

Equity Research

Calithera Biosciences, Inc.

CALA: Q2--CB-839 Steady As She Goes In Multiple Ph. I(b) Cohorts '839 Combo Data And Arginase Inhibitor Into Clinic By Mid-2016

Outperform / V

**Sector: Biotechnology
Market Weight**

Earnings Estimates Revised Up

EPS	2014A	2015E		2016E	
		Curr.	Prior	Curr.	Prior
Q1 (Mar.)	(\$22.80)	(\$0.44) A	NC	NE	
Q2 (June)	(24.22)	(0.44) A	(0.46)	NE	
Q3 (Sep.)	(16.85)	(0.54)	NC	NE	
Q4 (Dec.)	(0.39)	(0.61)	(0.58)	NE	
FY	(\$4.67)	(\$2.02)	NC	(\$2.31)	(2.32)
CY	(\$4.67)	(\$2.02)		(\$2.31)	
FY P/EPS	NM	NM		NM	
Rev.(MM)	\$0	\$0		\$0	

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, * = Company is on the Priority Stock List

2014 quarters may not sum to FY 2014 due to differences in shares outstanding and rounding.

• **Summary:** Following the August 10, 2015 market close, CALA reported Q2 financial results for a quarter highlighted by (1) selection of the lead clinical candidate for its arginase inhibitor program (CB-1158), (2) presentation of multiple CB-839 preclinical abstracts at the American Association for Cancer Research Meeting (AACR), and (3) updated Phase I monotherapy data for CB-839 at the American Society of Clinical Oncology (ASCO) and European Hematology Association (EHA) Meetings in May/June. While it has been CALA's long-term strategy to advance glutaminase inhibitor CB-839 to market in combination with various standard-of-care regimens, in our view, it is clear from data to date that single-agent CB-839 is capable of generating prolonged cases of durable disease stabilization in solid tumors (41% SD for greater than or equal to 3 cycles at the optimal dosing schedule), an objective response in acute myeloid leukemia [AML], is well-tolerated (importantly no central nervous system toxicities), is successfully inhibiting the glutaminase enzyme target (based on pharmacodynamic data), and CALA's seasoned clinical team has identified the optimal dosing regimen. With the recent initiation of three Ph. I(b) combination dosing cohorts with the go-forward regimen (and three more planned by the end of 2015), we now look to data late in 2015 for more mature monotherapy data (at the optimal 600mg b.i.d. dosing regimen) and mid-2016 for combination data to assess CB-839's true clinical potential. With Calithera currently trading at an enterprise value of roughly \$30 million, we believe this assumes an overly bearish view of CB-839's longer-term potential. Based on changes to our model our 2016E EPS loss narrows to \$2.31 from -\$2.32.

• **Broad ongoing CB-839 clinical program to reveal key tumor types/blood cancers for advancement into Ph. II in H2 2016.** Calithera continues to conduct and has reported initial data from the three Ph. I monotherapy studies and is currently assessing CB-839 at the go-forward 600mg twice daily (b.i.d.), food-fed dosing regimen in five solid tumors and one blood cancer. Calithera has started or plans to start six Ph. I(b) combination dosing cohorts for CB-839 with various standard-of-care regimens in triple-negative breast (TNBC), clear cell renal cell carcinoma (RCC), and KRAS mutant non-small cell lung (NSCLC) cancers and multiple myeloma (MM) and AML. *Please refer to Exhibit #1 for more details. (Continued on the following page)*

Valuation Range: \$19.00 to \$20.00

We use a sum-of-parts valuation using P/S multiples of 4.0-5.5x multiple applied to 2025E revenue of ~\$386M discounted at 18-20%. Key risks include clinical trial failure, a safety signal for CB-839, and financing risk.

Investment Thesis:

We believe CALA is under-valued based on CB-839's long-term potential in end-stage myeloma and triple-negative breast cancer.

Ticker	CALA
Price (08/10/2015)	\$6.64
52-Week Range:	\$5-34
Shares Outstanding: (MM)	17.9
Market Cap.: (MM)	\$118.9
S&P 500:	2,104.18
Avg. Daily Vol.:	945,222
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	75.0%
CY 2015 Est. P/EPS-to-Growth:	0.0x
Last Reporting Date:	08/10/2015
	After Close

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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Please see page 5 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 08/11/15 unless otherwise stated.

