

Equity Research

Calithera Biosciences, Inc.

CALA: We Are Initiating Coverage With An Outperform Rating
CB-839: Novel Cancer Therapy Targeting Cancer Cell Metabolism

Outperform / V

Sector: Biotechnology
 Market Weight

Initiation of Coverage

• **Summary:** We are initiating coverage of Calithera with an Outperform rating and a \$19-20 valuation range. We see CALA as an attractive, early-stage hematology/oncology company that is positioned to become a leading player in cancer cell metabolism, an area of significant research interest. We're encouraged by early Phase I data for CB-839, an oral inhibitor of glutaminase, and believe 2015 updates will further define its early, but promising profile, LT potential, and paths to market in solid tumors/blood cancers. Our range is based on a SOTP analysis using out-yr sales multiples adjusted for probabilities of success in triple-negative breast cancer and multiple myeloma. 2014/2015 EPS are -\$1.39/-1.63.

• **CB-839: the first glutaminase inhibitor to thread the needle on efficacy and safety?** CB-839 inhibits glutaminase, the essential enzyme needed for conversion of glutamine to glutamate, which is a key nutrient for creation of energy and TCA cycle intermediates needed to support cancer cell growth and survival. Initial Ph. I dose-escalation monotherapy data suggest signals of activity, but most important, a tolerable profile with no CNS toxicity -- the Achilles' heel of prior glutaminase inhibitors. We believe the three solid tumor/blood cancer Ph. I studies are well designed and that their adaptive designs should allow for rapid movement into Ph. I(b) TNBC and MM combination studies by late 2014 and Ph. II by 2016. A novel PD biomarker assay may allow for identification of patients most likely to respond to CB-839, increasing the likelihood of Ph. II/III success.

• **The year 2015 to be key for defining CB-839's profile and providing catalysts for CALA.** The initial detailed look at monotherapy data should occur at the AACR and/or ASCO Meetings, with important Ph. I(b) TNBC and MM combination studies data expected by the end of 2015. In addition, monotherapy data should dictate if CB-839 can be used to treat rare orphan cancers that harbor TCA cycle enzyme driver mutations, which may offer faster paths to market.

• **Experienced management team leveraging Kyprolis success.** A number of CALA senior management were involved in Kyprolis' development while at Proteolix, acquired by Onyx in 2009. We believe this prior experience is highly leverageable and has been evident, in our view, for CB-839 based on a thorough and broad pre-clinical program, well-designed Ph. I/II studies and long-term (LT) strategy, identification and ongoing validation of a novel biomarker assay, and involvement of key U.S. investigators in solid tumors and blood cancers.

• **Pipeline highlighted by immuno-oncology pre-clinical asset, to enter Ph. I in 2016.** CALA's arginase inhibitor may enable re-activation of the body's cytotoxic T-cells. Theoretical proof-of-principal exists from IDO inhibitors, where antagonism allows for re-expression of tryptophan to activate T-cells.

Valuation Range: \$19.00 to \$20.00 from NE to NE

Our sum-of-parts valuation (SOTP) uses P/S multiples of 4.0-5.5x applied to 2025E revenue of \$398MM discounted at 18-20%. Key risks include clinical trial failure, a safety signal for CB-839, and financing risk.

Investment Thesis:

We believe CALA is under-valued based on CB-839's long-term potential in end-stage myeloma and triple-negative breast cancer.

Please see page 3 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 10/27/14 unless otherwise stated.

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	2013A	2014E	2015E
EPS		Curr. Prior	Curr. Prior
Q1 (Mar.)	NE	NE A NC	(\$0.34) NE
Q2 (June)	NE	(1.22) A NC	(0.37) NE
Q3 (Sep.)	NE	(0.28) NE	(0.40) NE
Q4 (Dec.)	NE	(0.31) NE	(0.44) NE
FY	(\$3.03)	(\$1.39)	NE (\$1.63)
CY	(\$3.03)	(\$1.39)	(\$1.63)
FY P/EPS	NM	NM	NM
Rev.(MM)	\$0	\$0	\$0

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
 NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
 V = Volatile, * = Company is on the Priority Stock List

CALA has not provided Q1 to Q4 2013 EPS, only full-year 2013 EPS.

2014 and 2015 quarters may not sum to their annual due to differences in shares outstanding and rounding.

Ticker	CALA
Price (10/24/2014)	\$11.04
52-Week Range:	\$6-12
Shares Outstanding: (MM)	17.9
Market Cap.: (MM)	\$197.6
S&P 500:	1,964.58
Avg. Daily Vol.:	0
Dividend/Yield:	\$0.00/0.0%
LT Debt: (MM)	\$0.0
LT Debt/Total Cap.:	0.0%
ROE:	NM
3-5 Yr. Est. Growth Rate:	75.0%
CY 2014 Est. P/EPS-to-Growth:	NM
Last Reporting Date:	06/30/2014

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

Matthew J. Andrews, Senior Analyst
 (617) 603-4218

matthew.j.andrews@wellsfargo.com

Brian Abrahams, M.D., Senior Analyst
 (212) 214-8060

brian.abrahams@wellsfargo.com

Shin Kang, Ph.D., Associate Analyst
 (212) 214-5036

shin.kang@wellsfargo.com

Ronald Hsu, M.D., Associate Analyst
 (212) 214-5064

ronald.hsu@wellsfargo.com

Together we'll go far



Company Description:

Calithera Biosciences, Inc. (South San Francisco, California) is engaged in the research, development, and commercialization of small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancers. Calithera's lead program is CB-839, an oral inhibitor of the glutaminase enzyme, and is currently in three Phase I studies and plans to initiate a Ph. II program in triple-negative breast cancer and multiple myeloma in early 2016. Behind CB-839 Calithera has a pre-clinical arginase inhibitor compound which is expected to enter human studies in early 2016.

