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 12, 2019

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

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

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 12, 2019, the Company issued a press release announcing its results of operations for the three and nine months ended September 30, 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 November 12, 2019.

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 12, 2019

Exhibit 99.1

Catalyst Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Corporate Update

- Firdapse® Launch Momentum Continues with Q3 Net Revenues of $30.9 Million

-Third Quarter GAAP Net Income of $13.6 Million

-Catalyst Provides Net Revenue Guidance – Approximately $100 Million for FY 2019 and range of $135 Million to $155 Million for FY 2020

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

CORAL GABLES, Fla., November 12, 2019 (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 third quarter ended September 30, 2019 and provided a corporate update.

"We are pleased with the continued strength of our commercial launch for Firdapse® in adult LEMS patients and are very encouraged by the feedback we have received from LEMS patients, including high levels of satisfaction regarding their treatment journey through *Catalyst Pathways*™, our patient assistance program," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. "While the U.S. launch of Firdapse remains our primary focus, we have made significant progress on our other strategic priorities. These include our recent filing of a New Drug Submission (NDS) for Firdapse with Health Canada, for which we have been granted a Priority Review. In addition, we recently met with Japanese regulatory authorities about registration requirements to obtain approval of Firdapse for Japan. Our team has done an excellent job in executing our business plan this year, and we are on track to meet all of our goals and objectives for 2019 as we move into the new year."

Q3-19 Financial Results

- Reported product revenue, net in the third quarter 2019 of $30.9 million
- Reported net income of $13.6 million, or $0.13 per basic and diluted share, in the third quarter of 2019, compared with a net loss of $7.8 million, or $0.08 per basic and diluted share, for the third quarter of 2018
- Selling, general and administrative expenses for the third quarter of 2019 totaled $8.1 million as compared to $3.6 million in the third quarter of 2018
- Research and development expenses for the third quarter of 2019 were $4.6 million as compared to $4.5 million for the third quarter of 2018
- Ended September 30, 2019 with $81.6 million in cash and investments and no funded debt

Recent Developments and Highlights

- Reported a total of 494 cumulative Firdapse unique patient enrollments at the end of the third quarter since commercial launch at beginning of year
- Reported that over 170 patients previously naïve to any form of3,4-DAP were enrolled in *Catalyst Pathways* at the end of the third quarter
- Over 370 patients actively receiving an insurance-reimbursed Firdapse prescription at the end of the third quarter
- Announced top-line results from CMS-001 Phase 3 trial of Firdapse for CMS
- Continued with global expansion efforts of Firdapse for LEMS with recent meetings with Japanese regulatory authorities to discuss regulatory path forward in Japan
- Recently 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 2019 net revenues to be approximately $100 million
- The Company expects full-year 2020 net revenues to be in the range of $135 million to $155 million
- Both the 2019 and the 2020 net revenue forecast assume only sales of Firdapse for the treatment of adult LEMS patients

Upcoming Milestones

- Expect to meet with the FDA beforeyear-end to discuss CMS-001 study outcome and path forward
- Expect to report top-line results from Phase 3 trial for MuSK-MG in the first half of 2020
- Expect to report top-line results from the SMA Type 3 proof of concept trial in the first half of 2020

Financial Results

For the quarter ended September 30, 2019, Catalyst reported net income of $13,630,179, or $0.13 per basic and diluted share, compared to a net loss of $7,838,873, or $0.08 per basic and diluted share, for the same period in 2018. For the nine months ended September 30, 2019, Catalyst reported net income of $23,945,624, or $0.23 per basic and diluted share, as compared to a net loss of $19,503,905, or $0.19 per basic and diluted share, for the same period in 2018.

Catalyst launched its first product, Firdapse, in January 2019. Product revenue, net for the quarter and nine months ended September 30, 2019 were $30,897,444 and $72,183,782, respectively. Cost of sales for the quarter and nine months ended September 30, 2019 were $4,387,461 and $10,360,874, respectively.

