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 16, 2022

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

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**

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))

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 16, 2022, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2021 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 16, 2022
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 16, 2022

Exhibit 99.1

Catalyst Pharmaceuticals Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

Total 2021 Revenues Increased Approximately 18% YoY to $141 Million

Strong 2022 Revenue Growth Expected, Supported by FIRDAPSE® Orphan Drug Exclusivity

New Patent Issuances Strengthens FIRDAPSE Long-Term Commercial Potential to 2034

Actively Pursuing Opportunities to Diversify Commercial and Development Portfolio

Strong Cash and Investments Position of $191 Million and No Funded Debt

Company to Host a Conference Call and Webcast on March 17, 2022, at 8:30 AM ET

CORAL GABLES, Fla., March 16, 2022 — 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 2021 and provided a corporate update.

"We achieved strong financial performance during 2021, marked by our sustained focus on commercial and operational execution, which created a sizeable foundation as we continue to execute on our business strategy and invest in our long-term growth," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst. "We entered 2022 with great momentum, having received affirmation of the orphan drug exclusivity for FIRDAPSE coupled with the issuance of three new patents directed to the treatment of patients suffering from LEMS, further reinforcing and diversifying our existing patent exclusivity to 2034. These important milestones significantly reinforce the product's commercial durability and are defining inflection points supporting the Company's continued growth. We believe we are well-positioned to build upon our success and are optimistic about the future of the Company as we diligently pursue opportunities to diversify our commercial and development portfolio, which aligns with our core mission to deliver value to our patients, healthcare providers, and shareholders."

RECENT BUSINESS HIGHLIGHTS

- Received positive outcome from U.S. Courts reaffirming the orphan drug exclusivity for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS").

- Transition of LEMS patients previously treated with Ruzurgi® is occurring seamlessly through Catalyst Pathway's differentiated "patient first" product access support program, established for all patients seeking access to FIRDAPSE for LEMS treatment.
- Sustained U.S. product revenue growth through enhanced awareness and education to patients and healthcare professionals, including our focus on paraneoplastic LEMS and oncology.
- Anticipate submission of a supplemental New Drug Application ("sNDA") to the U.S. Food and Drug Administration ("FDA") to support the approved use of FIRDAPSE for the treatment of pediatric LEMS patients before the end of the first quarter.
- Further strengthened the long-term commercial potential of FIRDAPSE as a result of the issuance of three new patents covering additional patient amifampridine metabolizer types, further adding to its current U.S. patent exclusivity protection until 2034.
- Received favorable Canadian Federal Court ruling enforcing FIRDAPSE's Innovative Drug data protections, resulting in the setting aside of the approval of Ruzurgi®.
- Provided 2022 total revenue guidance of $195 million—$205 million supported by U.S. market exclusivity and an enhanced intellectual property portfolio for FIRDAPSE.
- Advanced global initiatives with the initiation of a Phase 3 registrational study by sub-licensee partner DyDo Pharma to evaluate the efficacy and safety of FIRDAPSE for the treatment of LEMS in Japan.
- Continued to advance strategic initiatives to acquire a differentiated portfolio of innovative products to treat rare diseases, with a goal of driving long-term sustainable growth.
- Partnered with rare disease patients and advocacy groups supporting the 2022 Global Rare Disease Day to help raise awareness and amplify patients' voices for the need for new treatments.

Fourth Quarter and Full Year 2021 Financial Results

Total revenues: Total revenue in the fourth quarter of 2021 was $38 million, compared to total fourth quarter 2020 revenues of $31 million, representing an increase of approximately 24% year-over-year. The full year 2021 total revenues were $141 million, compared to total revenues of $119 million for 2020, representing an increase of approximately 18% year-over-year.

Total product revenue, net: Total product revenue, net in the fourth quarter of 2021 was $38 million, compared to $31 million for the fourth quarter of 2020, representing an increase of approximately 24% year-over-year. Full year 2021 product revenue, net was $138 million, compared to $119 million for the full year 2020, representing an increase of approximately 16% year-over-year.

Operating income: Operating income for the fourth quarter of 2021 was $13 million, compared to $9 million in the fourth quarter of 2020. Full year 2021 operating income was $52 million, compared to $41 million for the full year 2020.

Research and development expenses: In the fourth quarter of 2021, research and development expenses were $5 million, compared to $4 million in the fourth quarter of 2020. Research and development expenses for the full year 2021 were $17 million, compared to $16 million for the full year 2020.

Selling, general, and administrative expenses: Selling, general, and administrative expenses for the fourth quarter of both 2021 and 2020 were $13 million. Selling, general, and administrative expenses for full year 2021 were $50 million, compared to $44 million for full year of 2020.

GAAP Net Income for the fourth quarter of 2021 was $9 million ($0.09 per basic and diluted share), compared to $11 million ($0.11 per basic and diluted share) for the fourth quarter of 2020. Net income for full year 2021 was $39 million ($0.38 per basic and $0.37 per diluted share), compared to full year 2020 net income of $75 million ($0.72 per basic and $0.71 per diluted share). Net income for the fourth quarter of 2020 benefitted from $3 million of income tax benefit. Net income for full year 2020 benefitted from $33 million of income tax benefit, including the one-time recording of an approximately $31.6 million deferred tax asset upon reversal of a valuation allowance.

Non-GAAP Financial Measures

Non-GAAP[1] net income for the fourth quarter of 2021 was $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 expense of $1 million, (ii) depreciation of $33 thousand, and (iii) the provision for income taxes of $4 million. This compares to non-GAAP[1] net income for the fourth quarter of 2020 of $10 million ($0.10 per basic and diluted share), which excludes from GAAP net income of $11 million (i) stock-based compensation expense of $1 million, (ii) depreciation of $19 thousand, and (iii) a benefit for income taxes of $3 million.

