Calithera Biosciences, Inc. (CALA)

CALA Reports 1Q15 Earnings Results

MARKET DATA

Price	$9.52
52-Week Range:	$6.51 - $33.48
Shares Out. (M):	17.6
Market Cap ($M):	$167.6
Average Daily Vol. (000):	301.0
Cash (M):	$94
Cash/Share:	$5.69
Enterprise Value (M):	$343
Float (M):	17.8
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$0.0	$0.0	--
	2Q	$0.0	$0.0	--
	3Q	$0.0	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	--	($0.39)	--
	2Q	($1.22)	($0.42)	--
	3Q	($0.29)	($0.43)	--
	4Q	($0.37)	($0.44)	--
	FY	**($1.47)**	**($1.69)**	**($3.29)**
	P/E	NM	NM	NM

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $9.52 | Target Price: $20.00

INVESTMENT HIGHLIGHTS

Calithera Biosciences reports 1Q15 results and highlights an expanding pipeline; reiterate our Market Outperform rating and $20 price target based on a synthesis of DCF, SOTP and comparable valuation methodologies. CALA recorded a net operating loss of $7.9MM, slightly greater than JMP's estimate of $7.7MM. R&D spend was $5.6MM, comparable to JMP's estimate of $5.7MM, which was primarily attributable to expenses associated with the advancement of the lead company asset, CB-839, into Phase I clinical trials, the advancement of CALA's arginase program and license fees associated with its recently-added hexokinase program. SG&A spend of $2.2MM was also comparable to the $2.0MM JMP estimate. CALA finished the quarter with a strong balance sheet of $94.3MM in cash, cash equivalents and investments and continues to function as a lean operation, providing a year-end guidance of $65MM in cash. A comparison of 1Q15 results versus JMP estimates and changes to our model are provided in Figure 2. We remind investors that as a development-stage biotech company, in our view, CALA continues to be a story of clinical execution with its lead asset, CB-839, rather than of earnings.

CB-839 on track and on show. CALA initiated three Phase I studies in 2014 with its lead agent, CB-839 (currently in the Phase Ib dose expansion phase with an RP2D of 600mg BID), in three tumor types: solid tumors, multiple myeloma and acute leukemias. In these trials, CALA will also use biomarkers that have been identified to predict sensitivity to the drug. Thus far, CALA has identified two such biomarkers. In the triple negative breast cancer patients (TNBC), high expression of glutaminase predicts sensitivity, for instance; and in multiple myeloma, high levels of the enzyme pyruvate carboxylase (PC) confers resistance to the cells. We look forward to the upcoming poster presentation at the annual ASCO meeting in Chicago, May 29-June 2, where updated PK, PD, safety and biologic activity data from the Phase I studies (mostly in solid tumors) are expected to be shown.

Key data could drive new trials. At this year's AACR conference in Philadelphia, CALA presented preclinical data that could serve to direct the development of CB-839 in non-small cell lung cancer, renal cell carcinoma, and other solid tumor and hematologic indications. Key findings included potential biomarkers, KRAS and EGFR mutations, where enhanced sensitivity to CB-839 was observed as in non-small cell lung cancer lines harboring these mutations (Figure 2). Additionally, synergistic activity was observed with AstraZeneca's (AZN, NC) MEK inhibitor, selumetinib in KRAS mutant NSCLC cell lines both in vitro and in vivo; as well as with Genentech's (NC) EGFR inhibitor, Tarceva (erlotinib) in several NSCLC cell lines, including an EGFR-resistant animal model lacking the T790M gate-keeper mutation. Synergy was also observed in renal cell carcinoma cell lines with Novartis' (NVS, NC) mTOR inhibitor Afinitor

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(everolimus). Taken together, if the data hold, we anticipate that CALA will pursue drug combination studies in NSCLC and/or RCC patients with the above agents in the near future.

