Calithera Biosciences Reports Second Quarter 2016 Financial Results and Recent Highlights

August 9, 2016

- *Two novel agents that modulate tumor and immune cell metabolism in clinical development*
- *Calithera to host conference call today at 4:30pm ET*

SOUTH SAN FRANCISCO, Calif., Aug. 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 second quarter ended June 30, 2016. As of June 30, 2016, cash, cash equivalents and investments totaled $60.4 million.

"During the second quarter, we significantly advanced our pipeline of novel cancer therapeutics," said Susan Molineaux, Ph.D., President and Chief Executive Officer of Calithera. "Data presented on the tumor metabolism drug CB-839 at the American Society of Clinical Oncology helped us to define a path forward for clinical development in renal cell carcinoma and triple negative breast cancer. With the FDA's acceptance of our IND for our metabolic immune checkpoint drug candidate CB-1158, we now have two novel metabolic agents targeting tumor and immune cell metabolism in clinical development."

Second Quarter 2016 and Recent Highlights

- **FDA acceptance of Investigational New Drug Application for CB-1158.** In July 2016, the U.S. Food and Drug Administration (FDA) accepted the company's Investigational New Drug (IND) application for CB-1158 for the treatment of solid tumors. CB-1158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, an immunosuppressive enzyme in myeloid-derived suppressor cells responsible for T-cell suppression. Arginase exerts its immunosuppressive effect by depleting the amino acid arginine in the tumor microenvironment and preventing activation and proliferation of the immune system's cytotoxic T-cells and natural killer (NK) cells. Inhibition of arginase activity reverses this immunosuppressive block and restores T-cell function. The Phase I clinical trial will enroll patients with advanced solid tumors treated with CB-1158 as a monotherapy, as well as in combination with an anti-PD1 antibody.
- **CB-839 solid tumor combination data presented at the American Society of Clinical Oncology.** In June 2016, Calithera presented clinical data for CB-839 in combination with everolimus in renal cell carcinoma, and CB-839 in combination with paclitaxel in triple negative breast cancer. Among ten renal cell carcinoma patients treated in the everolimus combination group, the overall disease control rate was 80%, including one partial response. Among eight clear cell and papillary patients, the disease control rate was 100%. The median time on study exceeded the expected progression free survival for everolimus alone in this population. Fifteen triple negative breast cancer patients were treated with CB-839 in combination with paclitaxel. The majority of patients had received at least three prior lines of therapy. Most patients had received prior taxanes in either the neo-adjuvant, adjuvant or metastatic setting. Among patients treated with CB-839 doses of at least 600 mg bid (n=8), there were 3 partial responses (38%) and disease control (response or stable disease) in 7 patients (88%). Two of the partial responses were observed in patients refractory to paclitaxel in a prior course of therapy. CB-839 in combination with either everolimus or paclitaxel has been well tolerated to date, with adverse events that have been manageable and reversible.

Selected Second Quarter 2016 Financial Results

Research and development expenses were $7.8 million for the three months ended June 30, 2016, compared with $5.5 million for the same period in the prior year. The increase of $2.2 million was primarily attributed to increased development activities in Calithera's arginase inhibitors program.

General and administrative expenses were $2.7 million for the three months ended June 30, 2016, compared with $2.3 million for the same period in the prior year. The increase of $0.3 million was primarily due to higher employment related expenses, including stock-based compensation expense.

Net loss for the three months ended June 30, 2016 was $10.4 million, or $0.55 per share.

Conference Call Information

Calithera will host its second quarter financial results and corporate update conference call today, August 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 58075870. 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 the Company's conference call to discuss financial results for its third 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, an immunosuppressive enzyme in myeloid-derived suppressor cells responsible for T-cell suppression. 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.

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 Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	**2015**	**2016**	**2015**
Operating expenses:				
Research and development	$ 7,776	$ 5,533	$ 14,842	$ 11,163
General and administrative	2,665	2,341	5,256	4,578
Total operating expenses	10,441	7,874	20,098	15,741
Loss from operations	(10,441)	(7,874)	(20,098)	(15,741)
Interest income, net	83	56	158	65
Net loss	$ (10,358)	$ (7,818)	$ (19,940)	$ (15,676)
Net loss per share, basic and diluted	$ (0.55)	$ (0.44)	$ (1.07)	$ (0.87)
Weighted average common shares used to compute net loss per share, basic and diluted	18,987	17,963	18,688	17,955

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

	June 30, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 60,380	$ 71,925
Working capital	57,601	68,662
Total assets	63,229	75,750
Total liabilities	5,010	3,962
Accumulated deficit	(104,438)	(84,498)
Total stockholders' equity	58,219	71,788

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Primary Logo

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