

**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): August 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 August 9, 2021, the Company issued a press release announcing its results of operations for the three and six months ended June 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 August 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: August 9, 2021



Catalyst Pharmaceuticals Announces Second Quarter 2021 Financial Results and Provides Corporate Update

-Q2 2021 Total Net Revenues of \$36.4 Million Reflect Strong Quarter over Quarter Growth

-Q2 2021 GAAP Net Income of \$12.2 Million; Non-GAAP Net Income of \$17.4 Million

-\$155.3 Million in Cash and Investments and no Funded Debt at End of Q2-2021

-Catalyst to Host Quarterly Conference Call at 8:30 AM ET Tomorrow

CORAL GABLES, Fla., August 9, 2021 (GLOBE NEWSWIRE) — 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 second quarter ended June 30, 2021 and provided a corporate update.

“I am very pleased that our operational plan for 2021 and year to date financial results continue to deliver as originally planned, despite not yet being back to pre-Covid conditions. I believe that this portends well for the balance of the year, as we anticipate that patient access to physician practices will continue to improve. This should lead to abbreviated diagnostic times for new Lambert-Eaton Myasthenic Syndrome (LEMS) patients, which will mean that these patients will have access to Firdapse® much sooner,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “Additionally, in line with our strategic objectives we have recently expanded our senior leadership team with highly regarded pharmaceutical executives to help us accelerate our business and portfolio development activities and continue the transformation of the company.”

Q2-21 Financial Results

- Total revenues in Q2 2021 were \$36.4 million, a 23% increase from \$29.6 million for Q2 2020.
- Total Firdapse® product revenue, net in Q2 2021 was \$33.6 million, a 14% increase from \$29.6 million, net for Q2 2020.
- Operating income in Q2 2021 was \$15.8 million, up from \$10.3 million in Q2 2020.
- GAAP net income in Q2 2021 was \$12.2 million, or \$0.12 per basic and \$0.11 per diluted share, compared with GAAP net income in Q2 2020 of \$9.8 million, or \$0.09 per basic and diluted share.
- Research and development expenses were \$4.5 million for Q2 2021 compared to \$4.4 million for Q2 2020.
- Selling, general and administrative expenses for Q2 2021 totaled \$11.5 million compared to \$10.8 million for Q2 2020.
- During Q2 2021, repurchased 732,951 shares of the Company’s common stock for approximately \$3.7 million.
- Ended Q2 2021 with \$155.3 million in cash and investments and no funded debt.

Corporate Milestones

- Announced exclusive license and supply agreement with DyDo Pharma for the development and commercialization of Firdapse® in Japan.
- During July 2021, strengthened our senior leadership team with onboarding of Dr. Preethi Sundaram as Chief Product Development Officer, who will lead our product portfolio development and management.
- Expanded our strategic focus to include acquiring or in-licensing innovative, technology platforms and earlier stage programs in all therapeutic categories with the exclusion of oncology.
- Actively engaged in evaluation of potential acquisitions and partnerships of innovative products or companies.
- Second Firdapse® patent issued, further strengthening our intellectual property portfolio.
- Added Molly Harper, a seasoned pharmaceutical executive, to our board of directors.
- Hired a new Vice President to lead investor relations. This executive will join us on August 16, 2021.

Balance Sheet and Key Activities in 2021

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

- Expansion of U.S. commercialization of Firdapse®.
- Continue support for our Firdapse® long-acting formulation and other development programs.
- Expanding, prosecuting and protecting our portfolio of intellectual property.
- Expansion of investments in research and development, including acquiring earlier stage rare disease opportunities and innovative technology.

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 August 9, 2021.

Non-GAAP Financial Measures

Non-GAAP¹ net income for Q2-21 was \$17.4 million (\$0.17 per basic and \$0.16 per diluted share), which excludes from GAAP net income of \$12.2 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 Q2-20 of \$12.2 million (\$0.12 per basic and \$0.11 per diluted share), which excludes from GAAP net income of \$9.8 million (i) stock-based compensation expense of \$1.8 million, (ii) depreciation of \$29 thousand, and (iii) the provision for income taxes of \$0.6 million. A tabular presentation of non-GAAP¹ net income for the three months and six months ended June 30, 2021 and 2020 is included on page 5 of this press release.

