

**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): November 6, 2024**

**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<br>on Which Registered | Ticker<br>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.

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**Item 8.01 Other Events**

On November 6, 2024, the Company issued a press release announcing its results of operations for the three and nine months ended September 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 November 6, 2024.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)



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

*Reports Q3 2024 Total Revenues of \$128.7 Million, Representing a 25.3% YoY Increase*

*Record Revenues Driven by Continued Organic Growth in its Rare Disease Franchise*

*Robust Financial Performance Highlights Operational Excellence and Strong Commercial Execution*

*FIRDAPSE® Q3 2024 Net Product Revenues of \$79.3 Million, Representing a 19.7% YoY Increase*

*AGAMREE® Q3 2024 Net Product Revenues of \$15.0 Million, Demonstrating Early U.S. Launch Success*

*FYCOMPA® Q3 2024 Net Product Revenues of \$32.1 Million*

*Q3 2024 GAAP Net Income of \$43.9 Million, \$0.35 Per Share Diluted*

*Q3 2024 Non-GAAP Net Income of \$71.1 Million, \$0.57 Per Share Diluted*

*Updating 2024 Full Year Total Revenue Guidance to Between \$475 Million and \$485 Million*

*Conference Call and Webcast to be Held on November 7, 2024, at 8:30 AM ET*

**CORAL GABLES, Fla., November 6, 2024** - Catalyst Pharmaceuticals, Inc. (“Catalyst” or “Company”) (Nasdaq: CPRX) today reported financial results for the third quarter of 2024 and provided a corporate update.

“Our strong financial performance reflects our unwavering commitment to operational and commercial excellence, driving sustained momentum and long-term growth. The early success of our newest product, AGAMREE®, along with the continued robust organic growth of our flagship product, FIRDAPSE®, highlights the strength of our U.S. commercial strategy, with revenues exceeding expectations and significantly contributing to our overall success,” stated Richard J. Daly, President and CEO of Catalyst. “Through our strategic partnerships, we are advancing initiatives to expand the geographic footprint of our rare disease portfolio in key territories outside the U.S. As we pursue opportunities aligned with our long-term growth objectives and forge new partnerships to broaden our global presence, our achievements to date underscore the strength of our strategic vision to address critical unmet medical needs, driven by the outstanding execution of our teams. With a resolute focus on sustained growth and value creation, we are optimistic about the path ahead and remain confident in meeting our full-year 2024 revenue guidance, laying a strong foundation for continued success.”

## Financial Highlights

For the Three Months Ended September 30,

(In thousands, except per share data)

|  | 2024      | 2023        | % Change |
|--|-----------|-------------|----------|
| Product Revenue, Net                             | \$126,424 | \$ 102,617  | 23.2%    |
| FIRDAPSE Product Revenue, Net                    | \$ 79,303 | \$ 66,224   | 19.7%    |
| FYCOMPA Product Revenue, Net                     | \$ 32,075 | \$ 36,393   | (11.9%)  |
| AGAMREE Product Revenue, Net                     | \$ 15,046 | N/A         | N/A      |
| GAAP Net Income (Loss)                           | \$ 43,884 | (\$ 30,764) | 242.6%   |
| Non-GAAP Net Income (Loss)**                     | \$ 71,080 | (\$ 25,643) | 377.2%   |
| GAAP Net Income (Loss) Per Share – Basic         | \$ 0.37   | (\$ 0.29)   | 227.6%   |
| Non-GAAP Net Income (Loss) Per Share – Basic**   | \$ 0.60   | (\$ 0.24)   | 350.0%   |
| GAAP Net Income (Loss) Per Share – Diluted       | \$ 0.35   | (\$ 0.29)   | 220.7%   |
| Non-GAAP Net Income (Loss) Per Share – Diluted** | \$ 0.57   | (\$ 0.24)   | 337.5%   |

As of September 30, 2024, and December 31, 2023

(In thousands)

|                           |           |            |        |
|---------------------------|-----------|------------|--------|
| Cash and Cash Equivalents | \$442,331 | \$ 137,636 | 221.4% |
|---------------------------|-----------|------------|--------|

\*\* 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.

