Calithera Biosciences Reports Third Quarter 2015 Financial Results and Recent Highlights

November 9, 2015

-Single Agent Solid Tumor Clinical Benefit Seen With Tumor Metabolism Inhibitor CB-839

-Continued Signs of Activity, Tolerability, and Durability

-First Preclinical Data Presented For Immuno-Oncology Arginase Inhibitor CB-1158

-IND filing Remains on Track for 1H 2016

-Calithera to Host Conference Call Today at 4:15pm Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2015 (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 third quarter ended September 30, 2015. As of September 30, 2015, cash, cash equivalents and investments totaled $81.9 million.

“In the third quarter, we continued to move clinical programs forward with presentations of data at key medical meetings,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “We presented dose expansion monotherapy cohorts for our lead product CB-839 at the AACR-EORTC-NCI meeting, and we are currently opening enrollment across six combination cohorts. For our lead immuno-oncology program, we presented initial preclinical data for CB-1158, an oral, small molecule arginase inhibitor with the potential to treat cancer by blocking the immunosuppression of the tumor micro-environment. We believe that we have multiple opportunities to positively impact clinical outcomes for cancer patients by building a pipeline of novel therapeutic product candidates.”

Third Quarter 2015 and Recent Highlights

- **CB-839 Solid Tumor Phase 1 data presented at the AACR-NCI-EORTC meeting.** On November 8, 2015, solid tumor phase 1 data were presented at the American Association of Cancer Research (AACR)-National Cancer Institute (NCI)-European Organization for Research and Treatment of Cancer (EORTC) meeting that demonstrated the clinical activity, tolerability and unique mechanism of action of CB-839 as a single agent in patients with solid tumors. Among efficacy-evaluable patients across a range of tumor types treated on the twice daily schedule of CB-839 administered with food, 22 of 50 patients (44%) had stable disease (SD) or better lasting at least 3 cycles (63 days). One renal cell carcinoma (RCC) patient has an ongoing partial response (PR; on study > 5 months); this patient showed a 32% reduction in target lesions by RECIST with generalized shrinkage of lymph node metastases. Among the 15 evaluable patients with RCC, 9 (60%) had SD or PR, with four patients remaining on study.
- **Arginase inhibitor CB-1158 preclinical data presented at the AACR-NCI-EORTC Meeting.** Calithera selected CB-1158 as the clinical candidate for Calithera’s first immuno-oncology program targeting inhibition of arginase, a critical T-Cell immunosuppressive enzyme produced by myeloid-derived suppressor cells in tumors. On November 6, 2015, Calithera presented data at the AACR-NCI-EORTC meeting showing that CB-1158 is a highly selective, orally bioavailable, small molecule inhibitor of human arginase with nanomolar potency. Administration of CB-1158 to mice results in a dose-dependent increase in tumor arginine levels, consistent with target inhibition. Evaluation of anti-tumor efficacy in immunocompetent syngeneic mouse models has shown that oral administration of CB-1158 results in significant inhibition of tumor growth, and it combines well with checkpoint inhibitors with no evidence of additional toxicity.
- **Augmented Board of Directors.** In September 2015, Calithera appointed Sunil Agarwal, M.D., Senior Vice President and Chief Medical Officer at Ultragenyx, to the company's Board of Directors.

Anticipated Upcoming Milestones

- Hematologic Phase 1 clinical trial data by year end 2015
- Initiation of six CB-839 combination expansion cohorts by year end 2015
- CB-839 combination therapy data in mid-2016
- Filing of investigational new drug application (IND) for arginase inhibitor CB-1158 in the first half of 2016

Selected Third Quarter 2015 Financial Results

Research and development expenses were $6.8 million for the three months ended September 30, 2015, compared with $3.9 million for the same period in the prior year. The increase of $2.9 million was primarily attributed to higher expenses associated with the continued advancement of CB-839 and investments in the Company’s arginase inhibitor program.

General and administrative expenses were $2.2 million for the three months ended September 30, 2015, compared with $1.3 million for the same period in the prior year. The increase of $0.9 million was primarily due to higher employment-related expenses, including stock-based compensation expense and professional service fees associated with operating as a publicly-traded company.

Net loss for the three months ended September 30, 2015 was $8.9 million.

Financial Guidance for 2015

Calithera is updating its guidance of its cash, cash equivalents and investments to be at least $70 million at the end of 2015, exclusive of any license milestone payments or funds arising from any additional new collaborations or partnerships, equity financings or other new sources.

Conference Call Information

Calithera will host its third quarter financial results and corporate update conference call today, November 9th at 4:15 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 62242412. 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 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 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 ability to build a pipeline of novel therapeutic product candidates, the timing and expected enrollment 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 and Calithera's receipt of clinical data from 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 most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 6,752	$ 3,894	$ 17,915	$ 11,395
General and administrative	2,198	1,347	6,776	3,488
Total operating expenses	8,950	5,241	24,691	14,883
Loss from operations	(8,950)	(5,241)	(24,691)	(14,883)
Other income, net	50	2	115	4
Net loss	$ (8,900)	$ (5,239)	$ (24,576)	$ (14,879)
Net loss per share, basic and diluted	$ (0.49)	$ (16.85)	$ (1.36)	$ (61.90)
Weighted average common shares used to compute net loss per share, basic and diluted	18,105	311*	18,005	240*

*Pre-IPO conversion of preferred shares to common shares

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

	September 30, 2015	December 31, 2014
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 81,887	$ 101,969

Working capital	77,926	99,742
Total assets	84,530	104,770
Total liabilities	5,935	4,404
Accumulated deficit	(76,430)	(51,854)
Total stockholders' equity	78,595	100,366

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