

**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): March 15, 2023

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 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 March 15, 2023, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2022 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 March 15, 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: March 15, 2023

**Catalyst Pharmaceuticals Reports Fourth Quarter and Full Year 2022
Financial Results and Provides Business Update**

Achieved Record 2022 Total Net Revenues of \$214 Million, a 52% YoY Increase

Achieved FIRDAPSE® Q4 2022 Net Product Revenues of \$61 Million, a 59% YoY Increase

Newly Acquired FYCOMPA® Product Expected to be Accretive to EBITDA and EPS in 2023

Reaffirming Forecast of 2023 Total Net Product Revenues, including FYCOMPA, of between \$375 Million and \$385 Million

Recently Acquired Patents Further Strengthens FIRDAPSE Long-Term Commercial Potential to 2037

Actively Pursuing Opportunities to Further Diversify our Product Portfolio

Ended 2022 with Cash and Cash Equivalents of \$298 Million

Company to Host a Conference Call and Webcast on Thursday, March 16, 2023, at 8:30 AM ET

CORAL GABLES, Fla., March 15, 2023 — Catalyst Pharmaceuticals, Inc. (“Catalyst”) (Nasdaq: CPRX), a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases, today reported financial results for the fourth quarter and full year 2022 and provided a business update.

“Catalyst delivered an exceptional performance as we ended 2022 with robust revenue growth driven by another consecutive quarter of strong organic growth, further adding to our already substantial balance sheet. Our exceptional financial results and continued momentum underscore the successful execution of our strategic initiatives across all fronts, and we believe that we are poised to deliver another record year of sustained growth in 2023,” stated Patrick J. McEnany, Chairman and CEO of Catalyst. “Over the year, we strategically and financially transformed our business with a focused approach to accelerating growth and portfolio expansion. As we entered 2023, we broadened our portfolio with the acquisition of FYCOMPA®, further strengthening our position within key neuroscience markets. As we look to complete the successful integration of the FYCOMPA franchise by mid-year, we will continue to drive organic growth across our product portfolio while capturing synergies with the FIRDAPSE® franchise to capitalize on the compelling revenue potential of our expanding product portfolio.”

McEnany continued, “We remain confident in our ability to accelerate our business’s growth potential as we continue to evaluate opportunities to further expand our product portfolio with clinically differentiated medicines in rare neurological and epileptic diseases. Coupled with our many achievements and the financial strength of our business, we believe that we are well positioned to drive significant value for all of our stakeholders, anchored by our unwavering commitment to our patient communities. Lastly, we believe that our expanding patent portfolio is solid, and we will vigorously defend and prosecute any and all infringers.”

RECENT BUSINESS HIGHLIGHTS

- Achieved record full-year total net revenue of \$214 million, representing a 52% increase YoY driven by consecutive quarterly FIRDAPSE net product revenue growth.
- Reported continued growth for FIRDAPSE, achieving net product revenue of \$61 million for Q4 2022, representing robust growth of a 59% increase compared to Q4 2021.
- Launched awareness and education thoracic oncology programs to patients and healthcare professionals, expanding our reach to small-cell lung cancer patients with LEMS that may benefit from treatment with FIRDAPSE.
- Expanded our commercial portfolio by acquiring the U.S. commercial rights for FYCOMPA on January 24, 2023; FYCOMPA net product revenues are estimated to be \$130 million for the 11 months ended December 2023 and FYCOMPA sales are expected to be accretive to our EBITDA and EPS in 2023.
- Provided full-year 2023 total product net revenue guidance, including FYCOMPA sales, of between \$375 million and \$385 million.
- Plans are underway to seek approval from the FDA to increase the approved FIRDAPSE maximum daily dosage from 80mg to 100mg.
- In Japan, our sublicensee, Dydo Pharma, is continuing its Phase 3 registrational study evaluating the efficacy and safety of FIRDAPSE as a treatment for LEMS patients; we anticipate completion of that study in late 2023, and if the study is successful, we anticipate the filing of an application to market the product in Japan in the second quarter of 2024.
- For the second consecutive year, Catalyst was named among Forbes 2023 America's Best Small Companies.
- For the second consecutive year, Catalyst partnered with leading advocacy groups to support International Rare Disease Day on February 28, 2023, shedding light on the important need for therapies to treat rare diseases.
- Continued to advance strategic initiatives to acquire a differentiated portfolio of innovative products to treat rare neurological and epileptic diseases to drive long-term sustainable growth.
- Strengthened our intellectual property estate for FIRDAPSE with two additional patents resulting from the purchase of RUZURGI in July 2022, one of which is now listed in the FDA's Orange Book.

- Expect to launch our inaugural Environmental, Social, and Governance (“ESG”) Report in the first half of 2023.

