

**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, 2021**

**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**

**355 Alhambra Circle  
Suite 1250  
Coral Gables, FL 33134**  
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.

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**Item 8.01 Other Events**

On March 15, 2021, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2020 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, 2021](#)

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





## Catalyst Pharmaceuticals Announces Fourth Quarter and Year-End 2020 Financial Results and Provides Corporate Update

- *Firdapse® Q4-20 Net Revenues of \$31.0 Million, FY-20 Net Revenues of \$119.1 Million*

- *GAAP Net Income of \$75.0 Million for Fiscal Year 2020*

- *\$140.3 Million in Cash and Investments and No Funded Debt*

- *Company to Host Quarterly Conference Call at 8:30 am ET Tomorrow*

**CORAL GABLES, Fla., March 15, 2021 (GLOBE NEWSWIRE)** — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, today reported financial results for the fourth quarter and year ended December 31, 2020 and provided a corporate update.

“We are extremely pleased with our continued commercial execution of the Firdapse® launch during 2020. Despite the challenges of dealing with COVID-19, we were able to grow our revenues 16% during 2020 over 2019. As the country and physician practices are starting to re-open as we enter a post-pandemic period, we believe that we are well positioned to accelerate our rate of growth with new patient starts and revenue as the year progresses,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “We believe that our strong balance sheet, earnings power and borrowing capability has us well-positioned to execute on our strategic initiative to expand our product and pipeline portfolio of therapies to treat other rare diseases. As we began 2021 with incredible momentum, we are confident that we have the team that can deliver our ambitious goals for this year and beyond.”

### Q4-20 and FY-20 Financial Results

- Total revenue, net in Q4-20 was \$31.0 million, compared to \$30.1 million for Q4-19. Total revenue, net for FY 2020 was \$119.1 million, compared to \$102.3 million for FY 2019, an increase of 16% year over year.
- Operating income in Q4-20 was \$8.6 million, compared to \$8.0 million in Q4-19. Operating income in FY-20 was \$41.3 million, compared to \$31.8 million in FY-19, an increase of 30% year over year.
- Net income in Q4-20 was \$11.4 million, or \$0.11 per basic and diluted share, compared with net income in Q4-19 of \$7.9 million, or \$0.08 per basic and \$0.07 per diluted share. Net income in FY-20 was \$75.0 million, or \$0.72 per basic and \$0.71 per diluted share, compared with net income in FY-19 of \$31.9 million, or \$0.31 per basic and \$0.30 per diluted share.
- Net income for FY-2020 includes \$33.1 million (\$0.32 per basic and \$0.31 per diluted share) of tax benefit from recording the deferred tax asset, including the reversal of the valuation allowance in Q3-20.

- Research and development expenses for Q4-20 were \$4.2 million as compared to \$6.3 million for Q4-19. Research and development expenses for FY-20 were \$16.5 million as compared to \$18.8 million for FY-19.
- Selling, general and administrative expenses for Q4-20 were \$13.4 million, compared to \$11.4 million in Q4-19. Selling, general and administrative expenses for FY-20 were \$44.2 million, compared to \$36.9 million in FY-19.
- Ended 2020 with \$140.3 million in cash and investments and no funded debt.

### **Corporate Highlights and Milestones**

- Achieved record revenues for Firdapse® in treating adult LEMS patients.
- Initial patent was issued in the fourth quarter of 2020 for the use of 3,4-diaminopyridine (the patent expires in 2034 with four other patents pending in that estate).
- Expansion of the company's strategic focus to include acquiring or in-licensing innovative, technology platforms and earlier stage programs in other therapeutic categories outside of neuromuscular diseases.
- Commenced a national search for a key executive, a Chief Product Development Officer, to strategically develop and manage portfolio planning and R&D activities.
- Actively engaged in evaluation of potential acquisition of products or companies.

