

Reason for report:

## EARNINGS

## CALITHERA BIOSCIENCES, INC.

## Three CB-839 Trials To Report Starting in 2Q and Preclinical IO Data in Fall

• **Bottom Line:** CALA's 4Q:14 call continued to highlight the solid clinical progress with lead candidate CB-839 (glutaminase inhibitor, Phase I) with 61 patients enrolled through December and another 100 patients expected to be enrolled in 2015. While the IND for arginase inhibitor program is pushed out slightly to 1Q:16 (from late 2015/early 2016 recently), management appears quite excited about the profile of its compound with preclinical data expected in the fall. While the activity of CB-839 remains to be seen and the sensitivity to the compound could be context-dependent requiring patient selection or combination, we are increasing our PT from \$13 to \$19 based on increased probability of success (from 10% to 15%) due to the apparent good safety to date.

• **ASCO and EHA data to include both dose escalation and expansion cohorts.** For CB-839, it appears that most of the 61 patients enrolled by the end of Dec. were solid tumor patients and data are expected at ASCO (5/29-6/2, Chicago) and should include some data on patients being enrolled to the dose expansion cohort. Data on patients from each of the two liquid tumor Phase I trials (in acute lymphocytic leukemia/acute myeloid leukemia, and multiple myeloma/non-Hodgkin's lymphoma, respectively) are expected at EHA (6/11-14, Vienna), though multiple myeloma may be more a focus for ASH (12/5-8, Orlando) where combination data are expected. In addition, combination data in breast cancer are expected at SABCS (12/8-12, San Antonio). According to management, most of the patients in the dose escalation portion of the studies were treated below the Phase II dose of 600 mg twice a day, therefore the dose expansion cohort may offer a better opportunity for seeing activity. Management indicated that it tested doses as high as 1000 mg tid, but determined that 600 mg bid was sufficient based on PK/PD analysis (no dose-limiting toxicities were identified).

• **Five AACR presentations focus on preclinical combinations.** Two oral presentations at AACR discuss the potential of CB-839 in lung cancer as well as synergy with signal transduction pathway inhibitors. CB-839 sensitivity was found to be correlated with the expression of phospho-Rb, Smad3, c-Myc and MEK2, which may serve as candidates for biomarker for CB-839. Management also stated that specific metabolic genetic mutations appear to be the best biomarker for CB-839.

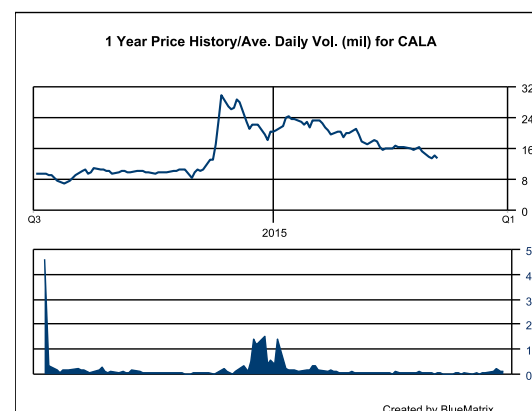
• **Immuno-oncology (IO) program (arginase inhibitor) could present preclinical data in fall.** Although IND timeline is pushed back slightly, management appears excited about the profile of its candidates.

• **Model update:** CALA ended 2014 with \$102M in cash and guided to end 2015 with \$65M, which in turn is projected to support operations through 2017. Based on 4Q:14 and 2014 reported spending, and management guidance, we increase our 2015 R&D and G&A estimates.

## Key Stats:

(NASDAQ:CALA)

