

**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 9, 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

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 November 9, 2021, the Company issued a press release announcing its results of operations for the three and nine months ended September 30, 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 November 9, 2021.](#)

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 9, 2021



Catalyst Pharmaceuticals Reports Third Quarter 2021 Financial Results

*Continued Strong Financial and Operational Performance in the Third Quarter 2021
FIRDAPSE® Revenue of \$35.9 Million Increased 23.1% Compared to Third Quarter 2020*

Plans to Seek to Expand the U.S. Approval of FIRDAPSE To Include Pediatric LEMS Patients

Strong Cash Position \$174.8 Million Supports Long-term Growth Strategy

Company to Host Quarterly Conference Call on November 10, 2021, at 8:30 AM ET

CORAL GABLES, Fla., November 9, 2021 — Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases, today reported financial results for the third quarter ended September 30, 2021, and provided a corporate update.

“We delivered another quarter of strong financial results while making important progress on all fronts,” said Patrick J. McEnany, Chairman and CEO of Catalyst. “We reported a record quarter for net sales for FIRDAPSE®, further underscoring the strength of our commercial capabilities while advancing our efforts in support of the orphan drug exclusivity of FIRDAPSE for the treatment of LEMS. We continued to execute on all key growth initiatives, including plans to expand the label for FIRDAPSE to include all LEMS patients, including the very few pediatric patients diagnosed with LEMS. Our quarterly achievements demonstrate continued performance excellence supported by several key strategic decisions that have positioned Catalyst firmly for the future. In saying that, we are excited about the path ahead as we continue to execute across all fronts to drive sustainable growth for the long term. “

Operational Highlights

- Achieved record net FIRDAPSE revenue in the third quarter of 2021 of \$35.9 million driven by strong patient persistency and new patient enrollments, representing a 6.7% increase compared to the second quarter 2021.
- Received favorable decision from the U.S. 11th Circuit Court of Appeals supporting the orphan drug exclusivity for FIRDAPSE® (amifampridine) Tablets 10 mg for LEMS treatment in the U.S.
- Strengthened the intellectual property portfolio for FIRDAPSE with a second patent published in the Orange Book, extending the intellectual property to 2034, with additional patents pending.

- Advancing global expansion initiative with partner DyDo Pharma to initiate a small registrational trial for the development of FIRDAPSE® (amifampridine) Tablets 10 mg for the treatment of Lambert-Eaton myasthenic syndrome in Japan in early 2022.
- Work continues on our long-acting candidate formulation of amifampridine phosphate for the treatment of LEMS.
- Plans underway to file a supplemental NDA for FIRDAPSE for the treatment of pediatric LEMS.
- After much evaluation, we are ending the development program for Musk-MG but will continue to support patients currently receiving FIRDAPSE to treat their MuSK-MG symptoms through investigator-initiated programs, in accordance with FDA regulations.
- Strong cash position increases scope of business development initiatives to expand the focus beyond FIRDAPSE through acquisition or in-licensing of products or companies.
- The Company repurchased 949,746 million shares during the third quarter 2021 under its share buyback program, at an average price of \$5.32 per share, bringing the total shares purchased through September 30, 2021 to 1,749,746 shares, at an average price of \$5.15 per share.

Third Quarter 2021 Financial Results

- **Total Net FIRDAPSE Revenue** in the third quarter of 2021 was \$35.9 million, a 23.1% increase compared to \$29.2 million for the third quarter of 2020.
- **Total Operating Income** in the third quarter of 2021 was \$14.0 million, compared to \$11.7 million in the third quarter of 2020.
- **Research and Development Expenses** in the third quarter of 2021 were \$4.5 million, compared to \$3.7 million in the third quarter of 2020.
- **Selling, General, and Administrative Expenses** for the third quarter of 2021 were \$12.2 million, compared to \$10.0 million for the third quarter of 2020.
- **Cash and Investments** were approximately \$174.8 million as of September 30, 2021, approximately \$20 million increase when compared to \$155.3 million as of June 30, 2021, with no funded debt in either period.
- **GAAP Net Income** for the third quarter of 2021 was \$10.3 million (\$0.10 per basic and diluted share), compared to \$43.3 million (\$0.42 per basic and \$0.41 per diluted share) for the third quarter of 2020. Net income for the nine months ended September 30, 2021 was \$30.2 million (\$0.29 per basic and \$0.28 per diluted share), compared to \$63.5 million (\$0.61 per basic and \$0.60 per diluted share) for the comparable nine month period. Net income for the third quarter of 2020 benefitted from the one-time recording of an approximately \$31.6 million deferred tax asset, upon reversal of a valuation allowance.

