

Reason for report:

FLASH NOTE

Seamus Fernandez
(617) 918-4011
Seamus.Fernandez@Leerink.com

Kathryn C. Alexander
(617) 918-4568
Kathryn.Alexander@Leerink.com

Swati Kumar
(617) 918-4576
Swati.Kumar@Leerink.com



LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

KYTHERA BIOPHARMACEUTICALS, INC.

Open-Label Study Results Reinforce Conviction in U.S. Ph III Clinical Success

• **Bottom Line:** We believe yesterday's announcement of top line interim study results from Study ATX-101-11-26, an open-label, long-term study evaluating ATX-101 for the reduction of submental fat in 165 U.S. patients, is very supportive of our thesis on the high probability of clinical success of the U.S. Phase III clinical trials. We and MEDACorp regulatory and clinical KOLs continue to believe KYTH's U.S. Ph III studies are overpowered to deliver a positive outcome on the composite endpoint agreed upon with FDA, and the open-label trial data reinforces this view, in our opinion. We note that both Ph III U.S. studies are fully recruited with data likely in 3Q'13.

• **Solid efficacy results in line with our and management's expectations.** The efficacy results from the open-label study are consistent with previous ATX-101 trial results. Patients at least 18 years old with stable body weight, and body mass index (BMI) of less than 40.0 and with submental fat rated by both clinicians and subjects as moderate, severe or extreme (rated 2, 3 or 4 on the Clinician Reported Submental Fat Rating Scale and Patient Reported Submental Fat Rating Scale) and considered undesirable by the patient (characterized by a score of 0, 1, or 2 on the Subject Self-Ratings Scale) received 2 mg/cm² ATX-101 for up to six treatment visits spaced 28 days apart. The results include patients who had completed Visit 9, or three months after last injection, which is the same study endpoint as the ongoing U.S. and Canadian Phase III pivotal trials. Mean changes from baseline in submental fat measured 12 weeks after last injection were -1.3 on the CR-SMFRS & -1.2 on PR-SMFRS. In addition, 71.3% of subjects had at least a 1-grade improvement on the CR-SMFRS / PR-SMFRS composite and 14.0% had at least a 2-grade improvement on the same composite measure. We had the opportunity to speak with KYTH management about these results, and response rates of 71.3% and 14.0% were not surprising to KYTH.

• **Rates of success on the 1 & 2-grade composite measures more consistent with success rates in the U.S. Ph IIb study vs. the EU Ph III post hoc analysis.** Response rates observed in the Phase IIb study, where patients received up to six treatments, were a composite 1-grade improvement of 57.1% and a composite 2-grade improvement of 9.5%. We note that the post hoc analysis of the combined European Phase III trials showed that ATX-101 demonstrated a composite 1-grade improvement of 49.0% and a composite 2-grade improvement of 7.5%.

• **Side effects were consistent with previous studies.** Adverse events were mostly mild to moderate, and transient. The most common adverse events were bruising, numbness, pain, swelling, redness, induration, itching and nodule formation. We also note that a drop-out rate of less than 10% supports ATX-101's good tolerability profile.

•

ATX-101 treatment persistence was good, with most patients completing all 6 monthly treatments. Although this is what one would

Key Stats:

(NASDAQ:KYTH)

| | |
|---------------------------------------|----------------|
| S&P 600 Health Care Index: | 810.33 |
| Price: | \$23.73 |
| 52 Week High: | \$28.34 |
| 52 Week Low: | \$16.00 |
| Shares Outstanding (mil): | 20.6 |
| Market Capitalization (mil): | 488.8 |

expect in an open-label safety study, we believe it is encouraging data nonetheless.



LEERINK SWANN



Disclosures Appendix

Analyst Certification

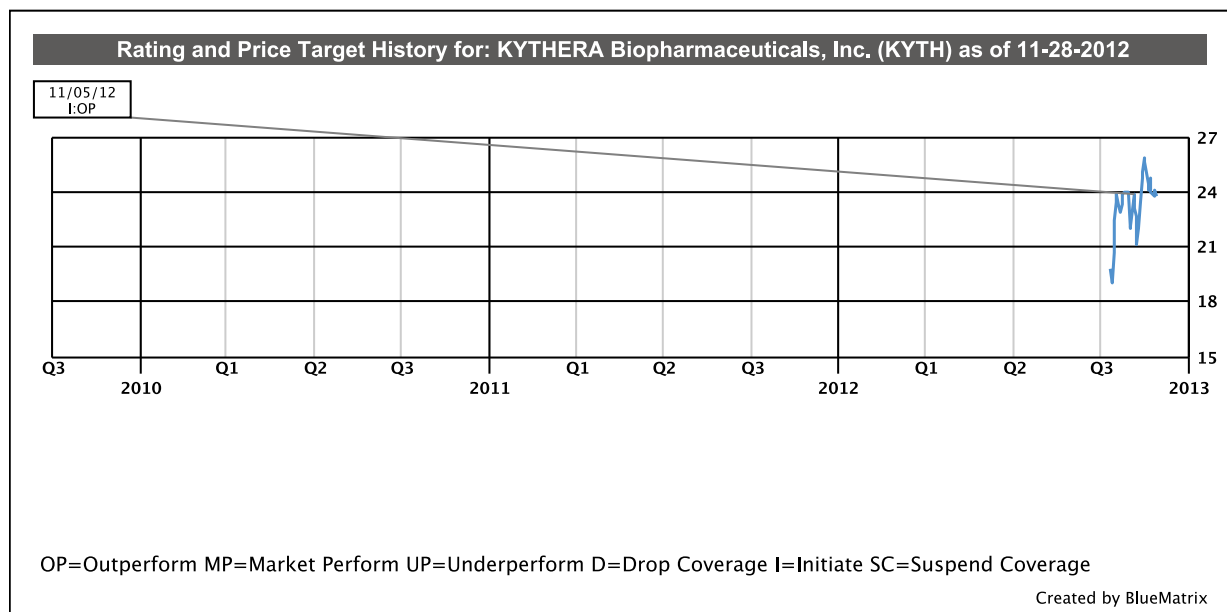
I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

