# 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 8, 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 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 November 8, 2023, the Company issued a press release reporting its results of operations for the three and nine months ended September 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 November 8, 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: November 8, 2023

**Exhibit 99.1**

**Catalyst Pharmaceuticals Reports Strong Third Quarter 2023 Financial Results and Corporate Update**

*Third Quarter 2023 Total Net Revenues of $102.7 Million, a 79.4% Increase YOY*

*Third Quarter 2023 GAAP Net Loss per Share of $(0.29) Diluted, Impacted by an $81.5 Million One Time Non-Recurring IPR&D Expense Related to the Acquisition of AGAMREE® License*

*Third Quarter 2023 Non-GAAP Net Income of $55.9 Million, $0.49 per Share Diluted*

*Reported U.S. FDA Approval of AGAMREE® (vamorolone) for Duchenne Muscular Dystrophy*

*sNDA Seeking to Increase FIRDAPSE® Maximum Daily Dose to 100 mg Accepted for Filing by the FDA*

*Two New FIRDAPSE Patents Have Recently been Allowed; Upon Issuance will be Posted to the FDA's Orange Book, Further Strengthening our Intellectual Property Portfolio*

*Raising Full Year 2023 Total Revenue Guidance to Between $390 Million and $395 Million*

*Conference Call and Webcast to be Held on November 9, 2023, at 8:30 AM ET*

**CORAL GABLES, Fla., November 8, 2023 -** Catalyst Pharmaceuticals, Inc. ("Catalyst" or "the Company") (Nasdaq: CPRX) today reported financial results for the third quarter of 2023 and provided a corporate update.

"Our strong results in the third quarter reflect our exceptional strategic execution and substantial investment in assisting the physician community to better identify and treat LEMS patients with and without small-cell lung cancer. Our quarterly results were exceptional, having attained several significant milestones that have transformed the long-term growth trajectory of our Company," stated Patrick J. McEnany, Catalyst's Chairman and CEO. "We are working diligently in preparation for the commercial launch of AGAMREE® during the first quarter of 2024. We are pleased to be able to provide AGAMREE to the DMD community, many who have been anxiously awaiting the availability of a steroid with a favorable safety profile. Our highly skilled and experienced neuromuscular commercial and medical affairs teams will be ready to hit the ground running for the commercial launch of AGAMREE. As we look ahead to the coming year, we are confident in our ability to execute our strategic plans, laying the foundation for continued growth and sustained progress."

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

| For the Three Months Ended September 30, | 2023 | 2022 | % Change |
|---|---|---|---|
| Total Net Product Revenues | $102,617 | $ 57,173 | 79.5% |
| FIRDAPSE Net Product Revenues | $ 66,224 | $ 57,173 | 15.8% |
| FYCOMPA Net Product Revenues | $ 36,393 | N/A | N/A |
| GAAP Net Income (Loss) | $ (30,764) | $ 22,748 | (235.2)% |
| Non-GAAP Net Income ** | $ 55,870 | $ 28,615 | 95.2 % |
| GAAP Net Income (Loss) Per Share - Basic | $ (0.29) | $ 0.22 | (231.1)% |
| Non-GAAP Net Income Per Share – Basic** | $ 0.52 | $ 0.28 | 85.7 % |
| GAAP Net Income (Loss) Per Share – Diluted | $ (0.29) | $ 0.20 | (242.1)% |
| Non-GAAP Net Income Per Share – Diluted** | $ 0.49 | $ 0.26 | 88.5 % |
| As of September 30, 2023, and December 31, 2022 Cash and Cash Equivalents | $120,971 | $298,395 | (59.4%) |

