



LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

KYTHERA BIOPHARMACEUTICALS, INC.

Slight ATX-101 Ph III Data Unblinding Delay Benign; We Remain Buyers

• **Bottom Line:** In concert with its 1Q:13 results, KYTH announced that Ph III efficacy results are now expected in late 3Q/early 4Q, approximately a three-month delay to previous mid-2013 guidance. This slight delay to the planned unblinding of efficacy data to incorporate the additional three-month safety follow up data is entirely a reflection of the company's slightly more conservative reading of PDUFA V guidance vs. mgmt's prior expectations. KYTH also noted that its partner Bayer likely will file its MAA to include full U.S. Ph III safety data, but guidance for an MAA filing in 2013 (and by extension major 2014 approval milestones) was unchanged. Our confidence in positive U.S. Ph III results remains extremely high. We remain buyers with a DCF valuation of \$28/shr.

• **KYTH 1Q:13 earnings better than we expected on lower R&D spend.** KYTH reported 1Q:13 EPS loss of \$0.77, which was \$0.19 higher than our est driven by lower-than-expected R&D costs. The company ended the quarter with \$87.6M in cash. Mgmt estimates current cash will be sufficient to fund the company for at least the next 12 mos. Our updated model reflects a two-quarter delay of the EU launch. Due to the relatively modest royalty, the delay has little impact on our valuation.

• **We have extremely high conviction in U.S. Ph III clinical & regulatory success.** KYTH has successfully completed Ph IIb U.S. and Ph III EU studies with convincing efficacy and safety. We and MEDACorp regulatory and clinical KOLs believe KYTH's U.S. Ph III studies are overpowered to deliver a positive outcome on the composite endpoint agreed upon with the FDA. KOLs see no hurdles to FDA approval should the U.S. studies replicate the Ph III EU results. Both studies are fully recruited with data likely in 3Q:13. In addition, 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, are supportive of our thesis on the high probability of clinical success of the U.S. Phase III clinical trials, and the drop out rate of less than 10% in this study suggests good overall tolerability.

• **Our research suggests a compelling opportunity for ATX-101 with U.S. peak sales potential of \$500M+.** The 3Q:12 MEDACorp survey of 62 U.S. cosmetic physician specialists (click [HERE](#)) suggests strong demand for ATX-101. Among dermatologists and plastic surgeons polled, most expect to use it, and over half will actively promote the procedure. On average, physicians predict rapid uptake among injectable-experienced patients with the expectation that ATX-101 will increase their overall patient volume with synergistic benefits on other injectable procedures. Finally, >40% of physicians surveyed expressed interest in using ATX-101 off-label. These results support our modeled U.S. peak sales forecast of \$500M+.

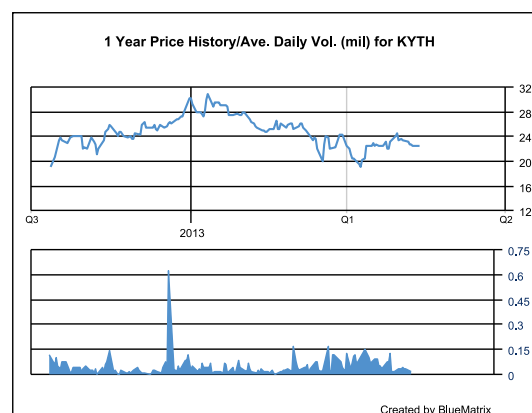
Key Stats:

(NASDAQ:KYTH)

S&P 600 Health Care Index:	966.39
Price:	\$22.59
52 Week High:	\$31.93
52 Week Low:	\$14.07
Shares Outstanding (mil):	20.6
Market Capitalization (mil):	\$465.4
Book Value/Share:	0.00
Cash Per Share:	\$4.85
Dividend (ann):	\$0.00
Dividend Yield:	0.0%
Est LT EPS Growth:	10%
P/E to LT EPS Growth (FY13):	NM
Valuation:	\$28 on DCF analysis

General: Est LT EPS Growth '17E-'25E

Shares Outstanding (mil): Note: EPS calculation includes dilutive effect of ~3M warrants, options, and performance shares outstanding.



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	0.0	0.0	0.0	0.0	0.0	(\$0.68)	(\$1.02)	(\$1.40)	(\$1.04)	(\$4.15)	NM
2013E - New	0.0A	--	--	--	0.0	(\$0.77)A	(\$0.65)	(\$0.61)	(\$0.87)	(\$2.91)	NM
2013E - Old	--	--	--	--	0.0	--	--	--	--	(\$2.46)	NM
2014E	--	--	--	--	\$0.1	--	--	--	--	(\$2.34)	NM

Source: Company Information and Leerink Swann LLC Research

Revenues in millions excluding milestones; operating EPS excluding milestones



INVESTMENT THESIS

We rate shares of Kythera Outperform. We recommend purchase of KYTH based on: (1) compelling prospects for clinical and regulatory success in the U.S. and Europe for a first-in-class product (ATX-101) for the treatment of submental (double chin) fat reduction, (2) evidence of strong physician demand for ATX-101 that supports U.S. peak sales prospects of >\$500M and will capitalize on the rapidly growing facial aesthetics market, (3) a deep management team with experience across pharma/biotech and cosmetic dermatology, (4) tiered royalties and regulatory and commercial milestones from partner Bayer Dermatology on OUS sales of ATX-101, and (5) upside to our revenue estimates for off-label use or new ATX-101 indications in other areas of the body. We believe these positive factors substantially outweigh the risks of: (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 (4) disappointing North American Phase III data for ATX-101. Our DCF valuation is \$28/share excluding any potential new indications or off label use outside of the initial indication for treatment of submental fat.

