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 9, 2023

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 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 August 9, 2023, the Company issued a press release announcing its results of operations for the three and six months ended June 30, 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 August 9, 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: August 9, 2023

Exhibit 99.1

Catalyst Pharmaceuticals Reports Strong Second Quarter 2023 Financial Results and Provides Corporate Update

Achieved Record Q2 2023 Total Net Revenues of $99.6 Million

Achieved FIRDAPSE® 2023 Second Quarter Net Revenues of $64.9 Million, a 22% Increase YOY

Achieved 2023 Second Quarter GAAP EPS Diluted of $0.33 Compared to $0.20 for Q2 2022

Achieved 2023 Second Quarter Non-GAAP EPS Diluted of $0.53 Compared to $0.28 for Q2 2022

During Q3-23 Completed the Acquisition of the North American License for Vamorolone

Submitted sNDA for FIRDAPSE Seeking to Increase the Maximum Indicated Dose to 100 mg per Day

Completed the Integration of our FYCOMPA® Commercial and MSL Teams

Raising Full Year 2023 Total Revenue Guidance of Between $380 Million and $390 Million

Conference Call and Webcast to be Held on August 10, 2023, at 8:30 AM ET

CORAL GABLES, Fla., August 9, 2023 - Catalyst Pharmaceuticals, Inc. (“Catalyst” or “the Company”) (Nasdaq: CPRX) today reported financial results for the second quarter of 2023 and provided a corporate update.

“We are extremely pleased with the remarkable progress we achieved during the first half of 2023, fueled by the sustained and exceptional organic growth of FIRDAPSE, a significant contributor to our revenue accomplishments. Moreover, our sales of FYCOMPA, which we acquired at the end of January 2023, have bolstered our success for the first half of 2023, and we have recently completed our integration of the FYCOMPA team and believe that FYCOMPA will be a synergistic and meaningful contributor to our future revenue potential,” stated Patrick J. McEnany, Chairman and CEO of Catalyst. “Our most recent acquisition, which we closed in July, is the North American license for vamorolone, a late-stage asset with a PDUFA action date of October 26th, 2023, for the treatment of Duchenne muscular dystrophy. Assuming approval, this product is expected to further strengthen our neuromuscular product portfolio. Results achieved from these significant accomplishments have established a robust foundation to advance our strategic initiatives and reinforce the durability of our near and long-term growth potential. We look forward to achieving numerous important milestones in the second half of this year to further build an even more vital business.”

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

For the Three Months Ended June 30,	2023	2022	% Change
Total Net Product Revenues	$ 99.5	$ 53.0	87.5%
FIRDAPSE Net Product Revenues	$ 64.9	$ 53.0	22.3%
FYCOMPA Net Product Revenues	$ 34.6	N/A	N/A
GAAP Net Income	$ 37.8	$ 21.6	74.7%
Non-GAAP Net Income **	$ 60.4	$ 30.3	99.2%
GAAP Net Income Per Share - Basic	$ 0.36	$ 0.21	69.0%
Non-GAAP Net Income Per Share – Basic**	$ 0.57	$ 0.29	92.8%
GAAP Net Income Per Share – Diluted	$ 0.33	$ 0.20	67.9%
Non-GAAP Net Income Per Share – Diluted**	$ 0.53	$ 0.28	91.5%
Cash and Cash Equivalents	$ 178.8 (a)	$ 220.8	

(a) Post June 30, 2023, cash was used for the following: (i) $75 million for the North American License for vamorolone; (ii) approximately $15 million for the equity investment in Santhera; and (iii) $10 million to pay the second installment of the purchase price for the Ruzurgi acquisition.

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

Recent Business Highlights

- Achieved all-time high total revenues of $99.6 million for Q2 2023, an 87.5% YoY increase, and a 16.7% increase compared to Q1 2023, bolstered by continued organic growth of FIRDAPSE and the addition of FYCOMPA net product revenues.
- Achieved an all-time record high of FIRDAPSE net product revenue of $64.9 million for the second quarter of 2023, representing an exceptional 22.3% YoY increase.
- Reported strong FYCOMPA net product revenues of $34.6 million and completed the seamless integration of the FYCOMPA commercial and medical affairs teams during the second quarter of 2023.
- Raised 2023 full-year total revenue guidance to between $380 million and $390 million.
- Appointed Ms. Tamar Thompson to our Board of Directors.
- Acquired the North American license for vamorolone, a treatment candidate for Duchenne muscular dystrophy, from Santhera Pharmaceuticals, with a PDUFA date of October 26, 2023. Developing the commercial plan for an anticipated launch (assuming approval of the product by the PDUFA date) in Q1-24.
- Submitted sNDA seeking to increase the maximum daily dosage of FIRDAPSE (amifampridine) to 100mg for the treatment of Lambert-Eaton myasthenic syndrome.
- Anticipate that DyDo Pharma, our partner in Japan, will submit their NDA for FIRDAPSE (amifampridine) to the Pharmaceuticals and Medical Devices Agency, (“PMDA”) by the end of 2023. Under our license with SERB (previously BioMarin), when this submission to PMDA is completed, it will provide us with further geographical rights for FIRDAPSE and we will begin exploring partnerships, especially in specifically targeted markets like China and South Korea.
- Continue to pursue the acquisition of innovative rare neurological and epilepsy assets in alignment with our portfolio expansion strategy.
- Launched the Company’s inaugural ESG Report highlighting the Company’s ESG strategy, areas of focus, and meaningful progress in key areas.

Financial Results for Second Quarter 2023

Product Revenues, Net: Product revenues, net in the second quarter of 2023, were $99.5 million, compared to $53.0 million for the second quarter of 2022, representing an increase of 87.5% year-over-year.

