March 14, 2018

Catalyst Pharmaceuticals Announces Fourth Quarter and Year-End 2017 Financial Results and Provides Corporate Update

--Firdapse® NDA to be Resubmitted Before the End of this Quarter

--Significant Progress with MuSK-MG Regulatory and Clinical Program

--$84M Year-End Cash and Investments

--Company to Host Quarterly Conference Call at 5:00 pm ET Today

CORAL GABLES, Fla., March 14, 2018 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (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, 2017.

"Throughout 2017, we made significant progress in successfully completing our second Phase 3 trial evaluating Firdapse for the treatment of Lambert-Eaton Myasthenic Syndrome (LEMS) and successfully completing the required abuse liability studies that confirmed that Firdapse does not exhibit abuse potential. We also continued to build our rare neuromuscular disease platform as we prepared to enroll subjects in our Phase 3 clinical trial for MuSK antibody positive myasthenia gravis and our proof-of-concept clinical trial for spinal muscular atrophy Type 3," said Patrick J. McEnany, Chairman and Chief Executive Officer of Catalyst Pharmaceuticals, Inc. "We remain on track to resubmit our NDA for Firdapse this quarter, and we are actively engaged in pre-commercialization activities for a potential launch of Firdapse."

2017 and Recent Highlights

- Announced top-line results in LMS-003 trial, reaching both primary and secondary endpoints and completed required abuse liability studies
- Announced positive data from investigator-sponsored trial of Firdapse in treating MuSK antibody positive Myasthenia Gravis
- Confirmed timeline for NDA resubmission for Firdapse expected first quarter of 2018 following a positive Type C meeting recently held with the FDA
- Announced Phase 2 study of Firdapse in ambulatory patients with Spinal Muscular Atrophy (SMA) Type 3
- Reached an agreement with the FDA under SPA for Phase 3 Firdapse in MuSK-MG trial
- Reinitiated pre-commercialization activities for a potential launch of Firdapse
- Raised $53.8M in net proceeds from a public offering in November
- Ended December 31, 2017 with $84.0 million in cash and investments and no debt

Upcoming Milestones

- Resubmit NDA for Firdapse in the first quarter of 2018
- Enroll first subject in Phase 3 trial for MuSK-MG in H1 2018
- Enroll first subject in SMA Type 3 proof of concept trial in the second quarter of 2018
- Expect to complete enrollment in the Phase 3 CMS (CMS-001) trial before the end of 2018 and to report top-line results from this trial in the first quarter of 2019

Fourth Quarter and Full-Year 2017 Financial Results

For the year ended December 31, 2017, Catalyst reported a GAAP net loss of $18,412,377, or $0.21 per basic and diluted share, compared to a GAAP net loss of $18,072,452, or $0.22 per basic and diluted share, for the 2016 fiscal year. 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. In comparison, Non-GAAP[1] net loss for the year ended December 31, 2016 was $18,958,589, or $0.23 per basic and diluted share, which excludes non-cash gain of $886,137 attributable to the change in fair value of liability-classified warrants.

For the quarter ended December 31, 2017, Catalyst reported a GAAP net loss of $5,387,698, or $0.06 per basic and diluted share, compared to a GAAP net loss of $4,163,320, or $0.05 per basic and diluted share, for the 2016 fiscal year. For the fourth quarter of 2017, Non-GAAP[1] net loss was the same as GAAP net loss as there were no Non-GAAP[1] adjustments. In comparison, Non-GAAP[1] net loss for the fourth quarter of 2016 was $4,270,266, or $0.05 per basic and diluted share, which excludes non-cash gain of $106,946 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the year ended December 31, 2017 were $11,375,237, compared to $11,369,941 for the 2016 fiscal year. For the fourth quarter of 2017, research and development expenses were $3,404,634, compared to $2,820,654 for the fourth quarter of 2016. Research and development expenses in 2017 were consistent with amounts expended in 2016, and included expenses related to ongoing studies and trials for Firdapse, the costs of Catalyst's Firdapse Expanded Access Program, and costs of Catalyst's CPP-115 and generic Sabril® programs. Catalyst expects that its R&D spend for 2018 will continue to be substantial as Catalyst completes its clinical trial for CMS, continues its Expanded Access Program, continues its clinical programs for MuSK-MG and SMA Type 3, prepares the NDA submission for Firdapse, and manufactures Firdapse launch supplies.

