

Calithera Biosciences, Inc. (CALA)

CALA Pipeline Candidates Featured at AACR-NCI-EORTC Conference

MARKET DATA

Price	\$7.42
52-Week Range:	\$4.31 - \$33.48
Shares Out. (M):	17.6
Market Cap (\$M):	\$130.6
Average Daily Vol. (000):	167.0
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

MARKET OUTPERFORM | Price: \$7.42 | Target Price: \$20.00

INVESTMENT HIGHLIGHTS

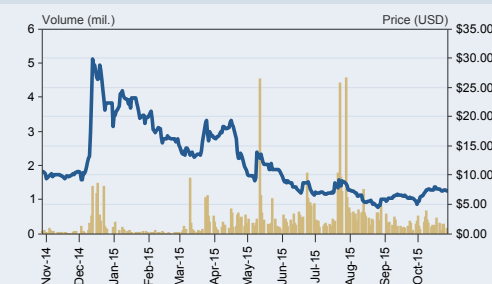
Calithera Biosciences to present data from both its glutaminase and arginase inhibitor programs at the “Triple Meeting”; reiterate our Market Outperform rating and \$20 price target based on a synthesis of DCF, SOTP, and comparable valuation methodologies. In an incremental update of its ongoing Phase I trial, Abstract C49 highlights the study evaluating CALA's glutaminase inhibitor CB-839, given in 21-day cycles, in patients with advanced and/or refractory solid tumors. Safety data were collected from 85 patients from a total of 93 patients enrolled as of July 24 2015 (up from the 76 described at ASCO). The total updated 93 patients comprised of the 32 patients on a three times daily dosing schedule (100-800mg TID), who were described previously, and 61 patients on a twice-daily fed schedule (600-1000mg BID), up from the 27 patients described earlier. In our view, although the data are positive given the low rate of adverse events and rates of clinical activity, we are particularly interested in the update on patients harboring TCA cycle mutations enrolled in the study. The 27th EORTC-NCI-AACR (“Triple Meeting”) Symposium will be held on Nov. 5-9 in Boston.

Arginase inhibitor preclinical data to make its debut. The restoration of arginine levels, which is often found depleted in tumors, by antagonizing the immunosuppressive activity of myeloid derived tumor cells (MDSCs) enables T-cell activation and proliferation in order for the T-cell to mount an anti-tumor response. Abstract A195 describes the isolation of a potent and selective arginase inhibitor, CB-1158 with an IC₅₀ of less than 100nM in a cell assay. In the cell types tested, inhibition of the enzyme arginase did not have any effect on proliferation. However, in peripheral blood mononuclear cells (PBMCs) derived from a patient with renal cell carcinoma containing both suppressive MDSCs and cytotoxic T cells, the addition of an arginase inhibitor produced a dose-dependent increase in T cell proliferation over vehicle controls. According to the abstract, CB-1158 compound appears to have high oral bioavailability in mice and rats. Of significance, treatment with the agent in mice bearing lung tumors resulted in a 3-4 fold increase in tumor arginine levels. In a different mouse model, dosing with single agent CB-1158 demonstrated anti-tumor activity, with concomitant increase in systemic plasma arginine. Evaluation of the tumors treated with CB-1158 revealed an increase in CD3+ T-cell infiltrates, consistent with an immune-based mechanism of the agent. Importantly, CB-1158 had no impact on rodent body weight or serum chemistry enzymes. We look forward to reviewing the data in greater detail at the meeting.

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

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



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FOR DISCLOSURE AND FOOTNOTE INFORMATION, REFER TO JMP FACTS AND DISCLOSURES SECTION.

CB-839 demonstrating single-agent clinical activity in the Phase I trial. Stable disease was defined as being on the study and having a median of >5 cycles (range of 3-18) of treatment. According to the abstract, 15 (65%) patients remain on the study. Radiographic stable disease (SD) was observed in the 19% (6/31 response-evaluable patients) on the TID schedule and a remarkable 40% (17/43 response-evaluable) on the BID schedule. Of note, at ASCO, 41% was reported on the BID schedule in seven patients out of 17 response-evaluable, while 19% (6/31) was also reported in the TID schedule. These SD patients included 64% (6/11) RCC patients (up from one previously reported) on the BID schedule, five of whom remain on study. Further, a TNBC patient has maintained SD for more than a year and has demonstrated a 23% reduction in tumor burden. At ASCO, two TNBC patients had been reported with SD.

Consistent manageable adverse events observed. With a total of 85 patients enrolled, the study continues to demonstrate a low rate of Grade 3/4 adverse events (AEs), with only 9.4% (8/85) of patients experiencing Grade 3/4 AEs attributable to the drug (vs. the previously reported 13.6% (8/59)). The one dose limiting toxicity (DLT) accounted for was previously reported, related to a Grade 3 increase in creatinine levels in a patient with diabetes at the 250 mg TID dose. Additionally, most of the Grade 3 elevations in transaminases occurred at the TID schedule in 18.8% (6/32) patients, with only one Grade 3 event occurring among the patients receiving the BID regimen (1/53), which is the recommended Phase 2 dose (R2PD). We also note that the rates of adverse events are likely in line with patients with advanced disease, given the heavily pretreated population.

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 that 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	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	Initiation 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: JMP Securities LLC and Company Reports

FIGURE 2. Income Statement

Calithera Biosciences (CALA)	1Q15A	2Q15A	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Income Statement (\$MM)	1Q15A	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)	\$ (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 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-839 and advance its future pipeline candidates, exposing existing shareholders to some degree of dilution risk.

JMP FACTS AND DISCLOSURES

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JMP Securities expects to receive OR intends to seek compensation for investment banking services from Calithera Biosciences, Inc. in the next 3 months.

JMP Securities Investment Opinion Definitions:

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.

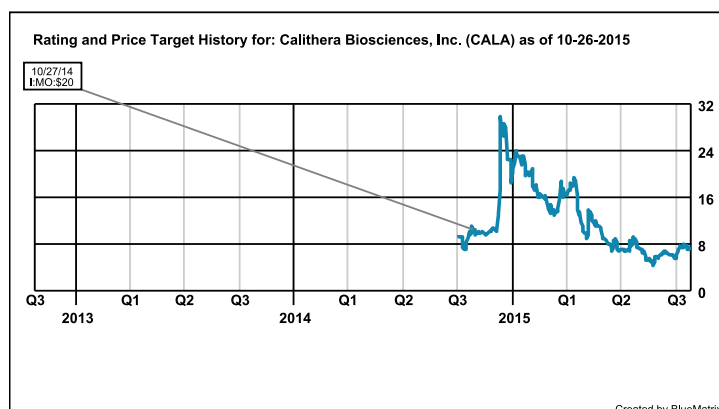
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

JMP Securities Research Ratings and Investment Banking Services: (as of October 27, 2015)

JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months	% of Co's With This Rating
MARKET OUTPERFORM	Buy	305	63.94%	Buy	305	63.94%	84	27.54%
MARKET PERFORM	Hold	148	31.03%	Hold	148	31.03%	15	10.14%
MARKET UNDERPERFORM	Sell	6	1.26%	Sell	6	1.26%	0	0%
COVERAGE IN TRANSITION		17	3.56%		17	3.56%	0	0%
TOTAL:		477	100%		477	100%	100	20.96%

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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