

Reason for report:

EARNINGS

CALITHERA BIOSCIENCES, INC.

CB-839 Clinical Program Gains Speed and Breadth

• **Bottom Line:** CALA's 1Q:15 EPS call highlighted continued good clinical progress with its lead program CB-839 (glutaminase inhibitor), which is undergoing testing in several expansion cohorts as both a single agent and in multiple combination regimens in solid tumors, AML and multiple myeloma after completing dose escalation. Two additional programs, targeting arginase and hexokinase II, remain in preclinical development, but an IND filing on CALA's lead arginase candidate is planned for 1H:16. Our price target remains \$19.

• **CB-839 clinical data at ASCO and EHA should provide a solid read on PK, PD and safety, with perhaps a first glimpse of efficacy.** CALA will be presenting a poster with single-agent data from its solid tumors Phase I trial at ASCO on 05/30/15. Management indicated that the actual presentation at ASCO will contain substantial clinical data beyond that outlined in the abstract, as PK, PD, efficacy and safety data obtained after abstract submission will be included with a very recent safety data cutoff. This should result in the addition of a meaningful number of patients to the ASCO dataset. Single-agent CB-839 data from the Phase I leukemia trial will be presented at the European Hematology Association meeting in mid-June and will comprise almost exclusively AML patients. CALA stressed that, for both trials, only a subset of patients to be presented received substantial exposure to the drug; hence a potential read on efficacy could be preliminary.

• **CB-839 to be tested in multiple combination regimens in expansion cohorts.** In its phase I solid tumor trial, CALA is currently enrolling 4 single-agent expansion cohorts in triple-negative breast cancer (TNBC), KRAS-mutant non-small cell lung cancer (NSCLC), clear-cell renal carcinoma and rare cancers with driver mutations in the TCA cycle enzymes. A first combination expansion cohort, evaluating CB-839 in combination with paclitaxel in TNBC, appears to be enrolling already. Management indicated that a second combination expansion cohort in renal cell carcinoma, testing CB-839 in combination with everolimus, will open shortly, and that two additional combination cohorts in multiple myeloma will open in the near future. CALA believes that first combination data will become available in late-2015.

• **Model Update.** CALA reported no revenue, R&D expenses of \$5.6M, G&A expenses of \$2.2M, and net loss from operations of \$7.9M for 1Q:15. The company ended the quarter with \$94.3M in cash, cash equivalent and investments, and expects this balance to decrease to no less than \$65M by YE:15. We updated our model to reflect these changes.

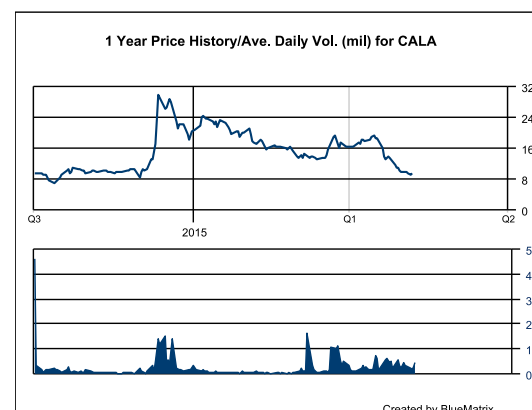
Key Stats:

(NASDAQ:CALA)

S&P 600 Health Care Index: 1,603.74
Price: \$9.52
Price Target: \$19.00
Methodology:

