# **Equity Research**

## Flash Comment



May CALA-NASDAQ--Outperfo

Biotechnology

## CALA: EHA Abstract Reports 1st Objective Response For CB-839 In AML

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Sector Rating: Biotechnology, Market Weight

\*\*Today abstracts for the European Hematology Association Meeting were released. Calithera provided its first meaningful up 8 3 9 i n A c u t e M y e l o i d L e u k e m i a (A M L) s i n c e t h e S e p t e m b e r 2 0 1 http://learningcenter.ehaweb.org/eha/2015/20th/99749/christopher.molineaux.phase.1.study.safety.and.tolerability.of.incre f=010674p6m3e841.

\*\*Consistent with the Ph. I dose-escalation solid tumor study, doses from 100mg-1,000mg t.i.d. have been administered in and/or refractory AML patients (failed more than 1 prior therapy), as of March 2015.

\*\*Clinical activity: 1) Calithera reported its 1st objective response with CB-839 monotherapy in a single patient who achieved marrow response with incomplete recovery of blood counts (CRi). The dose wasn't noted in the abstract. 2) 33% disease s (range: 4-10 CB-839 cycles). Recall in the ASCO abstract, 28% of advanced solid tumor patients achieved SD with respo cancers. 3) Pharmacokinetic/pharmacodynamics (PK/PD): at 600, 800, 1,000mg t.i.d., 94%+ inhibition of glutaminase was patients with active disease (up to 58% leukemic blast counts).

\*\*Safety: consistent with the solid tumor ASCO abstract no clinically meaningful central nervous system adverse events observed (a key issue which halted development of prior glutaminase inhibitors), no dose-limiting toxicities, limited cases transaminases/bilirubin, and no Grade3+ treatment-related AEs in greater than 10% of patients.

\*\*While Calithera ultimately plans to develop CB-839 in combination with various standard-of-care regimens and has emb ambitious Ph. I(b) combination program (five studies planned/soon-to-launch in triple-negative breast, clear-cell renal-ce myeloma, and AML), we believe reporting of its first objective response in a difficult population is an important clinical m Calithera as it demonstrates CB-839 is an active compound, validates Calithera's broad preclinical development program/s targeting of cancer cell metabolism as a therapeutic approach, and increases the potential for improved efficacy as part combinations.

\*\*BOTTOM LINE: While early, CB-839's overall profile in solid tumor/blood cancers continues to positively evolve suggestin clinical activity with a tolerable safety profile. Following weakness in CALA shares post-AACR we continue to see Calither valued longer-term.

Calithera Biosciences, Inc. (CALA-NASDAQ)

Price as of 5/20/2015: \$10.85

FY 15 EPS: \$-2.02 FY 16 EPS: \$-2.32 Shares Out.: 17.9 MM Market Cap.: \$194.21 MM

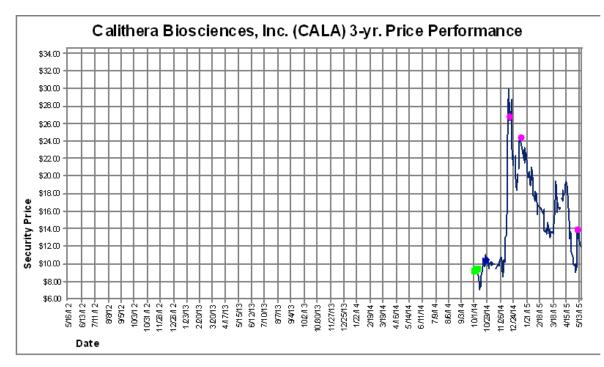
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|---|------------|------------------------|----------------|---------------|----------------|------------------|
| 0 | 10/3/2014  |                        | IPO at \$10.00 |               |                |                  |
|   | 10/27/2014 |                        | 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

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- Rating Down grade
- Rating Upgrade
   Valuation Range Change
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   Analyst Change
  - 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

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

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