Calithera Biosciences Reports Third Quarter 2018 Financial Results and Recent Highlights

November 7, 2018

-Calithera to Host Conference Call Today at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2018 (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, 2018. As of September 30, 2018, cash, cash equivalents and investments totaled $141.5 million.

“Calithera continues to advance the development of our novel oncometabolism clinical candidates,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. “In this quarter we broadened the development of the novel glutaminase inhibitor CB-839 with two new clinical trial collaborations with Pfizer. We are actively enrolling CANTATA and ENTRATA, two randomized trials of CB-839 for the treatment of patients with renal cell carcinoma, with data from the ENTRATA trial expected in 2019. In addition, we and our partner Incyte expect data on INCB001158 to be presented at a medical meeting in the first half of 2019.”

Third Quarter 2018 and Recent Highlights

- **Announced two new clinical trial collaborations to evaluate Pfizer’s CDK4/6 inhibitor palbociclib, also known as IBRANCE®, and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor talazoparib also known as TALZENNA®, each in combination with Calithera’s glutaminase inhibitor CB-839.** Calithera will initiate Phase 1/2 clinical studies in the first quarter of 2019. Preclinical data suggest that CB-839 synergizes with CDK4/6 inhibitors by enhancing cell cycle arrest and blocking cancer cell proliferation. CB-839 also synergizes preclinically with PARP inhibitors to impair DNA synthesis, enhance DNA damage, and block cancer cell proliferation.

- **Two Randomized Combination Trials of CB-839 in Combination for the Treatment of Renal Cell Carcinoma.** The ENTRATA trial, a randomized double-blind study of late line patients, will enroll approximately 66 patients to receive either CB-839 plus everolimus or everolimus alone. Topline results are expected in 2019. The CANTATA trial is a randomized, global, double-blind trial comparing patients treated with cabozantinib and CB-839 to patients treated with cabozantinib alone. Topline results are expected in 2020. The trial will enroll patients with clear cell renal cell carcinoma who have previously received one or two prior lines of therapy. The trial, originally designed to enroll 300 patents has been enlarged to approximately 400 patients. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CB-839 in combination with cabozantinib for the treatment of this patient population. Updated Phase 1b data of CB-839 combined with cabozantinib presented in the quarter demonstrated a disease control rate of 100%, and response rate of 50% in 10 evaluable patients with clear cell RCC.

- **INCB001158 Arginase Inhibitor Immuno-oncology Program.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, and in combination with immunotherapies and chemotherapy. INCB001158 is being developed as part of a collaboration and license agreement with Incyte. Data from INCB001158 is expected to be presented at a medical meeting in the first half of 2019.

- **CB-280 Arginase Inhibitor for the Treatment of Cystic Fibrosis.** Arginase is believed to be critical in the pathology of cystic fibrosis. It impairs production of nitric oxide and generates metabolites of arginine that may impair lung function. CB-280 is an orally administered small molecule inhibitor of arginase. An investigational new drug (IND) application for CB-280 with the FDA is planned for the first half of 2019.

- **CB-708 Oral Small Molecule CD73 Inhibitor.** The immuno-oncology target CD73 is an enzyme that plays a critical role in the process of ATP conversion to adenosine. An IND application for CB-708, an orally administered small molecule inhibitor of CD73, is planned for 2019.

Selected Third Quarter 2018 Financial Results

Cash, cash equivalents and investments totaled $141.5 million at September 30, 2018.

Research and development expenses were $16.4 million for the three months ended September 30, 2018, compared with $10.8 million for the same period in the prior year. The increase of $5.6 million was due to an increase in the CB-839 program, including for the CANTATA trial which opened in 2018, an increase in the INCB001158 program, including Incyte’s co-funding of development costs, an increase in the CB-280 program, as well as investment in early stage research.

General and administrative expenses were $3.1 million for both the three months ended September 30, 2018 and 2017 due to consistent headcount and stock-based compensation expense.

Net loss from operations for the three months ended September 30, 2018 was $18.8 million, or $0.52 per share.

Conference Call Information

Calithera will host an update conference call today, November 7, at 2:00 p.m. Pacific Time/ 5:00 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 9368596. 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 is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. 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 and enrollment of Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's collaboration with Pfizer and Incyte, 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,	
	2018	**2017**	**2018**	**2017**
Revenue:				
Collaboration revenue	$ —	$ 7,254	$ 22,254	$ 18,701
Total revenue	—	7,254	22,254	18,701
Operating expenses:				
Research and development	16,420	10,833	49,218	27,615
General and administrative	3,087	3,074	10,093	9,230
Total operating expenses	19,507	13,907	59,311	36,845
Loss from operations	(19,507)	(6,653)	(37,057)	(18,144)
Interest income, net	658	582	1,927	1,292
Net loss	$ (18,849)	$ (6,071)	$ (35,130)	$ (16,852)
Net loss per share, basic and diluted	$ (0.52)	$ (0.17)	$ (0.98)	$ (0.53)
Weighted average common shares used to compute net loss per share, basic and diluted	36,405	35,475	36,021	32,072

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

	September 30, 2018	**December 31, 2017**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 141,456	$ 186,154
Working capital	134,213	128,640
Total assets	147,674	192,455

Deferred revenue	—	31,045
Total liabilities	11,764	42,148
Accumulated deficit	(176,671)	(150,333)
Total stockholders' equity	135,910	150,307

Contact:
Jennifer McNealey
ir@Calithera.com
650-870-1071

Source: Calithera Biosciences, Inc.