We value KYTH shares at \$28/share based on our DCF valuation which calculates cash flows through 2025, applies a 12% discount rate and assume a 0% growth rate on the terminal value of KYTH cash flow in 2025.

Risks to Valuation

Key risks/uncertainties are: (1) economic sensitivity of self-pay products; (2) regulatory risk; (3) a slower-than-expected launch of ATX-101 in North American and European markets; and (3) disappointing North American Phase III data for ATX-101.





| Distribution of Ratings/Investment Banking Services (IB) as of 09/30/12 | | | | |
|---|-------|---------|-----------------------|---------|
| Rating | Count | Percent | IB Serv./Past 12 Mos. | |
| | | | Count | Percent |
| BUY [OP] | 102 | 58.30 | 29 | 28.40 |
| HOLD [MP] | 73 | 41.70 | 3 | 4.10 |
| 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.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® 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.

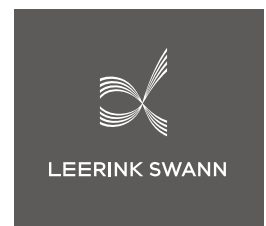
Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

Outperform (Buy): We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® 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 asset management group and 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 Publishing 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, the Private Client Division, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

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

Leerink Swann LLC makes a market in KYTHERA Biopharmaceuticals, Inc.

Leerink Swann LLC has acted as the manager for a public offering of KYTHERA Biopharmaceuticals, Inc. in the past 12 months.

©2012 Leerink Swann LLC. All rights reserved. This document may not be reproduced or circulated without our written authority.

| Leerink Swann 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 |
| | Marko Kozul, M.D. | (415) 905-7221 | marko.kozul@leerink.com |
| | Michael Schmidt, Ph.D. | (617) 918-4588 | michael.schmidt@leerink.com |
| | Irene Lau | (415) 905-7256 | irene.lau@leerink.com |
| | Gena Wang, Ph.D. | (212) 277-6073 | gena.wang@leerink.com |
| Life Science Tools & Diagnostics | Dan Leonard | (212) 277-6116 | dan.leonard@leerink.com |
| | John L. Sullivan, CFA | (617) 918-4875 | john.sullivan@leerink.com |
| Pharmaceuticals/Major | Seamus Fernandez | (617) 918-4011 | seamus.fernandez@leerink.com |
| | Kathryn Alexander | (617) 918-4568 | kathryn.alexander@leerink.com |
| | Swati Kumar | (617) 918-4576 | swati.kumar@leerink.com |
| Specialty Pharmaceuticals, Generics | Jason M. Gerberry, JD | (617) 918-4549 | jason.gerberry@leerink.com |
| Medical Devices, Cardiology & Orthopedics | Danielle Antalffy | (212) 277-6044 | danielle.antalffy@leerink.com |
| | Richard Newitter | (212) 277-6088 | richard.newitter@leerink.com |
| | Robert Marcus, CFA | (212) 277-6084 | robert.marcus@leerink.com |
| | Kathleen McGrath | (212) 277-6020 | kathleen.mcgrath@leerink.com |
| Healthcare Services | Jason Gurda, CFA | (212) 277-6023 | jason.gurda@leerink.com |
| | Jason Twizell | (212) 277-6049 | jason.twizell@leerink.com |
| | George Villarina | (212) 277-6012 | george.villarina@leerink.com |
| Healthcare Technology & Distribution | David Larsen, CFA | (617) 918-4502 | david.larsen@leerink.com |
| | Christopher Abbott | (617) 918-4010 | chris.abbott@leerink.com |
| Sr. Editor/Supervisory Analyst | Mary Ellen Eagan, CFA | (617) 918-4837 | maryellen.eagan@leerink.com |
| Supervisory Analysts | Robert Egan | | bob.egan@leerink.com |
| | Amy N. Sonne | | amy.sonne@leerink.com |
| | | | |
| New York | Boston | San Francisco | |
| 1251 Avenue of Americas, 22 nd Floor | One Federal Street, 37 th Floor | 201 Spear Street, 16 th Floor | |
| New York, NY 10020 | Boston, MA 02110 | San Francisco, CA 94105 | |
| (888) 347-2342 | (800) 808-7525 | (800) 778-1164 | |