Calithera Biosciences Reports Second Quarter 2022 Financial Results and Recent Highlights

August 15, 2022

-- Conference Call and Webcast Scheduled for 5:00 p.m. ET on Monday, August 15, 2022 --

SOUTH SAN FRANCISCO, Calif., Aug. 15, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, today announced its financial results for the second quarter ended June 30, 2022.

“We continue to deliver on our commitment to efficiently advance our clinical programs, successfully initiating two new clinical trials and sharing program updates at two important medical conferences,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “We look forward to sharing data from the ongoing mivavotinib and sapanisertib phase 2 trials by the first quarter of 2023, as well as providing an update on the progress of our preclinical synthetic lethality VPS4 program by the end of 2022.”

Second Quarter 2022 and Other Recent Highlights

- **Initiated patient enrollment in phase 2 trial evaluating mivavotinib (SYK inhibitor) in r/r non-GCB DLBCL.** In June, Calithera announced enrollment of the first patient in a multicenter phase 2 clinical trial (NCT05319028) evaluating the spleen tyrosine kinase (SYK) inhibitor mivavotinib (CB-659) in patients with relapsed/refractory non-germinal center B-cell like (non-GCB) diffuse large B-cell lymphoma (DLBCL), a DLBCL subpopulation that primarily comprises patients with activated B-cell like disease (ABC). The main study objectives are to confirm previously seen single-agent activity in non-GCB DLBCL patients, evaluate activity according to MYD88/CD79b mutational status, and refine dose/schedule in this patient population. The primary endpoints of the study are overall response rate as assessed by an independent radiology review committee and safety. Mivavotinib has the potential to be the first treatment specifically for non-GCB DLBCL, a population of patients with a historically poorer prognosis and therefore high unmet need, and potential to be the first treatment for a genetically-defined subset of ABC in patients with MyD88/CD79 mutations. Approximately 50% of all ABC DLBCL tumors have one or both of these mutations. Data from the ongoing phase 2 trial could position Calithera to initiate a study with registrational intent in biomarker-specific DLBCL populations. Calithera plans to share data from this trial by the first quarter of 2023.

  In July, Calithera presented a trial-in-progress poster at the Pan Pacific Lymphoma Conference detailing the design of this phase 2 study.

- **Initiated patient enrollment in phase 2 trial sapanisertib (dual mTORC 1/2 inhibitor) in sqNSCLC.** In July, Calithera announced enrollment of the first patient in a phase 2 clinical trial (NCT05275673) of the dual mTORC 1/2 inhibitor sapanisertib (CB-228) in patients with relapsed/refractory NRF2 (NFE2L2)-mutated squamous non-small cell lung cancer (sqNSCLC). The study is designed to confirm the selective activity of sapanisertib in NRF2-mutated tumors compared to wild-type tumors, and to refine dose in this biomarker-defined population. The primary endpoints of the study are investigator-assessed overall response rate (ORR) per RECIST v1.1, and safety. Data from this study could position Calithera to initiate a study with registrational intent in biomarker-specific sqNSCLC populations. Calithera plans to share data from this trial by the first quarter of 2023.

- **Announced presentation of phase 1/2 data from sapanisertib/telaglenastat combination study.** In a mini oral session at the International Association for the Study of Lung Cancer (IASLC) 2022 World Conference on Lung Cancer (WCLC), Jonathan W. Riess, MD, MS, director of Thoracic Oncology and associate professor at UC Davis Comprehensive Cancer Center, presented dose-escalation findings from a multi-center phase 1/2 investigator-initiated study evaluating sapanisertib in combination with telaglenastat, an investigational glutaminase inhibitor, in biomarker-defined cohorts of patients with advanced non-small cell lung cancer (NSCLC). After evaluating five combination dosing levels in 13 patients, researchers determined that the sapanisertib/telaglenastat combination has a favorable tolerability profile at the recommended expansion dose. Early evidence of clinical benefit was observed in the dose-escalation cohort, including a partial response in a patient with NRF2-mutant squamous NSCLC and stable disease in a patient with KEAP1/NRF2-mutant adenosquamous NSCLC. As a next step, study investigators plan to enroll patients into one of four expansion cohorts evaluating sapanisertib plus telaglenastat in squamous NSCLC with and without NRF2 or KEAP1 mutations, and adenocarcinoma NSCLC with KRAS and KEAP1 or NRF2 mutations.