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 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 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. 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 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

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday, August 10, 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 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.

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.

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.

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 Firdapse® for other indications and 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 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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Product revenue, net	\$ 33,636	\$ 29,605	\$ 63,841	\$ 58,741
License and other revenue	2,729	—	2,729	—
Total revenues	<u>36,365</u>	<u>29,605</u>	<u>66,570</u>	<u>58,741</u>
Operating costs and expenses:				
Cost of sales	4,545	4,140	9,226	8,291
Research and development	4,450	4,350	7,457	8,573
Selling, general and administrative	11,532	10,833	24,248	20,896
Total operating costs and expenses	<u>20,527</u>	<u>19,323</u>	<u>40,931</u>	<u>37,760</u>
Operating income	15,838	10,282	25,639	20,981
Other income, net	62	111	143	448
Net income before income taxes	15,900	10,393	25,782	21,429
Provision for income taxes	3,719	613	5,938	1,223
Net income	<u>\$ 12,181</u>	<u>\$ 9,780</u>	<u>\$ 19,844</u>	<u>\$ 20,206</u>
Net income per share:				
Basic	<u>\$ 0.12</u>	<u>\$ 0.09</u>	<u>\$ 0.19</u>	<u>\$ 0.20</u>
Diluted	<u>\$ 0.11</u>	<u>\$ 0.09</u>	<u>\$ 0.18</u>	<u>\$ 0.19</u>
Weighted average shares outstanding:				
Basic	<u>103,407,803</u>	<u>103,414,523</u>	<u>103,610,138</u>	<u>103,410,881</u>
Diluted	<u>107,734,924</u>	<u>106,730,423</u>	<u>107,299,262</u>	<u>106,433,862</u>

CATALYST PHARMACEUTICALS, INC.
RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP net income	\$ 12,181	\$ 9,780	\$ 19,844	\$ 20,206
Non-GAAP adjustments:				
Stock-based compensation expense	1,518	1,794	3,089	3,314
Depreciation	31	29	128	43
Income tax provision	3,719	613	5,938	1,223
Non-GAAP net income	<u>\$ 17,449</u>	<u>\$ 12,216</u>	<u>\$ 28,999</u>	<u>\$ 24,786</u>
Non-GAAP net income per share:				
Basic	<u>\$ 0.17</u>	<u>\$ 0.12</u>	<u>\$ 0.28</u>	<u>\$ 0.24</u>
Diluted	<u>\$ 0.16</u>	<u>\$ 0.11</u>	<u>\$ 0.27</u>	<u>\$ 0.23</u>
Weighted average shares outstanding – basic	<u>103,407,803</u>	<u>103,414,523</u>	<u>103,610,138</u>	<u>103,410,881</u>
Weighted average shares outstanding – diluted	<u>107,734,924</u>	<u>106,730,423</u>	<u>107,299,262</u>	<u>106,433,862</u>

CATALYST PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 135,295	\$ 130,237
Short-term investments	19,980	10,041
Accounts receivable, net	6,292	5,987
Inventory	7,097	4,651
Prepaid expenses and other current assets	7,641	8,328
Total current assets	176,305	159,244
Operating lease right-of-use asset	3,201	—
Property and equipment, net	914	130
Deferred tax assets	28,701	32,971
Deposits	9	9
Total assets	<u>\$ 209,130</u>	<u>\$ 192,354</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,924	\$ 4,256
Accrued expenses and other liabilities	13,211	18,500
Total current liabilities	16,135	22,756
Operating lease liability, net of current portion	4,051	—
Total liabilities	20,186	22,756
Total stockholders' equity	188,944	169,598
Total liabilities and stockholders' equity	<u>\$ 209,130</u>	<u>\$ 192,354</u>