Calithera Biosciences, Inc. (CALA)

ASCO Abstract Demonstrates Activity of CB-839 in Phase I

MARKET OUTPERFORM | Price: $12.90 | Target Price: $20.00

MARKET DATA

Price	$12.90
52-Week Range:	$6.51 - $33.48
Shares Out. (M):	17.6
Market Cap ($M):	$227.0
Average Daily Vol. (000):	601.0
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
	Previous FY	NC	NC	($3.29)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

We reiterate our Market Outperform rating and $20 price target for Calithera Biosciences based on a synthesis of our DCF, SOTP and comparable company valuation methodologies. Abstract 2512, released as part of the American Society of Clinical Oncology (ASCO) abstracts last night, highlighted the progress that CALA has made with its first in class CB-839 glutaminase inhibitor. At the time of the abstract submission, 35 patients had been enrolled, receiving CB-839 doses from 100 to 800 mg TID and 600 mg BID. Radiographic stable disease (SD) was observed in seven (28%) of 25 efficacy-evaluable patients with a variety of solid tumors. In our view, the results bode well for the program given that many patients were presumably treated at sub-therapeutic levels in this dose ascending study. Further, the only patient-selection criteria used was based upon empiric preclinical findings. Investigators described CB-839 as well tolerated, although they did report ≥ Grade-3 treatment-related adverse events (AEs) in seven (20%) patients, including ALT/AST (four patients), creatinine, alkaline phosphatase, and GGT increases, lymphopenia, and hypoglycemia (one patient each). In our view, this rate of adverse events, possibly attributable to the treatment, is not unusual in patients with advanced disease of the kind enrolled in this study.

Investigators also noted that a Grade-3 increase in creatinine, which was considered unlikely related to CB-839, was a dose limiting toxicity at 250 mg TID. Overall it appears CB-839 has acceptable PK/PD characteristics with rapid absorption (Tmax one-two hours fasted and two-four hours fed), a four hour half-life, and > 90% glutaminase inhibition in platelets when CB-839 concentrations exceeded 450 nM. In addition, target inhibition was confirmed in tumors. At ASCO, we look forward to at least four months of updated data since the abstract submission deadline was February 3, 2015, including possible preliminary data in triple negative breast cancer (TNBC), non-small cell lung adenocarcinoma (NSCLC), renal cell carcinoma (RCC), mesothelioma, and tumors with mutations in enzymes of the TCA cycle.

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 Molineaux, founder 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. Finally, we are excited about the company's recently-added program in arginase inhibition, which

Michael G. King, Jr.
mking@jmpsecurities.com
(212) 906-3520

could potentially have a role in the immuno-oncology space in much the same way as IDO inhibitors have had in the inhibition of tryptophan and its attendant effect on T-regulatory (T-reg) cells.

FIGURE 1. Upcoming Milestones

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: Company Presentations

FIGURE 2. CALA 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: Company filings and JMP Securities LLC

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.
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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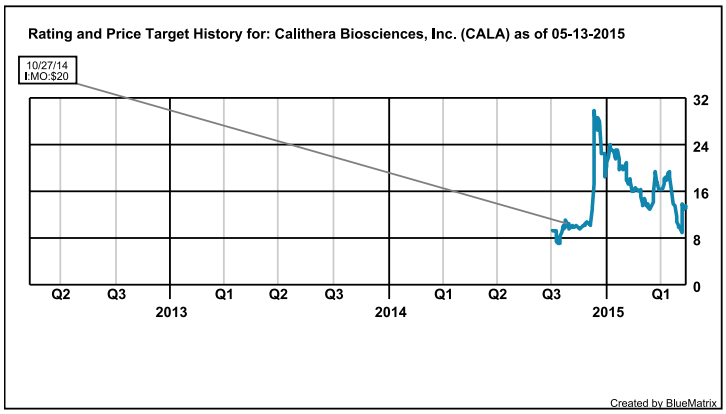
JMP Securities Research Ratings and Investment Banking Services: (as of May 14, 2015)