DCF analysis, 10% discount rate

52 Week High: \$33.48
52 Week Low: \$6.51
Shares Outstanding (mil): 17.9
Market Capitalization (mil): \$170.4
Book Value/Share: \$0.00
Cash Per Share: \$5.28
Dividend (ann): \$0.00
Dividend Yield: 0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2014A	0.0	0.0	0.0	0.0	0.0	(\$0.52)	(\$0.69)	(\$0.53)	(\$0.38)	(\$1.99)	NM
2015E - New	0.0A	0.0	0.0	0.0	0.0	(\$0.44)A	(\$0.49)	(\$0.54)	(\$0.60)	(\$2.08)	NM
2015E - Old	0.0A	0.0	0.0	0.0	0.0	(\$0.48)	(\$0.53)	(\$0.58)	(\$0.63)	(\$2.22)	NM
2016E - New	--	--	--	--	0.0	--	--	--	--	(\$2.84)	NM
2016E - Old	--	--	--	--	0.0	--	--	--	--	(\$3.03)	NM

Source: Company Information and Leerink Partners LLC Research

INVESTMENT THESIS

We rate CALA Outperform with a valuation of \$19. CALA is an early clinical-stage biotechnology company developing novel, potentially first-in-class agents for cancer by exploiting dysregulated metabolism of tumor cells and host immune response. We believe targeting cancer metabolism is an important new area of exploration for cancer therapeutics. We believe the rationale for targeting cancer metabolism is strong, given the elevated metabolic need as a hallmark of cancer and importantly altered metabolic pathways compared to normal cells. CALA's lead compound CB-839 (Phase I) is a specific inhibitor of glutaminase, which interferes with the increased glutamine metabolism seen in cancer cells. Based on preclinical data and biological rationale, glutaminase inhibitors could be especially interesting for settings where a high unmet need exists such as triple negative breast cancer as well as patients with Ras and Myc mutations. The effectiveness of a glutaminase inhibitor is likely context-dependent – patient selection and combinations could be key to success. Glutaminase clearly remains to be validated clinically as a target. Feedback we received is mixed and a concern about targeting glutaminase and perhaps metabolism in general is that cancer cells could potentially switch to a low-growth state, therefore these agents may not be cytotoxic but rather cytostatic. Data for CB-839 show that for at least some cells, CB-839 is cytotoxic. MEDACorp cancer biology specialists point out that the susceptibility to a glutaminase inhibitor varies considerably among different tumor cells therefore patient selection will likely need to be integral to development. In addition to CB-839, CALA has an interesting preclinical immuno-oncology program in targeting arginase, which has similarities to IDO inhibitors, which have drawn considerable attention recently. The management's proven track record with Kyprolis (AMGN) bodes well for a sustainable pipeline.

CALA – Upcoming Catalysts

Drug	Timing	Description
CB-839	5/30/2015 (ASCO meeting)	Poster presentation of phase I single-agent data in solid tumors
	June 11-14, 2015 (EHA)	Phase I single-agent data in AML
	mid-2015	open remaining combination expansion cohorts
	late 2015	Data from combination Phase 1b expansion cohorts
Arginase inhibitor	2H:15	Present preclinical data
	1H:16	Submit IND
Hexokinase II inhibitor	2015	Continue preclinical development

Source: Company reports, Leerink Partners estimates

CALA – Pipeline

Drug	Mechanism	Phase	Indications	n	Primary Endpoint	Trial initiation	Region
CB-839	Glutaminase Inhibitor	I	solid tumors (incl. TNBC, NSCLC, RCC and Mesothelioma)	165	Safety, tolerability	Feb. 2014	US
		I	AML, ALL	50	Safety, tolerability	Feb. 2014	US
		I	NHL, MM, WM	65	Safety, tolerability	Feb. 2014	US
Preclinical program	Arginase Inhibitor	Preclinical					
Preclinical program	Hexokinase II inhibitor	Preclinical					

Source: Company reports, Leerink Partners estimates

VALUATION

Our \$19 valuation for CALA is based on a DCF analysis and probability-weighted sales for CB-839 in triple-negative breast cancer (TNBC) and multiple myeloma (MM) with a probability of success of 15% for both indications. We use a 10% discount rate, which we believe is appropriate, as our valuation uses probability-weighted sales.

