# Calithera Biosciences Reports Third Quarter 2022 Financial Results and Business Update

November 14, 2022

**-- Conference Call and Webcast Scheduled for 5:00 p.m. ET on Monday, November 14, 2022 --**

SOUTH SAN FRANCISCO, Calif., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage, precision-oncology biopharmaceutical company, today announced its financial results for the third quarter ended September 30, 2022.

“Earlier in the fourth quarter, we were very pleased to announce that we received FDA Fast Track designation for sapanisertib. This designation facilitates more frequent communication with the Agency, as well as a number of other benefits that could support our efforts to bring sapanisertib to patients in this area of high unmet need more quickly,” said Susan Molineaux, PhD, president and chief executive officer of Calithera. “Today we also share that we have experienced site activation delays on both our sapanisertib and mivavotinib trials, leading to slower than anticipated enrollment for both these programs. We expect initial data from these studies will not be available until mid-2023.”

**Third Quarter 2022 and Other Recent Highlights**

- **Received FDA Fast Track designation for sapanisertib (dual mTORC 1/2 inhibitor).** In October, Calithera announced that sapanisertib has been granted Fast Track designation by the FDA for the treatment of adult patients with unresectable or metastatic squamous non-small cell lung cancer (sqNSCLC) whose tumors harbor the NRF2 mutation. Fast Track designation, which is designed to facilitate the development and expedite the review of therapeutic candidates with the potential to treat a serious or life-threatening condition where there is a major unmet medical need, provides a number of potential benefits including increased communication with the FDA, the ability to submit a marketing application on a rolling basis and the possibility of priority review.

- **Began enrolling patients in Phase 2 trial evaluating sapanisertib in sqNSCLC.** In July 2022, the Company began enrolling patients in its phase 2 clinical trial (NCT05275673) of the dual mTORC 1/2 inhibitor sapanisertib (CB-228) in patients with relapsed/refractory NRF2 (NFE2L2)-mutated 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. Calithera presented a trial-in-progress poster detailing the study design at the North American Conference on Lung Cancer in September 2022.

- **Continued patient enrollment activities in Phase 2 trial evaluating mivavotinib (SYK inhibitor) in r/r non-GCB DLBCL.** In June 2022, the Company began enrolling patients in its multicenter Phase 2 clinical trial (NCT05319028) evaluating mivavotinib (CB-659) in patients with relapsed/refractory non-germinal center B-cell like (non-GCB) diffuse large B-cell lymphoma (DLBCL). The main objectives of the study are to confirm previously observed single-agent activity in non-GCB DLBCL patients, evaluate activity according to MYD88/CD79b mutation 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. Details of the Phase 2 study design were presented in a trial-in-progress poster at the Pan Pacific Lymphoma Conference in July.

- **Continued to advance VPS4 program through lead optimization.** Calithera continued to advance multiple vacuolar protein sorting-associated protein 4A (VPS4A) and VPS4B inhibitors through lead optimization and plans to share updates on this program by the end of 2022.

**Selected Third Quarter 2022 Financial Results**

Cash and cash equivalents totaled $34.1 million at September 30, 2022. Based on its current operating plan, the Company expects it has sufficient cash to fund its operations into the second quarter of 2023. The Company is currently evaluating all options for its programs, including strategic collaboration or licensing agreements and actively considering the sale of certain programs, in order to extend its cash runway.

Research and development expenses for the third quarter 2022 were $6.5 million, compared to $11.6 million in the same period prior year. The decrease of $5.1 million was primarily due to decreases in the telaglenastat and CB-280 programs and investments in early stage research, partially offset by increases in the sapanisertib and mivavotinib programs.

General and administrative expenses for the third quarter 2022 were $3.0 million, compared to $6.3 million in the same period prior year. The decrease of $3.3 million was primarily due to decreased personnel-related costs and legal expenses.

Net loss was $9.8 million for the three months ended September 30, 2022.

**Conference Call Information**

Calithera will host an update conference call today, Monday, November 14, 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 the availability of initial data for the mivavotinib and sapanisertib trials by mid-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, Calithera's expectation that cash and cash equivalents will be sufficient to meet its current operating plan into the second quarter of 2023 and whether Calithera will be able to enter into strategic collaborations or licensing agreements or sell certain programs and sufficiently extend its cash runway. 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| Revenue: | | | | |
| License revenue | $ — | $ 6,750 | $ — | $ 9,750 |
| Total revenue | — | 6,750 | — | 9,750 |
| Operating expenses: | | | | |
| Research and development | 6,447 | 11,556 | 23,771 | 39,715 |
| General and administrative | 3,079 | 6,344 | 10,957 | 16,259 |
| Total operating expenses | 9,526 | 17,900 | 34,728 | 55,974 |
| Loss from operations | (9,526) | (11,150) | (34,728) | (46,224) |
| Other income (expense): | | | | |
| Transaction costs allocable to warrant liabilities | — | — | (475) | — |
| Change in fair value of warrants liabilities | (453) | — | 2,253 | — |
| Interest and other income (expense), net | 177 | (22) | 236 | 346 |
| Other income (expense), net | (276) | (22) | 2,014 | 346 |
| Net loss | $ (9,802) | $ (11,172) | $ (32,714) | $ (45,878) |

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **Balance Sheet Data:** | | |

| | | |
|---|---|---|
| Cash and cash equivalents | $ 34,068 | $ 59,537 |
| Working capital | 25,465 | 47,446 |
| Total assets | 37,083 | 64,756 |
| Total liabilities | 10,695 | 15,672 |
| Convertible preferred stock | 22,342 | 40,702 |
| Accumulated deficit | (505,680) | (491,326) |
| Total stockholders' equity | 26,388 | 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

Source: Calithera Biosciences, Inc.