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 18, 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 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 18, 2019, the Company issued a press release announcing its results of operations for the fourth quarter and fiscal year ended December 31, 2018 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 18, 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: March 18, 2019

Exhibit 99.1

Catalyst Pharmaceuticals Announces Fourth Quarter and Year-End 2018 Financial Results and Provides Corporate Update

CORAL GABLES, Fla., March 18, 2019 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq: CPRX), a 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, 2018 and provided a corporate update.

“2018 was a transformational year for Catalyst with the approval of Firdapse® (amifampridine phosphate) tablets, the first and only evidence-based, FDA approved treatment for patients with Lambert-Eaton myasthenic syndrome or LEMS. With this approval, all adult LEMS patients will now have affordable access to Firdapse,” said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals. “We are pleased with the robust momentum that we have seen since the launch of Firdapse, including patient enrollment forms, the breadth of prescribers, and positive reimbursement trends. In 2019, we will remain laser-focused on the commercial launch of Firdapse, as well as on our efforts in the clinic to evaluate Firdapse as a potential therapy to treat other rare neuromuscular diseases.”

2018 and Recent Highlights

- FDA approval of Firdapse for the treatment of LEMS in adults
- Launched Firdapse for LEMS in January 2019
- Introduced Catalyst Pathways™ program to ensure proper patient support on Firdapse
- Enrolled first patient in SMA Type 3 proof of concept trial
- Enrolled first patient in MuSK-MG phase 3 trial
- Entered into a definitive agreement to partner with Endo/Par Pharmaceutical for generic Sabril tablets
- Ended December 31, 2018 with $58.5 million in cash and investments and no debt

Upcoming Milestone

- First quarter revenue and initial launch results
- Expect to complete enrollment in MuSK-MG and CMS phase 3 clinical trials
- Expect top-line results from Phase 3 trial for MuSK-MG in the second half of 2019
- Expect top-line results from Phase 3 trial for CMS in the second half of 2019
- Expect top-line results for SMA Type 3 proof of concept trial in the first half of 2020

Fourth Quarter and Full-Year 2018 Financial Results

For the year ended December 31, 2018, Catalyst reported a GAAP net loss of $34,003,514, or $0.33 per basic and diluted share, compared to a GAAP net loss of $18,412,377, or $0.21 per basic and diluted share, for the 2017 fiscal year. For 2018, non-GAAP[1] net loss was the same as GAAP net loss, as there were no non-GAAP[1] adjustments. Excluding non-cash loss of $186,904 attributable to the change in fair value of liability-classified warrants, non-GAAP[1] net loss was $18,225,473, or $0.21 per basic and diluted share, for the year ended December 31, 2017.

For the quarter ended December 31, 2018, Catalyst reported a GAAP net loss of $14,499,609, or $0.14 per basic and diluted share, compared to a GAAP net loss of $5,387,698, or $0.06 per basic and diluted share, for the 2017 fiscal year. For the fourth quarter of 2018 and 2017, non-GAAP[1] net loss was the same as GAAP net loss as there were no non-GAAP[1] adjustments.

Research and development expenses for the year ended December 31, 2018 were $19,919,204, compared to $11,375,237 for the 2017 fiscal year. For the fourth quarter of 2018, research and development expenses were $8,416,969, compared to $3,404,634 for the fourth quarter of 2017. The increase in research and development for 2018 when compared to 2017 is primarily due to increases in consulting expenses as Catalyst prepared to submit its NDA for Firdapse during the first quarter of 2018, milestone expenses relating to the acceptance and approval of Catalyst's NDA submission, expenses from Catalyst's medical affairs program, and compensation and related personnel costs as Catalyst expanded its headcount to support its currently ongoing trials and programs. Catalyst expects that costs related to research and development activities will continue to be substantial in 2019 as Catalyst works towards completing trials evaluating Firdapse for the treatment of CMS, MuSK-MG and SMA Type 3, continues its Expanded Access Program for Firdapse, and begins development of a sustained release formulation for Firdapse.

