

Equity Research

Calithera Biosciences, Inc.

CALA: Q4--AACR, ASCO, EHA To More Fully Characterize CB-839

• **Summary:** After the 3/26/15 market close Calithera reported Q4/FY 2014 financial results for a quarter highlighted by CALA completing its initial public offering, continued advancement of its three Phase I dose-escalation, monotherapy studies for glutaminase inhibitor, CB-839, the company licensing a portfolio of arginase inhibitors from Mars Symbioscience, and presentations of pre-clinical and pharmacodynamic assay data for CB-839 at the 2014 ASH Meeting and San Antonio Breast Cancer Symposium. While posters/oral presentations for CB-839 at the AACR Meeting in April should provide investors with a greater appreciation for CB-839's preclinical profile – building on data at ASH and SABCS – we expect Ph. I monotherapy solid tumor data for CB-839 in the ASCO abstract in mid-May, more mature updated results at the ASCO Meeting in late May, and Ph. I monotherapy data in blood cancers at the EHA Meeting in mid-June will help build upon CB-839's early promising profile and further support the long-term promise of targeting solid tumor and blood cancers through cancer cells' metabolic processes. In our view, 2015 is catalyst rich, the management team has solid and leverageable prior clinical experience in developing Kyprolis, CB-839's Ph. I(b)/II clinical program is rational and well-designed, and we continue to see upside for shares as ongoing monotherapy and soon-to-commence combination studies generate objective responses and a clean central nervous system (CNS) toxicity profile through the year. Based on changes to our model (higher R&D expense) our 2015 EPS loss increases to -\$1.83 from -\$1.56.

• (Continued on the following page.)

Valuation Range: \$35.00 to \$40.00

We blend a sum-of-parts valuation using P/S multiples of 4.0-5.5x and P/E multiples of 25-30x applied to 2025E revenue of ~\$428MM and EPS of \$6.18, discounted at 15-18%. 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.

Outperform / V

Sector: Biotechnology

Market Weight

Earnings Estimate Revised Down

EPS	2014A	2015E		2016E	
		Curr.	Prior	Curr.	Prior
Q1 (Mar.)	(\$22.80)	(\$0.39)	(0.34)	NE	
Q2 (June)	(24.22)	(0.42)	(0.37)	NE	
Q3 (Sep.)	(16.85)	(0.50)	(0.40)	NE	
Q4 (Dec.)	(0.39)	(0.53)	(0.44)	NE	
FY	(\$4.67)	(\$1.83)	(1.56)	(\$1.99)	
CY	(\$4.67)	(\$1.83)		(\$1.99)	
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

2014 quarters may not sum to FY 2014 due to differences in shares outstanding and rounding.

Ticker	CALA
Price (03/27/2015)	\$16.82
52-Week Range:	\$6-34
Shares Outstanding: (MM)	17.9
Market Cap.: (MM)	\$301.5
S&P 500:	2,061.75
Avg. Daily Vol.:	302,739
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 2015 Est. P/EPS-to-Growth:	NM
Last Reporting Date:	12/31/2014
	After Close

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

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Please see page 7 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 03/27/15 unless otherwise stated.

