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 16, 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 March 16, 2020, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2019 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 16, 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: March 16, 2020

Catalyst Pharmaceuticals Reports Fourth Quarter and Year-End 2019 Financial Results and Provides Corporate Update

-Firdapse® Q4 Net Revenues of $30 Million, FY 19 Net Revenues of $102 Million

-GAAP Net Income of $32 Million for Fiscal Year 2019

-Catalyst Reiterates Net Revenue Guidance in the Range of $135 Million to $155 Million for FY 2020

-Firdapse Supply Chain in Solid Position-Significant Safety Stock

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

CORAL GABLES, Fla., March 16, 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 fourth quarter and year-ended December 31, 2019 and provided a corporate update.

Patrick J. McEnany, Catalyst's Chairman and CEO, stated: "2019 was an outstanding year for Catalyst as we evolved into a commercial-stage pharmaceutical company and successfully launched Firdapse® (amifampridine) tablets 10 mg in the U.S. for the treatment of adult LEMS patients. I am very proud of our patient-centric team's performance and it is inspiring to see how we are improving the lives of LEMS patients every day."
Mr. McEnany continued: "Catalyst has exceeded all expectations for product revenues and the number of patients who are currently being treated with Firdapse. We remain dedicated to expanding our label for Firdapse to include other neuromuscular conditions, including MuSK-MG where we expect to report top-line data in the second quarter of this year."

Mr. McEnany continued: "In the face of the coronavirus Covid-19 outbreak, we have been asked by patients, healthcare providers and investors about our ability to provide a continuous uninterrupted supply of Firdapse. Let me reassure you that we are well prepared and well-stocked for any contingencies. Our API (active pharmaceutical ingredients) and finished dosage form are sourced from U.S. manufacturers, which are some of the largest in the world. We also have a qualified second U.S. manufacturer of our finished dosage form, if ever required. Finally, as of today we have more than an adequate supply of Firdapse ready for shipment in the warehouse to meet patient's needs through the end of this year. We currently have a campaign underway that will within the next two weeks provide another six months of inventory beyond December. Our supply chain and safety stock are solid."

Q4-19 and FY-19 Financial Results

- Reported product revenue, net of $30.1 million in the fourth quarter 2019 and $102.3 million for the full year 2019
- Reported net income of $31.9 million for the 2019 year ($0.31 per basic share and $0.30 per diluted share), compared with a net loss of $34.0 million ($0.33 per basic and diluted share) for the year 2018

- Selling, general and administrative expenses for the fourth quarter of 2019 totaled $11.4 million as compared to $6.9 million in the fourth quarter of 2018
- Research and development expenses for the fourth quarter of 2019 were $6.3 million as compared to $8.4 million for the fourth quarter of 2018
- Ended December 31, 2019 with $94.5 million in cash and investments and no funded debt

Recent Developments and Highlights

- Reported a total of 532 cumulative Firdapse patient enrollments at the end of 2019 since commercial launch in January 2019
- Reported that over 190 patients previously naïve to any form of 3,4-DAP were enrolled in *Catalyst Pathways*™ at the end of the fourth quarter
- Completed enrollment in pivotal Phase 3 anti-MuSK antibody positive Myasthenia Gravis trial
- Over 345 patients actively receiving an insurance reimbursed Firdapse prescription at the end of 2019
- Ongoing commercial expansion, including growth in sales and marketing departments
- Filed New Drug Submission (NDS) with Health Canada for Firdapse to treat LEMS and have been granted a Priority Review

Revenue Guidance

- The Company expects full-year 2020 Firdapse net revenues to be in the range of $135 million to $155 million

Upcoming Milestones

- Expect to report top-line results from Phase 3 trial for MuSK-MG in the second quarter of 2020
- Expect to report top-line results from the SMA Type 3 proof of concept trial in the second quarter of 2020
- Expect potential approval of New Drug Submission (NDS) for Firdapse to treat LEMS in Canada in the second half of 2020
- Assuming the MuSK-MG trial is successful, we hope to submit a supplemental NDA for Firdapse for MuSK-MG around the end of 2020

Financial Results

For fiscal year ended December 31, 2019, Catalyst reported GAAP net income of $31,875,337, or $0.31 per basic share and $0.30 per diluted share, compared to a GAAP net loss of $34,003,514, or $0.33 per basic and diluted share, for the 2018 fiscal year. Excluding expenses related to stock-based compensation of $3,824,815, non-GAAP[1] net income for the fiscal year ended December 31, 2019 was $35,700,152, or $0.35 per basic share and $0.34 per diluted share. This compares to a non-GAAP[1] net loss of $30,452,870, or $0.30 per basic and diluted share, excluding stock-based compensation expense of $3,550,644, for the 2018 fiscal year.

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. Product revenue, net for the quarter and year ended December 31, 2019 were $30,122,555 and $102,306,337, respectively. Cost of sales for the quarter and year ended December 31, 2019 were $4,398,265 and $14,759,139, respectively. During fourth quarter and fiscal year 2018, Catalyst had no revenues from product sales and revenues from collaboration agreements of $500,000 from its collaboration with Endo for generic Sabril.

For the quarter ended December 31, 2019, Catalyst reported GAAP net income of $7,929,713, or $0.08 per basic share and $0.07 per diluted share, compared to a GAAP net loss of $14,499,609, or $0.14 per basic and diluted share, for the 2018 fiscal year.