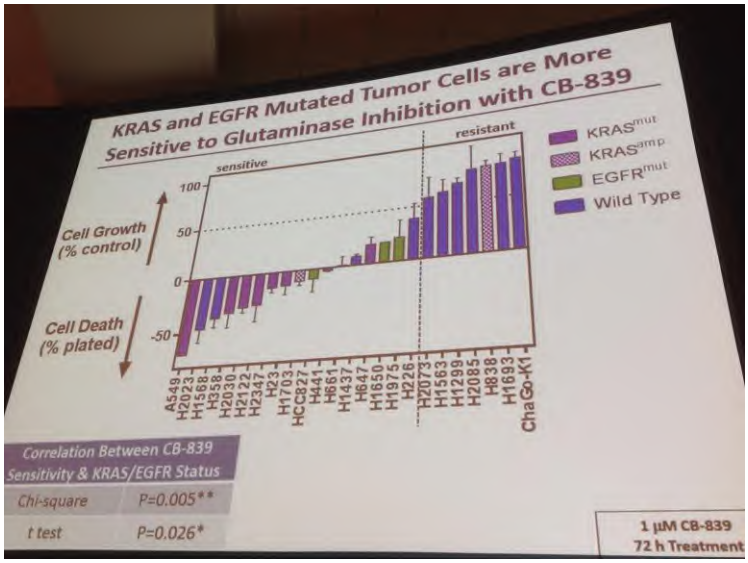
We remain bullish on CALA. Calithera is an early-stage, oncology-focused drug discovery and development company attempting to exploit the increasing knowledge of the cancer cell's ability to hijack the energy production mechanisms required for the utilization of energy from a variety of sources. The company's first product candidate, CB-839, is a novel inhibitor of glutaminase, an enzyme that converts glutamine to glutamate, the latter of which is a critical feedstock for the cell's energy production system. The company was founded by Susan and Chris Molineaux, two of the main founders of Proteolix, the company that developed Kyprolis (carfilzomib) and which was eventually sold to Onyx for $700MM. Onyx, in turn, sold to Amgen (AMGN, NC) in 2013 for $10 billion.

FIGURE 1. Upcoming Catalysts

Timing	Catalyst
1H15	Anticipated presentation of CB-839 (single agent) Phase I safety and efficacy in solid and heme tumors
1H15	Initiation of Phase Ib combo expansion trials (TNBC + paclitaxel)
mid-2015	Initiation of Phase Ib combo expansion trials (R/R MM + pomalidomide)
2H15	IND filing for arginase inhibitor

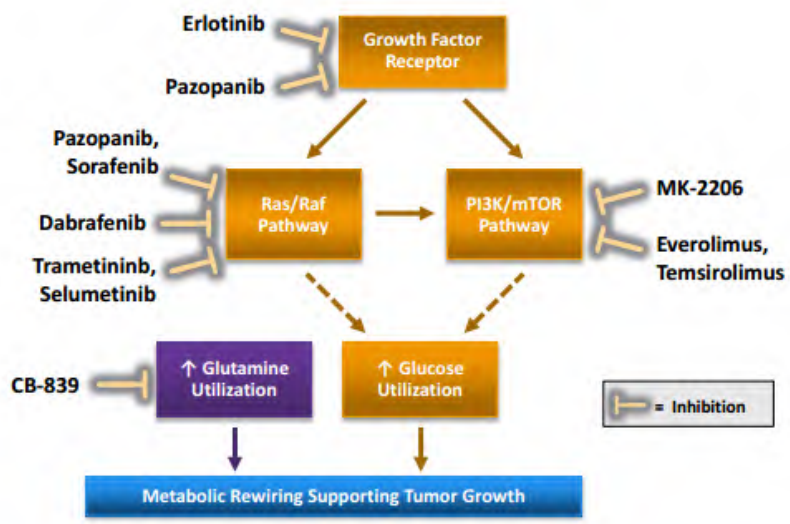
Source: JMP Securities LLC and Company Reports