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Together we'll go far



Continued from Front Page

- **CB-839 clinical program progressing well and timelines are on track.** The three Ph. I dose-escalation, monotherapy studies have completed enrollment with 61 patients, and a majority being enrolled in the solid tumors study (CX-839-001) vs. 24 as of late July 2014 (Please refer to Exhibit 1 for more details). Dose cohort expansion at 600mg b.i.d. is underway with a focus on renal-cell carcinoma (RCC), triple-negative breast (TNBC), non-small cell lung cancer (NSCLC) and rare TCA/Kreb's cycle driver enzyme mutations. Calithera has decided to expand the Ph. I(b) combination studies from two to four studies and will include: TNBC (CB-839 + paclitaxel), RCC (CB-839 + everolimus), and multiple myeloma (CB-839 + pomalidomide/dexamethasone and CB-839 + dexamethasone). Consistent with its analysis of preclinical data, Calithera has yet to identify a maximum tolerated dose in humans as it has escalated doses from 100mg t.i.d. (which was a pharmacologically active dose) up to 1,000mg t.i.d. Increasing concentrations of CB-839 (during dose escalation) has correlated with inhibition of glutaminase in platelets and within biopsy samples (from ongoing Ph. I study). Recall Calithera has previously reported four cases of disease stabilization at doses of 250mg, 400mg, and 600mg (including one TNBC patient with 13% tumor shrinkage), thus higher doses may lead to objective responses (in data to be presented at the ASCO and EHA Meetings), which would be encouraging in this advanced patient population (some patients up to 15 prior therapies) and for monotherapy dosing. The go-forward dose of 600mg b.i.d. was chosen based on pharmacodynamics data which indicate at trough levels this dose is able to maintain continuous inhibition of glutaminase (90%+ over a 24-hour period).
- **Safety profile continues to appear promising and generally consistent with prior data in the S-1 filing.** With ASCO and EHA Meeting abstracts submitted (and embargo policies in place), management provided a top-level overview of CB-839's safety profile to date, an unexpected surprise on the earnings call. In an analysis of 57 patients (from 61 recruited in Ph. I dose-escalation), a majority of adverse events have been mild to moderate and primarily Grade 1 or 2. Treatment-emergent Grade 3 or 4 events likely related to CB-839 which have occurred in 5%+ patients have included febrile neutropenia, thrombocytopenia, low sodium, and increases in alkaline phosphatase and ALT/AST enzymes. A single dose-limiting toxicity (DLT) of renal dysfunction occurred at the 250mg dose with no additional DLTs observed up to 1,000mg t.i.d. Importantly, there has been no significant CNS toxicity observed to date, consistent with data in the S-1. Recall CNS toxicity has been the key historical safety issue that led to termination of prior glutaminase inhibitors.
- **Upcoming data updates will help further characterize CB-839's profile** Five preclinical abstracts have been accepted for the AACR Meeting including two oral presentations on 4/21/2015, including (1) NSCLC data (Abstract #4710) jointly conducted with Dr. DeBerardinis (a leading expert in cancer cell metabolism at University of Texas Southwestern Medical Center) and (2) data for CB-839 combined with various validated signaling kinase inhibitors (Abstract #4711; e.g., Votrient [pan-TKI], Afinitor [mTOR], selumetinib [MEK], and Tarceva [EGFR]). These combination data would be important for Calithera designing future combination studies which may help expand CB-839's revenue opportunity as part of CB-839's life-cycle management strategy. Preclinical data suggest a number of these signal pathways are intricately linked to a cancer cell's glucose/glutamine needs and by targeting these pathways and glutaminase, enhanced efficacy may be feasible. Updated monotherapy data in solid tumors are to be presented at the ASCO Meeting including data for all doses studied, including those patients at the go-forward Ph. I(b) dose of 600mg who are response eligible. Ph. I monotherapy data from blood cancers (NHL, MM, ALL, AML) are to be presented at the EHA Meeting in mid-June for all doses studied and those patients who have been dosed at 600mg and are response eligible. Later in 2015 preliminary Ph. I(b) combination data in MM are expected at the ASH Meeting and in TNBC at the SABCS. As Ph. I data emerge during 2015 for solid tumors/blood cancers with rare TCA/Kreb's cycle driver mutations (e.g., paraganglioma, pheochromocytoma, and AML with IDH mutations) we could see additional updates from Calithera.
- **Financials:** Calithera reported a Q4 net loss of -\$0.39 (vs. our -\$0.33) driven by slightly higher than expected operating expenses. Cash as of 12/31/14 was \$102 million and the company has guided to roughly \$65 million at the end of 2015. Based on its current clinical strategy for CB-839, Calithera believes cash on hand will fund operations through 2017 when top-line Ph. II data emerge for its two planned combination studies in TNBC and R/R MM.