Research and Development Expenses: Research and development expenses were $4.0 million in both the second quarter of 2023 and 2022.

Selling, General, and Administrative Expenses: Selling, general, and administrative expenses for the second quarter of 2023 were $28.4 million, compared to $12.9 million in the second quarter of 2022.

Amortization of Intangible Assets: Amortization of intangible assets was $8.5 million in the second quarter of 2023, compared to $0 million in the second quarter of 2022. Intangible assets acquired subsequent to the second 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 second quarter of 2023 was $46.7 million, compared to $28.6 million in the second quarter of 2022, representing an increase of 63.5% year-over-year.

GAAP Net Income: GAAP net income for the second quarter of 2023 was $37.8 million ($0.36 per basic share and $0.33 per diluted share), compared to $21.6 million ($0.21 per basic share and $0.20 per diluted share) for the second quarter of 2022, representing a 74.7% increase YoY.

Non-GAAP Net Income: Non-GAAP net income for the second quarter of 2023 was $60.4 million ($0.57 per basic share and $0.53 per diluted share), compared to $30.3 million ($0.29 per basic share and $0.28 per diluted share) for the second quarter of 2022, representing a 92.8% increase YoY for each basic share and a 91.5% increase YoY for each diluted share.

Cash and Cash Equivalents: Cash and cash equivalents were $178.8 million as of June 30, 2023.

2023 Financial Guidance: The Company forecasts full-year 2023 total revenues, including FYCOMPA, to be between $380 million and $390 million, representing a 77% to 82% 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 June 30, 2023, and its results of operations can be found in the Company’s Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (“SEC”) on August 9, 2023.

Conference Call & Webcast Details

The Company will host a conference call and webcast on Thursday, August 10, 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 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. Further, on July 18, 2023, Catalyst acquired an exclusive license for North America for vamorolone, a promising best-in-class dissociative anti-inflammatory steroid treatment for Duchenne muscular dystrophy. Vamorolone has received FDA Orphan Drug and Fast Track designations and has been granted a PDUFA action date of October 26, 2023.

For more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at: www.catalystpharma.com. For the Full Prescribing and Safety Information for FIRDAPSE®, please visit www.firdapse.com. For the Full Prescribing Information for FYCOMPA®, please visit www.fycompa.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 NDA for vamorolone will be approved by the PDUFA date, or at all, (ii) Catalyst's ability to continue to sell its current products, (iii) whether Catalyst will continue to be profitable and cash flow positive, (iv) whether Catalyst's total revenue forecast for 2023 will prove to be accurate, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year, Catalyst's Quarterly Report on Form 10-Q for the first quarter of 2023, 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 June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Product revenue, net	$ 99,477	$ 53,049	$ 184,781	$ 96,082
License and other revenue	105	64	167	120
Total revenues	99,582	53,113	184,948	96,202
Operating costs and expenses:				
Cost of sales (a)	12,045	7,643	21,991	13,533
Research and development	3,954	3,983	7,516	7,386
Selling, general and administrative (a)	28,396	12,918	58,114	29,348
Amortization of intangible assets	8,488	—	15,019	—
Total operating costs and expenses	52,883	24,544	102,640	50,267
Operating income	46,699	28,569	82,308	45,935
Other income (expense), net	1,813	(324)	3,517	(231)
Net income before income taxes	48,512	28,245	85,825	45,704
Income tax provision	10,750	6,626	18,495	10,844
Net income	$ 37,762	$ 21,619	$ 67,330	$ 34,860
Net income per share:				
Basic	$ 0.36	$ 0.21	$ 0.64	$ 0.34
Diluted	$ 0.33	$ 0.20	$ 0.59	$ 0.32
Weighted average shares outstanding:				
Basic	106,258,790	102,795,600	105,911,936	102,788,719
Diluted	113,673,534	109,264,730	113,840,155	109,149,185

(a) exclusive of amortization of intangible assets

CATALYST PHARMACEUTICALS, INC.

RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
GAAP net income	$ 37,762	$ 21,619	$ 67,330	$ 34,860
Non-GAAP adjustments:				
Stock-based compensation expense	3,298	2,023	6,190	3,926
Depreciation	82	37	151	71
Amortization of intangible assets	8,488	—	15,019	—
Income tax provision	10,750	6,626	18,495	10,844
Non-GAAP net income	$ 60,380	$ 30,305	$ 107,185	$ 49,701
Non-GAAP net income per share:				
Basic	$ 0.57	$ 0.29	$ 1.01	$ 0.48
Diluted	$ 0.53	$ 0.28	$ 0.94	$ 0.46
Weighted average shares outstanding:				
Basic	106,528,790	102,795,600	105,911,936	102,788,719
Diluted	113,673,534	109,264,730	113,840,155	109,149,185

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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 178,787	$ 298,395
Accounts receivable, net	42,796	10,439
Inventory	10,751	6,805
Prepaid expenses and other current assets	8,634	5,167
Total current assets	240,968	320,806
Operating lease right-of-use asset	2,641	2,770
Property and equipment, net	1,203	847
License and acquired intangibles, net	175,595	32,471
Deferred tax assets, net	23,489	18,736
Total assets	$ 443,896	$ 375,630
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,421	$ 3,975
Accrued expenses and other liabilities	48,082	53,613
Total current liabilities	52,503	57,588
Operating lease liability, net of current portion	3,376	3,557
Other non-current liabilities	12,723	14,064
Total liabilities	68,602	75,209
Total stockholders' equity	375,294	300,421
Total liabilities and stockholders' equity	$ 443,896	$ 375,630