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	279	*62.00%*	Buy	279	*62.00%*	95	*34.05%*
MARKET PERFORM	Hold	140	*31.11%*	Hold	140	*31.11%*	17	*12.14%*
MARKET UNDERPERFORM	Sell	9	*2.00%*	Sell	9	*2.00%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.67%*		21	*4.67%*	4	*19.05%*
TOTAL:		450	*100%*		450	*100%*	116	*25.78%*

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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Jeffrey H. Spurr
Director of Research
(415) 835-3903

RESEARCH PROFESSIONALS

FINANCIAL SERVICES

Alternative Asset Managers
Devin Ryan (212) 906-3578
Brian McKenna (212) 906-3545

Commercial & Specialty Finance
Christopher York (415) 835-8965

Consumer Finance
David M. Scharf (415) 835-8942
Douglas Greiner (212) 906-3525

Financial Processing & Outsourcing
David M. Scharf (415) 835-8942
Douglas Greiner (212) 906-3525

Insurance
Matthew J. Carletti (312) 768-1784
Christine Worley (312) 768-1786
Solomon Mindlin (212) 768-1788

Investment Banks & Brokers
Devin Ryan (212) 906-3578
Brian McKenna (212) 906-3545

Mortgage Operating Companies
REITs: Agency, Hybrid, & Commercial Mortgage
Steven C. DeLaney (404) 848-7773
Trevor Cranston, CFA (415) 869-4431
Charter Robinson (757) 613-8955
Benjamin Zucker (212) 906-3529

HEALTHCARE

Animal Health
J. T. Haresco, III, PhD (415) 869-4477

Biotechnology
Liisa A. Bayko (312) 768-1785
Masha Chapman (415) 835-8944
Bhumika Sharma, PhD (312) 768-1795
Jason N. Butler, PhD (212) 906-3505
Harry Jenq, PhD (212) 906-3509
Nazibur Rahman (212) 906-3519
Michael G. King, Jr. (212) 906-3520
Bryan Czyzewski, PhD (212) 906-3577
Eric Ekland (212) 906-3540
Naureen Quibria, PhD (212) 906-3514

Healthcare Services & Facilities
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Brian Riley (415) 835-8908

Life Science Tools & Diagnostics
J. T. Haresco, III, PhD (415) 869-4477

Medical Devices & Supplies
David Turkaly (212) 906-3563
John Gillings (212) 906-3564

Specialty Pharmaceuticals

REAL ESTATE

Housing & Land Development
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Bharathwajan Iyengar (415) 835-3902

Lodging & Leisure
Robert A. LaFleur (212) 906-3510
Whitney Stevenson (212) 906-3538

Property Services
Mitch Germain (212) 906-3546
Peter Lunenburg (212) 906-3537

REITs: Healthcare, Residential, & Specialty
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Brian Riley (415) 835-8908

REITs: Office, Industrial, & Diversified
Mitch Germain (212) 906-3546
Peter Lunenburg (212) 906-3537

Residential Services
Peter L. Martin, CFA (415) 835-8904
Aaron Hecht (415) 835-3963
Bharathwajan Iyengar (415) 835-3902

TECHNOLOGY

Internet Security & Communications Infrastructure
Erik Suppiger (415) 835-3918
John Lucia (415) 835-3920

Internet & Digital Media
Ronald V. Josey III (212) 906-3528
Ignatius Njoku (415) 835-8960
Andrew Boone, CFA (415) 835-3957
Shweta Khajuria (415) 835-8916

Software
Patrick Walravens (415) 835-8943
Peter Lowry (415) 869-4418
Mathew Spencer (415) 835-8930
Greg McDowell (415) 835-3934
Rishi Jaluria (415) 835-3961

Wireless & Cloud Computing Technologies
Alex Gauna (415) 835-8998

ADDITIONAL CONTACTS

Thomas R. Wright
Director of Equities
(212) 906-3599

Thomas Healy
Head of Institutional Sales
(212) 906-3533

600 Montgomery Street, Suite 1100
San Francisco, CA 94111
www.jmpsecurities.com