Calithera Biosciences Reports Second Quarter 2017 Financial Results and Recent Highlights

August 8, 2017

-Calithera to Host Conference Call Today at 1:30 p.m. Pacific Time/ 4:30 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2017 (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 second quarter ended June 30, 2017. As of June 30, 2017, cash, cash equivalents and investments totaled $208.2 million.

“Recent highlights included the presentation of clinical trial results of CB-1158, a first-in-class small molecule arginase inhibitor, in an oral presentation at the American Society of Clinical Oncology, and the advancement of CB-839 into Phase 2 clinical trials in renal cell carcinoma and triple negative breast cancer,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “Looking forward to the second half of 2017, we plan to present clinical updates on CB-839, including the initial results of CB-839 dosed in combination with Bristol Myers Squibb’s Opdivo® (nivolumab) in the fourth quarter.”

Second Quarter 2017 and Recent Highlights

- **CB-839 Randomized Phase 2 Combination Trial in Renal Cell Carcinoma Initiated.** In August 2017, Calithera announced the initiation of a randomized, double blind, placebo controlled trial to evaluate the safety and efficacy of CB-839 in combination with everolimus versus placebo in approximately 250 patients with metastatic, clear cell renal cell carcinoma who have been treated with at least two lines of prior systemic therapy including a VEGFR-targeting tyrosine kinase inhibitor and at least one of either CABOMETYX™ (cabozantinib) or an active PD-1/PD-L1 inhibitor. CB-839 has been granted Fast Track designation for this indication.
- **CB-839 Triple Negative Breast Cancer Phase 2 Trial Initiated.** In July 2017, Calithera initiated a Phase 2 trial of CB-839 with paclitaxel in triple negative breast cancer patients. Four single arm, open label, cohorts of African American and non-African American patients will be treated in both the early stage setting, where patients have no prior treatment for metastatic disease, as well as the late stage setting, after at least two prior therapies for metastatic disease including prior taxane therapy. The primary endpoint of this trial is objective response rate. Additional data from the triple negative breast cancer development program are expected in the fourth quarter of 2017.
- **Collaboration with Bristol-Myers Squibb expanded.** In May 2017, Calithera’s existing collaboration evaluating Opdivo® (nivolumab) in combination with CB-839 was expanded to include additional renal cell carcinoma cohorts as well as non-small cell lung cancer and melanoma. Initial results of CB-839 dosed in combination with Bristol Myers Squibb’s Opdivo® are expected in the fourth quarter of 2017.
- **CB-1158 (INCB01158) Phase I Solid Tumor Data Presented at the American Society of Clinical Oncology Annual Meeting.** In June 2017, data was presented from the first 17 patients with advanced solid tumors dosed with CB-1158 as a single agent. Plasma levels of arginase were inhibited > 90% in all patients, and in 10 of 11 patients plasma arginine increased 1.5-fold or more. CB-1158 was generally well tolerated with no drug-related serious adverse events. The trial is continuing to enroll patients in the dose escalation phase of the study, and expansion cohorts in pre-defined tumor types, to be followed by combination studies with an anti-PD-1 antibody.

Selected Second Quarter 2017 Financial Results

Cash, cash equivalents and investments totaled $208.2 million at June 30, 2017, compared with $207.1 million at March 31, 2017. During the second quarter of 2017, Calithera received payment of a $12.0 million milestone under its global collaboration and license agreement with Incyte.

Revenue was $7.3 million for the three months ended June 30, 2017 and represents the portion of deferred revenue recognized in the second quarter from the Company’s collaboration and license agreement with Incyte.

Research and development expenses were $10.1 million for the three months ended June 30, 2017, compared with $7.8 million for the same period in the prior year. The increase of $2.3 million was primarily due to an increase in the CB-839 program, including for Phase 2 start-up activities, as well as investment in our early stage research programs, partially offset by decreases in the CB-1158 program including Incyte’s co-funding of development costs.

General and administrative expenses were $2.8 million for the three months ended June 30, 2017, compared with $2.7 million for the same period in the prior year. The increase of $0.1 million was primarily due to increases in professional services and higher personnel-related costs.

Net loss from operations for the three months ended June 30, 2017 was $5.2 million, or $0.15 per share.

Conference Call Information

Calithera will host an update conference call today, August 8th at 1:30 p.m. Pacific Time/ 4:30 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 63329558. 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 Calithera’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 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 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 being developed in collaboration with Incyte Corporation and is currently in a Phase 1 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 the timing of Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's ability to fund its clinical programs, 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 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,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Collaboration revenue	$ 7,255	$ —	$ 11,447	$ —
Total revenue	7,255	—	11,447	—
Operating expenses:				
Research and development	10,142	7,776	16,782	14,842
General and administrative	2,848	2,665	6,156	5,256
Total operating expenses	12,990	10,441	22,938	20,098
Loss from operations	(5,735)	(10,441)	(11,491)	(20,098)
Interest income, net	541	83	710	158
Net loss	$ (5,194)	$ (10,358)	$ (10,781)	$ (19,940)
Net loss per share, basic and diluted	$ (0.15)	$ (0.55)	$ (0.36)	$ (1.07)
Weighted average common shares used to compute net loss per share, basic and diluted	35,348	18,987	30,342	18,688

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

	June 30, 2017	**December 31, 2016**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 208,184	$ 51,781
Working capital	135,953	49,108
Total assets	214,082	54,796
Deferred revenue	45,553	—
Total liabilities	51,618	4,890
Accumulated deficit	(133,287)	(122,502)
Total stockholders' equity	162,464	49,906

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Primary Logo

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