RISKS TO VALUATION

Risks to our valuation include clinical, regulatory, commercial, and competitive risks for pipeline products. CALA's clinical programs are still at a relatively early stage, therefore significant uncertainties exist. As a development-stage company several years away from a commercial launch, there are also financing risks.

Calithera

(In '000s, except per share items)

	2012	2013					2014A					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
			1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE								
REVENUE:																			
CB-839(POS adjusted sales --US)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	13,832	80,965	154,830
royalty on OUS sales																	207	3,643	9,290
Milestone payments																			
Other, net																			
Total Revenue																	14,039	84,609	164,120
OPERATING EXPENSES:																			
Cost of product Sales																	968	5,668	10,838
Research and Development	6,558	9,900	3,318	4,183	3,894	4,972	16,367	5,630	6,630	7,630	8,630	28,520	42,780	64,170	70,587	77,646	85,410	93,951	103,346
General and Administrative	1,417	2,478	832	1,309	1,347	1,866	5,354	2,237	2,282	2,282	2,327	9,128	9,310	11,172	12,290	20,000	60,000	90,000	108,000
Royalties	-																		
Amortization of Acquired Intangible Assets																			
Operating Loss/ Income	(7,975)	(12,378)	(4,150)	(5,492)	(5,241)	(6,838)	(21,721)	(7,867)	(8,912)	(9,912)	(10,957)	(37,648)	(52,090)	(75,342)	(82,877)	(97,646)	(132,339)	(105,010)	(58,064)
Investment, Interest and Other Income, Net		1	1	1	2	5	9	9	5	5	5	24							
Gain on extinguishment of convertible preferred stock	2889																		
Change in fair value of convertible preferred stock warrant liability																			
Net Income before Taxes	(7,975)	(12,377)	(4,149)	(5,491)	(5,239)	(6,833)	(21,712)	(7,858)	(8,907)	(9,907)	(10,952)	(37,624)	(52,090)	(75,342)	(82,877)	(97,646)	(132,339)	(105,010)	(58,064)
Income tax rate%																		35%	35%
Income Tax									-									36,754	20,323
Net Loss	(5,086)	(12,377)	(4,149)	(5,491)	(5,239)	(6,833)	(21,712)	(7,858)	(8,907)	(9,907)	(10,952)	(37,624)	(52,090)	(75,342)	(82,877)	(97,646)	(132,339)	(68,257)	(37,742)
Basic and Diluted Net Loss per Common Share			(0.52)	(0.69)	(0.53)	(0.38)	(1.99)	(0.44)	(0.49)	(0.54)	(0.60)	(2.08)	(2.84)	(4.07)	(2.89)	(3.37)	(2.44)	(1.22)	(0.67)
Shares Used in Calculating Basic and Diluted Net Loss per Share(pro forma)			7,979	7,979	9,882	17,882	10,931	17,859	18,037	18,218	18,400	18,129	18,310	18,493	28,678	28,965	54,254	54,797	55,345
Dilutive shares			9,000	9,000	10,903	18,903	11,952	18,880	19,058	19,239	19,421	19,150	19,331	19,514	29,699	29,986	55,275	55,818	56,366
						5.69													
Cash and cash equivalents						110,911	101,969	101,969	94,275	85,368	75,462	64,509	64,509	12,419	(62,924)	(15,801)	(113,446)	79,215	10,958
Milestone payments																			
Capital raise																			
Shares issued															130,000	325,000			
Price per share															10,000	25,000			
Net Cash	-			27,750	110,911	101,969	101,969	94,275	85,368	75,462	64,509	64,509	12,419	\$ 67,076	\$ 13.00	\$ 13.00	79,215	10,958	(26,784)
Net cash per share								\$ 5.28											
Stock Options																			
Restricted stock							35.9												
Total							71.6			35.9 +71.6									
							107.5												
Stock price							(1,302)												
Market Cap									31.5										
EV									10.5										

Balance sheet data

Working Capital
Total assets
Convertible preferred stock warrant liability
Convertible preferred stock
Total stockholder's (deficit) equity

* 1H:14 results available but 1Q and 2Q were not broken out separately.