FIGURE 2. KRAS and EGFR Mutated Tumor Cells are More Sensitive to CB-839



Source: Company Presentation

FIGURE 3. CB-839 Shows Synergy with Multiple Drugs



Source: Company Reports

FIGURE 4. 1Q15 Results, Estimates and Changes to Our Model

CALA	1Q15 actual			2Q15 est		3Q15 est		4Q15 est		FY15 est		FY16 est		FY17 est		FY18 est	
	JMP est	Cons	JMP New	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New	JMP old	JMP New
Total revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**54.6**	**54.6**
R&D	5.7		5.6	6.5	6.5	7.3	7.3	8.0	8.0	27.5	27.4	55.0	54.9	110.0	109.7	170.5	170.1
SG&A	2.0		2.2	2.2	2.2	2.3	2.3	2.4	2.4	8.9	9.1	19.6	20.1	58.7	60.3	105.7	108.5
Total operating expense	**7.7**		**7.9**	**8.7**	**8.7**	**9.6**	**9.6**	**10.4**	**10.4**	**36.4**	**36.6**	**74.6**	**75.0**	**168.7**	**170.0**	**276.2**	**278.6**
Net income (loss)	**(7.7)**	**(7.7)**	**(7.9)**	**(8.7)**	**(8.7)**	**(9.6)**	**(9.6)**	**(10.4)**	**(10.4)**	**(36.4)**	**(36.6)**	**(74.6)**	**(75.0)**	**(168.7)**	**(170.0)**	**(228.2)**	**(230.6)**
EPS (diluted)	**($0.39)**	**($0.42)**	**($0.40)**	**($0.42)**	**($0.42)**	**($0.43)**	**($0.43)**	**($0.44)**	**($0.44)**	**($1.69)**	**($1.69)**	**($3.29)**	**($3.31)**	**($6.07)**	**($6.12)**	**($6.88)**	**($6.95)**

Source: JMP Securities LLC and Company Reports

FIGURE 5. Updated Income Statement

Calithera Biosciences (CALA)	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Income Statement ($MM)	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties:															
CB-839															
US Sales					-	-	-	54.6	310.5	625.0	965.1	1,268.5	1,459.7	1,551.8	1,616.9
ROW Royalties					-	-	-	-	6.3	41.1	86.6	132.9	182.8	211.1	226.2
Total Product Sales and Royalties	-	-	-	-	-	-	-	54.6	316.8	666.1	1,051.7	1,401.4	1,642.5	1,762.9	1,843.1
Cost of Goods Sold						-	-	6.5	37.3	75.0	115.8	152.2	175.2	186.2	194.0
Gross Profit	-	-	-	-	-	-	-	48.0	279.5	591.1	935.9	1,249.2	1,467.3	1,576.7	1,649.1
Operating Expenses:															
Research and development	5.6	6.5	7.3	8.0	27.4	54.9	109.7	170.1	221.1	265.3	291.8	321.0	353.1	388.4	427.3
% Growth					*66.5%*	*100.0%*	*100.0%*	*55.0%*	*30.0%*	*20.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*
% Total US Net Sales								*312%*	*71%*	*42%*	*30%*	*25%*	*24%*	*25%*	*26%*
General and administrative	2.2	2.2	2.3	2.4	9.1	20.1	60.3	108.5	157.4	196.7	216.4	235.9	254.8	267.5	280.9
Total operating expenses	7.9	8.7	9.6	10.4	36.6	75.0	170.0	278.6	378.5	462.0	508.2	556.9	607.9	655.9	708.2
Operating income (loss)	(7.9)	(8.7)	(9.6)	(10.4)	(36.6)	(75.0)	(170.0)	(230.6)	(98.9)	129.1	427.6	692.3	859.4	920.8	941.0
Operating margin (%)								*-422.5%*	*-31.2%*	*19.4%*	*40.7%*	*49.4%*	*52.3%*	*52.2%*	*51.1%*
Interest income															
Interest expense															
Total other income, net	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax income (loss)	(7.9)	(8.7)	(9.6)	(10.4)	(36.6)	(75.0)	(170.0)	(230.6)	(98.9)	129.1	427.6	692.3	859.4	920.8	941.0
Income tax benefit (provision)					0.0	0.0	0.0	0.0	4.9	(12.9)	(85.5)	(207.7)	(300.8)	(322.3)	(329.3)
Tax Rate									*5%*	*10%*	*20%*	*30%*	*35%*	*35%*	*35%*
Comprehensive income (loss)	(7.9)	(8.7)	(9.6)	(10.4)	(36.6)	(75.0)	(170.0)	(230.6)	(94.0)	116.2	342.1	484.6	558.6	598.5	611.6
Basic EPS to common shareholders	$ (0.40)	$ (0.42)	$ (0.43)	$ (0.44)	**$ (1.69)**	**$ (3.31)**	**$ (6.12)**	**$ (6.95)**	**$ (2.70)**	**$ 3.17**	**$ 8.90**	**$ 12.01**	**$ 13.19**	**$ 13.46**	**$ 13.10**
Diluted EPS to common shareholders	$ (0.40)	$ (0.42)	$ (0.43)	$ (0.44)	**$ (1.69)**	**$ (3.31)**	**$ (6.12)**	**$ (6.95)**	**$ (2.70)**	**$ 3.17**	**$ 8.90**	**$ 12.01**	**$ 13.19**	**$ 13.46**	**$ 13.10**
Basic shares outstanding	19.7	20.9	22.2	23.5	21.6	22.7	27.8	33.2	34.8	36.6	38.4	40.3	42.4	44.5	46.7
Diluted shares outstanding	19.7	20.9	22.2	23.5	21.6	22.7	27.8	33.2	34.8	36.6	38.4	40.3	42.4	44.5	46.7

