

Calithera Biosciences, Inc. (CALA)

Reports 4Q14 and FY14 Earnings Results and Highlights an Integrated Oncology Pipeline

MARKET DATA

Price	\$15.88
52-Week Range:	\$6.51 - \$33.48
Shares Out. (M):	17.6
Market Cap (\$M):	\$279.5
Average Daily Vol. (000):	527.0
Cash (M):	\$102
Cash/Share:	\$5.69
Enterprise Value (M):	\$343
Float (M):	17.8
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$15.88 | Target Price: \$20.00

INVESTMENT HIGHLIGHTS

Calithera Biosciences reports 4Q14 and FY14 results and highlights the recent in-licensing of two new targets; we reiterate our Market Outperform rating and \$20 price target, based on a synthesis of our DCF, SOTP, and comparable company valuation methodologies. We remind investors that as a development stage biotech company, CALA continues to be a story of clinical execution with its lead asset, CB-839, rather than of earnings. CALA recorded a net operating loss and EPS of \$6.8M and (\$0.37), respectively, greater than our estimates of \$5.7M and (\$0.31), as a result of greater than expected R&D spend (\$5M vs. our estimate of \$4.5M), and G&A spend (\$1.9M vs. our estimate of \$1.2M), attributable primarily to the continued advancement of CALA's lead molecule, CB-839, in Phase I clinical trials, and investments in two new programs. With cash and cash equivalents at the end of the quarter of \$102M, CALA continues to function as a lean operation, providing year-end guidance of \$65M in cash.

Boasting a broadened pipeline. Highlights of the call included CALA's recent in-licensing of a portfolio of inhibitors targeting tumor metabolism (hexokinase-II from Transtech), as well as a portfolio directed at immune-oncology pathways (arginase inhibitors from Mars Symbioscience), to round out a fully integrated cancer program. With the addition of these two programs, and CALA's glutaminase inhibitor (CB-839), it now has a broadened pipeline of inter-related programs that specifically target metabolic pathways which enable tumors to grow and evade the immune system.

CB-839 is on track and on show. 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. 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 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 oral session at the American Association of Cancer Research Annual Meeting (April 21, 3:35pm-3:50pm), where we expect to learn in greater detail of other potential biomarkers that CALA's investigators have identified potentially for future clinical development programs.

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.

FY DEC		2014A	2015E	2016E
Revenue (\$M)	1Q	NA	\$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
	Previous FY	(\$1.39)	(\$1.49)	(\$2.90)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



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

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

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 \$700M. Onyx, in turn, sold to Amgen (AMGN, NC) in 2013 for \$10B.

FIGURE 1. Upcoming Potential Catalysts

Timing	Catalyst
2Q15	Preclinical presentations at AACR (April 18-22, Philadelphia)
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: Company reports

FIGURE 2. Estimates and Actuals

CALA	4Q14		FY14		1Q15 est		2Q15 est		3Q15 est		4Q15 est		FY15 est		FY16 est		FY17 est		FY18 est	
	JMP est	Actual	JMP est	Actual	JMP est	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	0.0	0.0	0.0	54.6	54.6
R&D	4.5	5.0	16.0	16.5	5.7	5.7	6.5	6.5	7.3	7.3	8.0	8.0	21.5	27.5	43.0	55.0	86.0	110.0	133.3	170.5
SG&A	1.2	1.9	4.4	5.1	2.0	2.0	2.2	2.2	2.3	2.3	2.4	2.4	6.0	8.9	13.1	19.6	39.3	58.7	70.7	105.7
Total operating expense	5.7	6.8	20.4	21.6	7.7	7.7	8.7	8.7	9.6	9.6	10.4	10.4	27.5	36.4	56.1	74.6	125.3	168.7	204.0	276.2
Net income (loss)	(5.7)	(6.8)	(20.4)	(21.6)	(7.7)	(7.7)	(8.7)	(8.7)	(9.6)	(9.6)	(10.4)	(10.4)	(27.5)	(36.4)	(56.1)	(74.6)	(125.3)	(168.7)	(156.0)	(228.2)
EPS (diluted)	(\$0.31)	\$ (0.37)	(\$1.39)	\$ (1.47)	(\$0.39)	\$ (0.39)	(\$0.42)	\$ (0.42)	(\$0.43)	\$ (0.43)	(\$0.44)	\$ (0.44)	(\$1.49)	\$ (1.69)	(\$2.47)	\$ (3.29)	(\$4.51)	\$ (6.07)	(\$4.70)	\$ (6.88)