Beginning with the third quarter of 2024, Catalyst will no longer include acquisition in-process research and development ("IPR&D") in its non-GAAP financial measures. Previously reported non-GAAP net income for the third quarter of 2023 included \$81.5 million in acquisition IPR&D relating to Catalyst's acquisition, during that period, of the North American license for AGAMREE, which had not yet been approved by the U.S. Food and Drug Administration ("FDA") at the time of the acquisition. The commercialization was subsequently approved by the FDA during the fourth quarter of 2023. Prior period amounts have been revised to conform to the current period presentation. Catalyst is making this change to its presentation following discussions with the Staff of the Division of Corporation Finance of the U.S. Securities and Exchange Commission.

## Recent Business Highlights

- Achieved total revenues of \$128.7 million, including net product revenues of \$126.4 million for the third quarter (“Q3”) of 2024, reflecting a 23.2% increase over net product revenues for Q3 of 2023.
- Reported record quarterly FIRDAPSE net product revenues of \$79.3 million for Q3 2024, reflecting a 19.7% increase over Q3 2023, driven by sustained organic growth.
- Achieved robust AGAMREE net product revenues of \$15.0 million for Q3 2024, demonstrating continued momentum in its second full quarter of U.S. commercial availability.
- Reported FYCOMPA® net product revenues of \$32.1 million for Q3 2024, an 11.9% decrease compared to Q3 2023 revenues of \$36.4 million.
- Announced that DyDo Pharma, Inc. (Catalyst’s sub-licensee in Japan), received regulatory approval in Japan to commercialize FIRDAPSE 10 mg tablets for the treatment of Lambert-Eaton myasthenic syndrome in Japan, marking a key milestone in expanding the product’s commercial footprint. DyDo has advised Catalyst that it expects to launch in Japan by the end of Q4 2024.
- Announced an exclusive agreement with KYE Pharmaceuticals, Inc. for the Canadian commercial rights to AGAMREE for Duchenne muscular dystrophy and other potential indications, further expanding Catalyst’s North American footprint. This marks the licensing of Catalyst’s second rare disease product in Canada, and KYE has advised us that it expects to file a Health Canada application for AGAMREE by early 2025.
- Expect total revenues for the full year 2024 to be between \$475 million and \$485 million, which includes the \$2.1 million milestone payment received from DyDo that is included in License and other revenue.
- Revising full-year 2024 net product revenue guidance for FIRDAPSE to be between \$300 million and \$310 million; reaffirming FYCOMPA net product revenue guidance to be between \$130 million and \$135 million; and increasing AGAMREE net product revenue guidance to be between \$40 million and \$45 million, respectively.
- Revising full year research and development (“R&D”) expense guidance to less than \$15 million due to delays in the timing of certain R&D related initiatives.

## Third Quarter 2024 Financial Results

**Total revenues:** Total revenues during the third quarter of 2024 were \$128.7 million, compared to \$102.7 million for the third quarter of 2023, representing an increase of approximately 25.3%.

**Product revenue, net:** Product revenue, net for the third quarter of 2024 was \$126.4 million, compared to \$102.6 million for the third quarter of 2023, representing an increase of approximately 23.2%.

**License and other revenue:** License and other revenue includes \$2.1 million from the arrangement with DyDo for both the three and nine months ended September 30, 2024, which consisted of a milestone payment earned upon DyDo receiving regulatory approval to commercialize FIRDAPSE for the treatment of patients with LEMS in Japan.

**Research and development expenses:** Research and development expenses for the third quarter of 2024 were \$3.3 million, compared to \$83.7 million for the third quarter of 2023, representing a decrease of approximately 96.1%. Research and development expenses for the third quarter of 2023 included acquisition IPR&D of \$81.5 million.

**Selling, general and administrative expenses:** Selling, general and administrative expenses for the third quarter of 2024 were \$45.9 million, compared to \$33.6 million for the third quarter of 2023, representing an increase of approximately 36.7%.

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

**Operating income (loss):** Operating income (loss) for the third quarter of 2024 was \$50.9 million, compared to (\$37.2) million for the third quarter of 2023, representing an increase of approximately 236.9%.

**GAAP net income (loss):** GAAP net income (loss) for the third quarter of 2024 was \$43.9 million (\$0.37 per basic and \$0.35 per diluted share), compared to GAAP net income (loss) of (\$30.8) million ((\$0.29) per basic and diluted share) for the third quarter of 2023.