** 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.

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) the provision (benefit) for income taxes and (v) acquired in-process research & development costs. 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 record total net revenues of $102.7 million, reflecting a YoY increase of 79.4%
- Reached new all-time high FIRDAPSE® net product revenue of $66.2 million, reflecting an exceptional 15.8% year-over-year growth increase and 23.1% growth increase YTD.
- Achieved FYCOMPA® net product revenue of $36.4 million, establishing a 5.2% full-quarter increase compared to Q2 2023.
- Raised 2023 full-year total revenue guidance to between $390 million and $395 million.
- Announced FDA approval of AGAMREE® (vamorolone), a novel corticosteroid for the treatment of Duchenne muscular dystrophy.
- Anticipate AGAMREE commercial launch by our neuromuscular franchise teams in the first quarter of 2024.
- sNDA seeking to increase FIRDAPSE (amifampridine) maximum daily dose to 100mg for the treatment of Lambert-Eaton myasthenic syndrome was accepted for filing with a PDUFA action date of June 4, 2024.
- Two new patents for FIRDAPSE have recently been allowed and upon issuance will be added to the FDA's Orange Book further strengthening our intellectual property portfolio for FIRDAPSE.
- Expect submission of NDA for FIRDAPSE (amifampridine) by DyDo Pharma to PMDA in Japan by the end of 2023. Plans are being developed to expand the global footprint for FIRDAPSE into other Asian and South American markets through strategic partnerships upon acceptance of the NDA in Japan.
- Active due diligence is underway on several epilepsy and other neuroscience related opportunities, which hold further strategic potential for 2024 if a transaction is successfully completed.
- Appointed Richard J. Daly as the Company's new CEO, effective on January 1, 2024.
- Announced that Patrick J. McEnany, who will retire as the Company's CEO at the end of the year, was honored with the 2023 Lifetime Achievement Award by BioFlorida.

**Financial Results for the Third Quarter 2023**

**Product Revenues, Net**: Product revenues, net in the third quarter of 2023, were $102.6 million, compared to $57.2 million for the third quarter of 2022, representing an increase of 79.5% year-over-year.

**Research and Development Expenses:** Research and development expenses were $83.7 million in the third quarter of 2023 compared to $8.3 million for the third quarter of 2022. The increase in R&D for the third quarter 2023 is driven by a one-time charge of $81.5 million for in-process research and development (IPR&D) in connection with the asset acquisition of AGAMREE (vamorolone) during July 2023.

**Selling, General, and Administrative Expenses:** Selling, general, and administrative expenses for the third quarter of 2023 were $33.6 million, compared to $13.6 million in the third quarter of 2022.

**Amortization of Intangible Assets:** Amortization of intangible assets was $8.5 million in the third quarter of 2023, compared to $518 thousand in the third quarter of 2022. Intangible assets acquired after the third quarter of 2022 relate to the FYCOMPA rights acquired in the first quarter of 2023.

**GAAP Net Income (Loss):** GAAP net loss for the third quarter of 2023 was ($30.8) million (($0.29) per basic and diluted share), compared to net income of $22.7 million ($0.22 per basic share and $0.20 per diluted share) for the third quarter of 2022, representing a 235.2% decrease YoY.

**Non-GAAP Net Income**: Non-GAAP net income for the third quarter of 2023 was $55.9 million ($0.52 per basic share and $0.49 per diluted share), compared to $28.6 million ($0.28 per basic share and $0.26 per diluted share) for the third quarter of 2022, representing an 87.5% increase YoY for each basic share and an 88.5% increase YoY for each diluted share.

**Cash and Cash Equivalents**: Cash and cash equivalents were $121.0 million as of September 30, 2023.

**2023 Financial Guidance**: The Company forecasts full-year 2023 total revenues, including FYCOMPA, to be between $390 million and $395 million, representing an 82% to 84% 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 September 30, 2023, and its results of operations for the three and nine-month periods ended on that date, can be found in the Company's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") on November 8, 2023.

