Calithera Biosciences Reports First Quarter 2020 Financial Results and Recent Highlights

May 7, 2020

--Calithera to Provide Corporate Update via Conference Call and Webcast at 2:00 p.m. PT on May 7, 2020--

SOUTH SAN FRANCISCO, Calif., May 07, 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 first quarter ended March 31, 2020.

“We continued our positive momentum from 2019 into the first quarter 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. “This included significant progress toward the initiation of our first clinical trial evaluating telaglenastat in non-small cell lung cancer patients with NRF2/KEAP1 genetic mutations. In addition, we plan to announce top-line results from the randomized CANTATA trial in the fourth quarter.”

First Quarter 2020 and Other Recent Program Highlights

- **CANTATA randomized trial of telaglenastat and cabozantinib in advanced renal cell carcinoma (RCC).** The 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, Calithera plans to report top-line efficacy and safety data from the trial in the fourth quarter of 2020.
- **KEAPSAKE randomized trial in non-small cell lung cancer (NSCLC) patients with a NRF2/KEAP1 genetic mutation.** Mutation of the KEAP1/NRF2 pathway is present in approximately 20% of NSCLC and is associated with poor survival and resistance to standard-of-care therapy. Activation of this pathway leads to reliance upon glutaminase activity and sensitizes cells to glutaminase inhibition with telaglenastat. Given the challenges associated with opening new clinical studies during the current stage of the COVID-19 pandemic, Calithera expects to begin enrollment of the first patient in the third quarter of 2020. A trial-in-progress abstract describing the study design has been accepted for presentation at the American Society of Clinical Oncology 2020 Virtual Meeting (ASCO20). 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 renal cell carcinoma and triple-negative breast cancer. 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 for both trials. Dose expansion cohorts have been temporarily paused due to the COVID-19 situation. Calithera expects enrollment to resume in the second quarter of 2020.
- **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. Clinical trials being conducted by Calithera and Incyte evaluating INCB001158 are ongoing as planned.
- **CB-280 arginase inhibitor program**. Calithera has completed a first-in-human Phase 1 trial evaluating the safety, tolerability and pharmacokinetic profile of oral CB-280 in healthy volunteers. A Phase 1b clinical study in people with cystic fibrosis (CF), which is expected to start enrollment in the third quarter of 2020, given the challenges associated with opening new clinical studies during the current stage of the COVID-19 pandemic, will test multiple doses of CB-280 compared to placebo in approximately 30 adults with CF to determine a safe dose range, and evaluate pharmacodynamic effects of arginase inhibition in this population.

Selected First Quarter 2020 Financial Results

Cash, cash equivalents and investments totaled $138.1 million at March 31, 2020. In April 2020, Calithera completed an underwritten public offering of 5,750,000 shares of common stock. Cash, cash equivalents and investments as of March 31, 2020 exclude the approximately $33.5 million in net proceeds from the April offering.

Research and development expenses were $20.1 million for the three months ended March 31, 2020, compared to $20.2 million for the same period in the prior year. The decrease of $0.1 million was primarily due to a $1.2 million decrease in the INCB001158 program and a decrease of $0.8 million for investment in our early stage research programs, partially offset by an increase of $1.4 million in the telaglenastat program and an increase of $0.5 million in our CB-280 program.

General and administrative expenses were $4.9 million for the three months ended March 31, 2020, compared with $4.2 million for the same period in the prior year. The increase of $0.7 million was primarily related to $0.5 million higher professional services costs mainly for legal and consulting services, and $0.2 million in higher facility costs related to the expiration of our sublease in February 2020.

Interest and other income, net was $0.6 million for the three months ended March 31, 2020, compared to $0.7 million for the same period in the prior year.

Net loss for the three months ended March 31, 2020 was $24.4 million, or $0.38 per share.

Conference Call Information

Calithera will host an update conference call today, Thursday, May 7, 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 7543049. 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 March 31,	
	2020	**2019**
Operating expenses:		
Research and development	20,125	20,239
General and administrative	4,946	4,164
Total operating expenses	25,071	24,403
Loss from operations	(25,071)	(24,403)
Interest and other income, net	625	716
Net loss	$ (24,446)	$ (23,687)
Net loss per share, basic and diluted	$ (0.38)	$ (0.61)
Weighted-average common shares used to compute net loss per share, basic and diluted	64,556	38,866

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

	March 31,	**December 31,**

	2020	2019
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 138,110	$ 157,361
Working capital	122,123	140,172
Total assets	149,678	168,768
Total liabilities	22,013	26,342
Accumulated deficit	(310,547)	(286,101)
Total stockholders' equity	127,665	142,426

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Source: Calithera Biosciences, Inc.