

Calithera Biosciences, Inc. (CALA)

CALA Reports 2Q15 Earnings

MARKET DATA	
Price	\$6.64
52-Week Range:	\$5.94 - \$33.48
Shares Out. (M):	17.6
Market Cap (\$M):	\$116.9
Average Daily Vol. (000):	610.0
Cash (M):	\$88
Cash/Share:	\$4.91
Enterprise Value (M):	\$27
Float (M):	17.7
LT Debt (M):	\$0
Source: Thomson Reuters and JMP Securities LLC	

FY DEC		2014A	2015E	2016E
Revenue (\$M)	1Q	\$0.0	\$0.0A	
	2Q	\$0.0	\$0.0A	
	3Q	\$0.0	\$0.0	
	4Q	\$0.0	\$0.0	
	FY	\$0.0	\$0.0	\$0.0
EPS	1Q		(\$0.40)A	
	2Q	(\$1.22)	(\$0.42)A	
	3Q	(\$0.29)	(\$0.50)	
	4Q	(\$0.37)	(\$0.52)	
	FY	(\$1.47)	(\$1.86)	(\$3.63)
	P/E	NM	NM	NM
Previous	FY	NC	(\$1.69)	(\$3.31)
Source: Company re	eports ar	nd JMP Securitie	s LLC	



MARKET OUTPERFORM | Price: \$6.64 | Target Price: \$20.00

INVESTMENT HIGHLIGHTS

Calithera Bioscience reports 2Q15 results and highlights its pipeline progress; reiterate our Market Outperform rating and \$20 price target based on a synthesis of our DCF, SOTP and comparable company valuation methodologies. CALA recorded a net operating loss of \$7.9MM, less than our estimate of \$8.7MM. R&D spend was \$5.5MM, less than our estimate of \$6.5MM, primarily attributable to expenses associated with the advancement of the lead company asset, CB-839 into Phase I clinical trials and of CALA's arginase inhibitor program (CB-1158). SG&A spend of \$2.3MM was comparable to our \$2.2MM estimate. CALA finished the quarter with a strong balance sheet of \$88MM in cash, cash equivalents, and investments and continues to function as a lean operation, providing year-end guidance of \$65MM in cash. A comparison of 2Q15 results versus JMP estimates and changes to our model are provided in Figure 2. We remind investors that as a development stage biotech, CALA continues to be a story of clinical execution with its lead asset, CB-839 rather than of earnings.

Highlights of the call. Highlights included data presentations made at key scientific conferences this year (AACR, ASCO, and EHA), showcasing first-in-human data from CALA's lead asset, CB-839. Other noteworthy achievements included selection of a lead clinical arginase inhibitor program (CB-1158) in 2Q15. Near-term catalysts for CALA include: 1) CB-1158 preclinical (in vitro and in vivo) data including PK/PD and early safety data in animals; 2) data from expansion cohorts (in TNBC, renal, NSCLC-KRAS, and TCA mutants) at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics (i.e., the "triple meeting"); and 3) single-agent CB-839 data at ASH, primarily in AML patients with the possibility of combination data (pomalidomide/dexamethasone/CB-839 and dexamethasone/CB-839) in myeloma, depending upon enrollment.

We remain bullish on CALA. Calithera is an early-stage, oncology-focused drug discovery and development company that is 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 primary founders of Proteolix, the company that developed Kyprolis (carfilzomib) and that was eventually sold to Onyx for \$700MM. Onyx, in turn, was sold to Amgen (AMGN, NC) in 2013 for \$10 billion.

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FIGURE 1. Upcoming Catalysts

Timing	Drug	Catalyst
4Q15	CB-839	Additional data from Phase I single agent trials in solid tumors (expansion cohorts) at AACR-NCI-EORTC
4Q15	CB-1158	Preclinical data from arginase inhibitor at AACR-NCI-EORTC
4Q15	CB-839	Additional data from Phase I heme tumors at ASH (single agent data)
2H15	CB-839	Initial data from Phase I combination trials
YE15	CB-839	Intitiation of combination expansion cohorts
YE15	CB-839	Completion of enrollment of monotherapy expansion cohorts
1H16	CB-1158	IND filing for arginase inhibitor
mid-2016	CB-839	Phase I combination trial solid tumor data
mid-2016	CB-839	Phase I clinical trial data in myeloma and AML (both monotherapy and combination)