**Non-GAAP net income (loss):** Non-GAAP net income (loss) for the third quarter of 2024 was \$71.1 million (\$0.60 per basic and \$0.57 per diluted share), compared to non-GAAP net income (loss) of (\$25.6) million ((\$0.24) per basic and diluted share) for the third quarter of 2023.

**Cash and cash equivalents:** Cash and cash equivalents were \$442.3 million as of September 30, 2024.

Catalyst's Form 10-Q for the third quarter of 2024, filed with the U.S. Securities and Exchange Commission on November 6, 2024, provides more detailed financial information and analysis of Catalyst's financial condition and results of operations.

#### **Conference Call & Webcast Details**

The Company will host a conference call and webcast on Thursday, November 7, 2024, at 8:30 AM ET to discuss the financial results and provide a business update.

**US/Canada Dial-in Number:** 800-715-9871  
**International Dial-in Number:** 646-307-1963

A webcast will be accessible under the investor section on the Company's website at [www.catalystpharma.com](http://www.catalystpharma.com). A webcast replay will be available on the Catalyst website for 30 days after the event.

### **About Catalyst Pharmaceuticals**

Catalyst Pharmaceuticals, Inc. (Nasdaq: CPRX) is a biopharmaceutical company committed to improving the lives of patients with rare diseases. With a proven track record of bringing life-changing treatments to the market, Catalyst's focus is on in-licensing, commercializing, and developing innovative therapies. Guided by its deep commitment to patient care, Catalyst prioritizes accessibility, ensuring patients receive the care they need through a comprehensive suite of support services designed to provide seamless access and ongoing assistance. Catalyst maintains a well-established U.S. presence while actively seeking to expand its global commercial footprint through strategic partnerships. Catalyst is headquartered in Coral Gables, FL., and was recognized on the Forbes 2024 list as one of America's most successful small-cap companies. For more information, please visit Catalyst's website at [www.catalystpharma.com](http://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) whether the launch of AGAMREE® will continue to surpass initial expectations and exceed 2024 full-year revenue forecasts for sales of the product that have been 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 that is 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, (viii) whether DyDo can successfully commercialize FIRDAPSE in Japan, and (ix) 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 third 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 and 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<br>Ended September 30, |                    | For the Nine Months<br>Ended September 30, |                    |
|---|---|--------------------|--|--------------------|
|   | 2024  | 2023               | 2024                                       | 2023               |
| Product revenue, net                    | \$ 126,424                                  | \$ 102,617         | \$ 347,518                                 | \$ 287,398         |
| License and other revenue               | 2,271                                       | 71                 | 2,396                                      | 238                |
| Total revenues                          | <u>128,695</u>                              | <u>102,688</u>     | <u>349,914</u>                             | <u>287,636</u>     |
| Operating costs and expenses:           |   |                    |  |                    |
| Cost of sales (a)                       | 19,277                                      | 14,167             | 47,202                                     | 36,158             |
| Research and development                | 3,284                                       | 83,662             | 8,850                                      | 91,178             |
| Selling, general and administrative (a) | 45,880                                      | 33,560             | 133,548                                    | 91,674             |
| Amortization of intangible assets       | 9,345                                       | 8,487              | 28,033                                     | 23,506             |
| Total operating costs and expenses      | <u>77,786</u>                               | <u>139,876</u>     | <u>217,633</u>                             | <u>242,516</u>     |
| Operating income (loss)                 | 50,909                                      | (37,188)           | 132,281                                    | 45,120             |
| Other income (expense), net             | 6,296                                       | (833)              | 9,801                                      | 2,684              |
| Net income (loss) before income taxes   | 57,205                                      | (38,021)           | 142,082                                    | 47,804             |
| Income tax provision (benefit)          | 13,321                                      | (7,257)            | 34,129                                     | 11,238             |
| Net income (loss)                       | <u>\$ 43,884</u>                            | <u>\$ (30,764)</u> | <u>\$ 107,953</u>                          | <u>\$ 36,566</u>   |
| Net income (loss) per share:            |   |                    |  |                    |
| Basic                                   | <u>\$ 0.37</u>                              | <u>\$ (0.29)</u>   | <u>\$ 0.92</u>                             | <u>\$ 0.34</u>     |
| Diluted                                 | <u>\$ 0.35</u>                              | <u>\$ (0.29)</u>   | <u>\$ 0.87</u>                             | <u>\$ 0.32</u>     |
| Weighted average shares outstanding:    |   |                    |  |                    |
| Basic                                   | <u>118,931,153</u>                          | <u>106,568,137</u> | <u>117,976,056</u>                         | <u>106,133,077</u> |
| Diluted                                 | <u>125,407,279</u>                          | <u>106,568,137</u> | <u>124,519,838</u>                         | <u>113,751,370</u> |

