Calithera Biosciences Reports Fourth Quarter and Full Year 2016 Financial Results and Recent Highlights

March 16, 2017

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

SOUTH SAN FRANCISCO, Calif., March 16, 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 fourth quarter and year ended December 31, 2016. As of December 31, 2016, cash, cash equivalents and investments totaled $51.8 million. Subsequent to the end of the year, Calithera received an upfront payment of $45.0 million from its global collaboration and license agreement with Incyte Corporation and gross proceeds of $46.0 million from the sale of common stock to Incyte and through its at-the-market program with Cowen and Company LLC.

“2016 was a transformative year for Calithera as our lead product candidate CB-839 entered into multiple novel combination trials and progressed towards Phase II, and CB-1158 advanced into clinical development leading to a partnership with Incyte Pharmaceuticals for a strategic development and commercialization collaboration in January 2017,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “Looking forward to 2017, we expect to highlight new clinical data from each of our clinical programs at scientific meetings, with clinical data expected from CB-1158 in the first half of the year, and multiple clinical updates on CB-839 combination trials in the second half of 2017. This includes the first clinical data presentation of CB-839 dosed in combination with Bristol Myers Squibb’s Opdivo.”

Fourth Quarter 2016 and Recent Highlights

- **CB-1158: Global Research, Development and Commercialization Collaboration with Incyte.** In January 2017, Incyte and Calithera announced the global collaboration and license agreement for the research, development and commercialization of the first in class, small molecule arginase inhibitor CB-1158. Under the terms of the collaboration and license agreement, Calithera has received an up-front payment of $45 million from Incyte in addition to an $8 million equity investment. CB-1158 entered clinical trials in September 2016, and pharmacodynamic data on the first three patients was presented at the Society for Immunotherapy of Cancer (SITC) meeting in November 2016.

- **CB-839: Phase I Triple Negative Breast Cancer Combination Data at the 2016 San Antonio Breast Cancer Symposium (SABCS).** New data was presented at the 2016 SABCS in December 2016 on 28 triple negative breast cancer patients treated with CB-839 in combination with paclitaxel; 23 patients were evaluable for efficacy. Among evaluable patients treated with CB-839 doses of at least 600 mg bid (n=16), there were 5 partial responses (31%) and disease control (response or stable disease) in 11 patients (69%). In addition, the combination overcame resistance to paclitaxel in heavily pretreated TNBC patients. There was a 38% response rate and 50% disease control rate in patients who received prior taxanes in the metastatic setting. There was a 50% response rate among taxane-refractory African American patients.

- **CB-839: Phase I Renal Cell Carcinoma Combination Data at the 28th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics.** In a plenary session at the EORTC-NCI-AACR Symposium in November 2016, new data was presented with CB-839 in combination with everolimus. Fifteen renal cell carcinoma patients were treated and evaluable for response, including 12 clear cell patients, and three papillary patients. Ninety-three percent (93%) had disease control; one patient had a partial response, one patient had progressive disease, and 13 patients had stable disease. The median progression free survival was 8.5 months and for the majority of patients, their time on therapy was longer than their time on treatment in their prior therapy. In the clear cell patient population the disease control rate was 100%.

- **At-the-Market Program.** In 2017, Calithera received approximately $38.0 million in gross proceeds, $36.9 million in net proceeds, from the sale of common stock pursuant to its at-the-market offering program with Cowen.

- **Key Management Appointments.** Curtis Hecht was named Senior Vice President of Business and Corporate Development, Frank Parlati was named Vice President of Research, and Jennifer McNealey was named Vice President of Investor Relations and Strategy.

Selected Fourth Quarter and Year-end 2016 Financial Results

Cash, cash equivalents and investments totaled $51.8 million at December 31, 2016, compared with $71.9 million at December 31, 2015. Subsequent to the end of the year, Calithera received a $45.0 million upfront payment from Incyte and an additional $44.8 million in net proceeds from sales of common stock in 2017.

Research and development expenses for the full year 2016 were $27.7 million, compared with $23.7 million in the prior year. The increase of $4.0 million was due to an increase of $2.3 million due to higher employment related expenses and an increase of $1.7 million primarily related to the advancement of CB-1158 to a phase 1 clinical trial. Research and development expenses for the fourth quarter of 2016 were $6.6 million, compared to $5.8 million for the same period last year.

General and administrative expenses for the full year 2016 were $10.6 million, compared with $9.1 million in the prior year. The increase of $1.5 million in 2016 was primarily due to higher employment related expenses, including stock based compensation expense. General and administrative expenses for the fourth quarter of 2016 were $3.0 million, compared to $2.3 million for the same period last year. Loss from operations for the three months and year ended December 31, 2016 was $9.5 million and $38.0 million, respectively.

Financial Guidance for 2017

Calithera expects that its cash, cash equivalents and investments will be between $95 and $105 million at the end of 2017, exclusive of any funds arising from new

collaborations or partnerships, milestone payments, additional equity financings or other new sources.

Conference Call Information

Calithera will host an update conference call today, March 16th at 1:30 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 83671541. 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 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, 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 currently in a Phase I 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 initiation 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, Calithera's receipt of clinical data from its clinical trials, and Calithera's cash and investments balance at the end of 2017. 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 Balance Sheets Financial Data
(in thousands)
(unaudited)

	December 31, 2016	December 31, 2015
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 51,781	$ 71,925
Working capital	49,108	68,662
Total assets	54,796	75,750
Total liabilities	4,890	3,962
Accumulated deficit	(122,502)	(84,498)
Total stockholders' equity	49,906	71,788

Calithera Biosciences, Inc.
Selected Statements of Operations Financial Data
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 6,593	$ 5,833	$ 27,748	$ 23,748
General and administrative	3,011	2,295	10,586	9,071
Total operating expenses	9,604	8,128	38,334	32,819
Loss from operations	(9,604)	(8,128)	(38,334)	(32,819)
Interest income, net	84	60	330	175
Net loss	$ (9,520)	$ (8,068)	$ (38,004)	$ (32,644)

Net loss per share, basic and diluted	$ (0.45)	$ (0.44)	$ (1.95)	$ (1.81)
Weighted average common shares used to compute net loss per share, basic and diluted	21,045	18,163	19,486	18,045

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Primary Logo

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