Fourth Quarter and Full Year 2022 Financial Results

Product Revenues: Product revenue, net in the fourth quarter of 2022, was \$61 million, compared to \$38 million for the fourth quarter of 2021, representing an increase of approximately 59% year-over-year. The full-year 2022 product revenue net was \$214 million, compared to \$138 million for 2021, representing an increase of approximately 55% year-over-year. The increases resulted from new patients who were transferred to FIRDAPSE in the first and second quarter of 2022 when RUZURGI was removed from the market and continued organic growth of LEMS patients taking FIRDAPSE.

Total revenue: Total revenues in the fourth quarter of 2022 was \$61 million, compared to \$38 million for the fourth quarter of 2021, representing an increase of approximately 59% year-over-year. Full-year 2022 revenues, net was \$214 million, compared to \$141 million for the full year 2021, representing an increase of approximately 52% year-over-year.

Research and development expenses: Research and development expenses in the fourth quarter of 2022 were \$4 million, compared to \$5 million in the fourth quarter of 2021. Research and development expenses for the full year 2022 were \$20 million, compared to \$17 million for the full year 2021.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the fourth quarter of 2022 were \$15 million compared to \$13 million in the fourth quarter of 2021. Selling, general, and administrative expenses for the full year 2022 were \$58 million, compared to \$50 million for 2021.

Operating income: Operating income for the fourth quarter of 2022 was \$31 million, compared to \$13 million in the fourth quarter of 2021, representing an increase of approximately 142%. Full-year 2022 operating income was \$102 million, compared to \$52 million for the full year 2021, representing an increase of approximately 94%.

GAAP Net Income for the fourth quarter of 2022 was \$25 million (\$0.24 per basic and \$0.22 per diluted share), compared to \$9 million (\$0.09 per basic and diluted share) for the fourth quarter 2021. Net income for the full year 2022 was \$83 million (\$0.80 per basic and \$0.75 per diluted share), compared to the full year 2021 net income of \$39 million (\$0.38 per basic and \$0.37 per diluted share).

Cash and Equivalents were \$298 million as of December 31, 2022.

Share repurchase program: The Company implemented a share repurchase program in March 2021 to purchase up to \$40 million in shares from the open market. As of December 31, 2022, the Company had repurchased approximately 3.2 million shares of Catalyst common stock in the open market, at an average price of \$5.92 per share, for a total purchase price of approximately \$19.0 million, leaving approximately \$21 million for future purchases under the program. At present, we are not purchasing shares under our share repurchase program, but rather are retaining cash for use in our business development activities.

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 2022, which was filed with the U.S. Securities and Exchange Commission on March 15, 2023.

Non-GAAP¹ Financial Measures

Non-GAAP net income for the fourth quarter of 2022 was \$36 million (\$0.34 per basic and \$0.31 per diluted share), which excludes from GAAP net income of \$25 million (i) stock-based compensation expense of \$2 million, (ii) depreciation of \$35 thousand, (iii) amortization of \$580 thousand, and (iv) the provision for income taxes of \$8 million. This compares to Non-GAAP net income for the fourth quarter of 2021 of \$14 million (\$0.14 per basic and \$0.13 per diluted share), which excludes from GAAP net income of \$9 million (i) stock-based compensation of \$1 million, (ii) depreciation of \$33 thousand, and (iii) the provision for income taxes of \$4 million.

Non-GAAP net income for full year 2022 was \$114 million (\$1.10 per basic and \$1.02 per diluted share), which excludes from GAAP net income of \$83 million (i) stock-based compensation expense of \$8 million, (ii) depreciation of \$141 thousand, (iii) amortization of \$1.1 million, and (iv) the provision for income taxes of \$22 million. This compares to Non-GAAP net income for full year 2021 of \$59 million (\$0.57 per basic and \$0.55 per diluted share), which excludes from GAAP net income of \$39 million (i) stock-based compensation of \$6 million, (ii) depreciation of \$192 thousand, and (iii) the provision for income taxes of \$13 million.

2023 Financial Guidance: The Company forecasts full-year 2023 total revenues, including FYCOMPA, to be in the range of between \$375 million and \$385 million, representing a 75% - 80% increase in total revenues as compared to 2022. Key guidance assumptions included in this forecast reflect a continued recovery in macroeconomic and healthcare activity throughout 2023 as it relates to the current COVID-19 environment.

¹ 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 the 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 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 and amortization expense, and (iii) the provision for income taxes. Non-GAAP income per share is calculated by dividing non-GAAP income by the weighted average common shares outstanding.

Conference Call & Webcast Details

The Company will host a conference call and webcast on Thursday, March 16, 2023, at 8:30 AM ET to discuss the financial results and provide a business update.

US/Canada Dial-in Number: (877) 407-8912

International Dial-in Number: (201) 689-8059

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 and up. 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.

