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): February 28, 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 February 28, 2024, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2023 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 February 28, 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 W. Kalb
Michael W. Kalb
Executive Vice President and Chief Financial Officer

Dated: February 28, 2024

Catalyst Pharmaceuticals Reports Strong Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

Achieved Record 2023 Total Revenues of $398.2 Million, an 85.9% Increase Compared to 2022

Achieved Record Fourth Quarter 2023 Total Revenues of $110.6 Million, an 82.0% Increase Compared to Fourth Quarter 2022

Reported 2023 GAAP Net Income of $71.4 Million, $0.63 Per Share Diluted

Reported 2023 Non-GAAP Net Income of $223.2 Million, $1.96 Per Share Diluted

Bolstered Neuroscience Commercial Portfolio with the FDA Approval of AGAMREE®

Commercial Launch of AGAMREE on Track for Q1 2024

Full Year 2024 Total Revenues Guidance of Between $455 Million and $475 Million

Conference Call and Webcast to be Held on February 29, 2024, at 8:30 AM ET

CORAL GABLES, Fla., February 28, 2024 - Catalyst Pharmaceuticals, Inc. ("Catalyst" or "Company") (Nasdaq: CPRX) today reported financial results for the fourth quarter and full year 2023 and provided a business update.

"In 2023, Catalyst delivered exceptional financial performance demonstrated by robust revenue growth, exceeding our full-year guidance. Our confidence for continued growth is strengthened by the outstanding execution of our strategic initiatives, expansion of our product portfolio, and a growing commercial presence in the U.S. neuroscience market," stated Richard J. Daly, CEO of Catalyst. "As we enter this year with compelling momentum, our commitment to execution and advancement of our initiatives, with a concentration on orphan CNS and other strategic adjacencies, remains resolute. With an imminent U.S. commercial launch for AGAMREE®, we are well poised to propel further growth. We eagerly anticipate making this innovative therapy available to eligible Duchenne muscular dystrophy patients. Coupled with our accomplishments, substantial cash reserves, and prudent financial management, we aim to further fuel our growth through strategic avenues that will deliver further value while upholding our steadfast commitment to serving our patient communities."

Financial Highlights

For the Year Ended December 31, ***(In thousands, except share data)***	**2023**	**2022**	**% Change**
Net Product Revenue	$396,502	$213,938	85.3%
FIRDAPSE® Net Product Revenue	$258,426	$213,938	20.8%
FYCOMPA® Net Product Revenue	$138,076	N/A	N/A
GAAP Net Income	$ 71,410	$ 83,079	(14.0%)
Non-GAAP Net Income **	$223,155	$113,865	96.0%
GAAP Net Income Per Share - Basic	$ 0.67	$ 0.80	(16.3%)
Non-GAAP Net Income Per Share – Basic**	$ 2.10	$ 1.10	90.9%
GAAP Net Income Per Share – Diluted	$ 0.63	$ 0.75	(16.0%)
Non-GAAP Net Income Per Share – Diluted**	$ 1.96	$ 1.02	92.2%
As of December 31,			
Cash and Cash Equivalents	$137,636	$298,395	(53.9%)

** 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, (iv) acquired in-process research & development costs, and (v) 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 record total revenues of $110.6 million for Q4 2023 and Full Year 2023 total revenues of $398.2 million, representing robust growth of 82.0% compared to Q4 2022 (QoQ) and 85.9% compared to Full Year 2022 (YoY), respectively.
- Achieved record FIRDAPSE net product revenue of $69.8 million for Q4 2023 and $258.4 million for the Full Year 2023, representing growth of 15.0% compared to Q4 2022 and 20.8% compared to Full Year 2022, respectively.
- Achieved record FYCOMPA net product revenue of $39.3 million for Q4 2023 and $138.1 million for the Full Year 2023.
- Provided Full-Year 2024 total revenue guidance of between $455 million and $475 million, reflecting net product revenue of approximately $295 million to $310 million for FIRDAPSE, AGAMREE net product revenue of approximately $25 million to $30 million and FYCOMPA net product revenue of approximately $130 million to $135 million.
- Announced appointments of Dr. Steven Miller to Executive Vice President, Chief Operating and Scientific Officer, Jeffrey Del Carmen to Executive Vice President, Chief Commercial Officer, and newly appointed Michael Kalb as Executive Vice President, Chief Financial Officer.
- Bolstered the neuroscience franchise commercial portfolio with the FDA approval of AGAMREE for the treatment of Duchenne muscular dystrophy for patients aged two years and older.
- On track for the U.S. commercial launch of AGAMREE in the first quarter of 2024.
- Announced that collaboration partner, DyDo Pharma, Inc., reported that it submitted a New Drug Application to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) in December 2023, seeking marketing approval for FIRDAPSE (amifampridine), with the review period expected to be approximately nine months from the submission date.
- Strengthened FIRDAPSE intellectual property estate with two new U.S. patents issued covering methods of treating LEMS with FIRDAPSE under fasting and fed conditions of dosing.
- Completed a $150.0 million common stock offering in January 2024 with net proceeds of approximately $140.1 million, to be used to fund the potential acquisition of new product candidates and for general corporate purposes.
- Ranked on Forbes 2024 List of America’s Most Successful Small-Cap Companies.
- Partnered with Sofie’s Journey to bring focus on epilepsy at the 11th Annual Epilepsy Awareness and Education Expo.