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Together we'll go far



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- **Upcoming milestones for H2 2015 (the “Triple” Meeting and the SABCS) and mid-2016 (AACR [?], ASCO, and EHA Meetings).** Preclinical data for CALA’s lead arginase inhibitor, CB-1158, are expected in H2 2015, and we believe potentially at the AACR “Triple” Meeting in Boston in November. CB-1158 represents CALA’s initial entry into the immuno-oncology field. The initial Ph. I study is expected to start sometime later in H1 2016 or mid-2016, paced by filing of the Investigational New Drug Application. Updated CB-839 600mg b.i.d. monotherapy data in solid tumors are expected in Q4, and for TNBC may be presented at the 2015 San Antonio Breast Cancer Symposium (SABCS) in December. Initial Ph. I(b) combination data in solid tumors and blood cancers are expected in mid-2016 at the ASCO and EHA Meetings, respectively, and potentially at the April AACR Meeting (paced by enrollment and maturity of data). *Please refer to Exhibit #2 for more details.*
- **Financials.** Calithera reported a Q2 net loss of \$0.44 (vs. our -\$0.46), generally in line with our expectations. Cash as of June 30, 2015, was \$88.2 million and the company reiterated its guidance of \$65 million on hand at the end of 2015 (even in light of the increase in the Ph. I cohort expansion and Ph. I(b) combination studies). Based on its current clinical strategy for CB-839, Calithera believes cash on hand will fund operations through 2017 when top-line Ph. II data emerge for two potential combination studies in TNBC and R/R MM.

Exhibit 1. Ongoing CB-839 Ph. I Monotherapy and Combination Studies and Clinical Activity

Solid Tumor/Hematologic Cancer		Clinical activity at the T1D schedule	Clinical activity at the 600/800 BID food fed schedule*
Ongoing single agent dose expansion cohorts	Triple-negative breast	n=1 SD (-23%, +6%)	n=1 (-1%)
	Renal-cell carcinoma (clear-cell)	n=2 SD (-6%, +18%)	n=2 (+9%, +19%)
	Non-small cell lung (KRAS mutant)	n=1 SD (+1%)	None
	Rare TCA cycle driver mutations	None	n=3 (-4%, +11%, +13%)
	Acute Myeloid Leukemia	CRi (n=1); blast count reductions of 10-58% (n=3)	None; only 2 dosed at this schedule as of EHA Meeting Data
	Note: mesothelioma, multiple myeloma, non-Hodgkin's Lymphoma, and acute lymphoblastic leukemia patients were studied as monotherapy with four cases of SD reported to date (2 each in myeloma and mesothelioma).		
Combination dose expansion cohorts	TNBC: CB-839 + paclitaxel	Ongoing (as of late June 2015)	
	MM: CB-839 + dexamethasone		
	MM: CB-839 + pomalidomide/dexamethasone		
	RCC: CB-839 + everolimus	Planned and to start soon	
	NSCLC: CB-839 + erlotinib		
	AML: CB-839 + azacitadine		

Source: Company reports, Konopleva et al. (EHA 2015), Harding et al. (ASCO 2015), and Wells Fargo Securities, LLC

Note: Stable disease (SD) is defined as tumor growth up to 20% OR tumor shrinkage to -30%, thus we present shrinkage (-%) or growth (+%) based on CALA's data. * = go-forward monotherapy and combination dose-expansion cohorts. CRi= complete response with incomplete blood count recovery.

Exhibit 2. Calithera Biosciences, Inc.'s Upcoming Milestones Chart

Agent	Timing	Event
CB-839	Q4 2015	Present Ph. I monotherapy 600mg cohort expansion data for the solid tumor study.
	December 8-12, 2015	Present the Ph. I 600mg cohort expansion for the TNBC study at the SABCS (San Antonio, Texas).
	Late 2015	Complete enrollment of the Ph. I monotherapy and initiate all planned Ph. I(b) combination studies.
	June 2016	Present more mature Ph. I(b) combination data from multiple solid tumor and hematologic cancer cohorts at the ASCO and EHA Meetings.
	Mid-2016	Meet with FDA (and CHMP/EMA) to discuss Ph. I(a)/(b) data and Ph. II protocols.
	Q3 2016+	Initiate the Ph. II randomized studies in TNBC and MM (and possibly other solid tumors including those with rare TCA driver mutations). Both studies to potentially include 100's of patients.
	End 2017/H1 2018	Complete the Ph. II randomized studies (potentially in TNBC and MM).
	2018	Initiate Ph. III studies in to be determined cancers (potentially TNBC and MM).
CB-1158 (arginase Inhibitor)	November 5-9, 2015	Present preclinical data at the AACR-NCI-EORTC "Triple Meeting".
	H1 2016	Submit the IND to regulatory agencies.
	Late Q2/early Q3 2016	Initiate a Ph. I clinical program.
Hexokinase inhibitor	H2 2016/2017	Submit the IND to regulatory agencies.