Exhibit 1. CB-839's Ph. I/II Clinical Program

Study	"N"	Population	Phase I(b) portion of program	Potential Phase II design
CX-839-001	~100	TNBC	CB-839 + paclitaxel (n=10-12 patients)*	TNBC: Randomized: CB-839 + pac vs. pac + placebo (n= ~200-300; TBD)
		NSCLC		
		RCC	CB-839 + everolimus (n=10-12 patients)*	
		Driver mutations*		
CX-839-002	~65	MM	CB-839 + pomalidomide/dexamethasone and CB-839 + dexamethasone (n=10-12 patients in each cohort)*	MM: Randomized: CB-839/pom/dex vs. pom/dex/placebo (n= ~200-300; TBD)
		NHL		
CX-839-003	~40-50	ALL		TBD
		AML^		

Source: Company reports, www.clinicaltrials.gov, and Wells Fargo Securities, LLC

Note: * = rare mutations such as GIST and HLRCC and will represent ~10% of recruited patients; ^ = can include treatment-naïves if 60+ years and are ineligible for transplant or standard chemotherapy. # = depending on activity could increase to 30 patients.

Exhibit 2. CB-839 Profile as of Q3 2014. Note: To be updated at the ASCO and EHA Meetings in June.

Baseline characteristics of patients and types of solid tumor blood cancers across the studies		
24 enrolled as of July 25, 2014 with relapsed/refractory disease with mean of 5 priors and some up to 15 prior therapies.		
001 Study	Dosing at 400mg	N=15 (5 colorectal; 5 triple-negative breast; 2 renal cell; 1 each: cholangiocarcinoma, sarcoma, mesothelioma)
002 Study	Dosing at 250mg	N=3 (multiple myeloma)
003 Study	Dosing at 600mg	N=6 (5 AML; 1 ALL)
Preliminary safety and efficacy in monotherapy dose-escalation phase		
Efficacy	Mesothelioma (N=1)	Duration: 5 cycles
	Multiple Myeloma (n=2)	Duration: 5 cycles
	TNBC (n=1)	On therapy; 3 cycles
		13% tumor shrinkage
Safety	Grade 1: 21 cases	Most common: nausea, vomiting, and fatigue.
	Grade 2: 2 cases	Anemia; had baseline Grade 1 anemia.
		2nd patient: worsening fatigue.
	Grade 3: 2 cases	Elevated creatinine with baseline diabetic nephropathy and severe proteinuria.*
		Neutropenia; had baseline Grade 2 neutropenia.

Source: Company reports and Wells Fargo Securities, LLC

Note: * = considered a Dose-limiting toxicity and Serious AE as patient was hospitalized.

Exhibit 3. Calithera's Upcoming Milestone Schedule

Agent	Timing	Event
	April 18-22, 2015	Present additional pre-clinical data in five posters/oral presentations at the AACR Meeting (Philadelphia, PA). Dr. DeBerardinis to present abstract/analysis on CB-839 and cancer cell metabolism.
	May 29 - June 2, 2015	Present the initial Ph. I monotherapy efficacy/safety data in solid tumors and in any response-assessable patients at the 600mg cohort expansion dose, at the ASCO Meeting (Chicago, Illinois).
	June 11-14, 2015	Present the initial Ph. I monotherapy efficacy/safety data in blood cancers and in any response-assessable patients at the 600mg cohort expansion dose, at the EHA Meeting (Vienna, Austria).
	December 5-9, 2015	Present the Ph. I monotherapy and combination data for the MM/NHL and ALL/AML studies at the ASH Meeting.
	December 8-12, 2015	Present the Ph. I combination data for the TNBC study at the SABCS.
	End 2015/early 2016	Report the Ph. I monotherapy and combination data for the solid tumor studies.
	H1 2016	Complete the Ph. I monotherapy and Ph. I(b) combination studies.
	H1 2016	Meet with FDA (and CHMP/EMA) to discuss Ph. I(a)/(b) data and Ph. II protocols.
	Mid-2016	Initiate the Ph. II randomized studies in TNBC and MM (and possibly other solid tumors including those with rare driver mutations). Both studies to potentially include 100's of patients.
	End 2017/H1 2018	Complete the Ph. II randomized studies in TNBC and MM.
Arginase Inhibitor	2015	Complete various preclinical toxicology and other studies.
	End 2015/early 2016	Submit the IND to regulatory agencies.
	H1 2016	Initiate a Ph. I clinical program.
Hexokinase inhibitor	H2 2016/2017	Submit the IND to regulatory agencies.