---

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

Non-GAAP[1] net income for the full year 2021 was $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 expense of $6 million, (ii) depreciation of $192 thousand, and (iii) the provision for income taxes of $13 million. This compares to non-GAAP[1] net income for full year 2020 of $48 million ($0.47 per basic and $0.45 per diluted share), which excludes from GAAP net income of $75 million (i) stock-based compensation expense of $6 million, (ii) depreciation of $92 thousand, and (iii) a benefit for income taxes of $33 million, as the Company recorded the deferred tax asset during the third quarter of 2020. A tabular presentation of non-GAAP[1] net income for the three months and full year ended December 31, 2021 and 2020 is included below.

More detailed financial information and analysis can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which was filed with the Securities and Exchange Commission ("SEC") on March 16, 2022.

Cash and investments were $191 million as of December 31, 2021, with no funded debt.

Share repurchase program: The Company implemented a share repurchase program in March 2021. As of December 31, 2021, the Company had repurchased 2.2 million shares of Catalyst common stock in the open market, at an average price of $5.47 per share, for a total purchase price of $12.1 million.

2022 Financial Guidance: The Company forecasts full year 2022 total revenues to be in the range of between $195 million and $205 million, representing a 38%—45% increase in total revenues as compared to 2021, with cash operating expenses for the full year 2022 expected to be in the range of $65 million to $70 million. Key guidance assumptions included in these forecasts reflect a continued recovery in macroeconomic and healthcare activity throughout 2022 as it relates to the current COVID-19 environment.

Conference Call & Webcast Details

The Company will host a conference call and webcast on Thursday, March 17, 2022, 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

A webcast and accompanying materials will be accessible under the investor section on the Company's website at www.catalystpharma.com. A replay of the webcast will be available on the Catalyst website for 30 days following the date of the event.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on in-licensing, developing, and commercializing novel medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, best-in-class medicines for rare diseases. Catalyst's New Drug Application for FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of adults with Lambert-Eaton myasthenic syndrome ("LEMS") was approved in 2018 by the U.S. Food & Drug Administration ("FDA"), and FIRDAPSE is commercially available in the United States as a treatment for adults with LEMS. 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.

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 continuing effect of the COVID-19 pandemic on Catalyst's net product revenues and net income, (ii) Catalyst's ability to locate and acquire new product candidates through acquisition or in-licensing, (iii) Catalyst's ability to successfully develop any new product candidates acquired or in-licensed, (iv) whether Catalyst's total revenue forecast for 2022 will prove to be accurate, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2021 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.

Source: Catalyst Pharmaceuticals, Inc.

Media Contact
David Schull
Russo Partners
(858) 717-2310
david.schull@russopartnersllc.com

Investor Contact
Mary Coleman
Catalyst Pharmaceuticals, Inc.
(305) 420-3200
mcoleman@catalystpharma.com

###

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,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenue, net	$ 38,266	$ 30,882	$ 137,997	$ 118,790
License and other revenue	43	133	2,836	283
Total revenues	38,309	31,015	140,833	119,073
Operating costs and expenses:				
Cost of sales	7,348	4,869	21,884	17,039
Research and development	4,992	4,175	16,936	16,497
Selling, general and administrative	13,227	13,353	49,628	44,234
Total operating costs and expenses	25,567	22,397	88,448	77,770
Operating income	12,742	8,618	52,385	41,303
Other income, net	71	106	282	587
Net income before income taxes	12,813	8,724	52,667	41,890
Income tax provision (benefit)	3,504	(2,713)	13,185	(33,093)
Net income	$ 9,309	$ 11,437	$ 39,482	$ 74,983
Net income per share:				
Basic	$ 0.09	$ 0.11	$ 0.38	$ 0.72
Diluted	$ 0.09	$ 0.11	$ 0.37	$ 0.71
Weighted average shares outstanding:				
Basic	103,108,077	103,694,845	103,379,349	103,512,913
Diluted	108,956,513	105,838,449	107,795,585	106,242,273

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,	
	2021	2020	2021	2020
GAAP net income	**$ 9,309**	**$ 11,437**	**$ 39,482**	**$ 74,983**
Non-GAAP adjustments:				
Stock-based compensation expense	1,472	1,469	6,073	6,261
Depreciation	33	19	192	92
Income tax provision (benefit)	3,504	(2,713)	13,185	(33,093)
Non-GAAP net income	$ 14,318	$ 10,212	$ 58,932	$ 48,243
Non-GAAP net income per share:				
Basic	$ 0.14	$ 0.10	$ 0.57	$ 0.47
Diluted	$ 0.13	$ 0.10	$ 0.55	$ 0.45
Weighted average shares outstanding:				
Basic	103,108,077	103,694,845	103,379,349	103,512,913
Diluted	108,956,513	105,838,449	107,795,585	106,242,273

CATALYST PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31, 2021	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 171,445	$ 130,237
Short-term investments	19,821	10,041
Accounts receivable, net	6,619	5,987
Inventory	7,870	4,651
Prepaid expenses and other current assets	4,351	8,328
Total current assets	210,106	159,244
Operating lease right-of-use asset	3,017	—
Property and equipment, net	959	130
Deferred tax assets, net	23,697	32,971
Deposits	9	9
Total assets	$ 237,788	$ 192,354
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,768	$ 4,256
Accrued expenses and other liabilities	24,295	18,500
Total current liabilities	27,063	22,756
Operating lease liability, net of current portion	3,894	—
Total liabilities	30,957	22,756
Total stockholders' equity	206,831	169,598
Total liabilities and stockholders' equity	$ 237,788	$ 192,354