



Calithera Biosciences Reports Second Quarter 2015 Financial Results and Recent Highlights

August 10, 2015

First Clinical Data on Glutaminase Inhibitor CB-839 in Solid and Hematologic Malignancies

Immuno-oncology Program with Arginase Inhibitor CB-1158 on Track for Preclinical Data Release in Fourth Quarter and IND Filing in 1H 2016

Calithera to Host Conference Call Today at 4:30pm Eastern Time

SOUTH SAN FRANCISCO, Calif., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, announced today its financial results for the second quarter ended June 30, 2015. As of June 30, 2015, cash, cash equivalents and investments totaled \$88.2 million.

"In the second quarter, we presented data at key medical meetings and expanded our oncology pipeline with a new clinical candidate," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We presented initial clinical data for our lead product CB-839 at the American Society of Clinical Oncology and European Hematology association meetings, and we continue to be pleased with the rate of enrollment of our expansion cohorts. For our lead immuno-oncology program, we selected clinical candidate CB-1158, a small molecule arginase inhibitor with the potential to treat cancer by blocking the immunosuppression of the tumor micro-environment."

Second Quarter 2015 and Recent Highlights

Cancer Metabolism: CB-839, a first-in-class, oral, selective, potent inhibitor of glutaminase

- **Preclinical findings, including biomarker data, presented at the American Association of Cancer Research.** In April 2015, Calithera presented preclinical data that included the addition of two biomarkers and further evidence supporting synergies with approved agents. The biomarker data presented showed that KRAS and EGFR mutations correlate with enhanced sensitivity of CB-839 in non-small cell lung cancer cell lines. Data was also presented expanding on previously noted preclinical synergistic activity with other anti-cancer agents including mTOR inhibitors, EGFR inhibitors, and PARP inhibitors.
- **Solid Tumor Phase I data presented at the American Society of Clinical Oncology.** In May 2015, Calithera presented data that demonstrated the clinical activity, tolerability and unique mechanism of action of CB-839 as a single agent in patients with solid tumors. Robust inhibition of glutaminase was observed in platelets and tumor biopsies, with the magnitude of inhibition correlated with CB-839 exposure. Among evaluable patients, six of 31 (19%) on the three times a day without food schedule, and seven of 17 (41%) on the twice daily with food schedule had stable disease lasting at least 3 cycles (63 days). Calithera continues to enroll four single agent solid tumor expansion cohorts in patients with triple negative breast cancer, renal cell carcinoma, KRAS-mutated non-small cell lung cancer, and tumors harboring TCA cycle mutations. In addition, a combination expansion cohort with CB-839 and paclitaxel in triple negative breast cancer initiated enrollment, and combination cohorts with CB-839 and everolimus in renal cell carcinoma, and CB-839 and erlotinib in KRAS-mutated non-small cell lung cancer are planned.
- **Acute Leukemia Phase I data presented at the European Hematology Association.** In June 2015, Calithera presented data that demonstrated the clinical activity and tolerability of CB-839 in patients with relapsed and refractory acute leukemia. Among eighteen patients, including sixteen with acute myeloid leukemia (AML), one patient achieved a complete response in the bone marrow with incomplete recovery of peripheral counts (CRi). Five of 18 efficacy-evaluable patients across dose levels remained on therapy for at least 4 cycles. Monotherapy and combination expansion cohorts are planned, including combination with azacitadine. Additionally, a combination expansion cohort with pomalidomide and dexamethasone is ongoing in multiple myeloma patients.

Immuno-Oncology: CB-1158, a first-in-class, oral, selective, potent inhibitor of arginase

- **Arginase inhibitor CB-1158 selected as clinical candidate.** In June 2015, Calithera selected CB-1158 as its lead clinical candidate for the immuno-oncology program targeting inhibition of arginase, a critical immunosuppressive enzyme produced by myeloid-derived suppressor cells in tumors.

Anticipated Upcoming Milestones

- Enrollment of CB-839 monotherapy expansion cohorts by the end of 2015.
- Initiation of CB-839 combination expansion cohorts by the end of 2015.
- Solid tumor Phase I trial CB-839 monotherapy data in the fourth quarter of 2015 and combination therapy data in mid-2016.
- Hematologic Phase I clinical trial data in myeloma and AML (both monotherapy and combination) by mid-2016.
- Arginase inhibitor preclinical data in the second half of 2015.

- Filing of investigational new drug application (IND) for arginase inhibitor CB-1158 in the first half of 2016.

Selected Second Quarter 2015 Financial Results

Research and development expenses were \$5.5 million for the three months ended June 30, 2015, compared with \$4.2 million for the same period in the prior year. The increase of \$1.4 million was primarily attributed to higher expenses associated with the continued advancement of CB-839 and investments in the Company's arginase inhibitor program.

General and administrative expenses were \$2.3 million for the three months ended June 30, 2015, compared with \$1.3 million for the same period in the prior year. The increase of \$1.0 million was primarily due to higher employment related expenses, including stock-based compensation expense, professional service fees associated with operating as a publicly-traded company, and a license payment of \$0.2 million.

Net loss for the three months ended June 30, 2015 was \$7.8 million.

Financial Guidance for 2015

Calithera reiterates its guidance of its cash, cash equivalents and investments to be at least \$65 million at the end of 2015, exclusive of any license milestone payments or funds arising from any additional new collaborations or partnerships, equity financings or other new sources.

Conference Call Information

Calithera will host its second quarter financial results and corporate update conference call today, August 10th at 4:30 p.m. Eastern Time. The call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international), and reference to conference ID 5376452. 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 until the Company's conference call to discuss financial results for its third quarter of 2015.

About Calithera

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera's lead product candidate, CB-839, is currently being evaluated in three Phase 1 clinical trials in solid and hematological cancers. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

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 expected enrollment of Calithera's clinical trials, Calithera's ability fund its clinical programs, Calithera's filing of an investigational new drug application for its arginase inhibitor 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 most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, and other 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 Statements of Operations Financial Data

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2015	2014	June 30, 2015	2014
Operating expenses:				
Research and development	\$ 5,533	\$ 4,183	\$ 11,163	\$ 7,501
General and administrative	2,341	1,309	4,578	2,141
Total operating expenses	7,874	5,492	15,741	9,642
Loss from operations	(7,874)	(5,492)	(15,741)	(9,642)
Other income, net	56	1	65	2
Net loss	\$ (7,818)	\$ (5,491)	\$ (15,676)	\$ (9,640)
Net loss per share, basic and diluted	\$ (0.44)	\$ (24.22)	\$ (0.87)	\$ (47.14)
Weighted average common shares used to compute net loss per share, basic and diluted	17,963	227*	17,955	204*

*Pre-IPO conversion of preferred shares to common shares

Calithera Biosciences, Inc.

Selected Balance Sheets Financial Data

(in thousands)

(unaudited)

	June 30,	December 31,
	2015	2014
Balance Sheet Data:		
Cash, cash equivalents and investments	\$ 88,187	\$ 101,969
Working capital	75,180	99,742
Total assets	90,749	104,770
Total liabilities	4,434	4,404
Accumulated deficit	(67,530)	(51,854)
Total stockholders' equity	86,315	100,366

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