Source: Company reports and Leerink Partners

Disclosures Appendix

Analyst Certification

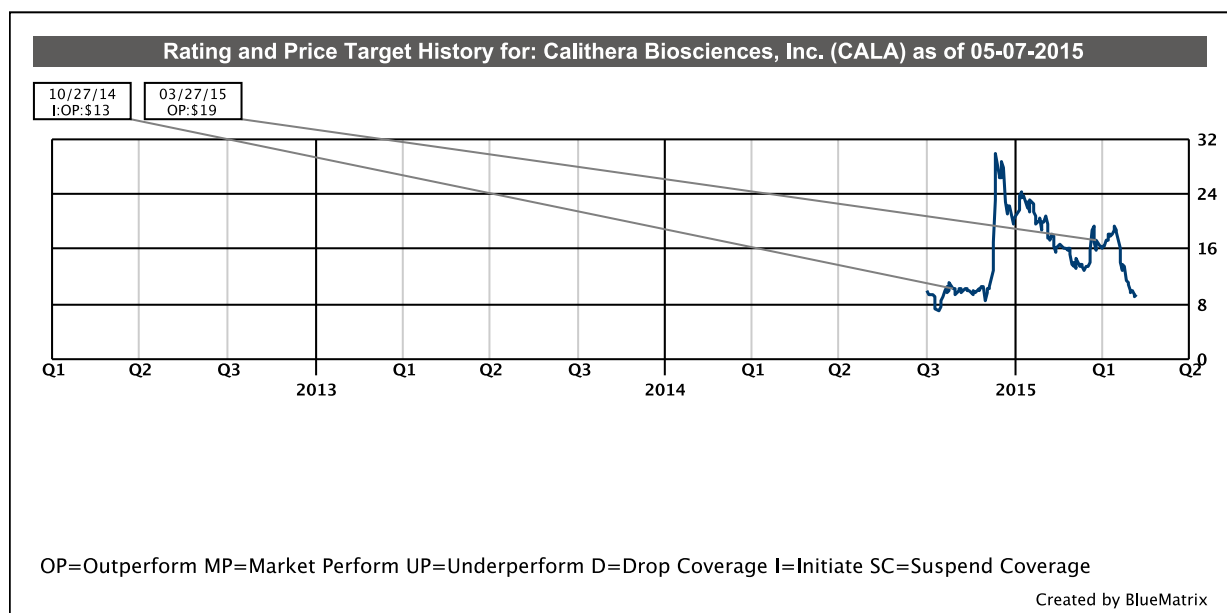
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

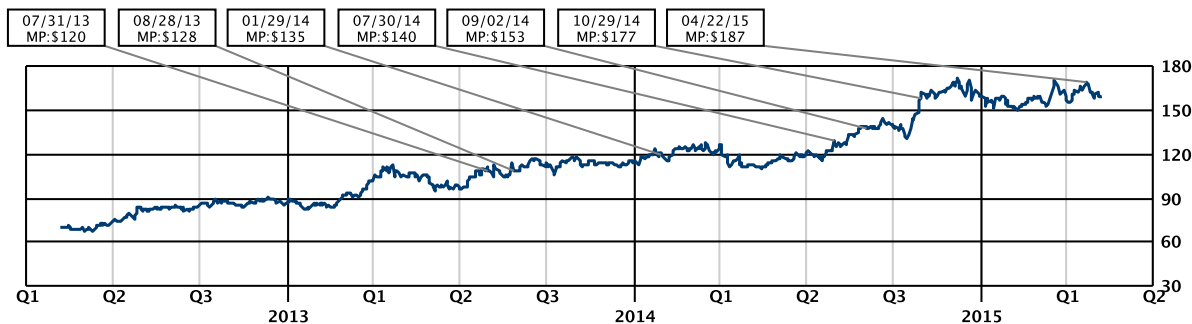
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Rating and Price Target History for: Amgen, Inc. (AMGN) as of 05-07-2015


Leerink Swann placed a Market Perform rating on AMGN on November 14, 2011. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

Distribution of Ratings/Investment Banking Services (IB) as of 03/31/15				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	151	70.20	55	36.00
HOLD [MP]	64	29.80	2	3.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

Important Disclosures

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.

