Calithera Biosciences Reports Second Quarter 2020 Financial Results and Recent Highlights

August 10, 2020

--Calithera to Provide Corporate Update via Conference Call and Webcast at 2:00 p.m. PT on August 10, 2020--

SOUTH SAN FRANCISCO, Calif., Aug. 10, 2020 (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, 2020.

"We continued our positive momentum from 2019 into the first half of 2020, further strengthening our cash position and advancing our key clinical development programs," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "Recently, we announced the initiation of the first clinical trial to evaluate our novel arginase inhibitor in cystic fibrosis, and we have also made significant progress toward the initiation of our first clinical trial evaluating telaglenastat in people with non-small cell lung cancer whose tumors have KEAP1 or NRF2 genetic mutations. We look forward to top-line results from our pivotal CANTATA trial in renal cell carcinoma in late fourth quarter of 2020 or early first quarter 2021."

Second Quarter 2020 and Other Recent Program Highlights

- **CANTATA randomized trial of telaglenastat and cabozantinib in advanced renal cell carcinoma (RCC).** The pivotal CANTATA trial is a global, randomized, double-blind clinical trial of telaglenastat combined with cabozantinib, in patients with advanced or metastatic RCC who have received one or two prior treatments. The CANTATA trial enrolled 444 patients at multiple centers globally. The primary endpoint is progression-free survival (PFS). In light of delays associated with COVID-19, and pending further developments in the ongoing pandemic, Calithera expects to report top-line efficacy and safety data from the trial in late fourth quarter of 2020 or early first quarter 2021.
- **KEAPSAKE randomized trial in non-small cell lung cancer (NSCLC) patients with a KEAP1 or NRF2 genetic mutation.** Mutations in the KEAP1/NRF2 pathway, which occur in an estimated 20 percent of NSCLC patients, are associated with aggressive tumor growth. Recently presented clinical data demonstrate that activation of this pathway, either through the loss of KEAP1 function or activation of NRF2, are associated with poor clinical outcomes among patients with NSCLC receiving front-line standard-of-care chemoimmunotherapy. Pre-clinical models have shown that activation of the KEAP1/NRF2 pathway makes tumors dependent on glutaminase activity for growth and survival, making these tumors exquisitely sensitive to inhibition of glutaminase activity by telaglenastat. The double-blind telaglenastat trial, which is open for enrollment, will enroll approximately 120 patients with stage IV non-squamous NSCLC with tumors that have the KEAP1 or NRF2 mutation. Patients will be randomized to receive telaglenastat or placebo, in combination with pembrolizumab, carboplatin and pemetrexed. The study will evaluate the safety and investigator-assessed PFS of telaglenastat plus these standard-of-care chemoimmunotherapies. Given the previously reported challenges associated with opening new clinical studies during the current stage of the COVID-19 pandemic, Calithera expects to enroll the first patient in the third quarter of 2020, pending further developments in the COVID-19 situation. Calithera plans to present interim data from this trial in 2021.
- **Pfizer clinical collaboration with the CDK4/6 inhibitor IBRANCE®, and the dual-mechanism poly (ADP-ribose) polymerase (PARP) inhibitor TALZENNA®, each in combination with telaglenastat.** In March 2019, Calithera initiated a Phase 1/2 trial of the combination of telaglenastat plus Talzenna in patients with solid tumors including expansion cohorts in RCC and triple-negative breast cancer. Dose escalation has been successfully completed. Following preliminary dose expansion, the company is no longer developing this combination. In July 2019, the company initiated a Phase 1/2 trial of the combination of telaglenastat plus Ibrance in patients with solid tumors including expansion cohorts in KRAS-mutated colorectal cancer and KRAS-mutated non-small cell lung cancer. Dose escalation has been completed and dose expansion cohorts are enrolling following a temporary pause due to the COVID-19 situation.
- **CB-280 arginase inhibitor program**. In July 2020, Calithera initiated a Phase 1b clinical trial in adult patients with cystic fibrosis and chronic airway infection. The randomized, double blind, placebo-controlled, dose escalation trial will evaluate multiple ascending doses of CB-280, dosed orally twice daily for 14 days, compared to placebo in up to 32 adult CF patients to determine a safe dose range for CB-280. The study follows the completion of a Phase 1 trial that evaluated the safety, tolerability and pharmacokinetic profile of CB-280 in healthy volunteers.
- **INCB001158 program.** INCB001158, an internally discovered molecule, is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, in combination with anti-PD-1 immunotherapy, and in multiple chemotherapy regimens. INCB001158 is being developed as part of a collaboration and license agreement with Incyte.

Selected Second Quarter 2020 Financial Results

Cash, cash equivalents and investments totaled $154.1 million at June 30, 2020. In April 2020, Calithera completed an underwritten public offering of 5,750,000 shares of common stock, resulting in net proceeds of approximately $33.5 million after deducting underwriting fees and offering

expenses.

Research and development expenses were $15.7 million for the three months ended June 30, 2020, compared to $20.9 million for the same period in the prior year. The decrease of $5.3 million was due to a $2.4 million decrease in the telaglenastat program, a $1.9 million decrease in the INCB001158 program and a decrease of $1.2 million for investment in early stage research programs, offset by a $0.2 million increase in the CB-280 program.

General and administrative expenses were $5.1 million for the three months ended June 30, 2020, compared with $4.0 million for the same period in the prior year. The increase of $1.1 million was primarily related to a $0.9 million increase in higher personnel-related and facility costs and $0.2 million higher professional services costs mainly for legal and consulting services.

Interest and other income, net was $0.4 million for the three months ended June 30, 2020, compared to $0.8 million for the same period in the prior year.

Net loss for the three months ended June 30, 2020 was $20.4 million, or $0.29 per share.

Conference Call Information

Calithera will host an update conference call today, Monday, August 10, 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 4562868. 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 receipt of top-line efficacy and safety data in the CANTATA trial; the timing of enrollment of the randomized trial in NSCLC patients with genetic mutation NRF2/KEAP1 and the presentation of interim data from this trial; the safety and anti-tumor activity of telaglenastat and cabozantinib, telaglenastat plus Talzenna and telaglenastat plus Ibrance; the development of INCB001158 by Calithera and Incyte; and the timing that CB-280 will enter 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.

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 15,656	$ 20,928	$ 35,781	$ 41,167
General and administrative	5,096	3,984	10,042	8,148
Total operating expenses	20,752	24,912	45,823	49,315
Loss from operations	(20,752)	(24,912)	(45,823)	(49,315)
Interest and other income, net	361	760	986	1,476
Net loss	$ (20,391)	$ (24,152)	$ (44,837)	$ (47,839)
Net loss per share, basic and diluted	$ (0.29)	$ (0.58)	$ (0.67)	$ (1.19)
Weighted-average common shares used to compute net loss per share, basic and diluted	69,516	41,303	67,036	40,091

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

	June 30, 2020	December 31, 2019
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 154,132	$ 157,361
Working capital	140,700	140,172
Total assets	164,927	168,768
Total liabilities	21,643	26,342
Accumulated deficit	(330,938)	(286,101)
Total stockholders' equity	143,284	142,426

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Source: Calithera Biosciences, Inc.