(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<br>Ended September 30, |                    | For the Nine Months<br>Ended September 30, |                    |
|--|---|--------------------|--|--------------------|
|  | 2024  | 2023               | 2024                                       | 2023               |
| <b>GAAP net income (loss)</b>                | \$ 43,884                                   | \$ (30,764)        | \$ 107,953                                 | \$ 36,566          |
| Non-GAAP adjustments:                        |   |                    |  |                    |
| Stock-based compensation expense             | 4,424                                       | 3,810              | 17,080                                     | 10,000             |
| Depreciation                                 | 106   | 81                 | 283  | 232                |
| Amortization of intangible assets            | 9,345                                       | 8,487              | 28,033                                     | 23,506             |
| Income tax provision (benefit)               | 13,321                                      | (7,257)            | 34,129                                     | 11,238             |
| Non-GAAP net income (loss)                   | <u>\$ 71,080</u>                            | <u>\$ (25,643)</u> | <u>\$ 187,478</u>                          | <u>\$ 81,542</u>   |
| <b>Non-GAAP net income (loss) per share:</b> |   |                    |  |                    |
| Basic  | <u>\$ 0.60</u>                              | <u>\$ (0.24)</u>   | <u>\$ 1.59</u>                             | <u>\$ 0.77</u>     |
| Diluted                                      | <u>\$ 0.57</u>                              | <u>\$ (0.24)</u>   | <u>\$ 1.51</u>                             | <u>\$ 0.72</u>     |
| <b>Weighted average shares outstanding:</b>  |   |                    |  |                    |
| Basic  | <u>118,931,153</u>                          | <u>106,568,137</u> | <u>117,976,056</u>                         | <u>106,133,077</u> |
| Diluted                                      | <u>125,407,279</u>                          | <u>106,568,137</u> | <u>124,519,838</u>                         | <u>113,751,370</u> |

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

|   | September 30,<br>2024<br>(unaudited) | December 31,<br>2023 |
|---|--------------------------------------|----------------------|
| <b>Assets</b>                                     |                                      |                      |
| Current Assets:                                   |                                      |                      |
| Cash and cash equivalents                         | \$ 442,331                           | \$ 137,636           |
| Accounts receivable, net                          | 58,266                               | 53,514               |
| Inventory   | 20,017                               | 15,644               |
| Prepaid expenses and other current assets         | 18,384                               | 12,535               |
| Total current assets                              | 538,998                              | 219,329              |
| Operating lease right-of-use asset, net           | 2,301                                | 2,508                |
| Property and equipment, net                       | 1,380                                | 1,195                |
| License and acquired intangibles, net             | 166,016                              | 194,049              |
| Deferred tax assets, net                          | 48,473                               | 36,544               |
| Investment in equity securities                   | 14,842                               | 16,489               |
| Total assets                                      | <u>\$ 772,010</u>                    | <u>\$ 470,114</u>    |
| <b>Liabilities and Stockholders' Equity</b>       |                                      |                      |
| Current Liabilities:                              |                                      |                      |
| Accounts payable                                  | \$ 11,563                            | \$ 14,795            |
| Accrued expenses and other liabilities            | 93,832                               | 61,268               |
| Total current liabilities                         | 105,395                              | 76,063               |
| Operating lease liability, net of current portion | 2,889                                | 3,188                |
| Other non-current liabilities                     | 2,785                                | 2,982                |
| Total liabilities                                 | 111,069                              | 82,233               |
| Total stockholders' equity                        | 660,941                              | 387,881              |
| Total liabilities and stockholders' equity        | <u>\$ 772,010</u>                    | <u>\$ 470,114</u>    |

Source: Catalyst Pharmaceuticals, Inc.

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