Fourth Quarter 2023 and Full Year 2023 Financial Results

Total revenues: Total revenues in the fourth quarter of 2023 were $110.6 million, compared to $60.8 million for the fourth quarter of 2022, representing an increase of approximately 82.0% quarter-over-quarter. For full-year 2023, total revenues were $398.2 million, compared to $214.2 million for the full-year 2022, representing an increase of approximately 85.9% YoY.

Product revenue, net: Product revenue, net in the fourth quarter of 2023, was $109.1 million, compared to $60.7 million for the fourth quarter of 2022, representing an increase of approximately 79.8% YoY. The full-year 2023 product revenue, net was $396.5 million, compared to $213.9 million for 2022, representing an increase of approximately 85.3% YoY.

Research and development expenses: In the fourth quarter of 2023, research and development expenses were $2.0 million, compared to $4.1 million in the fourth quarter of 2022. Research and development expenses for the full-year 2023 were $93.2 million (including a one-time charge of in-process research and development expense related to the acquisition of the license for AGAMREE in the amount of $81.5 million), compared to $19.8 million for the full-year 2022.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the fourth quarter of 2023 were $42.0 million compared to $14.1 million in the fourth quarter of 2022. Selling, general, and administrative expenses for the full year 2023 were $133.7 million, compared to $57.1 million for 2022. Both the QoQ and YoY increases were driven by incremental effort to support FYCOMPA and pre-launch investments in preparation for the acquisition of FYCOMPA in the first quarter of 2023 and the AGAMREE launch in the first quarter of 2024.

Amortization of intangible Assets. Amortization of intangible assets was $9.1 million in the fourth quarter of 2023), compared to $0.6 million in the fourth quarter of 2022. Amortization of intangible assets was $32.6 million in full-year 2023, compared to $1.1 million in full year 2022. Amortization of intangible assets acquired in 2023 relate to the FYCOMPA rights acquired during the first quarter of 2023 and the milestone payment made to Santhera upon the approval of AGAMREE during the fourth quarter of 2023.

Operating income: Operating income for the fourth quarter of 2023 was $41.7 million, compared to $30.8 million in the fourth quarter of 2022, representing an increase of approximately 35.4%. The full-year 2023 operating income was $86.8 million, compared to $101.8 million for the full year 2022, representing a decrease of approximately 14.8%, which is inclusive of the one-time AGAMREE related in-process R&D expense of $81.5 million in connection with the acquisition of the license.

GAAP net income: GAAP net income for the fourth quarter of 2023 was $34.8 million ($0.33 per basic and $0.31 per diluted share), compared to GAAP Net Income of $25.5 million ($0.24 per basic and $0.22 per diluted share) for the fourth quarter of 2022. GAAP net income for full year 2023 was $71.4 million ($0.67 per basic and $0.63 per diluted share), compared to the full year 2022 GAAP net income of $83.1 million ($0.80 per basic and $0.75 per diluted share).

Non-GAAP net income: Non-GAAP net income for the fourth quarter of 2023 was $60.1 million ($ 0.56 per basic and $0.53 per diluted share), compared to non-GAAP net income of $35.5 million ($0.34 per basic and $0.31 per diluted share) for the fourth quarter of 2022. Non-GAAP net income for full year 2023 was $223.2 million ($2.10 per basic and $1.96 per diluted share), compared to full year 2022 non-GAAP net income of $113.9 million ($1.10 per basic and $1.02 per diluted share).

Cash and cash equivalents: Cash and cash equivalents were $137.6 million as of December 31, 2023.

More detailed financial information and analysis of our financial condition and results of operations can be found in our Annual Report on Form 10-K for fiscal year 2023, which was filed with the U.S. Securities and Exchange Commission on February 28, 2024.

2024 Outlook

Product revenue, net: Bolstered by continued growth of FIRDAPSE and additional net product revenue from AGAMREE, which we expect to launch during the first quarter of 2024, we anticipate achieving total revenues in 2024 within the range of $455 million and $475 million, reflecting net product revenue of approximately $295 million to $310 million for FIRDAPSE, AGAMREE net product revenue of approximately $25 million to $30 million, and FYCOMPA net product revenue of approximately $130 million to $135 million.

