Calithera Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Highlights

March 31, 2022

Conference Call and Webcast Scheduled for 2:00 p.m. PT / 5:00 p.m. ET on Thursday, March 31, 2022

SOUTH SAN FRANCISCO, Calif., March 31, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, today announced its financial results for the fourth quarter and year ended December 31, 2021.

"In 2021, we made significant progress in streamlining our clinical development programs, prioritizing our resources, and establishing our focus on biomarker-driven approaches in oncology. Our acquisition of two promising clinical-stage investigational therapies, mivavotinib and sapanisertib, in the fourth quarter significantly contributed to our pipeline of targeted therapies and complemented our in-house programs underway," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "We also announced the first data from our internally-discovered preclinical synthetic lethality target VPS4, and we will present the first data from our novel VPS4A inhibitors at the AACR Annual Meeting. 2022 will be an exciting year as we initiate two phase 2 clinical trials for mivavotinib and sapanisertib. We plan to share data from these trials by the first quarter 2023."

Fourth Quarter 2021 and Recent Highlights

- **Transformed Calithera's precision-oncology pipeline with the acquisition of two clinical-stage compounds with demonstrated single-agent activity; expect to initiate two phase 2 trials in the first half of 2022 with data for both anticipated by the first quarter of 2023.**
    - **Mivavotinib (SYK inhibitor):** Calithera will explore mivavotinib in the treatment of patients with non-GCB (ABC) DLBCL with and without mutations in MyD88 and CD79. SYK is known to activate multiple cell-signaling pathways in activated B-cell like (ABC) DLBCL. Mivavotinib showed a substantially higher response rate in ABC (53%) compared to GCB (22%) DLBCL in a retrospective analysis of completed trials. In addition, recent preclinical studies have shown enhanced SYK activity and sensitivity to SYK inhibition in DLBCL and other Non-Hodgkin lymphomas harboring mutations in MyD88 and/or CD79, which comprise a distinct genetic subset of ABC DLBCL known to have poor outcomes with standard of care therapy. Approximately 50% of all ABC DLBCL tumors have one or both of these mutations. Data generated from this study could position the company to initiate a study with registrational intent in biomarker-specific populations in DLBCL.
    - **Sapanisertib (Dual mTORC 1/2 inhibitor):** Through the phase 2 study, Calithera intends to strengthen the existing data on sapanisertib as a monotherapy in patients with squamous non-small cell lung cancer (sqNSCLC) harboring a NRF2 (NFE2L2) mutation (approximately 15% prevalence), and evaluate its activity in NRF2 wildtype (WT) sqNSCLC. More than 25% of all NSCLC is squamous and these patients have few options beyond standard-of-care PD1 inhibitors and chemotherapy. NRF2-mutated tumors have been shown to have poorer prognosis than NRF2 WT tumors. There are currently no therapies approved specifically for NRF2-mutated cancers, therefore sapanisertib has the potential to address the needs of a substantial underserved patient population. Data generated from this study could position the company to initiate a registrational study in relapsed or refractory squamous NSCLC.
- **Discovered novel series of VPS4A inhibitors.** The first data from Calithera's preclinical synthetic lethality pipeline will be presented at the American Association for Cancer Research (AACR) 2022 Annual Meeting, on April 8, 2022. The accepted poster will detail Calithera's discovery of a novel series of VPS4A inhibitors that are currently advancing through lead optimization. VPS4A and VPS4B are paralog ATPases essential for remodeling intracellular organelle membranes. Membrane remodeling is an essential cellular function and loss of function of both VPS4 paralogs is lethal to cells. The preclinical data demonstrate that VPS4A genetic inhibition in cell lines with loss of VPS4B preferentially showed profound death in cancer cells. Calithera will present the discovery of a series of novel, small-molecule VPS4A inhibitors which have potential in the treatment of VPS4B-deleted tumors.
- **Discontinued KEAPSAKE trial of telaglenastat in NSCLC.** In November 2021, Calithera announced the discontinuation of the phase 2 telaglenastat KEAPSAKE clinical trial in patients with non-squamous NSCLC with genetic mutations in KEAP1/NRF2 based on a lack of clinical benefit observed in patients treated with telaglenastat in an interim analysis. Calithera has no plans to continue the development of telaglenastat at this time.
- **Presented first CB-280 phase 1b data at NACFC.** In November 2021, Calithera presented interim data from the Phase 1b trial of CB-280 at the North American Cystic Fibrosis Conference (NACFC). CB-280 was well tolerated, demonstrated linear pharmacokinetics (PK), and showed complete and continuous target inhibition in plasma at doses at or above

100mg. CB-280 also demonstrated robust pharmacodynamic (PD) effects, with rapid and significant dose-proportional increases in plasma arginine, the key driver of NO production. Enrollment and analysis of all four cohorts is now complete and evaluation of next steps is ongoing.

