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 11, 2020

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 1250** **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 CFR240.14d-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 May 11, 2020, the Company issued a press release announcing its results of operations for the quarter ended March 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 May 11, 2020.

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 11, 2020

Catalyst Pharmaceuticals Announces First Quarter 2020 Financial Results and Provides Corporate Update

-Firdapse® Q1 2020 Net Revenues of $29.1 Million

-First Quarter 2020 GAAP Net Income of $10.4 Million

-Catalyst Withdraws Previous 2020 Revenue Guidance Due to COVID-19 Uncertainties

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

CORAL GABLES, Fla., May 11, 2020 (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 first quarter ended March 31, 2020 and provided a corporate update.

“I am very proud of the way that the entire Catalyst team has quickly responded and adapted in these challenging and unprecedented times to ensure the safety of all employees, while still providing uninterrupted access to Firdapse® for LEMS patients and continuing our support with their healthcare providers, albeit remotely” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “We entered 2020 with a very clear operational plan to drive the growth of the Firdapse franchise, advance our clinical development programs, including MuSK antibody positive Myasthenia Gravis, and secure our supply chain and safety stock of Firdapse. We have made progress against all of these objectives and our first quarter results reflect the solid execution of this plan.”

Q1-20 Financial Results

- Reported net product revenue of $29.1 million in the first quarter 2020 compared to $12.4 million in the first quarter of 2019, an increase of $16.7 million, or 134%.
- Reported GAAP net income of $10.4 million, or $0.10 per basic and diluted share, for the first quarter of 2020, compared with a GAAP net loss of $645 thousand, or $0.01 per basic and diluted share, for the first quarter of 2019.
- Research and development expenses for the first quarter of 2020 were $4.2 million as compared to $3.3 million for the first quarter of 2019.
- Selling, general and administrative expenses for the first quarter of 2020 totaled $10.1 million as compared to $8.4 million in the first quarter of 2019.
- Ended March 31, 2020 with $101.8 million in cash and investments and no funded debt.

Recent Developments and Highlights

- In the first quarter nearly doubled the size of our field sales force and contracted with a rare-disease experienced inside sales agency to support our commercial efforts.
- Increased our marketing efforts in non-personal promotion and digital communications.
- 46 new LEMS patients were prescribed Firdapse in first quarter of 2020.

Financial Highlights and Guidance

- Withdrawing previously provided 2020 revenue guidance due to the uncertainties surrounding COVID-19 disruptions to the healthcare system.
- Strong balance sheet with $101.8 million in cash and investments, and no funded debt.
- Focused on exercising financial discipline.

Upcoming Milestones

- Expect to report top-line results from Phase 3 trial for MuSK-MG in the third quarter of 2020.
- Expect to report top-line results from the SMA Type 3 proof of concept trial before the end of 2020.
- Expect potential approval of New Drug Submission (NDS) for Firdapse to treat LEMS in Canada in the second half of 2020.
- Expect to submit a supplemental NDA for Firdapse for MuSK-MG, assuming successful completion of the MSK-002 trial, later this year or early next year.

COVID-19 Impact

- Issued a no travel and remote work policy for all Catalyst employees on March 16th.
- Our first quarter revenues were minimally impacted by COVID-19.
- We believe that our current base of LEMS patients on reimbursed Firdapse is fairly stable and very compliant to their medication regimen.
- Top-line data for MuSK-MG trial has moved to third quarter as a result of clinical trial sites temporarily suspending trial activities.
- Have not experienced any disruptions in the supply chain or production of Firdapse.
- Completed manufacturing campaigns to provide Firdapse inventory through June 2021, with new campaigns underway.
- 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.

Financial Results

For the quarter ended March 31, 2020, Catalyst reported net income of $10.4 million, or $0.10 per basic and diluted share, compared to a net loss of $645 thousand, or $0.01 per basic and diluted share, for the same period in 2019. Excluding expenses related to stock-based compensation of $1.5 million, non-GAAP[1] net income for the first quarter of 2020 was $11.9 million, or $0.12 per basic share and $0.11 per diluted share. This compares to a non-GAAP[1] net income of $289 thousand, or $0.00 per basic and diluted share, excluding stock-based compensation expense of $933 thousand, for the first quarter of 2019.

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1 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 measure in this press release excludes 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.

Catalyst launched its first product, Firdapse, in January 2019. Related product revenues, net for the quarter ended March 31, 2020 were $29.1 million compared to $12.4 million in the same period of 2019. Cost of sales for the quarter ended March 31, 2020 were $4.2 million compared to $1.7 million in the same period in 2019.

