® Product Launch

Reported Record Q2 2024 Total Revenues of $122.7 Million, Representing a 23.2% YoY Increase

FIRDAPSE® Q2 2024 Net Product Revenues of $77.4 Million, Reflecting Strong Organic 19.2% YoY Growth

AGAMREE® Q2 2024 Net Product Revenues of $8.7 Million Demonstrates a Strong Start to U.S. Commercialization

FYCOMPA® Q2 2024 Net Product Revenues of $36.5 Million, Representing a 5.7% YoY Increase

Q2 2024 GAAP Net Income of $40.8 Million, $0.33 Per Share Diluted

Q2 2024 Non-GAAP Net Income of $69.6 Million, $0.56 Per Share Diluted

Reaffirming 2024 Total Revenue Guidance of $455 Million – $475 Million, Expecting Results in the Upper Range of the Guidance

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

CORAL GABLES, Fla., August 7, 2024- Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today reported financial results for the second quarter of 2024 and provided a corporate update.

"Since the onset of this year, we have advanced with continued momentum, propelled by the strong performance of our established product portfolio and the successful U.S. commercial launch of AGAMREE. Our accomplishments have significantly strengthened our financial position, aligning with our revenue guidance for the year, and we believe that we are on track to achieve the upper end of our previously provided total revenue forecast," stated Richard J. Daly, President and CEO of Catalyst. "With unwavering confidence in our ability to execute our strategic objectives, we remain steadfast in our plans to capitalize on new opportunities to broaden our rare orphan portfolio with innovative and differentiated products and expand our market presence, as exemplified by our recent license agreement for AGAMREE in Canada. As we continue to execute our business strategy, we remain focused on enhancing our growth potential and delivering value to our stakeholders, while prioritizing the needs of our patient communities. Backed by our proven track record and dedicated team, we believe that we are well-positioned for sustained success."

Financial Highlights

For the Three Months Ended June 30,	2024	2023	% Change
(In thousands, except per share data)			
Product Revenue, Net	$122,653	$ 99,477	23.3%
FIRDAPSE Product Revenue, Net	$ 77,372	$ 64,898	19.2%
FYCOMPA Product Revenue, Net	$ 36,535	$ 34,579	5.7%
AGAMREE Product Revenue, Net	$ 8,746	N/A	N/A
GAAP Net Income	$ 40,794	$ 37,762	8.0%
Non-GAAP Net Income **	$ 69,631	$ 60,380	15.3%
GAAP Net Income Per Share - Basic	$ 0.35	$ 0.36	(2.8%)
Non-GAAP Net Income Per Share – Basic**	$ 0.59	$ 0.57	3.5%
GAAP Net Income Per Share – Diluted	$ 0.33	$ 0.33	0%
Non-GAAP Net Income Per Share – Diluted**	$ 0.56	$ 0.53	5.7%
As of June 30, 2024, and December 31, 2023			
(In thousands)			
Cash and Cash Equivalents	$375,693	$137,636	173.0%

** 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.

Recent Business Highlights

- Achieved strong results with total net product revenues amounting to $122.7 million for Q2 2024, reflecting a robust 23.3% YoY increase.
- Delivered outstanding FIRDAPSE net product revenues of $77.4 million for Q2 2024, evidenced by impressive 19.2% YoY growth.

- Successfully executed the U.S. commercial launch of AGAMREE, a novel corticosteroid treatment for Duchenne Muscular Dystrophy, yielding solid results and surpassing our initial expectations.
- Reported AGAMREE net product revenues of $8.7 million for Q2 2024, marking the first full quarter of U.S. commercial availability.
- Achieved Q2 2024 FYCOMPA net product revenues of $36.5 million, representing a 5.7% YoY performance.
- On May 30, 2024, the FDA approved the 100 mg maximum daily dose of FIRDAPSE, enhancing treatment flexibility for healthcare providers treating LEMS patients.
- In July 2024, Catalyst secured an exclusive license, supply, and commercialization agreement with KYE Pharmaceuticals, Inc., for AGAMREE in Canada, marking a pivotal strategic milestone in expanding the product's North American footprint.
- Published the Company's 2023 ESG Report in June 2024, highlighting key achievements and initiatives.
- We currently believe that our total revenue for the year ending December 31, 2024 will be in the upper half of our previously reported total revenue guidance of between $455 million and $475 million.
- We are reaffirming our full-year 2024 FIRDAPSE net product revenue guidance to be approximately $295 million to $310 million and our 2024 FYCOMPA net product revenue guidance to be approximately $130 million to $135 million, respectively.
- We are increasing our full-year 2024 net product revenue guidance for AGAMREE to be approximately $35 million to $40 million, based on the promising demand trend and an encouraging payer landscape.

Second Quarter 2024 Financial Results

Total revenues: In the second quarter of 2024, total revenues were $122.7 million, compared to $99.6 million for the second quarter of 2023, representing an increase of approximately 23.2%.

Product revenue, net: Product revenue, net for the second quarter of 2024 was $122.7 million, compared to $99.5 million for the second quarter of 2023, representing an increase of approximately 23.3%.