Source: Company Reports

FIGURE 2. 2Q15 Results, Estimates, and Changes to Our Model

CALA		2Q15 est		3Q1	5 est	4Q1	5 est	FY1	5 est	FY1	6 est	FY1	7 est	FY1	8 est
	JMP old	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
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	54.6	54.6
R&D SG&A	6.5 2.2		5.5 2.3	7.3 2.3	7.3 2.3	8.0 2.4	8.0 2.4	27.5 8.9	26.5 9.3	55.0 19.6	52.9 20.4	110.0 58.7	105.9 61.2	170.5 105.7	164.1 110.2
Total operating expense	8.7	8.6	7.9	9.6	9.6	10.4	10.4	36.4	35.7	74.6	73.3	168.7	167.1	276.2	274.3
Net income (loss)	(8.7)	(8.6)	(7.8)	(9.6)	(9.6)	(10.4)	(10.4)	(36.4)	(35.7)	(74.6)	(73.3)	(168.7)	(167.1)	(228.2)	(226.3)
EPS (diluted)	(\$0.42)	(\$0.45)	(\$0.44)	(\$0.43)	(\$0.50)	(\$0.44)	(\$0.52)	(\$1.69)	(\$1.86)	(\$3.29)	(\$3.63)	(\$6.07)	(\$6.63)	(\$6.88)	(\$7.43)

Source: JMP Securities LLC, Company reports, Thomson Reuters

FIGURE 3. Updated Income Statement

Calithera Biosciences (CALA)	19	Q15A	2Q15A	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Income Statement (\$MM)	1	Q15A	2Q15A	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	5.5	7.3	8.0	26.5	52.9	105.9	164.1	213.3	256.0	281.5	309.7	340.7	374.7	412.2
% Growth						60.6%	100.0%	100.0%	55.0%	30.0%	20.0%	10.0%	10.0%	10.0%	10.0%	10.0%
% Total US Net Sales									301%	69%	41%	29%	24%	23%	24%	25%
General and administrative		2.2	2.3	2.3	2.4	9.3	20.4	61.2	110.2	159.8	199.8	219.8	239.5	258.7	271.6	285.2
Total operating expenses		7.9	7.874	9.6	10.4	35.7	73.3	167.1	274.3	373.1	455.7	501.3	549.2	599.4	646.4	697.4
Operating income (loss)		(7.9)	(7.874)	(9.6)	(10.4)	(35.7)	(73.3)	(167.1)	(226.3)	(93.6)	135.4	434.6	700.0	868.0	930.3	951.7
Operating margin (%)									-414.6%	-29.5%	20.3%	41.3%	49.9%	52.8%	52.8%	51.6%
Interest income			0.056													
Interest expense																
Total other income, net		-	0.056	-	-	-	-	-	-	-	-	-	-	-		-
Pretax income (loss)		(7.9)	(7.818)	(9.6)	(10.4)	(35.7)	(73.3)	(167.1)	(226.3)	(93.6)	135.4	434.6	700.0	868.0	930.3	951.7
Income tax benefit (provision)						0.0	0.0	0.0	0.0	4.7	(13.5)	(86.9)	(210.0)	(303.8)	(325.6)	(333.1)
Tax Rate										5%	10%	20%	30%	35%	35%	35%
Comprehensive income (loss)		(7.9)	(7.818)	(9.6)	(10.4)	(35.7)	(73.3)	(167.1)	(226.3)	(88.9)	121.8	347.7	490.0	564.2	604.7	618.6
Basic EPS to common shareholders	\$	(0.40) \$	(0.44) \$	6 (0.50)	\$ (0.52)	\$ (1.86)	\$ (3.63)	\$ (6.63)	\$ (7.43)	\$ (2.78)	\$ 3.63	\$ 9.86	\$ 13.23	\$ 14.51	\$ 14.81	\$ 14.43
Diluted EPS to common shareholders	\$	(0.40) \$	(0.44) \$	(0.50)	\$ (0.52)	\$ (1.86)	\$ (3.63)	\$ (6.63)	\$ (7.43)	\$ (2.78)	\$ 3.63	\$ 9.86	\$ 13.23	\$ 14.51	\$ 14.81	\$ 14.43
Basic shares outstanding		19.7	18.0	19.0	20.2	19.2	20.2	25.2	30.5	32.0	33.6	35.3	37.0	38.9	40.8	42.9
Diluted shares outstanding		19.7	18.0	19.0	20.2	19.2	20.2	25.2	30.5	32.0	33.6	35.3	37.0	38.9	40.8	42.9

Source: JMP Securities LLC, 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-839 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.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

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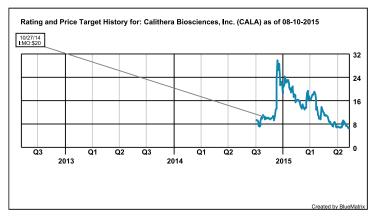
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							# Co's	
							Receiving	
							IB	
		# Co's	%		# Co's	%	Services in	% of Co's
	Regulatory	Under	of	Regulatory	Under	of	Past 12	With This
JMP Rating	Equivalent	Coverage	Total	Equivalent	Coverage	Total	Months	Rating
MARKET OUTPERFORM	Buy	287	62.39%	Buy	287	62.39%	84	29.27%
MARKET PERFORM	Hold	144	31.30%	Hold	144	31.30%	16	11.11%
MARKET UNDERPERFORM	Sell	8	1.74%	Sell	8	1.74%	0	0%
COVERAGE IN TRANSITION		21	4.57%		21	4.57%	4	19.05%
TOTAL:		460	100%		460	100%	104	22.61%

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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