Research and development expenses for the fiscal year ended December 31, 2019 were $18,842,752, compared to $19,919,204 for the 2018 fiscal year. For the fourth quarter of 2019, research and development expenses were $6,308,390, compared to $8,416,969 for the fourth quarter of 2018. Research and development expenses for the quarter and year ended December 31, 2019 primarily consisted of expenses for medical and regulatory affairs and quality assurance programs, as well as expenses from Catalyst's ongoing clinical trials and studies evaluating Firdapse for the treatment of other ultra-orphan neuromuscular diseases and its Expanded Access Program. Research and development expenses in the comparable period in 2018, primarily consisted of consulting expenses and milestones as the Company submitted and the FDA approved an NDA for Firdapse for the treatment of adults with LEMS, as well as expenses from Catalyst's clinical trials and studies and its Expanded Access Program. The Company expects that costs related to research and development activities will continue to be substantial throughout 2020 as Catalyst completes its on-going clinical trials and studies in MuSK-MG and SMA Type 3 and continues its Expanded Access Program and sustained release product development program for Firdapse.

Selling, general and administrative expenses for the fiscal year ended December 31, 2019 totaled $36,881,187, compared to $15,875,961 in the 2018 fiscal year. For the fourth quarter of 2019, selling, general and administrative expenses totaled $11,409,213, compared to $6,926,298 in the same period in 2018. The increase year over year is primarily due to increased selling expenses, including costs of commercial system implementation, expansion of the Company's sales force and supporting personnel, product launch expenses, market access and market research expenses, and professional fees associated with Catalyst's lawsuit against the FDA. 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 and pursues its lawsuit against the FDA.

At December 31, 2019, Catalyst had cash and cash equivalents and investments of $94.5 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 from this date.

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 16, 2020.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Tuesday, March 17, 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) whether the Company's forecast for net revenue in full year 2020 will prove correct, (ii) whether Catalyst can successfully increase sales of Firdapse from current levels through expansion of its sales personnel, (iii) whether, even if Catalyst achieves its forecasted net revenue targets, it will remain profitable, (iv) whether Catalyst will be able to compete successfully for adult LEMS patients against off-label use of Ruzurgi® (which is priced lower than Firdapse), (v) whether payors will, in the future, require that patients try off-label Ruzurgi first before such payors will approve Firdapse as a treatment for adult LEMS patients (vi) whether Catalyst's NDS for Firdapse accepted for filing with Health Canada will be approved; (vii) whether Catalyst will report results in its current clinical trials on a timely basis, particularly because of the possible impact of the recent coronavirus ourtbreak, (viii) whether Firdapse will ever be approved for the treatment of MuSK-MG, SMA Type 3, or any other disease, and (ix) the impact on our business generally of the economic disruptions that may occur because of the recent coronavirus outbreak, and (x) those other factors described in Catalyst's Annual Report on Form 10-K for fiscal year 2019 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. Investors are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date made. While Catalyst may voluntarily do so from time to time, Catalyst undertakes no commitment to update forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by applicable securities laws.

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CATALYST PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	(unaudited) For the Three Months Ended December 31,		For the Year Ended December 31,	
	2019	2018	2019	2018
Product revenue, net	$ 30,122,555	$ —	$102,306,337	$ —
Revenues from collaborative arrangement	—	500,000	—	500,000
Total revenues	30,122,555	500,000	102,306,337	500,000
Operating costs and expenses:				
Cost of sales	4,398,265	—	14,759,139	—
Research and development	6,308,390	8,416,969	18,842,752	19,919,204
Selling, general and administrative	11,409,213	6,926,298	36,881,187	15,875,961
Total operating costs and expenses	22,115,868	15,343,267	70,483,078	35,795,165
Operating income (loss)	8,006,687	(14,843,267)	31,823,259	(35,295,165)
Other income, net	398,683	343,658	1,585,774	1,291,651
Net income (loss) before income taxes	8,405,370	(14,499,609)	33,409,033	(34,003,514)
Provision for income taxes	475,657	—	1,533,696	—
Net income (loss)	$ 7,929,713	$ (14,499,609)	$ 31,875,337	$ (34,003,514)
Net income (loss) per share:				
Basic	$ 0.08	$ (0.14)	$ 0.31	$ (0.33)
Diluted	$ 0.07	$ (0.14)	$ 0.30	$ (0.33)
Weighted average shares outstanding:				
Basic	103,180,946	102,738,170	102,944,316	102,633,884
Diluted	106,567,001	102,738,170	106,020,936	102,633,884

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 89,511,710	$16,559,400
Short-term investments	5,007,050	36,922,213
Accounts receivable, net	10,536,997	—
Inventory	1,956,792	56,012
Prepaid expenses and other current assets	4,351,074	1,649,781
Total current assets	111,363,623	55,187,406
Investments	—	5,008,243
Operating lease right-of-use asset	793,252	—
Property and equipment, net	210,467	245,425
Deposits	8,888	8,888
Total assets	$112,376,230	$60,449,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 4,117,447	$ 2,337,367
Accrued expenses and other liabilities	19,981,295	7,173,987
Total current liabilities	24,098,742	9,511,354
Accrued expenses and other liabilities, non-current	—	154,799
Operating lease liability, net of current portion	647,532	—
Total liabilities	24,746,274	9,666,153
Total stockholders' equity	87,629,956	50,783,809
Total liabilities and stockholders' equity	$112,376,230	$60,449,962