Calithera Biosciences Reports Third Quarter 2016 Financial Results and Recent Highlights, and Raises Year-end Cash Guidance

November 9, 2016

Calithera to host conference call today at 4:30pm ET

SOUTH SAN FRANCISCO, Calif., Nov. 09, 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 and tumor immune cell metabolism targets for the treatment of cancer, announced today its financial results for the third quarter ended September 30, 2016. As of September 30, 2016, cash, cash equivalents and investments totaled $56.3 million.

"During the third quarter, we continued enrolling the two cohorts evaluating our glutaminase inhibitor CB-839 in triple negative breast cancer and in renal cell carcinoma. We expect to be in a position to provide additional updates at medical meetings in the fourth quarter," said Susan Molineaux, Ph.D., President and Chief Executive Officer of Calithera. "In addition, we opened two new immuno-oncology trials in the quarter, both of which should have an initial read out in 2017."

Third Quarter 2016 and Recent Highlights

- **CB-839: First patient enrolled and dosed in combination with checkpoint modulator.** In August 2016, we enrolled the first patient in a Phase 1/2 clinical trial assessing the safety and efficacy of CB-839, in combination with Opdivo® for the treatment of renal cell carcinoma (RCC), malignant melanoma and non-small cell lung cancer. The Phase 1/2 study will assess the safety, pharmacokinetics and pharmacodynamics of CB-839 and Opdivo®. The study will enroll patients with clear cell RCC who are naïve to checkpoint inhibitors, as well as clear cell RCC, melanoma, and non-small cell lung cancer patients who are receiving anti-PD-1 monotherapy as their current therapy without having a tumor response.
- **CB-839: Data in renal cell carcinoma selected for oral presentation.** In September, we announced that clinical data for CB-839 will be presented in a plenary session at the 28th Annual EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, November 29 to December 2, 2016 in Munich, Germany. The clinical presentation will be focused on data from Calithera's CB-839 Phase I RCC combination trial with everolimus.
- **CB-839: Data in triple negative breast cancer selected for presentation.** Clinical data for CB-839 will be presented at the San Antonio Breast Cancer Symposium in San Antonio, December 6 to 10, 2016 in San Antonio, Texas. The clinical presentation will be focused on data from Calithera's CB-839 Phase I triple negative breast cancer combination trial with paclitaxel.
- **CB-1158: First patient dosed in a phase 1 study of our first-in-class inhibitor of the immuno-oncology target arginase.** In September 2016, we announced dosing of the first patient in a Phase I clinical trial assessing the safety and efficacy of our drug candidate as a treatment for advanced solid tumors. Arginase is an enzyme in myeloid-derived suppressor cells (MDSCs), which prevents T-cell and natural killer (NK) cell activation in tumors.
- **Board of Directors.** In August 2016, Suzy Jones was appointed to our Board of Directors, and added to the Audit committee. Ms. Jones is currently Founder and Managing Partner of DNA Ink, a boutique life sciences advisory firm.

Selected Third Quarter 2016 Financial Results

Research and development expenses were $6.3 million for the three months ended September 30, 2016, compared with $6.8 million for the same period in the prior year. The decrease of $0.5 million was primarily due to the timing of manufacturing clinical supply to support our CB-839 and CB-1158 clinical trials, partially offset by increased personnel-related costs primarily due to higher headcount, salary increases and stock-based compensation expense, and costs associated with our licensing arrangements.

General and administrative expenses were $2.3 million for the three months ended September 30, 2016, compared with $2.2 million for the same period in the prior year. The increase of $0.1 million was primarily due to higher personnel-related costs as a result of higher headcount, salary increases and stock-based compensation expense.

Net loss for the three months ended September 30, 2016 was $8.5 million, or $0.44 per share.

Based on the results for the first nine months of 2016 and our current expectations for the remainder of the year, we are raising our guidance and expect cash, cash equivalents and investments will be at least $50 million at the end of 2016.

Conference Call Information

Calithera will host its third quarter financial results and corporate update conference call today, November 9th at 4:30 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and reference to conference ID 10450552. 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 until our conference call to discuss financial results for its fourth quarter of 2016.

About Calithera Biosciences

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 a potent, selective, reversible and orally bioavailable inhibitor of glutaminase. CB-839 takes advantage of the pronounced dependency many cancers have on the nutrient glutamine for growth and survival. It is currently being evaluated in Phase 1/2 clinical trials in combination with standard of care agents. 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. CB-1158 is currently in a Phase I clinical trial. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

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 Calithera's receipt of clinical data from its clinical trials and Calithera's ability to recruit and enroll patients in its clinical trials. 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 Annual Report on Form 10-K for the year ended December 31, 2015, and other 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 Balance Sheets Financial Data
(in thousands)
(unaudited)

	September 30, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 56,271	$ 71,925
Working capital	53,142	68,662
Total assets	58,924	75,750
Total liabilities	5,113	3,962
Accumulated deficit	(112,982)	(84,498)
Total stockholders' equity	53,811	71,788

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 6,313	$ 6,752	$ 21,155	$ 17,915
General and administrative	2,319	2,198	7,575	6,776
Total operating expenses	8,632	8,950	28,730	24,691
Loss from operations	(8,632)	(8,950)	(28,730)	(24,691)
Interest income, net	88	50	246	115
Net loss	$ (8,544)	$ (8,900)	$ (28,484)	$ (24,576)
Net loss per share, basic and diluted	$ (0.44)	$ (0.49)	$ (1.50)	$ (1.36)
Weighted average common shares used to compute net loss per share, basic and diluted	19,507	18,105	18,963	18,005

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Primary Logo

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