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 more information about Catalyst Pharmaceuticals, Inc., visit the Company's website at 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) the effect of the COVID-19 pandemic on Catalyst's business and results of operations, (ii) Catalyst's ability to successfully sell its current products, (iii) Catalyst's ability to locate and acquire new product candidates through acquisition or in-licensing, (iv) Catalyst's ability to sell products acquired that are already approved and to successfully develop any new product candidates acquired or in-licensed, (v) whether Catalyst's total revenue forecast for 2023 will prove to be accurate, (vi) whether Catalyst's patents will be sufficient to eliminate generic competition for FIRDAPSE after Catalyst's orphan drug exclusivity for FIRDAPSE for LEMS expires in late November 2025, (vii) whether legislative changes currently being considered by Congress that are intended to reduce the cost of prescription drug products will adversely affect Catalyst, and (viii) those factors described in Catalyst's Annual Report on Form 10-K for the 2022 fiscal year and Catalyst's other filings with the U.S. Securities and Exchange Commission ("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.

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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,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	\$ 60,683	\$ 38,266	\$ 213,938	\$ 137,997
License and other revenue	74	43	265	2,836
Total revenues	<u>60,757</u>	<u>38,309</u>	<u>214,203</u>	<u>140,833</u>
Operating costs and expenses:				
Cost of sales	11,195	7,348	34,393	21,884
Research and development	4,093	4,992	19,789	16,936
Selling, general and administrative	14,668	13,227	58,183	49,628
Total operating costs and expenses	<u>29,956</u>	<u>25,567</u>	<u>112,365</u>	<u>88,448</u>
Operating income	30,801	12,742	101,838	52,385
Other income (expense), net	2,207	71	2,881	282
Net income before income taxes	33,008	12,813	104,719	52,667
Income tax provision	7,537	3,504	21,640	13,185
Net income	<u>\$ 25,471</u>	<u>\$ 9,309</u>	<u>\$ 83,079</u>	<u>\$ 39,482</u>
Net income per share:				
Basic	<u>\$ 0.24</u>	<u>\$ 0.09</u>	<u>\$ 0.80</u>	<u>\$ 0.38</u>
Diluted	<u>\$ 0.22</u>	<u>\$ 0.09</u>	<u>\$ 0.75</u>	<u>\$ 0.37</u>
Weighted average shares outstanding:				
Basic	<u>104,583,296</u>	<u>103,108,077</u>	<u>103,374,606</u>	<u>103,379,349</u>
Diluted	<u>113,531,124</u>	<u>108,956,513</u>	<u>111,375,631</u>	<u>107,795,585</u>

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,	
	2022	2021	2022	2021
GAAP net income	\$ 25,471	\$ 9,309	\$ 83,079	\$ 39,482
Non-GAAP adjustments:				
Stock-based compensation expense	1,926	1,472	7,907	6,073
Depreciation	35	33	141	192
Amortization	580	—	1,098	—
Income tax provision	7,537	3,504	21,640	13,185
Non-GAAP net income	<u>\$ 35,549</u>	<u>\$ 14,318</u>	<u>\$ 113,865</u>	<u>\$ 58,932</u>
Non-GAAP net income per share:				
Basic	<u>\$ 0.34</u>	<u>\$ 0.14</u>	<u>\$ 1.10</u>	<u>\$ 0.57</u>
Diluted	<u>\$ 0.31</u>	<u>\$ 0.13</u>	<u>\$ 1.02</u>	<u>\$ 0.55</u>
Weighted average shares outstanding:				
Basic	<u>104,583,296</u>	<u>103,108,077</u>	<u>103,374,606</u>	<u>103,379,349</u>
Diluted	<u>113,531,124</u>	<u>108,956,513</u>	<u>111,375,631</u>	<u>107,795,585</u>

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

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 298,395	\$ 171,445
Short-term investments	—	19,821
Accounts receivable, net	10,439	6,619
Inventory	6,805	7,870
Prepaid expenses and other current assets	5,158	4,351
Total current assets	320,797	210,106
Operating lease right-of-use asset	2,770	3,017
Property and equipment, net	847	959
License and acquired intangibles, net	32,471	—
Deferred tax assets, net	18,736	23,697
Deposits	9	9
Total assets	<u>\$ 375,630</u>	<u>\$ 237,788</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 3,975	\$ 2,768
Accrued expenses and other liabilities	53,613	24,295
Total current liabilities	57,588	27,063
Operating lease liability, net of current portion	3,557	3,894
Other non-current liabilities	14,064	—
Total liabilities	75,209	30,957
Total stockholders' equity	300,421	206,831
Total liabilities and stockholders' equity	<u>\$ 375,630</u>	<u>\$ 237,788</u>