**Conference Call & Webcast Details**

The Company will host a conference call and webcast on Thursday, November 9, 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. 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 revenue forecast for 2023 will prove to be accurate, (vi) whether Catalyst will complete an acquisition of an epilepsy or other neuroscience related opportunity, and the timing of such acquisition; and (vii) 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 second 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 September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Product revenue, net | $ 102,617 | $ 57,173 | $ 287,398 | $ 153,255 |
| License and other revenue | 71 | 71 | 238 | 191 |
| Total revenues | 102,688 | 57,244 | 287,636 | 153,446 |
| Operating costs and expenses: | | | | |
| Cost of sales (a) | 14,167 | 9,665 | 36,158 | 23,198 |
| Research and development | 83,662 | 8,310 | 91,178 | 15,696 |
| Selling, general and administrative (a) | 33,560 | 13,649 | 91,674 | 42,997 |
| Amortization of intangible assets | 8,487 | 518 | 23,506 | 518 |
| Total operating costs and expenses | 139,876 | 32,142 | 242,516 | 82,409 |
| Operating income (loss) | (37,188) | 25,102 | 45,120 | 71,037 |
| Other income (expense), net | (833) | 905 | 2,684 | 674 |
| Net income (loss) before income taxes | (38,021) | 26,007 | 47,804 | 71,711 |
| Income tax provision (benefit) | (7,257) | 3,259 | 11,238 | 14,103 |
| Net income (loss) | $ (30,764) | $ 22,748 | $ 36,566 | $ 57,608 |
| Net income (loss) per share: | | | | |
| Basic | $ (0.29) | $ 0.22 | $ 0.34 | $ 0.56 |
| Diluted | $ (0.29) | $ 0.20 | $ 0.32 | $ 0.52 |
| Weighted average shares outstanding: | | | | |
| Basic | 106,568,137 | 103,318,572 | 106,133,077 | 102,967,280 |
| Diluted | 106,568,137 | 111,986,025 | 113,751,370 | 110,352,214 |

(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 September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| **GAAP net income (loss):** | $ (30,764) | $ 22,748 | $ 36,566 | $ 57,608 |
| Non-GAAP adjustments: | | | | |
| Stock-based compensation expense | 3,810 | 2,055 | 10,000 | 5,981 |
| Depreciation | 81 | 35 | 232 | 106 |
| Amortization of intangible assets | 8,487 | 518 | 23,506 | 518 |
| Income tax provision (benefit) | (7,257) | 3,259 | 11,238 | 14,103 |
| In-process R&D | 81,513 | — | 81,513 | — |
| Non-GAAP net income (loss) | $ 55,870 | $ 28,615 | $ 163,055 | $ 78,316 |
| **Non-GAAP net income per share:** | | | | |
| Basic | $ 0.52 | $ 0.28 | $ 1.54 | $ 0.76 |
| Diluted | $ 0.49 | $ 0.26 | $ 1.43 | $ 0.71 |
| **Weighted average shares outstanding:** | | | | |
| Basic | 106,568,137 | 103,318,572 | 106,133,077 | 102,967,280 |
| Diluted | 113,551,919 | 111,986,025 | 113,751,370 | 110,352,214 |

**CATALYST PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

***(in thousands)***

| | September 30, 2023 (unaudited) | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 120,971 | $ 298,395 |
| Accounts receivable, net | 48,049 | 10,439 |
| Inventory | 9,035 | 6,805 |
| Prepaid expenses and other current assets | 13,962 | 5,167 |
| Total current assets | 192,017 | 320,806 |
| Operating lease right-of-use asset | 2,575 | 2,770 |
| Property and equipment, net | 1,186 | 847 |
| License and acquired intangibles, net | 167,108 | 32,471 |
| Deferred tax assets, net | 37,428 | 18,736 |
| Investment in equity securities | 12,897 | — |
| Total assets | $ 413,211 | $ 375,630 |
| **Liabilities and Stockholders' Equity** | | |
| Current Liabilities: | | |
| Accounts payable | $ 4,598 | $ 3,975 |
| Accrued expenses and other liabilities | 53,208 | 53,613 |
| Total current liabilities | 57,806 | 57,588 |
| Operating lease liability, net of current portion | 3,282 | 3,557 |
| Other non-current liabilities | 3,575 | 14,064 |
| Total liabilities | 64,663 | 75,209 |
| Total stockholders' equity | 348,548 | 300,421 |
| Total liabilities and stockholders' equity | $ 413,211 | $ 375,630 |