



Calithera Biosciences Reports Third Quarter 2017 Financial Results and Recent Highlights

November 2, 2017

Calithera to Webcast Clinical Update on CB-839 on November 11, 2017

SOUTH SAN FRANCISCO, Calif., Nov. 02, 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 third quarter ended September 30, 2017. As of September 30, 2017, cash, cash equivalents and investments totaled \$196.5 million.

"In the quarter, Calithera advanced each of our internally discovered first-in-class, small molecule onco-metabolism clinical candidates. We initiated two new phase 2 trials with our oral glutaminase inhibitor and we recently initiated dosing of our oral arginase inhibitor in combination with a checkpoint inhibitor," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "Our clinical development plans are progressing and 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) at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC)."

Third Quarter 2017 and Recent Highlights

CB-839

- **Oral Presentation Accepted at SITC.** We will present clinical trial results from CB-839 dosed in combination with Opdivo® (nivolumab) in patients with advanced melanoma, renal cell carcinoma or non-small cell lung cancer in an oral presentation at the 32nd Annual Meeting of the Society for Immunotherapy of Cancer which is being held from November 10-12, 2017. We will also present the data in a poster format at the meeting, and we will host a clinical update webcast on Saturday, November 11th, 2017.
- **Initiated Randomized Phase 2 Combination Trial in Renal Cell Carcinoma.** In August 2017, we initiated 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. The primary endpoint of this trial is progression free survival, and CB-839 has been granted Fast Track designation for this indication.
- **Initiated Phase 2 Trial in Triple Negative Breast Cancer.** In July 2017, we initiated a Phase 2 trial of CB-839 with paclitaxel in patients with 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.

INCB01158

- **Initiated Combination Dosing.** In October 2017, the first patient was treated in the Phase I cohort of INCB01158 (formerly known as CB-1158) dosed in combination with Keytruda® (pembrolizumab), an anti-PD1 immune checkpoint inhibitor.

Corporate

- **Augmented Board of Directors.** In September 2017, Calithera appointed Blake Wise, President and Chief Operating Officer of Achaogen, to the company's Board of Directors.

Selected Third Quarter 2017 Financial Results

Cash, cash equivalents and investments totaled \$196.5 million at September 30, 2017.

Revenue was \$7.3 million for the three months ended September 30, 2017 and represents the portion of deferred revenue recognized in the third quarter from the company's collaboration and license agreement with Incyte.

Research and development expenses were \$10.8 million for the three months ended September 30, 2017, compared with \$6.3 million for the same period in the prior year. The increase of \$4.5 million was due to an increase in the CB-839 program to support our new and ongoing clinical trials, including the company's two Phase 2 trials which began in the third quarter of 2017, as well as investment in our early stage research programs, offset by decreases in the INCB01158 program, primarily due to Incyte's co-funding of development costs.

General and administrative expenses were \$3.1 million for the three months ended September 30, 2017, compared with \$2.3 million for the same

period in the prior year. The increase of \$0.8 million was due to increases in professional services and higher personnel-related costs.

Net loss from operations for the three months ended September 30, 2017 was \$6.1 million, or \$0.17 per share.

Conference Call Information

Calithera will webcast a clinical update on CB-839 on Saturday, November 11th at 3:30 p.m. Pacific Time/ 6:30 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 1878409. 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. INCB01158 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. INCB01158 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, 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 Consolidated Statements of Operations Financial Data

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Collaboration revenue	\$ 7,254	\$ —	\$ 18,701	\$ —
Total revenue	7,254	—	18,701	—
Operating expenses:				
Research and development	10,833	6,313	27,615	21,155
General and administrative	3,074	2,319	9,230	7,575
Total operating expenses	13,907	8,632	36,845	28,730
Loss from operations	(6,653)	(8,632)	(18,144)	(28,730)
Interest income, net	582	88	1,292	246
Net loss	\$ (6,071)	\$ (8,544)	\$ (16,852)	\$ (28,484)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.44)	\$ (0.53)	\$ (1.50)
Weighted average common shares used to compute net loss per share, basic and diluted	35,475	19,507	32,072	18,963

Calithera Biosciences, Inc.

Selected Consolidated Balance Sheet Financial Data

(in thousands)

(unaudited)

	September 30, 2017		December 31, 2016	
Balance Sheet Data:				
Cash, cash equivalents and investments	\$ 196,533		\$ 51,781	
Working capital	134,630		49,108	
Total assets	205,543		54,796	
Deferred revenue	38,299		—	
Total liabilities	47,451		4,890	
Accumulated deficit	(139,358)	(122,502)
Total stockholders' equity	158,092		49,906	

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Source: Calithera Biosciences, Inc.