- **Continued to advance VPS4 program through lead optimization.** Calithera previously announced internal discovery of a novel series of small-molecule inhibitors of vacuolar protein sorting-associated protein 4A (VPS4A) and VPS4B, as well as the presentation of data validating the synthetic-lethal interaction between the gene paralogs at the American Association for Cancer Research (AACR) 2022 Annual Meeting. Calithera believes these VPS4 inhibitors are the first active, on-target inhibitors of VPS4. Potent, selective, and pharmacologically active VPS4 inhibitors are expected to be

well-tolerated and have strong single-agent activity in tumors with these mutations. Calithera continues to advance multiple VPS4 series through lead optimization and plans to share updates on this program by the end of the year.

Selected Second Quarter 2022 Financial Results

Cash and cash equivalents totaled $41.8 million at June 30, 2022.

Research and development expenses for the second quarter 2022 were $7.8 million, compared to $12.8 million in the same period prior year. The decrease of $5.0 million was primarily due to decreases in the telaglenastat and CB-280 programs, partially offset by increases in the sapanisertib and mivavotinub programs.

General and administrative expenses for the second quarter 2022 were $3.6 million, compared to $4.5 million in the same period prior year. The decrease of $0.9 million was primarily due to decreased personnel-related costs.

Other income, net for the second quarter 2022 was $2.3 million, compared to other expense of $4,000 in the same period prior year, primarily attributable to the decrease in fair value of warrant liabilities.

Net loss was $9.1 million for the three months ended June 30, 2022.

Conference Call Information

Calithera will host an update conference call today, Monday, August 15, at 2:00 p.m. Pacific Time/5:00 p.m. Eastern Time. To register for dial-in access to the call, please use this link. 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, precision oncology biopharmaceutical company developing targeted therapies to redefine treatment for biomarker-specific patient populations. Driven by a commitment to rigorous science and a passion for improving the lives of people impacted by cancer, Calithera is advancing a robust pipeline of investigational, small-molecule oncology compounds with a biomarker-driven approach that targets genetic vulnerabilities in cancer cells to deliver new therapies for patients suffering from aggressive hematologic and solid tumor cancers for which there are currently limited treatment options.

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 safety, tolerability and efficacy of Calithera's product candidates, the overall advancement of Calithera's product candidates in preclinical development and clinical trials, including Calithera's plan to initiate two phase 2 clinical trials for mivavotinib and sapanisertib and plan to share data from these trials by the first quarter 2023, Calithera's ability to potentially initiate registrational studies in biomarker-specific populations in DLBC and relapsed or refractory squamous NSCLC, the expectation that VPS4 inhibitors will be well-tolerated and have strong single-agent activity in tumors with certain mutations, Calithera's plan to advance multiple VPS4 series through lead optimization and plan to share updates on this program by the end of the year, the unmet need in the treatment of patients with advanced disease, and management's expectation that Calithera's cash and cash equivalents will be sufficient to meet its operating plan through the second quarter of 2023. 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
License revenue	$ —	$ 3,000	$ —	$ 3,000
Total revenue	—	3,000	—	3,000
Operating expenses:				
Research and development	7,758	12,820	17,324	28,159
General and administrative	3,618	4,487	7,878	9,915

Total operating expenses	11,376	17,307	25,202	38,074
Loss from operations	(11,376)	(14,307)	(25,202)	(35,074)
Other income (expense):				
Transaction costs allocable to warrant liabilities	(475)	—	(475)	—
Change in fair value of warrants liabilities	2,706	—	2,706	—
Interest and other income (expense), net	68	(4)	59	368
Other income (expense), net	2,299	(4)	2,290	368
Net loss	$ (9,077)	$ (14,311)	$ (22,912)	$ (34,706)

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

	June 30, 2022	December 31, 2021
Balance Sheet Data:		
Cash and cash equivalents	$ 41,789	$ 59,537
Working capital	33,930	47,446
Total assets	45,558	64,756
Total liabilities	10,307	15,672
Convertible preferred stock	22,342	40,702
Accumulated deficit	(495,878)	(491,326)
Total stockholders' equity	35,251	8,382

CONTACTS:
Stephanie Wong
ir@Calithera.com
650.870.1063

INVESTORS:
Burns McClellan
Lee Roth
212.213.0006
lroth@burnsmc.com

MEDIA:
Sam Brown, Inc.
Hannah Hurdle
805.338.4752
hannahhurdle@sambrown.com

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