General and administrative expenses for the year ended December 31, 2018 totaled $15,875,961, compared to $7,304,399 in the 2017 fiscal year. For the fourth quarter of 2018, general and administrative expenses totaled $6,926,298, compared to $2,107,152 in the same period in 2017. Pre-commercialization costs of $6,897,483 and $809,584, respectively, were included in general and administrative expense in 2018 and 2017. The increase when compared to 2017 is primarily due to increases in pre-commercialization expenses, and headcount and corporate expenses as Catalyst built up its infrastructure and commercial programs in preparation for the launch of Firdapse in the first quarter 2019. Catalyst expects that going forward general and administrative expenses, excluding commercialization expenses, will be reported as selling expenses, and will continue to increase in 2019 as Catalyst continues to expand its operations to support the launch of Firdapse.

During the fourth quarter and year 2018, Catalyst had revenues of $500,000 from its collaboration with Endo for generic Sabril that began during December 2018. Catalyst had no revenues for the fourth quarter or year 2017.

At December 31, 2018, Catalyst had cash and investments of $58.5 million and no debt. Based on its current financial position and its forecasts of available cash, Catalyst believes that it has sufficient funds to support its operations for at least the next 12 months.

More detailed financial information and analysis can be found in Catalyst's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the Securities and Exchange Commission earlier today.

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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 loss the expense (or the income) associated with the change in fair value of the liability-classified warrants. Non-GAAP net loss per share is calculated by dividing non-GAAP net loss 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, March 19, 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 Investor's page of the Company's website at www.catalystpharma.com and clicking on the webcast link on the Investor's home page. A webcast replay will be available on the Catalyst website for 30 days following the call by visiting the Investor's 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), congenital myasthenic syndromes (CMS), 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 recently approved by the U.S. Food & Drug Administration ("FDA"), and Firdapse is now commercially available in the United States. 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 CMS, MuSK-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 Catalyst will be successful in commercializing Firdapse, (ii) whether, even if Catalyst is successful in commercializing Firdapse, Catalyst will become profitable, (iii) whether Firdapse will ever be approved for the treatment of CMS, MuSK-MG, SMA Type 3, or any other disease, and (iv) 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. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

Investor Contact
Brian Korb
The Trout Group LLC
(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

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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,	
	2018	2017	2018	2017
Revenues from collaborative arrangement	$ 500,000	$ —	$ 500,000	$ —
Operating costs and expenses:				
Research and development	$ 8,416,969	$ 3,404,634	$ 19,919,204	$ 11,375,237
General and administrative	6,926,298	2,107,152	15,875,961	7,304,399
Total operating costs and expenses	15,343,267	5,511,786	35,795,165	18,679,636
Loss from operations	(14,843,267)	(5,511,786)	(35,295,165)	(18,679,636)
Other income, net	343,658	124,088	1,291,651	454,163
Change in fair value of warrants liability	—	—	—	(186,904)
Loss before income taxes	(14,499 609)	(5,387,698)	(34,003,514)	(18,412,377)
Provision for income taxes	—	—	—	—
Net loss	$ (14,499 609)	$ (5,387,698)	$ (34,003,514)	$(18,412,377)
Net loss per share – basic and diluted	$ (0.14)	$ (0.06)	$ (0.33)	$ (0.21)
Weighted average shares outstanding – basic and diluted	102,738,170	91,451,695	102,633,884	85,802,487

CATALYST PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$16,559,400	$57,496,702
Short-term investments	36,922,213	26,516,711
Inventory	56,012	—
Prepaid expenses and other current assets	1,649,781	1,173,744
Total current assets	55,187,406	85,187,157
Investments	5,008,243	—
Property and equipment, net	245,425	191,385
Deposits	8,888	8,888
Total assets	$60,449,962	$85,387,430
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,337,367	$ 1,945,575
Accrued expenses and other liabilities	7,173,987	2,320,587
Total current liabilities	9,511,354	4,266,162
Accrued expenses and other liabilities, non-current	154,799	157,456
Total liabilities	9,666,153	4,423,618
Total stockholders' equity	50,783,809	80,963,812
Total liabilities and stockholders' equity	$60,449,962	$85,387,430