Calithera Biosciences, Inc. (CALA)

Initial Clinical Data for CB-839 in AML to be Featured at EHA 2015

MARKET OUTPERFORM | Price: $12.39 | Target Price: $20.00

MARKET DATA

Price	$12.39
52-Week Range:	$6.51 - $33.48
Shares Out. (M):	17.6
Market Cap ($M):	$218.1
Average Daily Vol. (000):	292.0
Cash (M):	$94
Cash/Share:	$5.25
Enterprise Value (M):	$141
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	$0.0A	--
	2Q	$0.0	$0.0	--
	3Q	$0.0	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	--	($0.40)	--
	2Q	($1.22)	($0.42)	--
	3Q	($0.29)	($0.43)	--
	4Q	($0.37)	($0.44)	--
	FY	**($1.47)**	**($1.69)**	**($3.31)**
	P/E	NM	NM	NM

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Calithera Biosciences' CB-839 to be featured in a presentation at EHA 2015; reiterate our Market Outperform rating and $20 price target based on a synthesis of DCF, SOTP and comparable valuation methodologies. Today's released abstracts for the 20th Congress of the European Hematology Association (EHA) to be held on June 11-14 in Vienna highlight CALA's clinical progress with its first-in-class glutaminase inhibitor, CB-839. Abstract #E947, entitled "Phase I Study: Safety and Tolerability of Increasing Doses of CB-839, an Orally Administered Small Molecule Inhibitor of Glutaminase, in Acute Leukemia," provides preliminary data suggesting not only safety, but clinical activity with the drug in patients with acute myeloid leukemia (AML). Of the 15 relapsed refractory efficacy-evaluable AML patients (as of March 1, 2015) treated with CALA's CB-839, stable disease (SD) was observed in five patients (33%), including one complete response (CR). Of equal significance, no dose limiting toxicities (DLTs) were identified at the time of the abstract submission and no adverse events associated with treatment above Grade 3 were observed in >10% patients. Although small in number, we believe the results are compelling and we are very encouraged by CALA's progress in this clinical setting. We look forward to the data from this clinical trial at EHA next month.

Abstract data to be updated at EHA. As a reminder, CALA initiated three Phase I studies in 2014 with its lead agent, CB-839 (currently in the dose expansion phase with an RP2D of 600mg BID) in three tumor types: solid tumors, multiple myeloma and acute leukemias. While we are already looking forward to the data on solid tumors at ASCO this year, at EHA, CALA will present updated data from the dose-escalation portion of the Phase 1 portion of the trial in acute leukemia patients. Briefly, oral CB-839 was administered at doses ranging from 100 mg to 1000mg three times daily (TID) to 15 R/R AML (over the age of 65 and ineligible for high dose therapy), continuously in 21 treatment cycles. Pharmacokinetic data were evaluated at Day 1 and Day 15. SD occurred in five (33%) of the 15 R/R AML patients at 4-10 cycles, with patients that remained on the study for an average of 134 days (>6 cycles). As mentioned, one patient on the study achieved a CR in the bone marrow with incomplete recovery of peripheral counts after six cycles of dosing. Treatment-related AEs were observed in >10% of patients, dosed TID, that were limited to increases in transaminase (n=4) and bilirubin (n=2) with no AEs at or above Grade 3 >10% of patients. According to clinicaltrials.gov, this study is expected to enroll up to a total of 50 patients. CALA has also indicated that in the dose-expansion phase, 11 patients are expected to enroll at the Phase II recommended dose in this trial (as with the other ongoing CALA trials).

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We are 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, was sold to Amgen (AMGN, NC) in 2013 for $10 billion.

FIGURE 1. Upcoming Catalysts

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

Source: JMP Securities LLC and Company Reports

FIGURE 2. Phase I Trial Design

Trial	Tumor Types	Trial Design
CX-839-001	Solid Tumors (including Triple-negative Breast Cancer (TNBC))	• Dose escalation in all solid tumors • Dose expansion cohorts in selected tumor types • Phase 1b in TNBC in combination with paclitaxel
CX-839-002	Multiple Myeloma (MM) Non-Hodgkin's Lymphoma (NHL)	• Dose escalation in MM and NHL • Dose expansion cohorts in MM and selected subtypes of NHL • Phase 1b in MM in combination with pomalidomide and dexamethasone
CX-839-003	Acute Lymphocytic Leukemia (ALL) Acute Myeloid Leukemia (AML)	• Dose escalation in ALL and AML • Dose expansion cohorts in ALL and AML

Source: Company Reports

FIGURE 3. Income Statement

Income Statement ($MM)	1Q15A	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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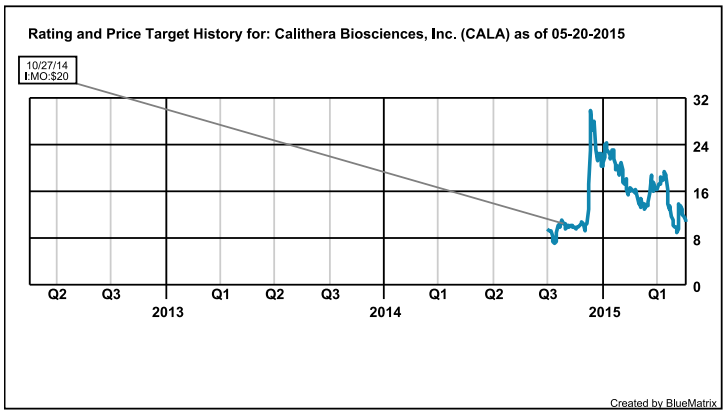
MARKET OUTPERFORM	Buy	280	*61.95%*	Buy	280	*61.95%*	94	*33.57%*
MARKET PERFORM	Hold	141	*31.19%*	Hold	141	*31.19%*	18	*12.77%*
MARKET UNDERPERFORM	Sell	9	*1.99%*	Sell	9	*1.99%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.65%*		21	*4.65%*	4	*19.05%*
TOTAL:		452	*100%*		452	*100%*	116	*25.66%*

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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