- **Promoted Emil T. Kuriakose, MD, to chief medical officer.** Former vice president and head of clinical development at Calithera, Dr. Kuriakose succeeded Dr. Keith Orford, who was appointed to the Calithera Board of Directors.

- **Priced a $10.0 Million Underwritten Public Offering of Common Stock and Warrants to Purchase Common Stock.** On March 29, 2022, the Company priced an underwritten public offering of 18,518,519 shares of its common stock at a price to the public of $0.54 per share. Each share of common stock is accompanied by a warrant to purchase one share of common stock at an exercise price of $0.54 per share, which is immediately exercisable and will expire 18 months from the date of issuance, or a short-term warrant, and a warrant to purchase one share of common stock at an exercise price of $0.54 per share, which is immediately exercisable and will expire 5 years from the date of issuance, or a long-term warrant. The gross proceeds to Calithera from the offering are expected to be approximately $10.0 million, before deducting underwriting discounts and commissions and estimated offering expenses. The offering is expected to close on April 1, 2022, subject to customary closing conditions.

Selected Fourth Quarter and Full Year 2021 Financial Results

Cash, cash equivalents and investments totaled $59.5 million at December 31, 2021, which the Company expects, together with proceeds from its $10.0 million public offering, will be sufficient to meet its operating plan through the second quarter of 2023.

Revenue for the full year 2021 was $9.8 million, compared to none in the prior year, and represents payments under collaboration agreements with Incyte and Antengene.

Research and development expenses for the full year 2021 were $53.4 million, compared to $71.0 million in the prior year. The decrease of $17.6 million was primarily due to a decrease in the telaglenastat program. Research and development expenses for the fourth quarter of 2021 were $13.7 million, compared to $17.1 million for the same period last year.

Research and development expenses related to asset acquisition for the full year 2021 were $50.9 million for our acquisition of sapanisertib and mivavotinib in the fourth quarter of 2021, and comprised of an upfront payment of $10.0 million in cash and $40.9 million attributed to the value of the Series A convertible preferred stock on the date issued, estimated using the Black-Scholes option-pricing model.

General and administrative expenses for the full year 2021 were $20.9 million, compared to $20.4 million in the prior year. General and administrative expenses for the fourth quarter of 2021 were $4.6 million, compared to $5.6 million for the same period last year.

Interest and other income, net for the full year 2021 was $0.3 million, compared to $1.3 million in the prior year. Interest and other income, net for the fourth quarter of 2021 was none, compared to $0.1 million for the fourth quarter of 2020.

Net loss for the three months and year ended December 31, 2021, was $69.2 million and $115.1 million, respectively.

Conference Call Information

Calithera will host an update conference call today, Thursday, March 31, at 2:00 p.m. Pacific Time/5:00 p.m. Eastern Time. The call may be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and referring to conference ID 9989324. 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 and other life-threatening diseases, 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 unmet need in the treatment of patients with advanced disease, management's expectation that Calithera's cash, cash equivalents and investments will be sufficient to meet its operating plan through the second quarter of 2023, and the timing of the closing of Calithera's recent public offering of common stock and warrants to purchase common stock. 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, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue:				
License revenue	$ —	$ —	$ 9,750	$ —
Total revenue	—	—	9,750	—
Operating expenses:				
Research and development	13,740	17,077	53,455	71,015
Research and development related to asset acquisition	50,875	—	50,875	—
General and administrative	4,594	5,586	20,853	20,372
Total operating expenses	69,209	22,663	125,183	91,387
Loss from operations	(69,209)	(22,663)	(115,433)	(91,387)
Interest and other income (expense), net	(1)	97	345	1,250
Net loss	$ (69,210)	$ (22,566)	$ (115,088)	$ (90,137)
Net loss per share, basic and diluted	$ (0.92)	$ (0.32)	$ (1.56)	$ (1.31)
Weighted average common shares used to compute net loss per share, basic and diluted	75,025	70,588	73,869	68,814

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

	December 31, 2021	December 31, 2020
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 59,537	$ 115,151
Working capital	47,446	100,302
Total assets	64,756	125,587
Total liabilities	15,672	23,216
Convertible preferred stock	40,702	—
Accumulated deficit	(491,326)	(376,238)
Total stockholders' equity	8,382	102,371

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

Source: Calithera Biosciences, Inc.