In the past 12 months, the Firm has received compensation for providing investment banking services to Calithera Biosciences, Inc. .

Leerink Partners LLC makes a market in Calithera Biosciences, Inc. and Amgen, Inc.

Leerink Partners LLC has acted as the manager for a public offering of Calithera Biosciences, Inc. in the past 12 months.

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Leerink Partners LLC Equity Research

Director of Equity Research	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
Associate Director of Research	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Healthcare Strategy	John L. Sullivan, CFA	(617) 918-4875	john.sullivan@leerink.com
	Alice C. Avanian, CFA	(617) 918-4544	alice.avanian@leerink.com
Biotechnology	Howard Liang, Ph.D.	(617) 918-4857	howard.liang@leerink.com
	Joseph P. Schwartz	(617) 918-4575	joseph.schwartz@leerink.com
	Michael Schmidt, Ph.D.	(617) 918-4588	michael.schmidt@leerink.com
	Gena Wang, Ph.D., CFA	(212) 277-6073	gena.wang@leerink.com
	Paul Matteis	(617) 918-4585	paul.matteis@leerink.com
	Jonathan Chang, Ph.D.	(617) 918-4015	jonathan.chang@leerink.com
	Richard Goss	(617) 918-4059	richard.goss@leerink.com
Life Science Tools and Diagnostics	Dan Leonard	(212) 277-6116	dan.leonard@leerink.com
	Justin Bowers, CFA	(212) 277-6066	justin.bowers@leerink.com
	Kevin C. Chen	(212) 277-6045	kevin.chen@leerink.com
Pharmaceuticals/Major	Seamus Fernandez	(617) 918-4011	seamus.fernandez@leerink.com
	Aneesh Kapur	(617) 918-4576	aneesh.kapur@leerink.com
Specialty Pharmaceuticals	Jason M. Gerberry, JD	(617) 918-4549	jason.gerberry@leerink.com
	Derek C. Archila	(617) 918-4851	derek.archila@leerink.com
Medical Devices, Cardiology & Orthopedics	Danielle Antalffy	(212) 277-6044	danielle.antalffy@leerink.com
	Puneet Souda	(212) 277-6091	puneet.souda@leerink.com
	Richard Newitter	(212) 277-6088	richard.newitter@leerink.com
	Ravi Misra	(212) 277-6049	ravi.misra@leerink.com
Healthcare Services	Ana Gupte, Ph.D.	(212) 277-6040	ana.gupte@leerink.com
Healthcare Technology & Distribution	David Larsen, CFA	(617) 918-4502	david.larsen@leerink.com
	Christopher Abbott	(617) 918-4010	chris.abbott@leerink.com
Digital Health	Steven Wardell	(617) 918-4097	steven.wardell@leerink.com
Sr. Editor/Supervisory Analyst	Mary Ellen Eagan, CFA	(617) 918-4837	maryellen.eagan@leerink.com
Supervisory Analysts	Randy Brougher		randy.brougher@leerink.com
	Robert Egan		bob.egan@leerink.com
	Amy N. Sonne		amy.sonne@leerink.com

New York
299 Park Avenue, 21st floor
New York, NY 10171
(888) 778-1653

Boston
One Federal Street, 37th Floor
Boston, MA 02110
(800) 808-7525

San Francisco
255 California Street, 12th Floor
San Francisco, CA 94111
(415) 905-7200