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 4. Calithera's Pipeline Chart

Calithera Biosciences, Inc. Pipeline Summary		
Candidate	Indication	Stage And Summary
CB-839	Triple Negative Breast Cancer (TNBC)	Phase I - Study CX-839-001 will enroll up to 100 patients with TNBC and other solid tumors, such as Non-Small Cell Lung Cancer. The Phase I(b) portion of the study in TNBC will assess the combination of CB-839 with paclitaxel based on preclinical studies which suggest synergistic activity. Preclinical data also suggest TNBC is more sensitive to CB-839 as opposed to Estrogen receptor (ER) positive or HER2+ breast cancers. As part of the ongoing Ph. I study Calithera will collect tumor biopsies to assess glutaminase levels in order to confirm the pharmacodynamic results of its assay for glutaminase in platelets (a biomarker). These data may also help identify TNBC patients more likely to respond to CB-839.
	Renal Cell Carcinoma (RCC)	Phase I - Calithera will study CB-839 in combination with everolimus in RCC as part of the Ph. I(b) program. Afinitor (everolimus) is an inhibitor of mTOR, an enzyme downstream of PI3K/AKT pathway, which is involved in stimulating the glycolysis pathway.
	Multiple Myeloma (MM)	Phase I - The Ph. I study CX-839-002 will enroll up to 65 MM and NHL patients who have failed at least two prior therapies. Preclinical data suggest synergistic activity for CB-839 with lenalidomide and pomalidomide. The Ph. I(b) study will assess the combination of CB-839/pomalidomide/dexamethasone and CB-839/dexamethasone. MM could offer a faster path to market if FDA agrees to a CB-839/pomalidomide/dexamethasone vs. pomalidomide/dexamethasone Ph. II study where objective response rate (ORR) is the primary endpoint. Europe is likely to require a more traditional Ph. III study with progression free survival (PFS) or overall survival (OS) as the primary endpoint. Calithera has identified a (negative) biomarker (pyruvate carboxylase) for CB-839 in MM patients, which may predict response to therapy.
	Non-Hodgkin's Lymphoma (NHL)	Phase I - NHL patients with Waldenstrom's, Diffuse Large B-cell, and other NHL sub-types who are relapsed or refractory to two prior lines of therapy will be enrolled in the CX-839-002 study.
	Acute Myeloid Leukemia (AML)	Phase I - Study CX-839-003 will enroll up to 50 ALL and AML patients who have failed at least one prior therapy. Newly diagnosed patients 60 years or older can enroll if they are not candidates for stem-cell transplantation or are unfit for standard chemotherapy. AML patients with isocitrate dehydrogenase (IDH)1 and IDH2 driver mutations are allowed to enroll in the study. Unlike Agios' AG-221 which targets the mutant IDH2 protein (over-expressed in AML and gliomas) in order to stop cancer cell growth, CB-839 blocks creation of glutamate which is needed to generate alpha-ketoglutarate and its oncometabolite 2-HG, which is important for IDH2 cancer cell growth.
	Acute Lymphoblastic Leukemia (ALL)	
	Hereditary leiomyomatosis and renal cell cancer (HLRCC)	Phase I - Ten to fifteen percent of patients recruited into the CX-839-001 study will have TCA cycle enzyme driver mutations, characterized by loss of function gene mutations for fumarate hydratase (FH) and succinate dehydrogenase (SDH) or gain of function mutations for IDH. HLRCC is characterized by a loss of function in the FH enzyme which leads to accumulation of fumarate, which is downstream of glutamate within the TCA cycle. By inhibiting glutaminase, reactivation of the FH enzyme may lead to cancer cell death in patients with this rare cancer. Less than 1% of renal cell carcinoma patients have the HLRCC mutation.
	Gastrointestinal Stromal Tumors (GIST)	Phase I - GIST, paragangliomas, pheochromocytomas, and RCC are characterized by loss of function in the succinate dehydrogenase (SDH) enzyme, which leads to accumulation of succinate which is downstream of glutamate within the TCA cycle. Less than 15% of GIST patients have this mutation (~3,000 patients). The CX-839-001 protocol includes 10-15% of patients with these tumor types.
Arginase Inhibitor	Combination studies for solid tumors	Discovery - Preclinical studies suggest synergies may exist for CB-839 with various growth factor signaling pathway inhibitors of EGFR, Ras/Raf, and PI3K/mTOR in various solid tumors, such as RCC, NSCLC, and sarcomas. This is based on the fact that cancer cell metabolism is driven in part by oncogenic transformation and/or loss of tumor suppressor gene function, which results in increasing reliance of cancer cells on glutamine. As a result, blockade of signaling pathways and glutaminase may lead to increased efficacy in a number of tumor types and blood cancers.
	Solid tumors	Preclinical - Potential proof-of-concept for inhibition of arginase has been demonstrated by Indoleamine 2, 3 doxygenase inhibitors, which antagonize the IDO enzyme, which depletes tryptophan, an amino acid important in T-cell activation. Myeloid-derived suppressor cells secrete arginase which down-regulates arginine, an amino acid important in activation, growth, and survival of cancer-fighting cytotoxic T cells. Arginine depletion has been observed in RCC, AML, breast, and pancreatic cancers. Inhibition of arginase may allow for up-regulation of arginine and restore activity of the body's cytotoxic T cells. In December 2014, Calithera in-licensed a portfolio of arginase inhibitors from Mars Symbioscience, which will complement its own in-house program.
Hexokinase Inhibitor	Cancers	Preclinical - In March 2015 Calithera licensed TransTech Pharma's HK II inhibitors. HK I and II can associate on the outer surface of the external membrane of mitochondria and HK II is the 1st enzyme involved in converting glucose to metabolites important for cancer cell growth/survival. HK II is over-expressed in a number of cancers and with levels up to 200x higher than non-cancerous tissues. Initially Calithera plans to develop an HK II inhibitor as monotherapy but longer-term may develop it in combination with CB-839.