Please refer to our detailed initiation report (38 pages) for more information.

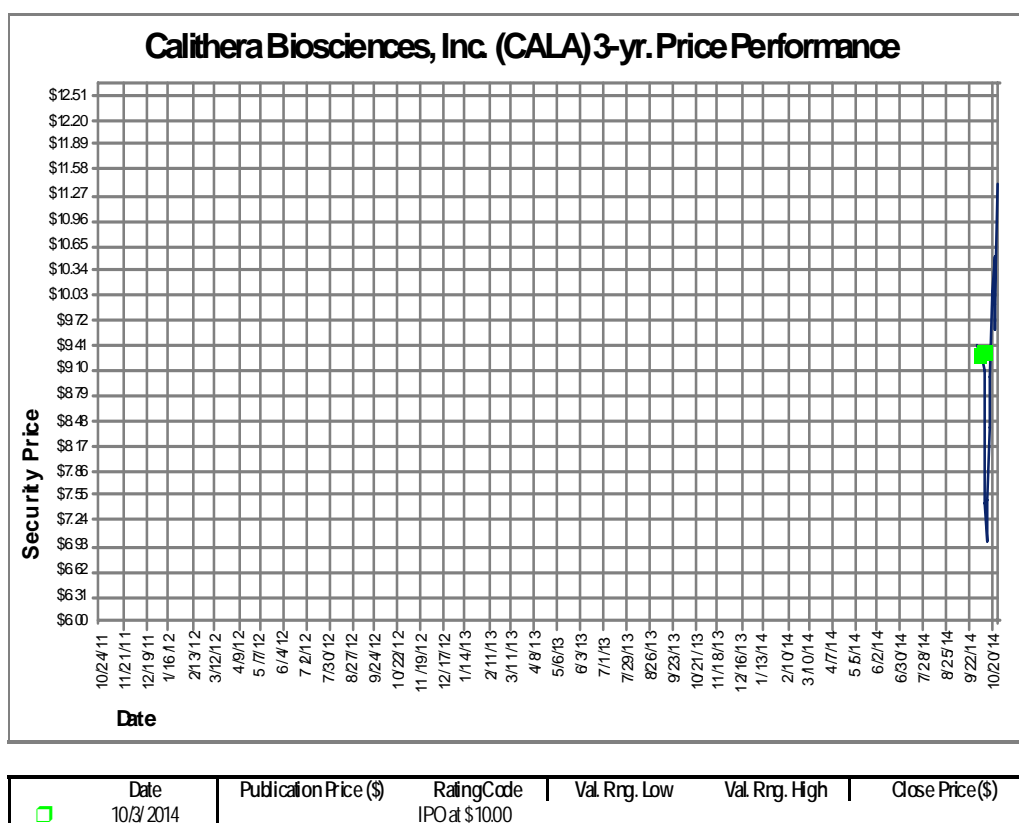
Key Risks

Clinical and development risks. Calithera's lead program CB-839 currently is in early Ph. I clinical studies for multiple solid tumors and blood cancers, while its arginase inhibitor program is in pre-clinical development. While there have been four cases of disease stabilization (including one that included tumor shrinkage of 13%) and no cases of neurotoxicity for CB-839, it is possible that even in Ph. I(b), combination studies efficacy (as measured by ORR) may not be sufficiently competitive with other development agents to warrant advancement into Ph. II and/or Ph. III. In addition, higher toxicities, clinically meaningful neurotoxicities, and an unexpected safety signal may emerge, which halts the development of CB-839. Historically severe neurotoxicity has been a key adverse event that has halted the development of previous glutaminase inhibitors.

Commercial risk. While current CEO Dr. Susan Molineaux, SVP, Development Dr. Chris Molineaux, and SVP, Research Dr. Mark Bennett helped to successfully advance Kyprolis into Ph. II development, prior to Onyx acquiring Proteolix (and then obtaining U.S. approval in 2012), Calithera's management team has limited experience in commercial operations. In order to market CB-839, Calithera may have to build a commercial organization in the United States and potentially, Europe, which requires significant financing and entails significant risk, due to the global macro-economy, healthcare budgets, and an increasingly complex reimbursement landscape.

Financing risk. Clinical drug development and establishment of commercial sales and marketing infrastructures is expensive and very challenging, in our view. Calithera's drug candidates may not be sufficiently efficacious, too toxic, or may become obsolete, due to competitors' programs, and, as a result, Calithera may be unable to successfully find a licensing partner to help development and/or market CB-839 and Calithera's other drug candidates. Thus, Calithera may have to issue additional common stock and/or convertible debt, which could lead to dilution of existing shareholders.

Required Disclosures



Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
- ▲ Rating Upgrade
- Valuation Range Change

- ◆ Initiation, Resumption, Drop or Suspend
- Analyst Change
- Split Adjustment

Rating Code Key

- | | |
|-----------------------|----------------|
| 1 Outperform/Buy | SR Suspended |
| 2 Market Perform/Hold | NR Not Rated |
| 3 Underperform/Sell | NE No Estimate |

Additional Information Available Upon Request

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CALA: Key risks include clinical trial failure, a safety signal for CB-839, and financing risk.

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2=Market Perform: The stock appears appropriately valued, and we believe the stock's total return will be in line with the market over the next 12 months. HOLD

3=Underperform: The stock appears overvalued, and we believe the stock's total return will be below the market over the next 12 months. SELL

SECTOR RATING

O=Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.

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V = A stock is defined as volatile if the stock price has fluctuated by +/-20% or greater in at least 8 of the past 24 months or if the analyst expects significant volatility. All IPO stocks are automatically rated volatile within the first 24 months of trading.

As of: October 26, 2014

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