## **Equity Research**

### Flash Comment



January 13, 2015 CALA-NASDAQ--Outperform (1) / V

Biotechnology

# CALA: On Track With CB-839 Ph. I Cohort Expansion, Initiation Of Combo Studies, And Solid Tumor Data At ASCO

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Sector Rating: Biotechnology, Market Weight

- \*\*On 1/12/2015 we met with CALA in San Francisco and below provide key highlights.
- \*\*Sixty patients have been enrolled in the three ongoing Ph. I monotherapy CB-839 studies (NHL/MM; AML/ALL; and solid tumors) with a majority of patients being enrolled with solid tumors.
- \*\*While doses have ranged from 100mg to 600mg+ (depending on the study), 600mg is the go-forward Ph. I dose based on safety/efficacy data to date and CALA's goal of achieving 90%+ continuous inhibition of glutaminase (based on pre-clinical data and PK/PD modelling). As a result, by early February, cohort expansion at 600mg b.i.d. will occur for five solid tumor types: renal cell, triple-negative breast (TNBC), mesothelioma, non small-cell lung, and rare TCA cycle enzyme mutations.
- \*\*Recall at the 2014 San Antonio Breast Cancer Symposium, CALA presented tumor biopsy data in three patients dosed at low doses of CB-839. These doses resulted in reductions of glutaminase in tumors of 70-80%. These data also correlated with platelet assays assessing glutaminase inhibition. As a result, CALA is confident that the 600mg dose should lead to greater reduction of glutaminase levels in vivo (and potentially improved efficacy).
- \*\*CALA is on track to commence the two Ph. I(b) combination studies in TNBC (CB-839/paclitaxel) and myeloma (CB-839/pomalidomide/dexamethasone) in Q1. Patients will initially be dosed at 400mg and then dose-escalated up to 600mg (following safety analyses for 400mg).
- \*\*An abstract will be submitted for the 2015 ASCO Meeting, which will focus on solid tumor data. Data from the two hematology studies are unlikely to be presented (until the ASH Meeting) due to less mature data as fewer patients have been enrolled. Data in the ASCO abstract will include all doses assessed with a sizeable portion coming from the 600mg dose.
- \*\*Importantly, Ph. I data continue to suggest that CB-839 avoids the CNS toxicities that plagued older glutaminase inhibitors where onset was rapid (usually in cycle one) and significant (generally Grade 3/4 in severity and usually required dose deescalation/discontinuation).

Calithera Biosciences, Inc. (CALA-NASDAQ)

Price as of 1/12/2015: \$22.86 FY 14 EPS: \$-2.40

FY 15 EPS: \$-1.56 Shares Out.: 17.9 MM Market Cap.: \$409.19 MM

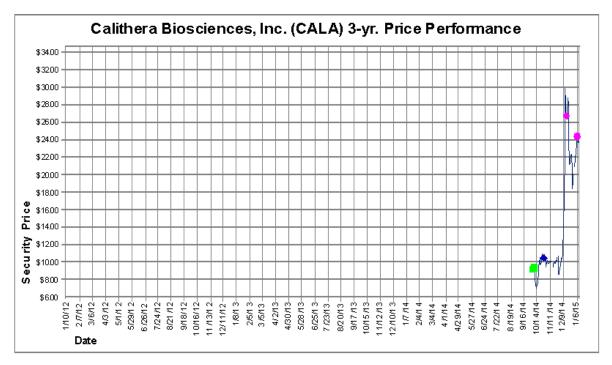
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|---|--------------|------------------------|----------------|---------------|----------------|------------------|
|   | 10/3/2014    |                        | IPO at \$10.00 |               |                |                  |
|   | 10/27 /2 014 |                        | 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            |
| • | 1/7/20 15    | 23.85                  | 1 1            | 35.00         | 40.00          | 24.40            |

Source: Wells Fargo Securities, LLC estimates and Reuters data

### Symbol Key

- Rating Downgrade
- Rating Upgrade
- Valuation Range Change

#### Initiation, Resumption, Drop or Suspend

An alyst Change

Split Adjustment

### Rating Code Key

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 Öutperform/Buy
 SR
 Suspended

 2
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 NR
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 3
 Underperform/Sell
 NE
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CALA: Key risks include clinical trial failure, a safety signal for CB-839, and financing risk.

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