

**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): May 10, 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

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	Ticker Symbol	Name of Exchange on Which Registered
Common Stock, par value \$0.001 per share	CPRX	NASDAQ Capital Market

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 May 10, 2021, the Company issued a press release announcing its results of operations for the three months ended March 31, 2021 and providing a business 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 May 10, 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: May 10, 2021



Catalyst Pharmaceuticals Announces First Quarter 2021 Financial Results and Provides Business Update

-Firdapse® Q1 2021 Net Revenues of \$30.2 Million

-First Quarter 2021 GAAP Net Income of \$7.7 Million; Non-GAAP Net Income of \$11.6 Million

-Recently Received Orphan Drug Designation for Firdapse® in Japan

-\$143.3 Million in Cash and Investments and no Funded Debt at end of Q1-2021

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

CORAL GABLES, Fla., May 10, 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 first quarter ended March 31, 2021 and provided a business update.

“I am extremely pleased with the execution of our operational plan for 2021 despite some continued headwinds due to the on-going COVID-19 pandemic. We are encouraged to see physician practices in many parts of the country opening their offices for in-person visits, but there are parts of the country that have been slow to re-open. What is most important is that our team has adapted and executed to ensure that all LEMS patients continue to have uninterrupted access to Firdapse®” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “As for the remainder of 2021, we are optimistic that we will continue to see the number of new patient enrollments accelerate which in turn will generate a strong uptake in Firdapse® revenues. At the same time we are advancing our other programs for the Firdapse® brand and are extremely focused on diversifying our product pipeline through acquisition or in-licensing activities that reflect our new strategic plan.”

Q1-21 Financial Results

- Total net revenue in Q1-21 was \$30.2 million, compared to \$29.1 million for Q1-20.
- Operating income in Q1-21 was \$9.8 million, compared to \$10.7 million in Q1-20.
- GAAP net income in Q1-21 was \$7.7 million, or \$0.07 per basic and diluted share, compared with net income in Q1-20 of \$10.4 million, or \$0.10 per basic and diluted share.
- Research and development expenses for the first quarter of 2021 were \$3.0 million as compared to \$4.2 million for the first quarter of 2020.
- Selling, general and administrative expenses for the first quarter of 2021 totaled \$12.7 million as compared to \$10.1 million in the first quarter of 2020.
- From inception during March 2021 of our share repurchase program through May 7, 2021 we have repurchased 507,555 common stock shares at an average price of \$4.49.
- Ended March 31, 2021 with \$143.3 million in cash and investments and no funded debt.

Corporate Milestones

- Expansion of our strategic focus to include acquiring or in-licensing innovative, technology platforms and earlier stage programs in other therapeutic categories outside of neuromuscular diseases.
- Commenced and made great progress in a national search for a Chief Product Development Officer, to oversee strategic development of any new drug candidates we acquire and manage portfolio planning and R&D activities (and we hope to onboard the person selected for this position in the second quarter of 2021).
- Actively engaged in evaluation of potential acquisitions of products or companies.
- Recently received Orphan Drug designation for Firdapse® in Japan.

Balance Sheet and Key Activities in 2021

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.
- Progressing further on our plan to obtain marketing authorization for Firdapse® in Japan.

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

Non-GAAP Financial Measures

Non-GAAP¹ net income for Q1-21 was \$11.6 million (\$0.11 per basic and diluted share), which excludes from GAAP net income of \$7.7 million (i) stock-based compensation expense of \$1.6 million, (ii) depreciation of \$0.1 million, and (iii) the provision for income taxes of \$2.2 million. This compares to non-GAAP¹ net income for Q1-20 of \$12.6 million (\$0.12 per basic and diluted share), which excludes from GAAP net income of \$10.4 million (i) stock-based compensation expense of \$1.5 million, (ii) depreciation of \$14 thousand, and (iii) the provision for income taxes of \$0.6 million. A tabular presentation of non-GAAP¹ net income for the first quarter of 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, May 11, 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 other rare diseases. 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 as a treatment for adults with LEMS. 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.

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 2021 net product revenues, (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 March 31,	
	2021	2020
Product revenue, net	\$ 30,205	\$ 29,137
Operating costs and expenses:		
Cost of sales	4,681	4,151
Research and development	3,007	4,223
Selling, general and administrative	12,716	10,063
Total operating costs and expenses	20,404	18,437
Operating income	9,801	10,700
Other income, net	81	336
Net income before income taxes	9,882	11,036
Provision for income taxes	2,219	610
Net income	\$ 7,663	\$ 10,426
Net income per share – basic and diluted	\$ 0.07	\$ 0.10
Weighted average shares outstanding – basic	103,814,725	103,407,347
Weighted average shares outstanding – diluted	106,680,344	106,534,600

CATALYST PHARMACEUTICALS, INC.

RECONCILIATION OF NON-GAAP METRICS (unaudited)

(in thousands, except share data)

	For the Three Months Ended March 31,	
	2021	2020
GAAP net income	\$ 7,663	\$ 10,426
Non-GAAP adjustments:		
Stock-based compensation expense	1,571	1,519
Depreciation	97	14
Income tax provision	2,219	610
Non-GAAP net income	\$ 11,550	\$ 12,569
Non-GAAP net income per share:		
Basic	\$ 0.11	\$ 0.12
Diluted	\$ 0.11	\$ 0.12
Weighted average shares outstanding – basic	103,814,725	103,407,347
Weighted average shares outstanding – diluted	106,680,344	106,534,600

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2021 (unaudited)	December 31, 2020
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 127,328	\$ 130,237
Short-term investments	15,971	10,041
Accounts receivable, net	5,601	5,987
Inventory	4,390	4,651
Prepaid expenses and other current assets	8,243	8,328
Total current assets	161,533	159,244
Operating lease right-of-use asset	3,309	—
Property and equipment, net	944	130
Deferred tax assets	31,421	32,971
Deposits	9	9
Total assets	<u>\$ 197,216</u>	<u>\$ 192,354</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,561	\$ 4,256
Accrued expenses and other liabilities	11,875	18,500
Total current liabilities	14,436	22,756
Operating lease liability, net of current portion	4,129	—
Total liabilities	18,565	22,756
Total stockholders' equity	178,651	169,598
Total liabilities and stockholders' equity	<u>\$ 197,216</u>	<u>\$ 192,354</u>