|                                       |                                 |
|---------------------------------------|---------------------------------|
| <b>S&amp;P 600 Health Care Index:</b> | <b>1,610.49</b>                 |
| <b>Price:</b>                         | <b>\$15.88</b>                  |
| Price Target:                         | \$19.00 from \$13.00            |
| Methodology:                          | DCF analysis, 10% discount rate |
| 52 Week High:                         | \$33.48                         |
| 52 Week Low:                          | \$6.51                          |
| Shares Outstanding (mil):             | 17.9                            |
| Market Capitalization (mil):          | \$284.3                         |
| Book Value/Share:                     | \$0.00                          |
| Cash Per Share:                       | \$5.69                          |
| 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    | (\$0.60) | (\$0.60) | (\$0.54) | (\$0.38) | (\$2.00) | NM  |
| 2015E - New | 0.0 | 0.0 | 0.0 | 0.0 | 0.0    | (\$0.48) | (\$0.53) | (\$0.58) | (\$0.63) | (\$2.22) | NM  |
| 2015E - Old | --  | --  | --  | --  | 0.0    | --       | --       | --       | --       | (\$1.10) | NM  |
| 2016E - New | --  | --  | --  | --  | 0.0    | --       | --       | --       | --       | (\$3.03) | NM  |
| 2016E - Old | --  | --  | --  | --  | 0.0    | --       | --       | --       | --       | (\$1.52) | 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 thereby interferes with 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 immunology 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              | mid 2015 (ASCO)   | Phase I data solid tumors                                    |
|                     | mid 2015 (EHA)    | Phase I data in ALL and AML                                  |
|                     | late 2015 (SABCS) | Data from combination Phase 1b with paclitaxel in TNBC       |
|                     | late 2015 (ASH)   | Phase I data in MM, combination data with pomalidomide in MM |
| Arginase inhibitors | 2H:15             | Present preclinical data                                     |
|                     | 1Q:16             | Submit IND   |

Source: Company reports

## CALA – Pipeline

| Drug                        | Mechanism/<br>Class      | Status       | Setting                                 | n   | Primary<br>Endpoint | Trial<br>initiation | Region |
|-----------------------------|--------------------------|--------------|---|-----|---------------------|---------------------|--------|
| CB-839                      | Glutaminase<br>Inhibitor | Phase I      | TNBC, NSCLC,<br>RCC and<br>Mesothelioma | 100 | Safety              | Feb. 2014           | US     |
| CB-839                      | Glutaminase<br>Inhibitor | Phase I      | AML, ALL                                | 50  | Safety              | Feb. 2014           | US     |
| CB-839                      | Glutaminase<br>Inhibitor | Phase I      | NHL, DLBCL,<br>MM, T-cell NHL           | 65  | Safety              | Feb. 2014           | US     |
| <b>Preclinical programs</b> |                          |              |   |     |                     |                     |        |
| Program                     |                          | Expected IND |   |     |                     |                     |        |
| Arginase inhibitor          |                          | 1Q:16        |   |     |                     |                     |        |
| Hexokinase II inhibitor     |                          |              |   |     |                     |                     |        |

Source: Company reports

## VALUATION

We are increasing our valuation for CALA from \$13 to \$19 based on the apparent good safety of CB-839 in a relatively sizable patient population of ~60, which we believe de-risks the program on safety and improves the probability of success. Our valuation is based on DCF analysis and probability-weighted sales for CB-839 in triple-negative breast cancer (TNBC) and multiple myeloma (MM) (both increased from 10% probability to 15%), with a 10% discount rate. We believe this discount rate is appropriate as we use probability-weighted sales for the products.

## RISKS TO VALUATION

Risks to our valuation include:

Early stage of development as lead candidate is still in Phase I with limited efficacy and safety data.

Novel targets that have not been validated clinically. As a potentially first in class agent, lead compound CB-839 targets an enzyme (glutaminase) that is still unproven as a target either clinically with a drug or genetically through mutation linkage. The broader approach of targeting cancer metabolism is also a new approach that does not have extensive validation.

Financing risks. CALA's current balance of cash or equivalents (\$102M) is expected to support operations through 2017 but additional financing will likely needed before CALA turns profitable.