Product revenue for FYCOMPA in 2024 will be affected by differences in variable consideration (gross-to-net) compared to 2023, when revenues were booked under Eisai's cost arrangements with distributors and government authorities. Starting on January 1, 2024, all such costs are tied to arrangements between the Company and those distributors and government agencies, which costs are likely to be higher than Eisai's costs, thereby increasing the gross-to-net deductions for FYCOMPA and correspondingly decreasing FYCOMPA net product revenue.

Research and development expenses: Due to the expected launch of the AGAMREE long-term safety and quality of life study, we anticipate research and development expenses in 2024 to approximate the amount that was incurred in 2022.

Selling, general, and administrative expenses: We anticipate a significant increase in selling, general and administrative expenses in 2024 due to the launch of AGAMREE and the accompanying support of three commercial products, compared to two in 2023.

Tax rate: We anticipate our effective tax rate to increase slightly for 2024.

Conference Call & Webcast Details

The Company will host a conference call and webcast on February 29, 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. Finally, 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.

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 https://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 AGAMREE can be successfully launched and whether that launch will occur in the first quarter of 2024, (ii) whether AGAMREE's commercialization will be successful and accretive to Catalyst, (iii) Catalyst's ability to continue to sell its current products, (iv) whether Catalyst will continue to be profitable and cash flow positive, (v) whether Catalyst's total revenues and net product revenue forecasts for 2024 will prove to be accurate, (vi) whether Catalyst will complete more acquisitions of products, and the timing of such acquisition; and (vii) those factors described in Catalyst's Annual Report on Form 10-K for the 2023 fiscal year, 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

(in thousands, except share data)

	(Unaudited) For the Three Months Ended December 31,		For the Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Product revenue, net	$ 109,104	$ 60,683	$ 396,502	$ 213,938
License and other revenue	1,464	74	1,702	265
Total revenues	110,568	60,757	398,204	214,203
Operating costs and expenses:				
Cost of sales (a)	15,809	11,195	51,967	34,393
Research and development	1,972	4,093	93,150	19,789
Selling, general and administrative (a)	42,036	14,088	133,710	57,085
Amortization of intangible assets	9,059	580	32,565	1,098
Total operating costs and expenses	68,876	29,956	311,392	112,365
Operating income	41,692	30,801	86,812	101,838
Other income, net	5,015	2,207	7,699	2,881
Net income before income taxes	46,707	33,008	94,511	104,719
Income tax provision	11,863	7,537	23,101	21,640
Net income	$ 34,844	$ 25,471	$ 71,410	$ 83,079
Net income per share:				
Basic	$ 0.33	$ 0.24	$ 0.67	$ 0.80
Diluted	$ 0.31	$ 0.22	$ 0.63	$ 0.75
Weighted average shares outstanding:				
Basic	106,714,944	104,583,296	106,279,736	103,374,606
Diluted	113,755,677	113,531,124	113,753,154	111,375,631

(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 December 31,		For the Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
GAAP net income:	$ 34,844	$ 25,471	$ 71,410	$ 83,079
Non-GAAP adjustments:				
Stock-based compensation expense	4,250	1,926	14,250	7,907
Depreciation	84	35	316	141
Amortization of intangible assets	9,059	580	32,565	1,098
Income tax provision	11,863	7,537	23,101	21,640
In-process R&D	—	—	81,513	—
Non-GAAP net income	$ 60,100	$ 35,549	$ 223,155	$ 113,865
Non-GAAP net income per share:				
Basic	$ 0.56	$ 0.34	$ 2.10	$ 1.10
Diluted	$ 0.53	$ 0.31	$ 1.96	$ 1.02
Weighted average shares outstanding:				
Basic	106,714,944	104,583,296	106,279,736	103,374,606
Diluted	113,755,677	113,531,124	113,753,154	111,375,631

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

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 137,636	$ 298,395
Accounts receivable, net	53,514	10,439
Inventory	15,644	6,805
Prepaid expenses and other current assets	12,535	5,167
Total current assets	219,329	320,806
Operating lease right-of-use asset	2,508	2,770
Property and equipment, net	1,195	847
License and acquired intangibles, net	194,049	32,471
Deferred tax assets, net	36,544	18,736
Investment in equity securities	16,489	—
Total assets	$ 470,114	$ 375,630
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 14,795	$ 3,975
Accrued expenses and other liabilities	61,268	53,613
Total current liabilities	76,063	57,588
Operating lease liability, net of current portion	3,188	3,557
Other non-current liabilities	2,982	14,064
Total liabilities	82,233	75,209
Total stockholders' equity	387,881	300,421
Total liabilities and stockholders' equity	$ 470,114	$ 375,630