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 5. Calithera's Income Statement

Calithera Biosciences, Inc. (CALA)

Statement of Operations

FY Ends December 31

(In 000's, except per share data.)

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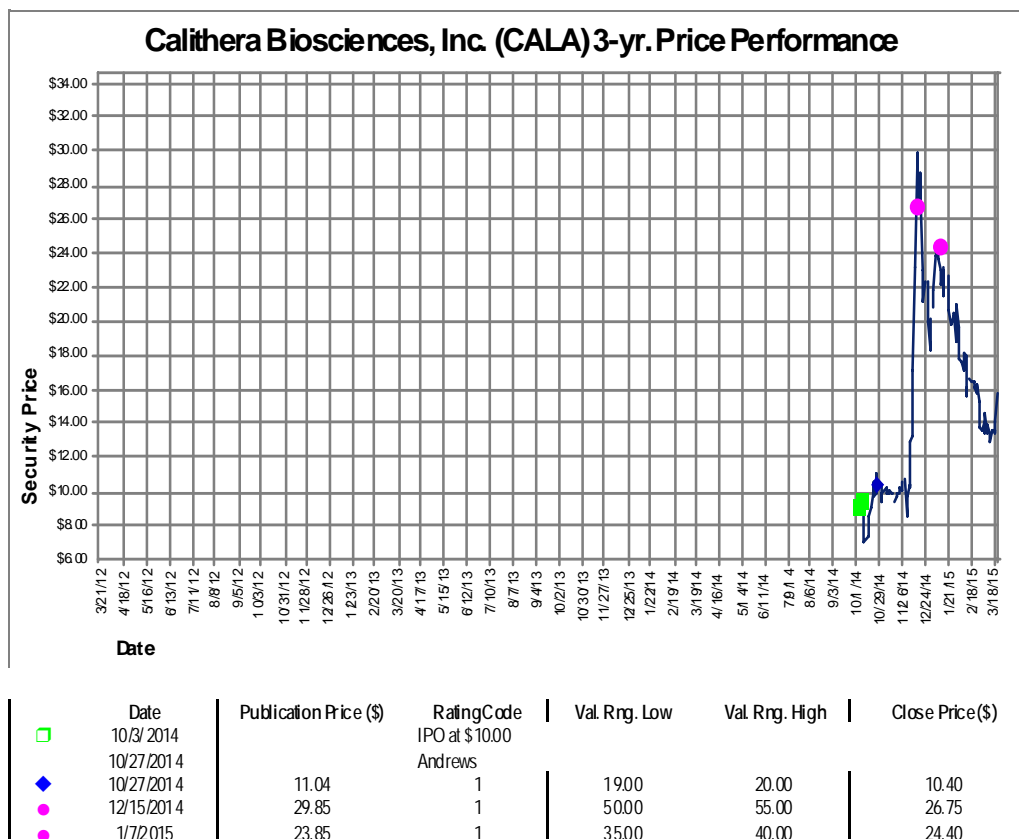
	FY 2014A	Q1 2015E	Q2 2015E	Q3 2015E	Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E
Revenues																
CB-839 U.S. Sales (40% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$7,243	\$60,238	\$135,243	\$245,536	\$373,020
Royalty on ex-U.S. sales of CB-839 (40% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$3,515	\$12,364	\$28,972	\$52,135
Collaboration revenue on CB-839 (40% probability)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$27,750	\$3,750	\$23,250	\$41,250	\$21,750	\$3,750	\$3,750	\$3,750
Total revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$27,750	\$3,750	\$23,250	\$48,493	\$85,503	\$151,357	\$278,258	\$428,905
Expenses																
Cost of Goods Sold	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$724	\$6,024	\$13,524	\$24,554	\$37,302
Research and development	\$16,367	\$5,000	\$5,500	\$7,000	\$7,500	\$25,000	\$30,000	\$35,000	\$35,000	\$35,000	\$37,500	\$35,000	\$37,500	\$40,000	\$40,000	\$45,000
General and administrative	\$3,213	\$2,000	\$2,000	\$2,000	\$2,000	\$8,000	\$6,000	\$6,750	\$10,000	\$20,000	\$25,000	\$52,500	\$62,500	\$70,000	\$77,500	\$82,500
Total Expenses	\$19,580	\$7,000	\$7,500	\$9,000	\$9,500	\$33,000	\$36,000	\$41,750	\$45,000	\$55,000	\$62,500	\$88,224	\$106,024	\$123,524	\$142,054	\$164,802
Profit/Loss from Operations	(\$19,580)	(\$7,000)	(\$7,500)	(\$9,000)	(\$9,500)	(\$33,000)	(\$36,000)	(\$41,750)	(\$17,250)	(\$51,250)	(\$39,250)	(\$39,731)	(\$20,521)	\$27,832	\$136,205	\$264,103
