March 15, 2016

Catalyst Pharmaceuticals Announces Fourth Quarter and Year-End 2015 Financial Results

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

CORAL GABLES, Fla., March 15, 2016 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Catalyst) (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today reported financial results for the fourth quarter and the year-ended December 31, 2015.

"2015 was a year of many accomplishments for Catalyst as we progressed with our NDA submission for Firdapse®, as well as the expansion of our product pipeline to include other potential indications for Firdapse," said Patrick J. McEnany, Chief Executive Officer of Catalyst. "As we work to resolve the regulatory pathway for Firdapse, we have continued to further develop our other drug candidates, which includes moving CPP-115 towards Phase 2 readiness and advancing our generic Sabril program."

2015 and Recent Highlights

- Appointed Brian Elsbernd as Senior Vice President of Legal and Compliance, Paul J. Merrigan as Chief Commercial Officer and Dr. Gary Ingenito as Chief Medical Officer
- Announced initiation of investigator-sponsored study of Firdapse in patients with MuSK-antibody positive Myasthenia Gravis
- Reported positive top-line results in Phase 1b trial of CPP-115
- Notice of Allowance of a U.S. patent application for the method of treating Tourette's Disorder with GABA-aminotransferase inactivators
- Initiated a clinical trial with Firdapse in pediatric patients with Congenital Myasthenic Syndromes (CMS)
- Announced the development strategy of a generic equivalent of Sabril®
- Completed a follow-on offering of $34.9 million net proceeds
- Increased our institutional shareholder base with a number of new life-science investors

Upcoming Milestones

- Meeting with FDA in early April 2016 and resubmitting our NDA for Firdapse, once we reach an understanding with the FDA as to what will be required for our NDA to be filed by the FDA for review
- Continue to build commercial preparedness for potential Firdapse launch
- Completion of clinical trial with Firdapse in pediatric patients with CMS
- Advancing CPP-115 towards Phase 2 readiness, including a Phase 1 dose ranging study evaluating CPP-115 at lower doses, subject to the availability of funding
- Development of generic equivalent of Sabril

Fourth Quarter and Full-Year 2015 Financial Results

For the year ended December 31, 2015, Catalyst reported a GAAP net loss of $20,232,958, or $0.25 per basic and diluted share, compared to a GAAP net loss of $15,509,061, or $0.24 per basic and diluted share, for the 2014 fiscal year.

Excluding non-cash gain of $65,005 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $20,297,963, or $0.25 per basic and diluted share for the year ended December 31, 2015. In comparison, Non-GAAP[1] net loss for the year ended December 31, 2014 was $14,515,195, or $0.23 per basic and diluted share, which excludes non-cash expense of $993,866 attributable to the change in fair value of liability-classified warrants.

For the quarter ended December 31, 2015, Catalyst reported a GAAP net loss of $5,815,158, or $0.07 per basic and diluted share, compared to a GAAP net loss of $3,490,030, or $0.05 per basic and diluted share, for the 2014 fiscal year.

Excluding non-cash gain of $389,596 attributable to the change in fair value of liability-classified warrants, Non-GAAP[1] net loss was $6,204,754 or $0.07 per basic and diluted share for the fourth quarter of 2015. In comparison, Non-GAAP[1] net loss for the fourth quarter of 2014 was $3,962,056, or $0.06 per basic and diluted share, which excludes non-cash gain of $472,026 attributable to the change in fair value of liability-classified warrants.

Research and development expenses for the year ended December 31, 2015 were $11,801,342, compared

to $10,117,774 for the 2014 fiscal year. For the fourth quarter of 2015, research and development expenses were $3,831,611, compared to $2,384,241 in the fourth quarter of 2014. Research and development expenses increased when compared to the same period in 2014 primarily due to continued activities related to ongoing studies and trials for Firdapse and CPP-115, the costs of our Firdapse Expanded Access Program and cost associated with the filing of our NDA for Firdapse. We expect that our R&D spend for 2016 will increase, primarily as a result of our continued clinical development efforts for Firdapse, including our recently started clinical trial for CMS in a pediatric population, our clinical program for MuSK Myasthenia Gravis and our Expanded Access Program.

