Calithera Biosciences Reports Second Quarter 2018 Financial Results and Recent Highlights

August 7, 2018

-Two Novel Programs Entering Clinical Development

-Calithera to Host Conference Call Today at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2018 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq: CALA), a clinical-stage pharmaceutical company focused on discovering and developing small molecule drugs that target novel and critical metabolic pathways in tumor and cancer-fighting immune cells, announced today its financial results for the second quarter ended June 30, 2018. As of June 30, 2018, cash, cash equivalents and investments totaled $152.2 million.

"In the second quarter we continued to execute our clinical development plans for our glutaminase inhibitor and arginase inhibitor programs, while deepening our pipeline with two novel programs entering clinical development," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We have advanced CB-280, a novel arginase inhibitor into development for the treatment of cystic fibrosis and we announced today our next oncometabolism drug candidate, CB-708, an orally bioavailable small molecule CD73 inhibitor."

Second Quarter 2018 and Recent Highlights

- **Enrolling Two Randomized Phase 2 Combination Trials of CB-839 in Combination for the Treatment of Renal Cell Carcinoma.** The ENTRATA trial, a randomized double-blind placebo-controlled study of late line patients, is enrolling approximately 66 patients to receive either everolimus and CB-839 or everolimus alone. It is now expected to enroll by the fourth quarter of 2018, or early 2019. CANTATA is a randomized double-blind placebo-controlled trial comparing advanced patients treated with cabozantinib and CB-839 to patients treated with cabozantinib alone. This trial will enroll approximately 300 clear cell renal cell carcinoma patients who have previously received one or two prior lines of therapy. The U.S. Food and Drug Administration (FDA) has granted Fast Track designation for CB-839 in combination with cabozantinib for the treatment of this patient population. The trial opened in 2018 and is expected to take approximately two years to reach the primary endpoint analysis.

- **Presented Results of CB-839 in Combination with Capecitabine at the 2018 American Society of Clinical Oncology.** A Phase 1 Investigator sponsored clinical trial of CB-839 plus capecitabine was presented at the 2018 American Society of Clinical Oncology (ASCO)[1] . In patients with late-line colorectal cancer that had progressed on at least one prior fluoropyrimidine-containing regimen, the median PFS was 26 weeks for patients with PIK3CA mutated cancer (n=7) and 16 weeks for patients with PIK3CA wild-type cancer (n=5,p=0.058). The Phase 2 portion of this study in patients with PIK3CA mutant colorectal cancer is ongoing.

- **Evaluating CB-839 in Combination with Paclitaxel in Triple Negative Breast Cancer (TNBC).** A Phase 2 trial evaluating CB-839 with paclitaxel in TNBC patients is ongoing. Four single arm, open label, cohorts of African American and non-African American patients are being treated in both the early and late stage settings. The primary endpoint of this trial is objective response rate and a number of predictive biomarkers are being assessed. Based on our preliminary Phase 2 clinical trial results and recent changes in the competitive landscape of TNBC, we do not plan to pursue further development of CB-839 plus paclitaxel in TNBC at this time.

- **Enrolling INCB001158 Clinical Trials.** INCB001158 is being evaluated in multiple clinical trials for the treatment of patients with solid tumors both as a monotherapy, and in combination with immunotherapies and chemotherapy. INCB001158 is being developed as part of a collaboration and license agreement with Incyte.

- **Advanced Arginase Inhibitor CB-280 for the Treatment of Cystic Fibrosis.** Arginase has been proposed to be critical in the pathology of cystic fibrosis by impairing production of nitric oxide. CB-280 is an orally administered small molecule inhibitor of arginase. An investigational new drug (IND) application for CB-280 with the U.S. FDA is planned for the first half of 2019.

- **Selected CD73 Small Molecule Inhibitor to Enter Clinical Development in 2019.** The enzyme CD73 is an oncometabolism target that plays a critical role in the process of ATP conversion to adenosine. An IND application for CB-708, an orally administered small molecule inhibitor of CD73, is planned in 2019.

- **R&D Day Planned on October 5, 2018 in New York City**. The meeting will focus on the Company's research and development programs, including CB-280 and CB-708. To access the live audio webcast or the subsequent archived recording, visit the Investors section of the Calithera website.

Selected Second Quarter 2018 Financial Results

Cash, cash equivalents and investments totaled $152.2 million at June 30, 2018.

Revenue was $17.1 million for the three months ended June 30, 2018, compared with $7.3 million for the same period in the prior year. In the second quarter of 2018, the Company completed the manufacturing services and technology transfer under its collaboration and license agreement with Incyte, which satisfied the performance obligation under ASC 606 and as a result all remaining deferred revenue was recognized.

Research and development expenses were $17.3 million for the three months ended June 30, 2018, compared with $10.1 million for the same period in the prior year. The increase of $7.2 million was due to an increase in the CB-839 program, including for the Phase 2 CANTATA trial which opened in 2018, an increase in the INCB001158 program, including Incyte's co-funding of development costs, an increase in the CB-280 program, including to support the IND application, as well as investment in early stage research.

General and administrative expenses were $3.5 million for the three months ended June 30, 2018, compared with $2.8 million for the same period in the prior year. The increase of $0.7 million was primarily due to increases in personnel-related costs.

Net loss from operations for the three months ended June 30, 2018 was $3.1 million, or $0.09 per share.

Conference Call Information

Calithera will host an update conference call today, August 7th at 2:00 p.m. Pacific Time/ 5:00 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and referring to conference ID 2057667. 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 is a clinical-stage biopharmaceutical company focused on fighting cancer by discovering, developing, and commercializing novel small molecule drugs that target tumor and immune cell metabolism. 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 timing and enrollment of Calithera's clinical trials, the clinical and commercial potential of its product candidates, Calithera's ability to fund its clinical programs, and Calithera's receipt of clinical data from its 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.

[1]*Research supported by a Stand Up To Cancer Colorectal Cancer Dream Team Translational Research Grant (Grant Number: SU2C-AACR-DT22-17). Stand Up To Cancer is a program of the Entertainment Industry Foundation. Research grants are administered by the American Association for Cancer Research, the scientific partner of SU2C.*

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue:				
Collaboration revenue	$ 17,065	$ 7,255	$ 22,254	$ 11,447
Total revenue	17,065	7,255	22,254	11,447
Operating expenses:				
Research and development	17,305	10,142	32,798	16,782
General and administrative	3,498	2,848	7,006	6,156
Total operating expenses	20,803	12,990	39,804	22,938
Loss from operations	(3,738)	(5,735)	(17,550)	(11,491)
Interest income, net	663	541	1,269	710
Net loss	$ (3,075)	$ (5,194)	$ (16,281)	$ (10,781)
Net loss per share, basic and diluted	$ (0.09)	$ (0.15)	$ (0.45)	$ (0.36)
Weighted average common shares used to compute net loss per share, basic and diluted	35,874	35,348	35,827	30,342

	June 30, 2018	December 31, 2017
Balance Sheet Data:		
Cash, cash equivalents and investments	$ 152,242	$ 186,154
Working capital	134,790	128,640
Total assets	158,975	192,455
Deferred revenue	—	31,045
Total liabilities	11,810	42,148
Accumulated deficit	(157,823)	(150,333)
Total stockholders' equity	147,165	150,307

Contact:
Jennifer McNealey
ir@Calithera.com
650-870-1071

Primary Logo

Source: Calithera Biosciences, Inc.