Source: JMP Securities LLC, Company reports

FIGURE 3. Updated Income Statement

Calithera Biosciences (CALA)	2012A	2013A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Income Statement (\$MM)	2012A	2013A	2014A	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	6.6	9.9	16.5	5.7	6.5	7.3	8.0	27.5	55.0	110.0	170.5	221.7	266.0	292.6	321.8	354.0	389.4	428.4
% Growth								66.9%	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%	43%	30%	25%	24%	25%	26%
General and administrative	1.4	2.5	5.1	2.0	2.2	2.3	2.4	8.9	19.6	58.7	105.7	153.3	191.6	210.8	229.8	248.2	260.6	273.6
Total operating expenses	8.0	12.4	21.6	7.7	8.7	9.6	10.4	36.4	74.6	168.7	276.2	375.0	457.6	503.4	551.6	602.2	650.0	702.0
Operating income (loss)	(8.0)	(12.4)	(21.6)	(7.7)	(8.7)	(9.6)	(10.4)	(36.4)	(74.6)	(168.7)	(228.2)	(95.4)	133.5	432.5	697.6	865.2	926.7	947.2
Operating margin (%)											-418.1%	-30.1%	20.0%	41.1%	49.8%	52.7%	52.6%	51.4%
Interest income																		
Interest expense																		
Total other income, net	-	0.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Pretax income (loss)	(8.0)	(12.4)	(21.6)	(7.7)	(8.7)	(9.6)	(10.4)	(36.4)	(74.6)	(168.7)	(228.2)	(95.4)	133.5	432.5	697.6	865.2	926.7	947.2
Income tax benefit (provision)			0.0					0.0	0.0	0.0	0.0	4.8	(13.3)	(86.5)	(209.3)	(302.8)	(324.3)	(331.5)
Tax Rate												5%	10%	20%	30%	35%	35%	35%
Comprehensive income (loss)	(8.0)	(12.4)	(21.6)	(7.7)	(8.7)	(9.6)	(10.4)	(36.4)	(74.6)	(168.7)	(228.2)	(90.7)	120.1	346.0	488.3	562.3	602.4	615.7
Basic EPS to common shareholders	\$ (366.13)	\$ (3.03)	\$ (1.47)	\$ (0.39)	\$ (0.42)	\$ (0.43)	\$ (0.44)	\$ (1.69)	\$ (3.29)	\$ (6.07)	\$ (6.88)	\$ (2.60)	\$ 3.28	\$ 9.01	\$ 12.10	\$ 13.28	\$ 13.54	\$ 13.18
Diluted EPS to common shareholders	\$ (366.13)	\$ (3.03)	\$ (1.47)	\$ (0.39)	\$ (0.42)	\$ (0.43)	\$ (0.44)	\$ (1.69)	\$ (3.29)	\$ (6.07)	\$ (6.88)	\$ (2.60)	\$ 3.28	\$ 9.01	\$ 12.10	\$ 13.28	\$ 13.54	\$ 13.18
Basic shares outstanding	0.0	4.1	14.7	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	0.0	4.1	14.7	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, 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.

JMP FACTS AND DISCLOSURES

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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.

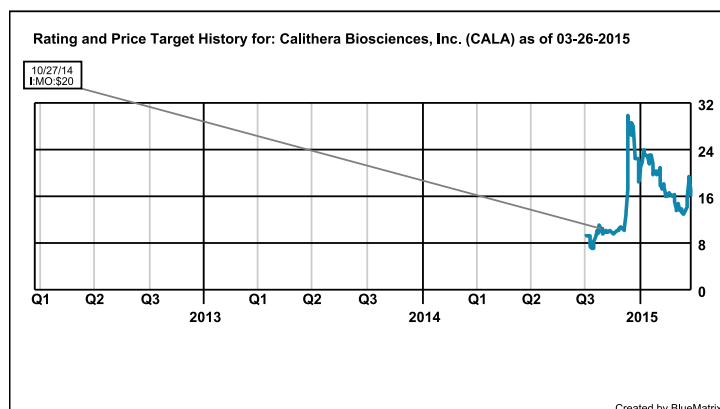
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	285	63.62%	Buy	285	63.62%	89	31.23%
MARKET PERFORM	Hold	153	34.15%	Hold	153	34.15%	21	13.73%
MARKET UNDERPERFORM	Sell	8	1.79%	Sell	8	1.79%	0	0%
COVERAGE IN TRANSITION		1	0.22%		1	0.22%	0	0%
TOTAL:		448	100%		448	100%	110	24.55%

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
Hannah Kim, CFA	(415) 835-8962

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

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

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
Michael G. King, Jr.	(212) 906-3520
Bryan Czyzewski, PhD	(212) 906-3577
Naureen Quibria, PhD	(212) 906-3514

Healthcare Services & Facilities

Peter L. Martin, CFA	(415) 835-8904
Aaron Hecht	(415) 835-3963

Life Science Tools & Diagnostics

J. T. Haresco, III, PhD	(415) 869-4477
Marie T. Casey, PhD	(415) 835-3955

Medical Devices

J. T. Haresco, III, PhD	(415) 869-4477
Marie T. Casey, PhD	(415) 835-3955

Medical Devices & Supplies

David Turkaly	(212) 906-3563
John Gillings	(212) 906-3564

Specialty Pharmaceuticals

Oren G. Livnat, CFA	(212) 906-3566
Nazibur Rahman	(212) 906-3519

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

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
Michael Wu	(415) 835-8996

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
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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