Research and development expenses for the third quarter of 2019 were $4,597,039 as compared to $4,538,369 in the third quarter of 2018. For the nine months ended September 30, 2019, research and development expenses were $12,534,362 as compared to $11,502,235 in the same period in 2018. Research and development expenses for the three and nine months ended September 30, 2019 primarily consisted of expenses for medical and regulatory affairs and quality assurance programs, as well as expenses from our ongoing clinical trials and studies evaluating Firdapse for the treatment of other ultra-orphan neuromuscular diseases and our Expanded Access Program. Research and development expenses in the comparable period in 2018, primarily consisted of consulting expenses as the Company submitted an NDA for Firdapse for the treatment of LEMS, as well as expenses from Catalyst's ongoing 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 2019 as it continues its on-going clinical trials and studies in MuSK-MG and SMA Type 3 and its Expanded Access Program for Firdapse.

Selling, general and administrative expenses for the third quarter of 2019 totaled $8,067,792 as compared to $3,644,234 in the third quarter of 2018. For the nine months ended September 30, 2019, selling, general and administrative expenses were $25,471,974 as compared to $8,949,663 in the same period in 2018. The increase when compared to the same period in 2018 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 2019 and into 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 September 30, 2019, Catalyst had cash and cash equivalents and investments of $81.6 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 Form10-Q, which was filed with the Securities and Exchange Commission (SEC) on November 12, 2019.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. ET, tomorrow, Wednesday, November 13, 2019 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 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), congenital myasthenic syndromes (CMS), 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.

Firdapse is being evaluated in clinical trials for the treatment ofMuSK-MG and SMA Type 3 and has received Orphan Drug Designation from the FDA for CMS and myasthenia gravis. Firdapse (amifampridine) 10 mg tablets is the first and only approved drug in Europe for the symptomatic treatment in adults 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) whether the Company's forecast for net revenue in full year 2019 and full year 2020 will prove correct, (ii) whether Catalyst can successfully increase sales of Firdapse through expansion of its sales personnel from current levels, (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 filed with Health Canada will be accepted for filing, and even if it is accepted for filing, whether it will be approved; (vii) whether Firdapse will ever be approved for the treatment of CMS, MuSK-MG, SMA Type 3, or any other disease, and (viii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2018 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 September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Product revenue, net	$ 30,897,444	$ —	$ 72,183,782	$ —
Operating costs and expenses:				
Cost of sales	4,387,461	—	10,360,874	—
Research and development	4,597,039	4,538,369	12,534,362	11,502,235
Selling, general and administrative	8,067,792	3,644,234	25,471,974	8,949,663
Total operating costs and expenses	17,052,292	8,182,603	48,367,210	20,451,898
Operating income (loss)	13,845,152	(8,182,603)	23,816,572	(20,451,898)
Other income, net	393,415	343,730	1,187,091	947,993
Net income (loss) before income taxes	14,238,567	(7,838,873)	25,003,663	(19,503,905)
Provision for income taxes	608,388	—	1,058,039	—
Net income (loss)	$ 13,630,179	$ (7,838,873)	$ 23,945,624	$ (19,503,905)
Net income (loss) per share:				
Basic	$ 0.13	$ (0.08)	$ 0.23	$ (0.19)
Diluted	$ 0.13	$ (0.08)	$ 0.23	$ (0.19)
Weighted average shares outstanding:				
Basic	102,974,105	102,641,504	102,864,571	102,598,740
Diluted	107,045,234	102,641,504	105,821,609	102,598,740

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$44,983,218	$16,559,400
Short-term investments	31,561,673	36,922,213
Accounts receivable, net	10,095,352	—
Inventory	599,801	56,012
Prepaid expenses and other current assets	3,339,399	1,649,781
Total current assets	90,579,443	55,187,406
Investments	5,008,800	5,008,243
Operating lease right-of-use asset	952,340	—
Property and equipment, net	141,088	245,425
Deposits	8,888	8,888
Total assets	$96,690,559	$60,449,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 4,147,029	$ 2,337,367
Accrued expenses and other liabilities	13,835,292	7,173,987
Total current liabilities	17,982,321	9,511,354
Accrued expenses and other liabilities, non-current	—	154,799
Operating lease liability, net of current portion	725,700	—
Total liabilities	18,708,021	9,666,153
Total stockholders' equity	77,982,538	50,783,809
Total liabilities and stockholders' equity	$96,690,559	$60,449,962