General and administrative expenses for the year ended December 31, 2017 totaled $7,304,399, compared to $7,910,260 in the 2016 fiscal year. For the fourth quarter of 2017, general and administrative expenses totaled $2,107,152, compared to $1,493,545 in the same period in 2016. The decrease in general and administrative expenses from 2017 to 2016 was primarily due to Catalyst's efforts to conserve cash after the receipt of the FDA's "refusal to file letter" for Firdapse. Catalyst expects that general and administrative costs will increase in 2018, as Catalyst prepares for the commercialization of Firdapse.

Catalyst had no revenues in the year 2017 or 2016.

At December 31, 2017, Catalyst had cash and investments of $84 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 through 2019 (without considering revenues and cash receipts that may be received in 2019 if Catalyst is successful in obtaining an approval of Firdapse and launching the product in 2019, of which there can be no assurance).

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, 2017, which was filed with the Securities and Exchange Commission, earlier today, March 14, 2018.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 5:00 p.m. ET, today, Wednesday, March 14, 2018 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), congenital myasthenic syndromes (CMS), MuSK antibody positive myasthenia gravis, and infantile spasms. Firdapse® has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of LEMS and Orphan Drug Designation for LEMS, CMS and myasthenia gravis. Firdapse is the first and only approved drug in Europe for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat refractory infantile spasms. CPP-115 has been granted U.S. Orphan Drug Designation for the treatment of infantile spasms by the FDA and has been granted E.U. Orphan Medicinal Product Designation for the treatment of West syndrome by the European Commission. In addition, Catalyst is developing a generic version of Sabril® (vigabatrin).

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 results of the LMS-003 trial, combined with the results of the Company's

previous Phase 3 trial, will be acceptable to the FDA as support for an approval of Firdapse for the treatment of LEMS, (ii) whether the results of the abuse liability studies undertaken by Catalyst will be acceptable to the FDA as support for an approval of Firdapse, (iii) whether any NDA submitted for Firdapse will be accepted by the FDA, and the timing of any such submission and acceptance, (iv) whether the receipt of breakthrough therapy designation for Firdapse will expedite the development and review of Firdapse by the FDA or the likelihood that the product will be found to be safe and effective, (v) whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, (vi) whether Firdapse will ever be approved for commercialization, (vii) whether Catalyst will be the first company to receive an approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, and (viii) those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2017 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.

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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.

CATALYST PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Operating costs and expenses:				
Research and development	$ 3,404,634	$ 2,820,654	$ 11,375,237	$ 11,369,941
General and administrative	2,107,152	1,493,545	7,304,399	7,910,260
Total operating costs and expenses	5,511,786	4,314,199	18,679,636	19,280,201
Loss from operations	(5,511,786)	(4,314,199)	(18,679,636)	(19,280,201)
Other income, net	124,088	43,933	454,163	321,612
Change in fair value of warrants liability	-	106,946	(186,904)	886,137
Loss before income taxes	(5,387,698)	(4,163,320)	(18,412,377)	(18,072,452)
Provision for income taxes	-	-	-	-
Net loss	$ (5,387,698)	$ (4,163,320)	$ (18,412,377)	$ (18,072,452)
Net loss per share - basic and diluted	$ (0.06)	$ (0.05)	$ (0.21)	$ (0.22)
Weighted average shares outstanding - basic and diluted	91,451,695	82,899,526	85,802,487	82,875,281

CATALYST PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 57,496,702	$ 13,893,064
Short-term investments	26,516,711	26,512,753
Prepaid expenses and other current assets	1,173,744	1,047,944
Total current assets	85,187,157	41,453,761
Property and equipment, net	191,385	244,204
Deposits	8,888	8,888

Total assets	$ 85,387,430	$ 41,706,853
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,945,575	$ 933,176
Accrued expenses and other liabilities	2,320,587	1,161,359
Total current liabilities	4,266,162	2,094,535
Accrued expenses and other liabilities, non-current	157,456	181,162
Warrants liability, at fair value	-	122,226
Total liabilities	4,423,618	2,397,923
Total stockholders' equity	80,963,812	39,308,930
Total liabilities and stockholders' equity	$ 85,387,430	$ 41,706,853

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