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 3. Calithera Biosciences, Inc.'s Income Statement

Calithera Biosciences, Inc. (CALA)

Statement of Operations

FY Ends December 31

(In 000's, except per share data.)

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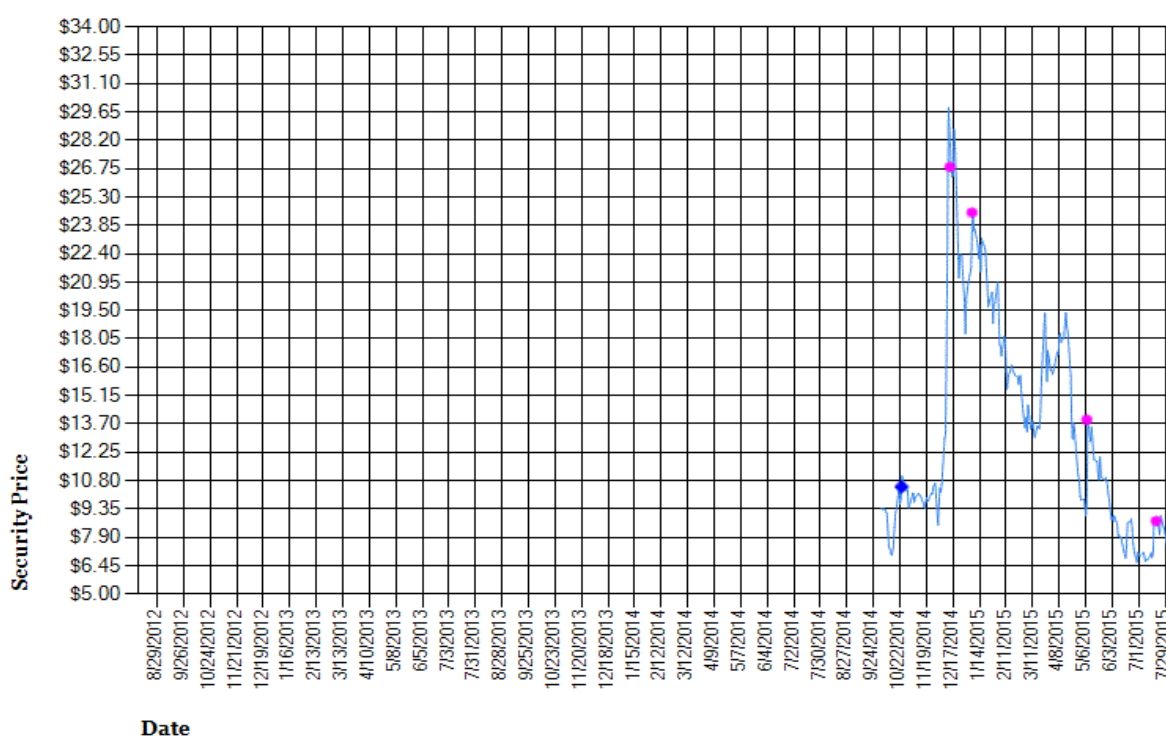
	FY 2014A	Q1 2015A	Q2 2015A	Q3 2015E	Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E
Revenues																
CB-839 U.S. Sales (30% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,432	\$45,178	\$101,432	\$184,152	\$279,765
Royalty on ex-U.S. sales of CB-839 (30% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$2,636	\$9,273	\$21,729	\$39,101
Collaboration revenue on CB-839 (30% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$32,375	\$4,375	\$27,125	\$48,125	\$25,375	\$4,375	\$4,375	\$4,375
Total revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$32,375	\$4,375	\$27,125	\$53,557	\$73,189	\$115,080	\$210,256	\$323,241
Expenses																
Cost of Goods Sold	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$543	\$4,518	\$10,143	\$18,415	\$27,977
Research and development	\$16,367	\$5,630	\$5,533	\$7,000	\$8,000	\$26,163	\$30,000	\$35,000	\$35,000	\$35,000	\$37,500	\$35,000	\$37,500	\$40,000	\$40,000	\$45,000
General and administrative	\$3,213	\$2,237	\$2,341	\$2,750	\$3,000	\$10,328	\$12,000	\$14,000	\$16,000	\$20,000	\$25,000	\$52,500	\$62,500	\$70,000	\$77,500	\$82,500
Total Expenses	\$19,580	\$7,867	\$7,874	\$9,750	\$11,000	\$36,491	\$42,000	\$49,000	\$51,000	\$55,000	\$62,500	\$88,043	\$104,518	\$120,143	\$135,915	\$155,477
Profit/Loss from Operations	(\$19,580)	(\$7,867)	(\$7,874)	(\$9,750)	(\$11,000)	(\$36,491)	(\$42,000)	(\$49,000)	(\$18,625)	(\$50,625)	(\$35,375)	(\$34,486)	(\$31,328)	(\$5,063)	\$74,341	\$167,765
Other Income	\$9	\$9	\$56	\$51	\$45	\$161	\$90	\$577	\$1,117	\$1,090	\$767	\$1,162	\$1,574	\$1,497	\$1,765	\$2,690
Gain on extinguishment of convertible preferred stock	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net profit (loss) before income tax expense	(\$19,571)	(\$7,858)	(\$7,818)	(\$9,699)	(\$10,955)	(\$36,330)	(\$41,910)	(\$48,423)	(\$17,508)	(\$49,535)	(\$34,608)	(\$33,324)	(\$29,754)	(\$3,566)	\$76,106	\$170,454
Income tax expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$19,026	\$42,614
Net income/(loss) (GAAP)	(\$19,571)	(\$7,858)	(\$7,818)	(\$9,699)	(\$10,955)	(\$36,330)	(\$41,910)	(\$48,423)	(\$17,508)	(\$49,535)	(\$34,608)	(\$33,324)	(\$29,754)	(\$3,566)	\$57,079	\$127,841
EPS (GAAP, diluted)	(\$4.67)	(\$0.44)	(\$0.44)	(\$0.54)	(\$0.61)	(\$2.02)	(\$2.31)	(\$1.88)	(\$0.65)	(\$1.84)	(\$1.28)	(\$1.04)	(\$0.92)	(\$0.11)	\$1.76	\$3.93
Shares Outstanding (Basic)	4,652	17,946	17,963	17,988	18,013	17,978	18,113	25,713	25,813	25,913	26,013	31,113	31,213	31,313	31,413	31,513
Shares Outstanding (Diluted)	5,673	18,968	18,984	19,009	19,034	18,999	19,134	26,734	26,834	26,934	27,034	32,134	32,234	32,334	32,434	32,534