General and administrative expenses for the year ended December 31, 2015 totaled $8,597,010, compared to $4,473,654 in the 2014 fiscal year. For the fourth quarter of 2015, general and administrative expenses totaled $2,360,068, compared to $1,599,620 in the same period in 2014. The increase in general and administrative expenses from prior year consists principally of increases in headcount and related expenses and pre-commercialization expenses, as we expanded our operations for the potential future commercialization of Firdapse.

Catalyst had no revenues in the year 2015 or 2014.

At December 31, 2015, Catalyst had cash and cash equivalents, certificates of deposit and short-term investments of $58.4 million and no debt. Catalyst believes that its existing capital resources will be sufficient to support its planned operations through the first quarter of 2017.

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 on March 15, 2016.

Conference Call

Catalyst management will host an investment-community conference call and webcast at 8:30 a.m. EDT on Wednesday, March 16, 2016 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), infantile spasms, and Tourette's Disorder. Catalyst's lead candidate, Firdapse® for the treatment of LEMS, has completed testing in a global, multi-center, double-blinded randomized pivotal Phase 3 trial resulting in positive top-line data. Firdapse for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and Orphan Drug designations for LEMS and CMS. Firdapse is the first and only European approved drug for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and 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 what additional supporting information will be required before the FDA will accept an NDA filing for Firdapse, whether any additional clinical studies or trials will be required before the FDA will accept an NDA filing for Firdapse for LEMS, 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, what clinical trials and studies will be required before Catalyst can file an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, the timing of any future NDA acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, whether the investigator-sponsored study evaluating Firdapse for the treatment of MuSK-MG will be successful, whether CPP-115 will be determined to be safe for humans, whether CPP-115 will be determined to be effective for the treatment of infantile spasm,

post-traumatic stress disorder, Tourette's Disorder or 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 files 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 2015 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 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.

STATEMENTS OF OPERATIONS (unaudited)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
	2015	**2014**	**2015**	**2014**
Operating costs and expenses:				
Research and development	$ 3,831,611	$ 2,384,241	$ 11,801,342	$ 10,117,774
General and administrative	2,360,068	1,599,620	8,597,010	4,473,654
Total operating costs and expenses	6,191,679	3,983,861	20,398,352	14,591,428
Loss from operations	(6,191,679)	(3,983,861)	(20,398,352)	(14,591,428)
Other income (loss), net	(13,075)	21,805	100,389	76,233
Change in fair value of warrants liability	389,596	472,026	65,005	(993,866)
Loss before income taxes	(5,815,158)	(3,490,030)	(20,232,958)	(15,509,061)
Provision for income taxes	-	-	-	-
Net loss	$ (5,815,158)	$ (3,490,030)	$ (20,232,958)	$ (15,509,061)
Net loss per share - basic and diluted	$ (0.07)	$ (0.05)	$ (0.25)	$ (0.24)
Weighted average shares outstanding - basic and diluted	82,794,704	68,899,154	80,858,393	64,142,534

CATALYST PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS

	December 31 , 2015	December 31, 2014
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 28,235,016	$ 9,096,778
Certificates of deposit	3,717,229	3,715,383
Short-term investments	26,444,150	26,462,962
Prepaid expenses and other current assets	1,504,738	4,552,698

Total current assets	59,901,133	43,827,821
Property and equipment, net	191,549	71,377
Deposits	8,888	8,888
Total assets	$ 60,101,570	$ 43,908,086
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,794,127	$ 1,814,210
Accrued expenses and other liabilities	1,646,476	4,040,816
Total current liabilities	3,440,603	5,855,026
Accrued expenses and other liabilities, non-current	176,293	15,839
Warrants liability, at fair value	1,008,363	2,794,891
Total liabilities	4,625,259	8,665,756
Total stockholders' equity	55,476,311	35,242,330
Total liabilities and stockholders' equity	$ 60,101,570	$ 43,908,086

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