Calithera Biosciences Reports Fourth Quarter and Full Year 2015 Financial Results and Recent Highlights

March 15, 2016

-CB-839 Combination Data submitted for Presentation at ASCO 2016

-IND to be submitted for Immuno-Oncology Candidate CB-1158 in mid-2016

-Calithera to Host Conference Call Today at 8:30 a.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., March 15, 2016 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, announced today its financial results for the fiscal fourth quarter and year ended December 31, 2015. As of December 31, 2015, cash, cash equivalents and investments totaled $71.9 million.

“In 2015, we made significant progress executing on our clinical development plan for CB-839, enrolling several monotherapy cohorts on our Phase 1 trials, while remaining on track with our IND-enabling studies for our immunotherapy arginase inhibitor, CB-1158, all while advancing internal preclinical programs,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “Looking forward to 2016, we expect to highlight new clinical data and scientific progress at oncology meetings, including CB-839 Phase 1b updates from our ongoing trials, dosing CB-839 in combination with other therapies. This is expected to occur initially in the second quarter of 2016, with further updates in the second half of the year. In addition, we plan on initiating a clinical trial of CB-839 in combination with a checkpoint inhibitor by mid-year. Our arginase inhibitor, CB-1158, is progressing towards the clinic with an IND filing expected mid-year.”

Fourth Quarter 2015 and Recent Highlights

- **CB-839 clinical date presented at major medical meetings.** The three phase I clinical trials with CB-839 in solid tumors and hematological malignancies continued to enroll throughout 2015, with 184 patients enrolled as of January 2016, across the three trials. New data presented at the AACR-NCI-EORTC meeting in November demonstrate stable disease across a variety of tumor types, as well as a single agent partial response in a renal cell carcinoma (RCC) patient. This patient showed a 32% reduction in target lesions by RECIST with generalized shrinkage of lymph node metastases. Among the fifteen evaluable patients with RCC, nine (60%) had stable disease or better, with stable disease lasting three cycles (63 days). Among efficacy-evaluable patients across a range of tumor types treated on the current dosing schedule of twice-daily, 22 of 50 patients (44%) experienced stable disease or better. Five stable disease patients currently on study have been treated with CB-839 for over 8 months without progression (2 triple negative breast cancer, 1 RCC, 1 mesothelioma and 1 IDH1 mutant chondrosarcoma). In addition, the first results of CB-839 dosed in combination therapy were presented at the American Society of Hematology Annual Meeting in December.

- **Arginase inhibitor CB-1158 preclinical data presented at the AACR-NCI-EORTC Meeting.** CB-1158, a highly selective, orally bioavailable, small molecule inhibitor of human arginase with nanomolar potency, demonstrated single agent efficacy in animal models. Inhibition of tumor growth was accompanied by a rapid increase in the local concentration of arginine, and the induction of multiple pro-inflammatory changes in the tumor microenvironment. CB-1158, when administered with anti-CTLA-4, increased CD8+ T-cell infiltrates in the tumor. The addition of CB-1158 to anti-CTLA-4 and anti-PD-1, significantly inhibited tumor growth in a mouse model that was resistant to dual checkpoint inhibitor therapy. CB-1158 was well tolerated as a single agent and in combination with checkpoint inhibitors in animal studies.

Selected Fourth Quarter and Year-end 2015 Financial Results

Cash, cash equivalents and investments totaled $71.9 million at December 31, 2015 compared with $102.0 million at December 31, 2014.

Research and development expenses for the full year 2015 were $23.7 million, compared with $16.4 million in the prior year. The increase of $7.4 million in 2015 was primarily attributed to higher expenses associated with Calithera’s arginase inhibitor program, including the selection of CB-1158 and its advancement through preclinical development, and continued enrollment of CB-839, Calithera’s first-in-class glutaminase inhibitor, in phase 1 clinical trials. Calithera expects to file an IND for the arginase inhibitor program mid-2016. Research and development expenses for the fourth quarter of 2015 were $5.8 million, compared to $5.0 million for the same period last year.

General and administrative expenses for the full year 2015 were $9.1 million, compared with $5.4 million in the prior year. The increase of $3.7 million in 2015 was primarily due to higher employment related expenses, including stock based compensation expense, and professional service fees relating to Calithera’s costs associated with operating as a publicly traded company. General and administrative expenses for the fourth quarter of 2015 were $2.3 million, compared to $1.9 million for the same period last year.

Loss from operations for the three months and year end ended December 31, 2015 was $8.1 million and $32.6 million, respectively.

Financial Guidance for 2016

Calithera expects that its cash, cash equivalents and investments will be at least $35 million at the end of 2016, exclusive of any funds arising from new collaborations or partnerships, equity financings or other new sources.

Conference Call Information

Calithera will host an update conference call today, March 15th at 8:30 a.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and reference to conference ID 63924357. To access the live audio webcast or the subsequent archived recording, visit the Investors

section of the Calithera website at www.calithera.com. The webcast will be recorded and available for replay on the company's website for 30 days.

About Calithera

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's lead product candidate, CB-839, is currently being evaluated in three Phase 1 clinical trials in solid and hematological cancers. CB-1158 is a first-in- class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body's cancer-fighting immune cells, known as cytotoxic T -cells. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to the timing of initiation of Calithera's clinical trials, Calithera's ability fund its clinical programs, Calithera's filing of an investigational new drug application for its arginase inhibitor, Calithera's receipt of clinical data from its clinical trials, and Calithera's cash and investments balance at the end of 2016. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's business can be found in Calithera's periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

Calithera Biosciences, Inc.
Selected Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	**2014**	**2015**	**2014**
Operating expenses:				
Research and development	$ 5,833	$ 4,972	$ 23,748	$ 16,367
General and administrative	2,295	1,866	9,071	5,354
Total operating expenses	8,128	6,838	32,819	21,721
Loss from operations	(8,128)	(6,838)	(32,819)	(21,721)
Interest income, net	60	5	175	9
Net loss	$ (8,068)	$ (6,833)	$ (32,644)	$ (21,712)
Net loss per share, basic and diluted	$ (0.44)	$ (0.39)	$ (1.81)	$ (4.67)
Weighted average common shares used to compute net loss per share, basic and diluted	18,163	17,743	18,045	4,652*

*Pre-IPO conversion of preferred shares to common shares

Calithera Biosciences, Inc.
Selected Balance Sheets Financial Data
(in thousands)
(unaudited)

	December 31,	
	2015	**2014**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 71,925	$ 101,969
Working capital	68,662	99,742
Total assets	75,750	104,770
Total liabilities	3,962	4,404
Accumulated deficit	(84,498)	(51,854)
Total stockholders' equity	71,788	100,366

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