| Calithera  |         |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           |           |          |
|--|---------|----------|---------|---------|---------|---------|----------|---------|---------|------------|----------|------------------|----------|----------|----------|-----------|-----------|-----------|----------|
| (In '000s, except per share items)   |         |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           |           |          |
|  | 2012    | 2013     |         |         |         |         | 2014A    |         |         |            |          | 2015E            | 2016E    | 2017E    | 2018E    | 2019E     | 2020E     | 2021E     | 2022E    |
|  |         |          | 1QA*    | 2QA*    | 3QA     | 4QA     |          | 1QE     | 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    | 3,751   | 3,751   | 3,894   | 4,972   | 16,367   | 6,000   | 7,000   | 8,000      | 9,000    | 30,000           | 45,000   | 67,500   | 74,250   | 81,675    | 89,843    | 98,827    | 108,709  |
| General and Administrative   | 1,417   | 2,478    | 1,071   | 1,071   | 1,447   | 1,866   | 5,454    | 2,500   | 2,550   | 2,550      | 2,601    | 10,201           | 10,405   | 12,486   | 13,735   | 20,000    | 60,000    | 90,000    | 108,000  |
| Royalties  | -       |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           |           |          |
| Amortization of Acquired Intangible Assets                                 |         |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           |           |          |
| Operating Loss/ Income   | (7,975) | (12,378) | (4,821) | (4,821) | (5,341) | (6,838) | (21,821) | (8,500) | (9,550) | (10,550)   | (11,601) | (40,201)         | (55,405) | (79,986) | (87,985) | (101,675) | (136,771) | (109,886) | (63,427) |
| Investment, Interest and Other Income, Net                                 |         | 1        | 1       | 1       | 2       | 5       | 9        | 5       | 5       | 5          | 5        | 20               |          |          |          |           |           |           |          |
| 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) | (4,820) | (4,820) | (5,339) | (6,833) | (21,812) | (8,495) | (9,545) | (10,545)   | (11,596) | (40,181)         | (55,405) | (79,986) | (87,985) | (101,675) | (136,771) | (109,886) | (63,427) |
| Income tax rate%   |         |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           | 35%       | 35%      |
| Income Tax   |         |          |         |         |         |         |          |         | -       |            |          |                  |          |          |          |           |           | 38,460    | 22,200   |
| Net Loss   | (5,086) | (12,377) | (4,820) | (4,820) | (5,339) | (6,833) | (21,812) | (8,495) | (9,545) | (10,545)   | (11,596) | (40,181)         | (55,405) | (79,986) | (87,985) | (101,675) | (136,771) | (71,426)  | (41,228) |
| Basic and Diluted Net Loss per Common Share                                |         |          | (0.60)  | (0.60)  | (0.54)  | (0.38)  | (2.00)   | (0.48)  | (0.53)  | (0.58)     | (0.63)   | (2.22)           | (3.03)   | (4.33)   | (3.07)   | (3.51)    | (2.52)    | (1.28)    | (0.73)   |
| 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  |         |          |         |         | 110,811 | 101,969 | 101,969  | 93,474  | 83,929  | 73,384     | 61,788   | 61,788           | 6,383    | (73,603) | (31,588) | (133,263) | 54,966    | (16,460)  | (57,687) |
| Milestone payments   |         |          |         |         |         |         |          |         |         |            |          |                  |          |          |          |           |           |           |          |
| Capital raise  |         |          |         |         |         |         |          |         |         |            |          |                  |          | 130,000  |          | 325,000   |           |           |          |
| Shares issued  |         |          |         |         |         |         |          |         |         |            |          |                  |          | 10,000   |          | 25,000    |           |           |          |
| Price per share  |         |          |         |         |         |         |          |         |         |            |          |                  |          | \$ 13.00 |          | \$ 13.00  |           |           |          |
| Net Cash   | -       |          |         | 27,750  | 110,811 | 101,969 | 101,969  | 93,474  | 83,929  | 73,384     | 61,788   | 61,788           | 6,383    | 56,397   | (31,588) | 191,737   | 54,966    | (16,460)  | (57,687) |
| Stock Options  |         |          |         |         |         |         |          |         |         |            |          | 102 to 65        |          |          |          |           |           |           |          |
| Restricted stock   |         |          |         |         |         |         | 35.9     |         |         |            |          | 25, 75           |          |          |          |           |           |           |          |
| Total  |         |          |         |         |         |         | 71.6     |         |         | 35.9 +71.6 |          | 102, end of 2017 |          |          |          |           |           |           |          |
|  |         |          |         |         |         |         | 107.5    |         |         |            |          |                  |          |          |          |           |           |           |          |
| Stock price  |         |          |         |         |         |         | (1,302)  |         |         |            |          |                  |          |          |          |           |           |           |          |
| Market Cap   |         |          |         |         |         |         |          |         | 31.5    |            |          |                  |          |          |          |           |           |           |          |
| EV   |         |          |         |         |         |         |          |         | 10.5    |            |          |                  |          |          |          |           |           |           |          |

|   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| <b>Balance sheet data</b>                     |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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