Non-GAAP Financial Measures

Non-GAAP¹ net income for Q3-21 was \$15.6 million (\$0.15 per basic and \$0.14 per diluted share), which excludes from GAAP net income of \$10.3 million (i) stock-based compensation expense of \$1.5 million, (ii) depreciation of \$31 thousand, and (iii) the provision for income taxes of \$3.7 million. This compares to non-GAAP¹ net income for Q3-20 of \$13.2 million (\$0.13 per basic and \$0.12 per diluted share), which excludes from GAAP net income of \$43.3 million (i) stock-based compensation expense of \$1.5 million, (ii) depreciation of \$30 thousand, and (iii) a benefit for income taxes of \$31.6 million, as the Company recorded the deferred tax asset during Q3-20. A tabular presentation of non-GAAP¹ net income for the three months and nine months ended September 30, 2021 and 2020 is included below.

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 measures in this press release exclude 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.

More detailed financial information and analysis can be found in the Company's Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on November 9, 2021.

Conference Call

Catalyst management will host a conference call and webcast on Wednesday, November 10, 2021, at 8:30 AM ET to discuss the financial results and provide a corporate update.

To access the call, please dial 877-407-8912 for the United States and Canada or 201-689-8059 for International. A webcast of the call will be available on the Investors section of the Company's website at www.catalystpharma.com. 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.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a commercial-stage, patient-centric biopharmaceutical company focused on in-licensing, developing, and commercializing novel high-quality medicines for patients living with rare diseases. With exceptional patient focus, Catalyst is committed to developing a robust pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. Catalyst's New Drug Application for FIRDAPSE[®] (amifampridine) Tablets 10 mg 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 as a treatment for adults with LEMS. Further, Canada's national healthcare regulatory agency, Health Canada, approved the use of FIRDAPSE (amifampridine) 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) Catalyst's ability to successfully develop and commercialize a long-acting formulation of FIRDAPSE, and (v) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2020 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 (unaudited)

(in thousands, except share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Product revenue, net	\$ 35,890	\$ 29,167	\$ 99,731	\$ 87,908
License and other revenue	64	150	2,793	150
Total revenues	35,954	29,317	102,524	88,058
Operating costs and expenses:				
Cost of sales	5,310	3,879	14,536	12,170
Research and development	4,487	3,749	11,944	12,322
Selling, general and administrative	12,153	9,985	36,401	30,881
Total operating costs and expenses	21,950	17,613	62,881	55,373
Operating income	14,004	11,704	39,643	32,685
Other income, net	68	33	211	481
Net income before income taxes	14,072	11,737	39,854	33,166
Income tax provision (benefit)	3,743	(31,603)	9,681	(30,380)
Net income	\$ 10,329	\$ 43,340	\$ 30,173	\$ 63,546
Net income per share:				
Basic	\$ 0.10	\$ 0.42	\$ 0.29	\$ 0.61
Diluted	\$ 0.10	\$ 0.41	\$ 0.28	\$ 0.60
Weighted average shares outstanding:				
Basic	103,196,550	103,535,431	103,470,762	103,452,025
Diluted	107,843,196	106,316,241	107,476,175	106,386,617

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,	
	2021	2020	2021	2020
GAAP net income	\$ 10,329	\$ 43,340	\$ 30,173	\$ 63,546
Non-GAAP adjustments:				
Stock-based compensation expense	1,512	1,478	4,601	4,792
Depreciation	31	30	159	73
Income tax provision (benefit)	3,743	(31,603)	9,681	(30,380)
Non-GAAP net income	<u>\$ 15,615</u>	<u>\$ 13,245</u>	<u>\$ 44,614</u>	<u>\$ 38,031</u>
Non-GAAP net income per share:				
Basic	<u>\$ 0.15</u>	<u>\$ 0.13</u>	<u>\$ 0.43</u>	<u>\$ 0.37</u>
Diluted	<u>\$ 0.14</u>	<u>\$ 0.12</u>	<u>\$ 0.42</u>	<u>\$ 0.36</u>
Weighted average shares outstanding – basic	<u>103,196,550</u>	<u>103,535,431</u>	<u>103,470,762</u>	<u>103,452,025</u>
Weighted average shares outstanding – diluted	<u>107,843,196</u>	<u>106,316,241</u>	<u>107,476,175</u>	<u>106,386,617</u>

CATALYST PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	September 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 154,836	\$ 130,237
Short-term investments	19,956	10,041
Accounts receivable, net	6,625	5,987
Inventory	6,950	4,651
Prepaid expenses and other current assets	4,428	8,328
Total current assets	192,795	159,244
Operating lease right-of-use asset	3,093	—
Property and equipment, net	951	130
Deferred tax assets	26,400	32,971
Deposits	9	9
Total assets	<u>\$ 223,248</u>	<u>\$ 192,354</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,752	\$ 4,256
Accrued expenses and other liabilities	17,862	18,500
Total current liabilities	20,614	22,756
Operating lease liability, net of current portion	3,973	—
Total liabilities	24,587	22,756
Total stockholders' equity	198,661	169,598
Total liabilities and stockholders' equity	<u>\$ 223,248</u>	<u>\$ 192,354</u>