Other Income	\$9	\$5	\$4	\$4	\$4	\$17	\$10	\$687	\$1,272	\$1,250	\$905	\$1,256	\$1,697	\$1,804	\$2,435	\$3,960
Gain on extinguishment of convertible preferred stock	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Net profit (loss) before income tax expense	(\$19,571)	(\$6,995)	(\$7,496)	(\$8,996)	(\$9,496)	(\$32,983)	(\$35,990)	(\$41,063)	(\$15,978)	(\$50,000)	(\$38,345)	(\$38,475)	(\$18,824)	\$29,637	\$138,640	\$268,064
Income tax expense	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$7,409	\$34,660	\$67,016
Net income/(loss) (GAAP)	(\$19,571)	(\$6,995)	(\$7,496)	(\$8,996)	(\$9,496)	(\$32,983)	(\$35,990)	(\$41,063)	(\$15,978)	(\$50,000)	(\$38,345)	(\$38,475)	(\$18,824)	\$22,227	\$103,980	\$201,048
EPS (GAAP, diluted)	(\$4.67)	(\$0.39)	(\$0.42)	(\$0.50)	(\$0.53)	(\$1.83)	(\$1.99)	(\$1.60)	(\$0.60)	(\$1.86)	(\$1.42)	(\$1.20)	(\$0.58)	\$0.69	\$3.21	\$6.18
Shares Outstanding (Basic)	4,652	17,946	17,971	17,996	18,021	17,984	18,121	25,721	25,821	25,921	26,021	31,121	31,221	31,321	31,421	31,521
Shares Outstanding (Diluted)	5,673	18,968	18,993	19,018	19,043	19,005	19,143	26,743	26,843	26,943	27,043	32,143	32,243	32,343	32,443	32,543

Source: Company reports, Form 10-K dated March 27, 2015, and Wells Fargo Securities, LLC estimates

Note: All revenues are probability-weighted.

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 and a preclinical hexokinase II inhibitor program, which it licensed from TransTech in March 2015.

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
 2 Market Perform/Hold
 3 Underperform/Sell
 SR Suspended
 NR Not Rated
 NE No Estimate

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Biotechnology

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

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As of: March 27, 2015

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