March 15, 2017

Catalyst Pharmaceuticals Announces Fourth Quarter and Year-End 2016 Financial Results and Provides Corporate Update

New Positive Phase 2/3 Data for Firdapse® Treating Myasthenia Gravis Patients with anti-MuSK Antibodies

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

CORAL GABLES, Fla., March 15, 2017 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare neuromuscular and neurological diseases, today reported financial results for the fourth quarter and the year-ended December 31, 2016.

"As many of you are aware, 2016 proved to be a challenging year for Catalyst, with difficult decisions on the regulatory front regarding the requirement that we conduct a second Phase 3 trial evaluating Firdapse® for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) before the FDA will accept any NDA submission that we make for Firdapse", said Patrick J. McEnany, Catalyst's Chairman and CEO. Mr. McEnany continued, "As we look forward into the balance of 2017, our primary focus is on completing the clinical trials required for LEMS and congenital myasthenic syndromes (CMS) by the middle of this year and having an NDA submitted and accepted by the FDA by year end. The clinical importance of the Firdapse programs are further illustrated by this morning's release of promising new top-line clinical data for the treatment of myasthenia gravis patients with anti-MuSK antibodies (MuSK-MG). Additionally, we are hopeful that discussions for partnering of our generic Sabril® and CPP-115 programs will lead to meaningful transactions this year for both programs."

2016 and Recent Highlights

- Began enrolling patients into second Phase 3 clinical trial to evaluate the efficacy and safety of Firdapse in patients with Lambert-Eaton Myasthenic Syndrome (LEMS)
- Reached an agreement with the FDA under a SPA for the protocol design, clinical endpoints, and statistical analysis approach to be taken in our second Phase 3 study evaluating Firdapse for LEMS
- Expanded Congenital Myasthenic Syndromes (CMS) trial with Firdapse beyond pediatric patients to include adult CMS patients and increased enrollment size
- Case report published on the efficacy of CPP-115 in a child with refractory infantile spasms in *Epilepsy & Behavior Case Reports*
- Continued to augment enrollment in the Firdapse expanded access program (EAP)
- Firdapse granted Orphan Drug Designation for the treatment of myasthenia gravis
- Ended 2016 with $40.4 million in cash and investments and no debt

Upcoming Milestones

- Complete enrollment in LEMS (LMS-003) and CMS (CMS-001) clinical trials
- Expect top-line results from LEMS and CMS trials; and NDA submission for Firdapse in second-half 2017
- Begin discussions with FDA and external experts about regulatory path forward for the MuSK-MG pivotal, U.S. multi-center trial
- Exploring alternatives for CPP-115 further development
- Ongoing development of generic equivalent of Sabril® (vigabatrin)
- In the second half of 2017 reinitiate pre-commercialization activities for a potential 2018 launch of Firdapse

Fourth Quarter and Full-Year 2016 Financial Results

For the year ended December 31, 2016, Catalyst reported a GAAP net loss of $18,072,452, or $0.22 per basic and diluted share, compared to a GAAP net loss of $20,232,958 or $0.25 per basic and diluted share, for the 2015 fiscal year. Excluding non-cash gain of $886,137 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $18,958,589, or $0.23 per basic and diluted share for the year ended December 31, 2016. In comparison, Non-GAAP[1] net loss for the year ended December 31, 2015 was $20,297,963, or $0.25 per basic and diluted share, which excludes non-cash gain of $65,005 attributable to the change in fair value of liability-classified warrants.

For the quarter ended December 31, 2016, Catalyst reported a GAAP net loss of $4,163,320, or $0.05 per basic and

diluted share, compared to a GAAP net loss of $5,815,158, or $0.07 per basic and diluted share, for the 2015 fiscal year. Excluding non-cash gain of $106,946 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $4,270,266 or $0.05 per basic and diluted share for the fourth quarter of 2016. In comparison, Non-GAAP[1] net loss for the fourth quarter of 2015 was $6,204,754, or $0.07 per basic and diluted share, which excludes non-cash gain of $389,596 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the year ended December 31, 2016 were $11,369,941, compared to $11,801,342 for the 2015 fiscal year. For the fourth quarter of 2016, research and development expenses were $2,820,654, compared to $3,831,611 for the fourth quarter of 2015. Research and development expenses decreased when compared to the same period in 2015 primarily due to continued activities related to ongoing studies and trials for Firdapse, including the costs of our Firdapse Expanded Access Program, and cost of our CPP-115 and generic Sabril programs. We expect that our R&D spend for 2017 will increase as we continue our clinical development efforts for Firdapse, including our second Phase 3 clinical trial for LEMS, our clinical trial for CMS in pediatric and adult populations, our clinical program for MuSK-MG, our Expanded Access Program and our generic Sabril program.