Research and development expenses for the first quarter of 2020 were $4.2 million, compared to $3.3 million in the first quarter of 2019. The increase of $915 thousand in research and development expenses for the first three months of 2020 is primarily attributable to increases in headcount, medical and regulatory affairs, quality assurance programs, and expenses from our Firdapse clinical trials and studies, as well as an increase in non-cash employee-stock based compensation. The Company expects that costs related to research and development activities will continue to be substantial throughout 2020 as Catalyst continues its clinical programs evaluating Firdapse in MuSK-MG and SMA Type 3, continues its Expanded Access Program and sustained release product development program for Firdapse, begins to evaluate Firdapse as a treatment for other neuromuscular diseases and, assuming positive results from the trial, prepares a sNDA for Firdapse for the treatment of MuSK-MG.

Selling, general and administrative expenses for the first quarter of 2020 totaled $10.1 million as compared to $8.4 million in the first quarter of 2019. The increase when compared to the same period in 2019 is primarily due to additional cost from expansion of the sales force and contracting with a rare-disease experienced inside sales agency, and an increase in non-cash stock-based compensation. The Company expects selling, general and administrative expenses to increase in 2020, as the Company continues to build its infrastructure and commercial and patient programs in support of Firdapse sales activities.

At March 31, 2020, Catalyst had cash and cash equivalents and investments of $101.8 million and no funded-debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations for at least the next 12 months.

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 11, 2020.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday, May 12, 2020 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 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 spinal muscular atrophy (SMA) Type 3. Catalyst's new drug application for Firdapse® (amifampridine) 10 mg tablets for the treatment of adults with LEMS was approved in November 2018 by the U.S. Food & Drug Administration ("FDA"), and Firdapse is now commercially available in the United States as a treatment for adults (age 17 and up) with LEMS. Prior to its approval, Firdapse for LEMS had received breakthrough therapy designation and orphan drug designation from the FDA.

Firdapse is currently being evaluated in clinical trials for the treatment of MuSK-MG and SMA Type 3 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 impact of the effects of the COVID-19 pandemic on Catalyst's 2020 net product revenues and on the timeline for reporting the top-line results from Catalyst's MuSK-MG trial and SMA Type 3 proof-of-concept study, and (ii) those factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2019 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.

Investor Contact
Brian Korb
Solebury Trout
(646) 378-2923
bkorb@troutgroup.com

Company Contact
Patrick J. McEnany
Catalyst Pharmaceuticals
Chief Executive Officer
(305) 420-3200
pmcenany@catalystpharma.com

Media Contact
David Schull
Russo Partners
(212) 845-4271
david.schull@russopartnersllc.com

CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Product revenue, net	$ 29,136,472	$ 12,448,438
Operating costs and expenses:		
Cost of sales	4,150,866	1,711,788
Research and development	4,222,811	3,307,959
Selling, general and administrative	10,063,048	8,416,460
Total operating costs and expenses	18,436,725	13,436,207
Operating income (loss)	10,699,747	(987,769)
Other income, net	336,233	343,266
Net income (loss) before income taxes	11,035,980	(644,503)
Provision for income taxes	609,965	—
Net income (loss)	$ 10,426,015	$ (644,503)
Net income (loss) per share – basic and diluted	$ 0.10	$ (0.01)
Weighted average shares outstanding – basic	103,407,347	102,747,923
Weighted average shares outstanding – diluted	106,534,600	102,747,923

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 101,750,937	$ 89,511,710
Short-term investments	—	5,007,050
Accounts receivable, net	6,918,563	10,536,997
Inventory	2,211,338	1,956,792
Prepaid expenses and other current assets	6,062,715	4,351,074
Total current assets	116,943,553	111,363,623
Operating lease right-of-use asset	730,284	793,252
Property and equipment, net	196,926	210,467
Deposits	8,888	8,888
Total assets	$ 117,879,651	$ 112,376,230
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,347,577	$ 4,117,447
Accrued expenses and other liabilities	16,287,936	19,981,295
Total current liabilities	17,635,513	24,098,742
Operating lease liability, net of current portion	568,421	647,532
Total liabilities	18,203,934	24,746,274
Total stockholders' equity	99,675,717	87,629,956
Total liabilities and stockholders' equity	$ 117,879,651	$ 112,376,230