Equity Research

Flash Comment



 $\label{eq:June 12, 2015} June~12, 2015 \\ \textbf{CALA-NASDAQ--Outperform~(1)}/V$

Biotechnology

CALA: CB-839 AML Update From EHA Meeting; On the Right Track...Complementing Solid Tumor Results From ASCO 2015

Matthew J. Andrews, Senior Analyst (617) 603-4218

Sector Rating: Biotechnology, Market Weight

**On 6/11/15 Calithera presented updated CB-839 monotherapy data at the European Hematology Association Meeting (http://www.calithera.com/wp-content/uploads/2015/06/European_Hematology_Association_2015.pdf). Of most interest are data in Acute Myeloid Leukemia (13 with Isocitrate dehydrogenase [IDH] wild-type, 2 with IDH2-mutation, and 1 with IDH1-mutation).

**Efficacy data are similar to the May online abstract/release with one Complete Remission with incomplete blood counts recovery (CRi). This IDH2 patient was dosed at 800mg three-times daily (t.i.d.), and remains on-study for 294+ days. Additional signals of activity include a 2nd patient with 30% peripheral blasts at baseline, which were reduced to 3% by day 20, but blast counts rose to 13% soon after discontinuing CB-839 (due to central nervous system [CNS] disease progression). Pharmacodynamic (PD) data from 3 selected patients dosed at 600-1,000mg t.i.d. with 10-58% blast counts demonstrate near complete inhibition of glutaminase levels (near the lower-level-of-quantification for Calithera's platelet assay), clearly demonstrating CB-839's on-target effects.

**To date, only two AML patients have been dosed at the go-forward 600mg twice-daily (b.i.d.) with food dose; one remains on study in cycle 3. Data for 600-1,00mg b.i.d. from the five ongoing monotherapy cohort expansion arms will provide further insight into the potential for improved efficacy and synergies for CB-839 as part of various Ph. I(b) combinations.

**Consistent with the American Society of Clinical Oncology (ASCO) Meeting, safety remains unremarkable with only 3 cases of potentially drug-related Grade-3 toxicities, no drug-related discontinuations, and no signals of clinically relevant CNS toxicities.

**Key upcoming events: (1) initial preclinical data for the arginase inhibitor program at the American-Association-for-Cancer-Research (AACR) "Triple Meeting" in November; (2) updated monotherapy 600mg b.i.d. cohort expansion data (end-2015); and (3) initial Ph. I(b) combination data (six planned/on-going cohorts; end-2015).

**BOTTOM LINE: CB-839 data at ASCO and EHA 2015 continue to demonstrate a good tolerability profile, desired PD/pharmacokinetic properties, and clinical activity as monotherapy. Our long-term thesis remains unchanged and continue to see CALA as over-sold following the April AACR Meeting where CB-839's overall profile was less well-defined.

Calithera Biosciences, Inc. (CALA-NASDAQ)

Price as of 6/11/2015: \$7.92

FY 15 EPS: \$-2.02 FY 16 EPS: \$-2.32 Shares Out.: 17.9 MM Market Cap.: \$141.77 MM

Please see Disclosure Appendix for rating definitions, important disclosures, and required analyst certifications.

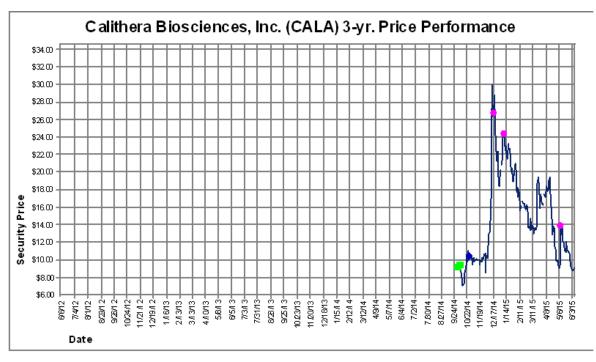
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Required Disclosures



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0	10/3/2014		IPO at \$10.00				
	10/27 /2014		Andrews				
•	10/27 /2014	11.04	1	1	19.00	20.00	10.40
•	12/15/2014	29.85	1	1	50.00	55.00	26.75
•	1/7/2015	23.85	1		35.00	40.00	24.40
•	5/8/2015	9.52	1	Т	27.00	30.00	13.87

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- Rating Down grade
- Rating Upgrade
- Valuation Range Change

Initiation, Resumption, Drop or Suspend

Analyst Change
Split Adjustment

Rating Code Key

1 Outperform/Buy SR Suspended 2 Market Perform/Hold NR Not Rated 3 Underperform/Sell NE No Estimate

Additional Information Available Upon Request

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CALA: Key risks include clinical trial failure, a safety signal for CB-839, and financing risk.

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As of: June 12, 2015

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