Equity Research

Flash Comment



October 27, 2015 CALA-NASDAQ--Outperform (1) / V

Biotechnology

CALA: "Triple" Meeting Update: More Patients, Longer Follow-up...CB-839's Monotherapy Profile Remains On the Right Track.

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Sector Rating: Biotechnology, Market Weight

- ***Abstracts are available for the American Association for Cancer Research "Triple Meeting" (11/5-11/9/15): http://www.abstractsonline.com/plan/start.aspx?mkey=%7bC69FoC7B-CFF2-4010-AC6C-DEAE12E60491%7d. The key incremental updates for CALA's CB-839 were in patients treated at the go-forward, Phase II 600mg+, twice-daily/food-fed doses [43 efficacy-evaluable and 53 safety-evaluable (vs. 17 and 27 in June)].
- **Posters for Ph. I/II monotherapy solid tumor data on CB-839 will be on 11/8/15 (Abstract C49) and preclinical data on CB-1158 (arginase inhibitor) will occur 11/6/15 (A195). We look to the CB-1158 poster for important data as the online abstract had limited information.
- **With additional patients and longer follow-up, CB'839's initial signals of efficacy are holding steady. Best response at the 600mg+ twice-daily dose remains stable disease (SD) at 40% vs. 41% (in June). In any patient achieving SD (including thrice-daily and dose-escalation), median time on drug/in study is 5+ months vs. 3+ months in June (reinforcing CB-839's relatively benign safety and good tolerability). The most durable SD to date remains in triple-negative breast (TNBC; previously reported) with duration of response at one-year+ and 23% tumor shrinkage. Updated data in renal-cell-carcinoma (RCC) indicate 64% SD, with five of 11 remaining on study and compares favorably to prior 50% SD. Recall at 600mg thrice-daily a RCC patient achieved 6% tumor shrinkage and remains on study at 11 cycles.
- **Still no surprises on CB-839's safety profile. Overall Grade-3+ drug-related events remain low at 9% and only one case of Gr3 reversible, asymptomatic transaminases elevation (2%; same as prior update).
- **By year-end CALA will have six Ph. I(b) combination studies (at the twice-daily, food-fed dose) underway in TNBC, myeloma (MM), RCC, non-small cell lung, and acute myeloid leukemia (AML).
- **Next monotherapy data could be at the American Society of Hematology Meeting with an update in AML and potentially MM.
- **BOTTOM LINE: Incrementally positive update with continued re-assuring safety and signals of durable efficacy as monotherapy. Ph. I(b) combination data in June remain critical for assessing CB-839's long-term potential in solid tumors and hematologic cancers.

Calithera Biosciences, Inc. (CALA-NASDAQ)

Price as of 10/26/2015: \$7.34

FY 15 EPS: \$-2.02 FY 16 EPS: \$-2.31 Shares Out.: 17.9 MM Market Cap.: \$131.39 MM

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

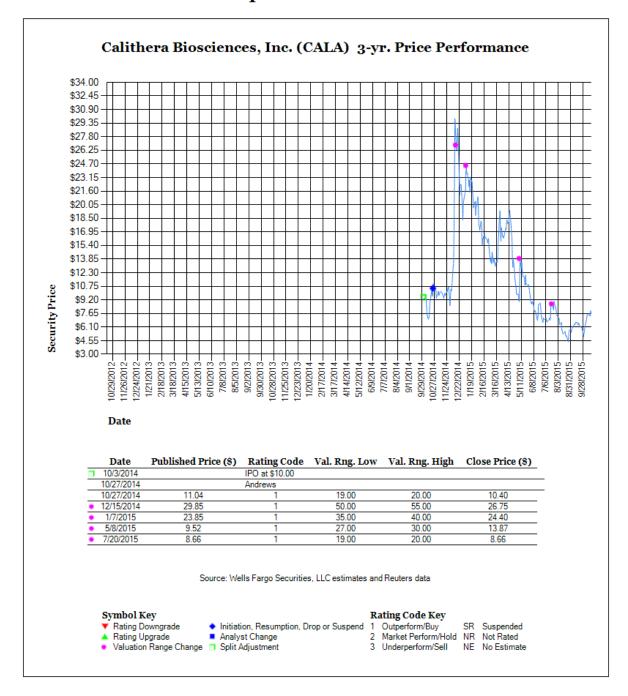
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Required Disclosures



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: October 27, 2015

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