Source: JMP Securities LLC and Company Reports

Company Description

Calithera Biosciences, based in San Francisco, CA, is a clinical-stage biotechnology company focused on the discovery and development of novel small molecules directed against cancer and immune cell metabolism to treat both solid tumor and hematologic malignancies. The company's lead product candidate, CB-839, is an internally discovered and wholly owned potent, oral selective inhibitor of glutaminase. Inhibition of glutaminase by CB-839, in effect, starves cancer cells of glutamate - a critical substrate for cancer cell metabolism, growth, and survival. CB-839 is currently in Phase I analysis in both solid and hematologic tumors. Planned Phase Ib cohorts in combination with standard of care agents in triple negative breast cancer and multiple myeloma are expected to be initiated. A second wholly owned pre-clinical candidate is Calithera's first-in-class arginase inhibitor, directed at immune checkpoint modulation and engaging the activation of cytotoxic T-cells. Calithera intends to submit an IND to the FDA for the arginase program in late 2015.

Investment Risks

Potential risks to our price target include, but are not limited to, clinical, regulatory, commercial, and competitive factors.

Scientific and clinical. Drug development is an inherently risky business. Cancer metabolism, and specifically, the role of glutaminase in cancer pathogenesis, remains largely unproven, creating significant risk associated with Calithera's scientific platform. Like all clinical trials, CB-839 clinical development carries some risk of failure. CB-839 may fail to maintain the requisite safety or to demonstrate meaningful efficacy to warrant further development through to regulatory approval.

Regulatory and commercial. The ability of Calithera or its potential partners to market its drugs depends on those drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

Competitive. Oncology drug development is an increasingly competitive field. Calithera faces competition from companies developing small molecule therapies also directed at cancer cell metabolism in ways that may resemble those of Calithera's pipeline. Small molecule oncology therapies employing other mechanisms of action are also in development by several biopharma companies to treat similar patient populations to that of CB-839 and may yield superior risk-benefit outcomes. Some of these companies may have access to greater resources, development, and commercial expertise compared to Calithera.

Financial. We anticipate that Calithera may seek additional equity financing in the form of a secondary offering in order to complete the development of CB-838 and advance its future pipeline candidates, exposing existing shareholders to some degree of dilution risk.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.
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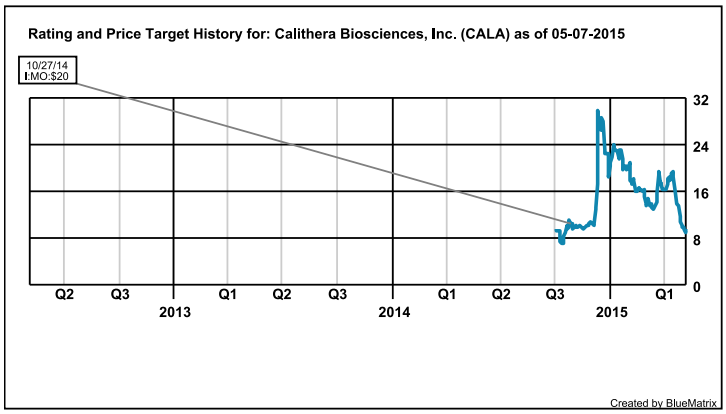
MARKET OUTPERFORM	Buy	279	*61.86%*	Buy	279	*61.86%*	94	*33.69%*
MARKET PERFORM	Hold	141	*31.26%*	Hold	141	*31.26%*	17	*12.06%*
MARKET UNDERPERFORM	Sell	9	*2.00%*	Sell	9	*2.00%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.66%*		21	*4.66%*	4	*19.05%*
TOTAL:		451	*100%*		451	*100%*	115	*25.50%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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