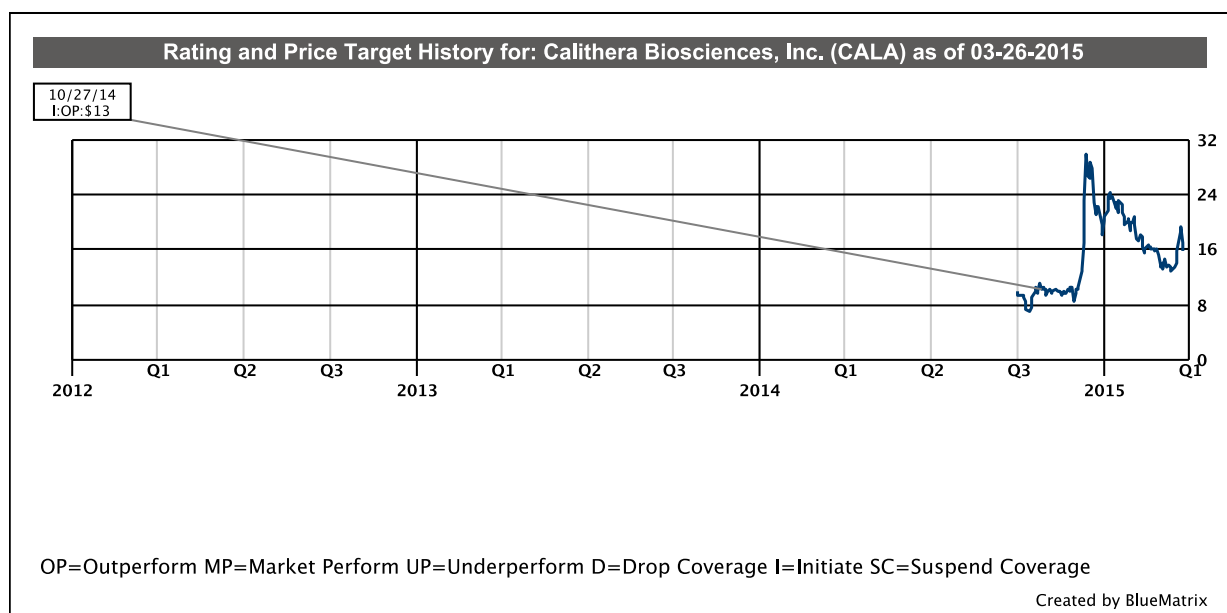
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

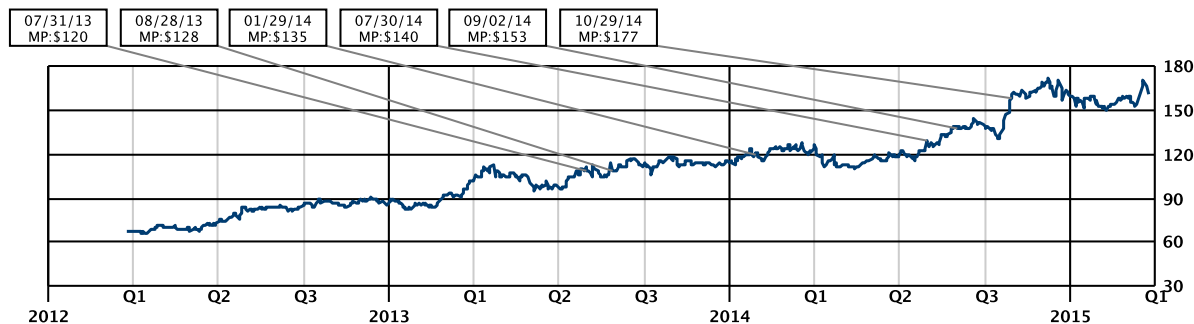
### Valuation

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### Risks to Valuation

- Early stage of development as lead candidate is still in Phase I with limited efficacy and safety data.
- Novel targets that have not been validated clinically. As a potentially first in class agent, lead compound CB-839 targets an enzyme (glutaminase) that is still unproven as a target either clinically with a drug or genetically through mutation linkage. The broader approach of targeting cancer metabolism is also a new approach that does not have extensive validation.
- Financing risks. CALA's current balance of cash or equivalents (\$102M) is expected to support operations through 2017, but additional financing will likely be needed before CALA turns profitable.



**Rating and Price Target History for: Amgen, Inc. (AMGN) as of 03-26-2015**


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 12/31/14 |       |         |                       |         |
|---|-------|---------|-----------------------|---------|
| Rating  | Count | Percent | IB Serv./Past 12 Mos. |         |
|   |       |         | Count                 | Percent |
| BUY [OP]  | 150   | 70.00   | 60                    | 40.00   |
| HOLD [MP]   | 64    | 30.00   | 1                     | 2.00    |
| 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

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Editorial Department at One Federal Street, 37th Floor, Boston, MA 02110.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction. 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

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