General and administrative expenses for the year ended December 31, 2016 totaled $7,910,260, compared to $8,597,010 in the 2015 fiscal year. For the fourth quarter of 2016, general and administrative expenses totaled $1,493,545, compared to $2,360,068 in the same period in 2015. The decrease in general and administrative expenses from prior year was primarily due to our efforts to conserve cash after the receipt of the FDA's "refusal to file letter" for Firdapse, partly offset by increases in pre-commercialization expenses, payroll and benefits, during the first half of 2016, including approximately $600,000 in severance costs related to the reduction-in-force that occurred in May 2016. We expect that general and administrative costs will remain consistent in future periods as we continue our efforts to conserve cash.

Catalyst had no revenues in the year 2016 or 2015.

At December 31, 2016, Catalyst had cash and cash equivalents and short-term investments of $40.4 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through at least the next 12 months.

More detailed financial information and analysis may be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, which was filed with the Securities and Exchange Commission on March 15, 2017.

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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 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. EDT on Thursday, March 16, 2017 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 diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), MuSK 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, and possibly refractory Tourette's Disorder. 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 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, the timing of Catalyst's second trial evaluating Firdapse for the treatment of LEMS and whether the trial will be successful, whether Catalyst's assumptions in its updated business plan will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements and on Catalyst's ability to get to an accepted NDA submission for Firdapse without the need for additional funding, what clinical trials and studies will be required before Catalyst can resubmit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether any NDA for Firdapse resubmitted to the FDA will ever be accepted for filing, the timing of any such NDA filing or acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether any future trial evaluating Firdapse for the treatment of MuSK-MG will be successful and whether Catalyst can obtain the funding required to conduct such a trial, whether Firdapse will ever be approved for commercialization, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 5-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, what additional testing will be required before CPP-115 is "Phase 2 ready", whether CPP-115 will be determined to be effective for the treatment of refractory infantile spasms or possibly Tourette's Disorder or for any other indications, whether Catalyst can successfully design and complete a bioequivalence study of its version of vigabatrin compared to Sabril that is acceptable to the FDA, whether any such bioequivalence study the design of which is acceptable to the FDA will be successful, whether any ANDA that Catalyst submits for a generic version of Sabril will be accepted for filing, whether any ANDA for Sabril accepted for filing by the FDA will be approved (and the timing of any such approval), whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2016 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.

CATALYST PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2016	**2015**	**2016**	**2015**
Operating costs and expenses:				
Research and development	$ 2,820,654	$ 3,831,611	$ 11,369,941	$ 11,801,342
General and administrative	1,493,545	2,360,068	7,910,260	8,597,010
Total operating costs and expenses	4,314,199	6,191,679	19,280,201	20,398,352
Loss from operations	(4,314,199)	(6,191,679)	(19,280,201)	(20,398,352)
Other income (loss), net	43,933	(13,075)	321,612	100,389
Change in fair value of warrants liability	106,946	389,596	886,137	65,005
Loss before income taxes	(4,163,320)	(5,815,158)	(18,072,452)	(20,232,958)
Provision for income taxes	-	-	-	-
Net loss	$ (4,163,320)	$ (5,815,158)	$(18,072,452)	$(20,232,958)
Net loss per share - basic and diluted	$ (0.05)	$ (0.07)	$ (0.22)	$ (0.25)
Weighted average shares outstanding - basic and diluted	82,899,526	82,794,704	82,875,281	80,858,393

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash and cash equivalents	$13,893,064	$28,235,016
Certificates of deposit	-	3,717,229
Short-term investments	26,512,753	26,444,150
Prepaid expenses and other current assets	1,047,944	1,504,738
Total current assets	41,453,761	59,901,133
Property and equipment, net	244,204	191,549
Deposits	8,888	8,888
Total assets	$41,706,853	$60,101,570
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 933,176	$ 1,794,127
Accrued expenses and other liabilities	1,161,359	1,646,476
Total current liabilities.	2,094,535	3,440,603
Accrued expenses and other liabilities, non-current	181,162	176,293
Warrants liability, at fair value	122,226	1,008,363
Total liabilities	2,397,923	4,625,259
Total stockholders' equity	39,308,930	55,476,311
Total liabilities and stockholders' equity	$41,706,853	$60,101,570

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