Calithera Biosciences Reports First Quarter 2016 Financial Results and Recent Highlights

May 10, 2016

- CB-839 Phase 1b Clinical Data to be Presented at ASCO 2016
- Key clinical leadership expansion
- Calithera to Host Conference Call Today at 4:30pm Eastern Time

SOUTH SAN FRANCISCO, Calif., May 10, 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 first quarter ended March 31, 2016. As of March 31, 2016, cash, cash equivalents and investments totaled $68.3 million.

“During the first quarter, we continued to advance our development pipeline by recruiting patients into clinical studies of CB-839, and preparing for an Investigational New Drug (IND) application for CB-1158, as well as expanding our clinical leadership team,” said Susan Molineaux, Ph.D., President and Chief Executive Officer of Calithera. “More recently, at the 2016 American Association of Cancer Research annual meeting, we and our collaborators presented four abstracts highlighting synergy studies of CB-839 and CB-1158. CB-839 is currently enrolling multiple combination cohorts in our Phase Ib clinical trials, for which updates are planned in June.”

First Quarter 2016 and Recent Highlights

- **Enrollment continues across CB-839 Phase Ib combination cohorts.** Data from the Phase I solid tumor trial has been accepted for presentation at the 2016 American Society of Clinical Oncology (ASCO) annual meeting. Initial results of CB-839 in combination with paclitaxel in patients with triple negative breast cancer will be presented in a poster and discussion on June 5, 2016. Initial results of CB-839 alone and in combination with everolimus in patients will renal cell carcinoma will be presented in a poster on June 6, 2016.
- **CB-839 preclinical findings, including combinations with immuno-oncology therapies, presented at the American Association of Cancer Research.** In April 2016, Calithera presented preclinical data for CB-839 in combination with immuno oncology-agents. The combination of CB-839 and anti-PD-L1 or anti-PD-1 substantially increased the number of tumor regressions seen in the CT26 syngeneic colon carcinoma model. Synergistic effects with CB-839 and anti-PD-L1 were also observed in a B16 melanoma model. Both of these agents are known to affect metabolism in the tumor microenvironment. Treatment with anti-PD-1 or PD-L1 increases glucose metabolism in T cells and CB-839 increases the amount of glutamine available for T cells because it inhibits the avid metabolism of glutamine by the tumor itself. T cells require adequate levels of these two key nutrients to expand and mount a strong anti-tumor response.
- **CB-1158 preclinical findings presented at the American Association of Cancer Research.** 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 an increase in the local concentration of arginine, and the induction of multiple pro-inflammatory changes in the tumor microenvironment. CB-1158 increased CD8+ T-cell infiltrates in a lung tumor model. The addition of CB-1158 to anti-CTLA-4 and anti-PD-1 significantly inhibited tumor growth and reduced metastases 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.
- **Key hire and promotion in clinical group.** Calithera announced today the expansion of its clinical group with the hiring of Sam Whiting, M.D., Ph.D. as Vice President of Clinical Development. Most recently, Dr. Whiting served as Vice President of Research and Clinical Development at Gradalis, Inc. Previously Dr. Whiting was an assistant member at the Fred Hutchinson Cancer Research Center (FHCRC), and assistant professor at the University of Washington where he was clinical director of gastrointestinal oncology. Dr. Whiting received his M.D. and Ph.D. degrees and completed his internal medicine residency at the University of Washington, and medical oncology fellowship at the FHCRC. Keith Orford, M.D., Ph.D., who joined Calithera in January 2015, has been promoted to Senior Vice President of Clinical Development.

Selected First Quarter 2016 Financial Results

Research and development expenses were $7.1 million for the three months ended March 31, 2016, compared with $5.6 million for the same period in the prior year. The increase of $1.4 million was primarily attributed to increased development activities in Calithera’s arginase inhibitors program as it plans to file an IND in mid-2016, partially offset by a decrease of $0.4 million related to Calithera’s licensing arrangements.

General and administrative expenses were $2.6 million for the three months ended March 31, 2016, compared with $2.2 million for the same period in the prior year. The increase of $0.4 million was primarily due to higher employment related expenses, including stock-based compensation expense.

Net loss from operations for the three months ended March 31, 2016 was $9.6 million.

Conference Call Information

Calithera will host its first quarter financial results and corporate update conference call today, May 10th 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 1418909. 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 second quarter of 2016.

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 Calithera's receipt of clinical data from its clinical trials; Calithera's intention to file an IND in mid-2016 related to its arginase inhibitors program (CB-1158) 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 March 31,	
	2016	**2015**
Operating expenses:		
Research and development	$ 7,066	$ 5,630
General and administrative	2,591	2,237
Total operating expenses	9,657	7,867
Loss from operations	(9,657)	(7,867)
Interest income, net	75	9
Net loss	$ (9,582)	$ (7,858)
Net loss per share, basic and diluted	$ (0.52)	$ (0.44)
Weighted average common shares used to compute net loss per share, basic and diluted	18,389	17,946

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

	March 31, 2016	**December 31, 2015**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 68,295	$ 71,925
Working capital	64,508	68,662
Total assets	71,562	75,750
Total liabilities	4,294	3,962
Accumulated deficit	(94,080)	(84,498)
Total stockholders' equity	67,268	71,788

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