### **Other Firdapse® Development Programs**

- Firdapse® long-acting formulation development program continues on schedule, with additional PK work expected to be conducted during 2021.
- A proof-of-concept study evaluating Firdapse® as a treatment for Hereditary Neuropathy with Liability to Pressure Palsies (HNPP) is scheduled to start in the third quarter of 2021.
- Plans to present MuSK-MG Firdapse® study hypotheses and a revised protocol to the FDA for discussion during the first half of 2021.

### **COVID-19 Impact**

- Issued a no travel and remote work policy for all Catalyst employees on March 16<sup>th</sup> of last year that has been partially rescinded on a regional basis as reopening has begun.
- Diligently working to reduce COVID-19 impact on new patient starts, enrollments and revenues.
- We believe that our current base of LEMS patients on reimbursed Firdapse® remains fairly stable and very compliant to their medication regimen.
- Have not experienced any disruptions in the supply chain or production of Firdapse® and believe the safety stock of Firdapse® is more than adequate for current anticipated needs.
- Proudly partnered with First Responder's Children's Foundation/COVID-19 Emergency Response Fund, which provides emergency grants to support frontline emergency and healthcare workers and their families enduring financial hardship during this COVID-19 pandemic.

### **Balance Sheet and Key Activities in 2021**

At December 31, 2020, Catalyst had cash and cash equivalents and investments of \$140.3 million and no funded debt.

The Company plans to continue investing in the following key activities in 2021:

- Expansion of investments in research and development, including acquiring earlier stage rare disease opportunities and innovative technology.
- Expanding, prosecuting and protecting our portfolio of intellectual property.
- Expansion of U.S. commercialization of Firdapse®.
- On-going development programs evaluating Firdapse® for the treatment of MuSK-MG and HNPP.
- Continue support for our Firdapse® long-acting formulation.
- Continue Japan regulatory activities to seek marketing authorization for Firdapse®.

More detailed financial information and analysis may be found in the Company's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission (SEC) on March 15, 2021.

### **Non-GAAP Financial Measure**

Excluding expenses related to stock-based compensation of \$1.5 million, non-GAAP<sup>1</sup> net income for Q4-20 was \$12.9 million, or \$0.12 per basic and diluted share. This compares to non-GAAP<sup>1</sup> net income of \$9.1 million, or \$0.09 per basic and diluted share, excluding stock-based compensation expense of \$1.1 million, for Q4-19. Excluding expenses related to stock-based compensation of \$6.3 million, non-GAAP<sup>1</sup> net income for FY-20 was \$81.2 million, or \$0.78 per basic share and \$0.76 per diluted share. This compares to a non-GAAP<sup>1</sup> net income of \$35.7 million, or \$0.35 per basic and \$0.34 per diluted share, excluding stock-based compensation expense of \$3.8 million, for FY-2019.

### **Conference Call**

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday March 16, 2021 to discuss the financial results and provide a corporate update. Investors who wish to participate in the conference call may do so by dialing (877) 407-8912 for domestic and Canadian callers or (201) 689-8059 for international callers. Those interested in listening to the conference call live via the internet may do so by visiting the Investors page of the company's website at [www.catalystpharma.com](http://www.catalystpharma.com) and clicking on the webcast link on the Investors home page. A webcast replay will be available on the Catalyst website for 30 days following the call by visiting the Investor page of the company's website at [www.catalystpharma.com](http://www.catalystpharma.com).

### **About Catalyst Pharmaceuticals**

Catalyst Pharmaceuticals is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases, including Lambert-Eaton myasthenic syndrome (LEMS), anti-MuSK antibody positive myasthenia gravis (MuSK-MG) and other neurological and neuromuscular disorders. Catalyst's New Drug Application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse® is commercially available in the United States. Further, Canada's national healthcare regulatory agency, Health Canada, recently approved the use of Firdapse® (amifampridine) for the treatment of patients in Canada with LEMS.

Firdapse® is currently being evaluated in clinical trials for the treatment of MuSK-MG and has received Orphan Drug Designation from the FDA for myasthenia gravis.