Research and development expenses: Research and development expenses for the second quarter of 2024 were $3.0 million, compared to $4.0 million for the second quarter of 2023, representing a decrease of approximately 24.5%.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the second quarter of 2024 were $40.7 million, compared to $28.4 million for the second quarter of 2023, representing an increase of approximately 43.4%, primarily relating to our preparation for and commercial launch of AGAMREE.

Amortization of intangible assets: Amortization of intangible assets was $9.3 million in the second quarter of 2024, compared to $8.5 million in the second quarter of 2023, representing an increase of approximately 10.1%.

Operating income: Operating income for the second quarter of 2024 was $54.2 million, compared to $46.7 million for the second quarter of 2023, representing an increase of approximately 16.2%.

GAAP net income: GAAP net income for the second quarter of 2024 was $40.8 million ($0.35 per basic and $0.33 per diluted share), compared to GAAP net income of $37.8 million ($0.36 per basic and $0.33 per diluted share) for the second quarter of 2023.

Non-GAAP net income: Non-GAAP net income for the second quarter of 2024 was $69.6 million ($0.59 per basic and $0.56 per diluted share), compared to non-GAAP net income of $60.4 million ($0.57 per basic and $0.53 per diluted share) for the second quarter of 2023.

Cash and cash equivalents: Cash and cash equivalents were $375.7 million as of June 30, 2024.

Our Form 10-Q for the second quarter of 2024, filed with the U.S. Securities and Exchange Commission on August 7, 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 Thursday, August 8, 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

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") in adults and pediatric patients 6 years of age 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. Most recently, on May 30, 2024, the FDA approved an increased maximum daily dose of 100 mg for FIRDAPSE for adults and pediatric patients weighing more than 45 kg.

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.

On July 18, 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 26, 2023. AGAMREE became commercially available by prescription in the U.S. on March 13, 2024. Further, in July 2024, Catalyst entered into an exclusive license, supply, and commercialization agreement for AGAMREE in Canada.

For more information about Catalyst, please visit the Company's website at www.catalystpharma.com. 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 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 continue to 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 and continue to be profitable and cash flow positive, (iv) whether Catalyst's total revenue forecast for 2024 included in this press release will prove to be accurate, (v) whether Catalyst will complete additional acquisitions of products, and the timing of any such acquisitions; (vi) the impact of pending Paragraph IV litigation relating to FIRDAPSE® if the results of these litigation matters are adverse, (vii) whether AGAMREE will be approved for commercialization in Canada, 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 second 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 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 June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Product revenue, net	$ 122,653	$ 99,477	$ 221,094	$ 184,781
License and other revenue	57	105	125	167
Total revenues	122,710	99,582	221,219	184,948
Operating costs and expenses:				
Cost of sales (a)	15,405	12,045	27,925	21,991
Research and development	2,985	3,954	5,566	7,516
Selling, general and administrative (a)	40,730	28,396	87,668	58,114
Amortization of intangible assets	9,344	8,488	18,688	15,019
Total operating costs and expenses	68,464	52,883	139,847	102,640
Operating income	54,246	46,699	81,372	82,308
Other income, net	1,542	1,813	3,505	3,517
Net income before income taxes	55,788	48,512	84,877	85,825
Income tax provision	14,994	10,750	20,808	18,495
Net income	$ 40,794	$ 37,762	$ 64,069	$ 67,330
Net income per share:				
Basic	$ 0.35	$ 0.36	$ 0.55	$ 0.64
Diluted	$ 0.33	$ 0.33	$ 0.52	$ 0.59
Weighted average shares outstanding:				
Basic	118,180,396	106,258,790	117,493,257	105,911,936
Diluted	124,655,999	113,673,534	124,028,752	113,840,155

(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 June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net income	$ 40,794	$ 37,762	$ 64,069	$ 67,330
Non-GAAP adjustments:				
Stock-based compensation expense	4,408	3,298	12,656	6,190
Depreciation	91	82	177	151
Amortization of intangible assets	9,344	8,488	18,688	15,019
Income tax provision	14,994	10,750	20,808	18,495
Non-GAAP net income	$ 69,631	$ 60,380	$ 116,398	$ 107,185
Non-GAAP net income per share:				
Basic	$ 0.59	$ 0.57	$ 0.99	$ 1.01
Diluted	$ 0.56	$ 0.53	$ 0.94	$ 0.94
Weighted average shares outstanding:				
Basic	118,180,396	106,258,790	117,493,257	105,911,936
Diluted	124,655,999	113,673,534	124,028,752	113,840,155

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

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 375,693	$ 137,636
Accounts receivable, net	57,172	53,514
Inventory	18,014	15,644
Prepaid expenses and other current assets	23,550	12,535
Total current assets	474,429	219,329
Operating lease right-of-use asset	2,371	2,508
Property and equipment, net	1,227	1,195
License and acquired intangibles, net	175,361	194,049
Deferred tax assets, net	39,889	36,544
Investment in equity securities	13,083	16,489
Total assets	$ 706,360	$ 470,114
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 7,116	$ 14,795
Accrued expenses and other liabilities	85,202	61,268
Total current liabilities	92,318	76,063
Operating lease liability, net of current portion	2,991	3,188
Other non-current liabilities	2,396	2,982
Total liabilities	97,705	82,233
Total stockholders' equity	608,655	387,881
Total liabilities and stockholders' equity	$ 706,360	$ 470,114

Source: Catalyst Pharmaceuticals, Inc.

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