Calithera Biosciences Reports Second Quarter 2019 Financial Results and Recent Highlights

August 8, 2019

--Calithera to Provide Corporate Update via Conference Call and Webcast at
2:00 p.m. PT on August 8, 2019--

SOUTH SAN FRANCISCO, Calif., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical stage biotechnology company focused on discovering and developing novel small molecule drugs for the treatment of cancer and other life-threatening diseases, announced today its financial results for the second quarter ended June 30, 2019. As of June 30, 2019, cash equivalents and investments totaled $153.2 million.

“In the second quarter, we achieved clinical proof of concept for our glutaminase inhibitor telaglenastat, with positive topline results of the randomized phase 2 ENTRATA study,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “After completing a secondary offering in the quarter, we are well positioned to execute on our strategy and advance our pipeline forward. In the second half of the year, we look forward to completing enrollment in our registrational CANTATA trial evaluating telaglenastat for the treatment of patients with renal cell carcinoma, as well as presenting data from our arginase inhibitor program INCB001158.”

Second Quarter 2019 and Recent Highlights

- **Achieved positive topline results in randomized Phase 2 ENTRATA study of telaglenastat (CB-839) with everolimus in renal cell carcinoma.** The ENTRATA trial (NCT03163667) was a Phase 2 randomized, double-blind trial designed to evaluate the safety and efficacy of telaglenastat in combination with everolimus versus placebo with everolimus in patients with advanced clear cell RCC who have been treated with at least two prior lines of systemic therapy, including at least one prior VEGFR-targeted tyrosine kinase inhibitor. The trial enrolled 69 patients at multiple centers in the United States. The primary endpoint of ENTRATA was progression-free survival (PFS). The combination doubled the median PFS in heavily pretreated patients with advanced RCC. Telaglenastat, when added to everolimus, doubled the median PFS to 3.8 months as compared to 1.9 months for everolimus alone and reduced the risk of disease progression or death by 36% (HR=0.64, p=0.079 one-sided). The primary endpoint of the trial was PFS per investigator assessment with a predetermined threshold of p≤0.2 one-sided. The secondary endpoint of overall survival is not yet mature.
- **Initiated Phase 1/2 clinical trial of telaglenastat in combination with palbociclib for solid tumors.** The Phase 1/2 clinical trial is evaluating telaglenastat in combination with Pfizer’s CDK4/6 inhibitor palbociclib, also known as Ibrance ®. The study will evaluate the safety and anti-tumor activity of telaglenastat plus palbociclib in patients with KRAS-mutated colorectal cancer (CRC) and KRAS-mutated non-small cell lung cancer (NSCLC).
- **Advanced INCB001158 arginase inhibitor immuno-oncology program.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with cancer 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 are expected to be presented at the European Society for Medical Oncology (ESMO) Congress in September.
- **Presented new preclinical data for CB-708 at AACR Annual Meeting.** CB-708 is a selective, oral inhibitor of CD73, an enzyme that synthesizes the immunosuppressive agent adenosine and is over expressed in multiple tumor types. By blocking adenosine production in the tumor, CB-708 is designed to enhance T-cell activation leading to anti-tumor activity. Calithera anticipates that CB-708 will enter clinical trials in the second half of 2019.
- **Completed public offering of common stock**. In June 2019, Calithera completed an underwritten public offering of common stock. Gross proceeds from the offering, before underwriting discounts and commissions and offering expenses, were $57.5 million.

Selected Second Quarter 2019 Financial Results

Cash, cash equivalents and investments totaled $153.2 million at June 30, 2019.

Research and development expenses were $20.9 million for the three months ended June 30, 2019, compared with $17.3 million for the same period in the prior year. The increase of $3.6 million was primarily due to a $1.5 million increase in the telaglenastat program, including for the CANTATA trial, an increase of $1.5 million in the INCB001158 program, and an increase of $0.7 million in the CB-280 program, partially offset by a decrease of $0.1 million for investment in our early stage research programs.

General and administrative expenses were $4.0 million for the three months ended June 30, 2019, compared with $3.5 million for the same period in the prior year. The increase of $0.5 million was related to higher professional services costs.

Net loss for the three months ended June 30, 2019 was $24.2 million, or $0.58 per share.

Conference Call Information

Calithera will host an update conference call today, Thursday, August 8 at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time. The call may be accessed

by dialing (855) 783-2599 (domestic) or (631) 485-4877 and referring to conference ID 9239839. 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 is a clinical-stage biopharmaceutical company pioneering the discovery and development of targeted therapies that disrupt cellular metabolic pathways to preferentially block tumor cells and enhance immune-cell activity. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer and other life-threatening diseases, Calithera is advancing a pipeline of first-in-clinic, oral therapeutics to meaningfully expand treatment options available to patients. 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 Calithera's clinical trials, the clinical and commercial potential of its product candidates; the trial design and enrollment of patients in the CANTATA and ENTRATA trials; clinical trials for INCB001158 and Calithera's agreement with Incyte; and the timing that CB-708 will enter clinical trials in 2019. 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.

SOURCE: Calithera Biosciences, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ —	$ 17,065	$ —	$ 22,254
Total revenue	—	17,065	—	22,254
Operating expenses:				
Research and development	20,928	17,305	41,167	32,798
General and administrative	3,984	3,498	8,148	7,006
Total operating expenses	24,912	20,803	49,315	39,804
Loss from operations	(24,912)	(3,738)	(49,315)	(17,550)
Interest and other income, net	760	663	1,476	1,269
Net loss	$ (24,152)	$ (3,075)	$ (47,839)	$ (16,281)
Net loss per share, basic and diluted	$ (0.58)	$ (0.09)	$ (1.19)	$ (0.45)
Weighted average common shares used to compute net loss per share, basic and diluted	41,303	35,874	40,091	35,827

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

	June 30, 2019	December 31, 2018
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 153,212	$ 136,153
Working capital	137,060	125,371
Total assets	166,376	142,725
Total liabilities	26,994	16,011

Accumulated deficit	(244,080	)	(196,170	)
Total stockholders' equity	139,382		126,714	

###

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

Source: Calithera Biosciences, Inc.