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<sup>1</sup> Statements made in this press release include a non-GAAP financial measure. 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). This non-GAAP financial measure is intended to enhance an overall understanding of Catalyst's current financial performance. Catalyst believes that the non-GAAP financial measure presented in this press release provides 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. The non-GAAP financial measures in this press release exclude from the calculation of net income (loss) the expense associated with non-cash stock-based compensation. Non-GAAP income (loss) per share is calculated by dividing non-GAAP income (loss) by the weighted average common shares outstanding.

## 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 impact of the effects of the COVID-19 pandemic on Catalyst's revenues and on the timeline for our trials or proof-of-concept studies, (ii) whether, even if Catalyst continues to be successful in commercializing Firdapse®, Catalyst will continue to achieve sustained positive cash flow and profitability, (iii) the effect on Catalyst's business and future results of operations of the approval by the FDA of Ruzurgi® for the treatment of pediatric LEMS patients (ages 6 to under 17); (iv) whether Catalyst's suit against the FDA seeking to vacate the FDA's approval of Ruzurgi® will ultimately be successful; (v) whether Firdapse® will ever be approved for commercialization for the treatment of MuSK-MG, or any other disease, (vi) whether we will be successful in executing on our strategic initiative to expand our product and pipeline therapies to treat other rare diseases, and (vii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2020 and its 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

	(unaudited)		For the Year	
	For the Three Months Ended December 31,		Ended December 31,	
	2020	2019	2020	2019
Product revenue, net	\$ 30,832,723	\$ 30,122,555	\$ 118,740,617	\$ 102,306,337
Revenues from collaborative arrangements	182,186	—	332,186	—
Total revenues	31,014,909	30,122,555	119,072,803	102,306,337
Operating costs and expenses:				
Cost of sales	4,869,658	4,398,265	17,039,157	14,759,139
Research and development	4,175,028	6,308,390	16,496,715	18,842,752
Selling, general and administrative	13,352,387	11,409,213	44,233,754	36,881,187
Total operating costs and expenses	22,397,073	22,115,868	77,769,626	70,483,078
Operating income (loss)	8,617,836	8,006,687	41,303,177	31,823,259
Other income, net	105,828	398,683	586,897	1,585,774
Net income (loss) before income taxes	8,723,664	8,405,370	41,890,074	33,409,033
Income tax provision (benefit)	(2,713,467)	475,657	(33,092,926)	1,533,696
Net income (loss)	\$ 11,437,131	\$ 7,929,713	\$ 74,983,000	\$ 31,875,337
Net income (loss) per share:				
Basic	\$ 0.11	\$ 0.08	\$ 0.72	\$ 0.31
Diluted	\$ 0.11	\$ 0.07	\$ 0.71	\$ 0.30
Weighted average shares outstanding:				
Basic	103,694,845	103,180,946	103,512,913	102,944,316
Diluted	105,838,449	106,567,001	106,242,273	106,020,936



CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 130,237,109	\$ 89,511,710
Short-term investments	10,041,068	5,007,050
Accounts receivable, net	5,987,426	10,536,997
Inventory	4,650,600	1,956,792
Prepaid expenses and other current assets	8,327,771	4,351,074
Total current assets	<u>159,243,974</u>	<u>111,363,623</u>
Operating lease right-of-use asset	—	793,252
Property and equipment, net	129,800	210,467
Deferred tax assets	32,971,264	—
Deposits	8,888	8,888
Total assets	<u>\$192,353,926</u>	<u>\$ 112,376,230</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 4,256,020	\$ 4,117,447
Accrued expenses and other liabilities	<u>18,500,267</u>	<u>19,981,295</u>
Total current liabilities	22,756,287	24,098,742
Operating lease liability, net of current portion	—	647,532
Total liabilities	22,756,287	24,746,274
Total stockholders' equity	<u>169,597,639</u>	<u>87,629,956</u>
Total liabilities and stockholders' equity	<u>\$192,353,926</u>	<u>\$ 112,376,230</u>