Equity Research

Flash Comment



June 1, 2015 CALA-NASDAQ--Outperform (1) / V

Biotechnology

CALA: CB-839 At ASCO 2015--Good Tolerability, Signals Of Efficacy, Broad Development Underway

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Sector Rating: Biotechnology, Market Weight

**On 5/30/15 updated CB-839 Phase I/II monotherapy data were presented in a poster and included in the Developmental Therapeutics Poster Discussion Session. Calithera also hosted an investor event (20-25 investors attended) which summarized the CB-839 program and highlighted its broad ongoing Ph. I/II program.

**Early signals of clinical activity in solid tumors and acute myeloid leukemia are encouraging. Twice-daily 600/800mg dosed with food has demonstrated improved efficacy of 41% (7/17) disease stabilization while thrice-daily dosing appears less efficacious at 19% SD (6/31). Four cases of tumor shrinkage have occurred (two at 600/800mg b.i.d.) while a near partial response (23% tumor shrinkage and durable out to roughly 10 months) in triple-negative breast cancer is the best response to date (dosed at 250mg t.i.d.). Recall Calithera has reported a marrow response with incomplete hematologic recovery (CRi) in an AML patient.

**No remarkable toxicities and a tolerable regimen. No significant drug-related adverse events (22% fatigue was most frequent), clinically significant central-nervous-system toxicities remain absent, and only two discontinuations due to an AE. Importantly, Grade 3 liver transaminases elevations decreased from five cases to one upon selection of 600mg b.i.d. dosed with food as the go-forward dose.

**The poster discussion session discussant, Dr. Wesolowski, noted the observed cases of SD and tumor shrinkage are significant due to the advanced stage of disease (median of three priors). At the investor event Dr. Infante (investigator in the study) noted while data are early, he felt CB-839's toxicity profile is manageable, was excited about its 1st-in-class profile, and pharmacokinetic and the platelet and tumor biopsy pharmacodynamics data demonstrate CB-839 is having an on-target effect is clinically active.

**CB-839's evolving profile and Calithera's thorough preclinical program (identifying six genetic/expression biomarkers) support the broad ongoing monotherapy cohort expansion at 600-1,000mg b.i.d. in five cancers and ongoing/planned Ph. I (b)/II in six solid tumor/blood cancers.

**Cohort expansion and initial combination data are expected later in 2015 with a broader dataset from the combination studies by mid-2016.

Calithera Biosciences, Inc. (CALA-NASDAQ)

Price as of 5/29/2015: \$10.47

FY 15 EPS: \$-2.02 FY 16 EPS: \$-2.32 Shares Out.: 17.9 MM Market Cap.: \$187.41 MM

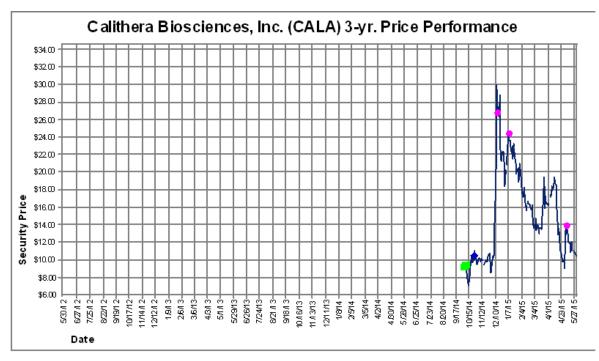
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	10/27 /2014		Andrews			
•	10/27/2014	11.04	1	19.00	20.00	10.40
•	12/15/2014	29.85	1	50.00	55.00	26.75
•	1/7/2015	23.85	1	35.00	40.00	24.40
•	5/8/2015	9.52	1	27.00	30.00	13.87

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- Rating Down grade
- Rating Upgrade
- Valuation Řange Change

Initiation, Resumption, Drop or Suspend

Analyst Change

Split Adjustment

Rating Code Key

Outplerform/Buy SR Suspended Market Perform/Hold NR Not Rated No Estimate Underperform/Sell

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

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M = Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.

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As of: June 1, 2015

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