Calithera Biosciences Reports Fourth Quarter 2020 Financial Results and Recent Highlights

March 16, 2021

--Calithera to Provide Corporate Update via Conference Call and Webcast at 2:00 p.m. PT on March 16, 2021--

SOUTH SAN FRANCISCO, Calif., March 16, 2021 (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 fourth quarter ended December 31, 2020. As of December 31, 2020, cash, cash equivalents and investments totaled $115.2 million.

“In the fourth quarter, we maintained a strong cash position and continued to advance our key clinical development programs, including the KEAPSAKE clinical trial evaluating telaglenastat in non-small cell lung cancer in patients with NRF2/KEAP1 genetic mutations, and the Ph1b trial of our arginase inhibitor CB-280 in cystic fibrosis patients,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “We look forward to sharing interim data from the KEAPSAKE trial and the results of the CB-280 trial in cystic fibrosis patients, each in the second half of 2021.”

Fourth Quarter 2020 and Recent Highlights

- **Announced top-line results of randomized CANTATA trial of telaglenastat with cabozantinib in advanced renal cell carcinoma (RCC).** The Phase 2 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. On January 4, 2021, Calithera announced topline results from the CANTATA clinical study and reported the trial did not meet the primary endpoint of improving progression free survival (PFS) in the study population.

- **Continued enrollment of the Phase 2 randomized KEAPSAKE trial in non-small cell lung cancer (NSCLC) patients with genetic mutation NRF2/KEAP1.** The double-blind KEAPSAKE trial 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 progression-free survival (PFS) of telaglenastat plus this standard-of-care chemoimmunotherapy regimen. Calithera anticipates sharing interim data from the KEAPSAKE trial in the second half of 2021.
- **Initiated a Phase 1b clinical trial of CB-280 in patients with cystic fibrosis**. In October, Calithera presented a trial in progress poster at the North American Cystic Fibrosis 2020 Virtual Conference. The presentation included preclinical study results which suggest CB-280 significantly improved lung function and reduced Pseudomonas aeruginosa colony-forming units in pre-clinical models. Arginase inhibition with CB-280 resulted in improved central airway resistance in CFTR knockout mice, and decreased lung infection in wild type and DeltaF508-CFTR-expressing mice infected with Pseudomonas aeruginosa. Enrollment in the Ph1b study is ongoing and Calithera expects to share data in the second half of 2021. In November 2020, Calithera was awarded up to $2.4M from the Cystic Fibrosis Foundation to support clinical development of CB-280.

- **Presented preclinical data for CB-668 IL4I1 program at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November.** CB-668 is a potent, selective, small-molecule, oral inhibitor of IL4I1, an amino acid oxidase that inhibits anti-tumor immunity and promotes tumor growth. IL4I1 regulates several aspects of adaptive immunity, including inhibition of cytotoxic T cells through its production of both hydrogen peroxide and activators of the aryl hydrocarbon receptor. CB-668 increases pro-inflammatory gene expression in tumors leading to an anti-tumor effect in mouse tumor models.

Selected Fourth Quarter and Full Year 2020 Financial Results

Cash, cash equivalents and investments totaled $115.2 million at December 31, 2020, which management believes will be sufficient to meet its current operating plan through 2022.

Research and development expenses for the full year 2020 were $71.0 million, compared to $76.3 million in the prior year. The decrease of $5.3 million was due to a $6.2 million decrease in the INCB001158 program and a $3.8 million decrease in early-stage research programs, partially offset by an increase of $2.7 million in the telaglenastat program and an increase of $2.0 million in the CB-280 program. Research and development expenses for the fourth quarter of 2020 were $17.1 million, compared to $17.9 million for the same period last year.

General and administrative expenses for the full year 2020 were $20.4 million, compared to $16.6 million in the prior year. The increase of $3.8 million was primarily related to a $2.5 million increase in personnel-related and facility costs and a $1.3 million increase in professional services costs. General and administrative expenses for the fourth quarter of 2020 were $5.6 million, compared to $4.6 million for the same period last year.

Interest and other income, net for the full year 2020 was $1.3 million, compared to $3.0 million in the prior year, mainly as a result of lower interest rates. Interest and other income, net for the fourth quarter of 2020 was $0.1 million, compared to $0.7 million for the fourth quarter of 2019.

Net loss for the three months and year ended December 31, 2020, was $22.6 million and $90.1 million, respectively.

Conference Call Information

Calithera will host an update conference call today, Tuesday, March 16, 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 6250035. 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 timing of enrollment of the randomized trial in NSCLC patients with genetic mutation NRF2/KEAP1 and the presentation of interim data from this trial; 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 be 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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 17,077	$ 17,902	$ 71,015	$ 76,290
General and administrative	5,586	4,551	20,372	16,605
Total operating expenses	22,663	22,453	91,387	92,895
Loss from operations	(22,663)	(22,453)	(91,387)	(92,895)
Interest and other income, net	97	725	1,250	3,035
Net loss	$ (22,566)	$ (21,728)	$ (90,137)	$ (89,860)
Net loss per share, basic and diluted	$ (0.32)	$ (0.39)	$ (1.31)	$ (1.90)
Weighted-average common shares used to compute net loss per share, basic and diluted	70,588	55,055	68,814	47,312

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

	December 31,	
	2020	**2019**
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 115,151	$ 157,361
Working capital	100,302	140,172
Total assets	125,587	168,768
Total liabilities	23,216	26,342

Accumulated deficit	(376,238)	(286,101)
Total stockholders' equity	102,371	142,426

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Source: Calithera Biosciences, Inc.