Source: Company reports, Form 10-Q dated May 11, 2015, and Wells Fargo Securities, LLC estimates

Note: All revenues are probability-weighted.

Company Description:

Calithera Biosciences, Inc. (South San Francisco, California) is engaged in the research, development, and commercialization of small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancers. Calithera's lead program is CB-839, an oral inhibitor of the glutaminase enzyme, and is currently in three Phase I studies and plans to initiate a Ph. II program in triple-negative breast cancer and multiple myeloma in early 2016. Behind CB-839 Calithera has a pre-clinical arginase inhibitor compound which is expected to enter human studies in early 2016 and a preclinical hexokinase II inhibitor program, which it licensed from TransTech in March 2015.

Required Disclosures**Calithera Biosciences, Inc. (CALA) 3-yr. Price Performance**

Date	Published Price (\$)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price (\$)
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
7/20/2015	8.66	1	19.00	20.00	8.66

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
- ▲ Rating Upgrade
- Valuation Range Change
- ◆ Initiation, Resumption, Drop or Suspend
- Analyst Change
- Split Adjustment

Rating Code Key

- 1 Outperform/Buy
- 2 Market Perform/Hold
- 3 Underperform/Sell
- SR Suspended
- NR Not Rated
- 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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2=Market Perform: The stock appears appropriately valued, and we believe the stock's total return will be in line with the market over the next 12 months. HOLD

3=Underperform: The stock appears overvalued, and we believe the stock's total return will be below the market over the next 12 months. SELL

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As of: August 10, 2015

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