KYTH 1Q:13 Variance Chart

\$MM	Actual Results			Leerink Ests.		Variance
	Q1'12A	Q1'13A	% Chg.	Q1'13E	% Chg.	
Total Revenue	0.00	0.00	NM	0.00	NM	0.00
COGS (\$MM)	0.00	0.00	NM	0.00	NM	0.00
SG&A (\$MM)	2.19	3.73	69.9%	3.50	59.7%	0.23
R&D (\$MM)	6.49	10.03	54.7%	14.00	115.8%	(3.97)
Other expense/(income)	0.00	0.00	NM	0.00	NM	0.00
Operating Income	(8.68)	(13.76)	58.5%	(17.50)	101.6%	3.74
Pretax Income	(8.81)	(14.13)	60.4%	(17.52)	98.9%	3.39
Tax	0.00	0.00	NM	0.00	NM	0.00
Tax rate %	0.00	0.00	NM	0.00	NM	0.00
Net Income	(8.81)	(14.13)	60.4%	(17.52)	98.9%	3.39
EPS	(0.68)	(0.77)	13.2%	(0.96)	40.4%	0.19
Basic Shares Outstanding	12.94	18.34	41.7%	18.33	41.7%	0.01
Consensus EPS		(0.77)	NM	(0.75)	NM	(0.02)

Source: Company information, Leerink Swann LLC estimates.

VALUATION

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



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 (4) disappointing North American Phase III data for ATX-101.

Kythera - Quarterly Income Statement Analysis 2011-2025E

(\$ in Millions, Except EPS)																				
(Year Ended December 31)	2011	2012	1Q13	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	CAGR 17E-25E
ATX-101	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12.0	100.8	264.8	351.0	421.5	466.0	500.1	511.9	518.7	511.3	496.4	8%
ATX-101 Bayer Royalty	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	6.2	17.4	33.8	36.6	37.2	37.3	35.5	33.2	30.2	27.1	24.5	-4%
Other Revenue	13.0	19.7	0.0	0.0	0.0	0.0	0.0	20.0	10.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	NM
Total Revenue Incl 1x Milestones	13.0	19.7	0.0	0.0	0.0	0.0	0.0	20.1	28.2	118.2	298.6	387.5	458.7	503.3	535.5	545.1	548.9	538.4	520.9	18%
Total Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	18.2	118.2	298.6	387.5	458.7	503.3	535.5	545.1	548.9	538.4	520.9	7%
Sublicense Expense	1.2	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	NM
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	18.6	49.0	64.9	78.0	86.2	92.5	94.7	96.0	94.6	91.8	8%
% of Sales	NM	NM	NM	NM	NM	NM	NM	0.0%	7.5%	15.8%	16.4%	16.8%	17.0%	17.1%	17.3%	17.4%	17.5%	17.6%	17.6%	1%
Gross Profit	(1.2)	(1.9)	0.0	0.0	0.0	0.0	0.0	0.1	16.8	99.6	249.6	322.6	380.7	417.1	443.0	450.4	452.9	443.8	429.0	7%
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	84.2%	83.6%	83.2%	83.0%	82.9%	82.7%	82.6%	82.5%	82.4%	82.4%	0%
R&D	15.8	43.2	10.0	9.0	8.0	13.0	40.0	35.0	35.0	35.0	36.0	38.8	45.9	50.3	53.6	54.5	54.9	53.8	52.1	5%
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	29.6%	12.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	-2%
SG&A	6.9	10.5	3.7	3.0	3.3	3.0	13.0	17.0	43.0	70.0	119.4	139.5	146.8	161.0	163.3	163.5	164.7	161.5	156.3	3%
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	59.2%	40.0%	36.0%	32.0%	32.0%	30.5%	30.0%	30.0%	30.0%	30.0%	-4%
Others	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	NM
Operating Income	(23.8)	(55.6)	(13.8)	(12.0)	(11.3)	(16.0)	(53.0)	(51.9)	(61.2)	(5.4)	94.2	144.3	188.1	205.7	226.1	232.4	233.4	228.4	220.7	11%
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	-4.6%	31.5%	37.2%	41.0%	40.9%	42.2%	42.6%	42.5%	42.4%	42.4%	4%
Non-Operating Items	(0.3)	(0.9)	(0.4)	(0.0)	(0.0)	(0.0)	(0.4)	(0.3)	0.4	0.3	0.0	0.1	0.4	0.8	1.4	2.1	2.8	3.6	4.4	NM
Pre-tax Income	(24.1)	(56.5)	(14.1)	(12.0)	(11.3)	(16.0)	(53.4)	(52.3)	(60.8)	(5.2)	94.2	144.4	188.5	206.5	227.6	234.5	236.2	232.0	225.1	12%
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	-4.4%	31.5%	37.3%	41.1%	41.0%	42.5%	43.0%	43.0%	43.1%	43.2%	4%
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	28.0%	28.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	3%
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	26.4	40.4	66.0	72.3	79.6	82.1	82.7	81.2	78.8	15%
Net Income	(24.1)	(56.5)	(14.1)	(12.0)	(11.3)	(16.0)	(53.4)	(52.3)	(60.8)	(5.2)	67.8	104.0	122.5	134.2	147.9	152.4	153.5	150.8	146.3	10%
Net Income Incl 1x Milestones	(11.2)	(36.8)	(14.1)	(12.0)	(11.3)	(16.0)	(53.4)	(32.3)	(50.8)	(5.2)	67.8	104.0	122.5	134.2	147.9	152.4	153.5	150.8	146.3	
% of Sales	NM	NM	NM	NM	NM	NM	NM	NM	NM	-4.4%	22.7%	26.8%	26.7%	26.7%	27.6%	28.0%	28.0%	28.0%	28.1%	3%
Average Shares Outstanding	11.1	14.0	18.3	18.3	18.3	18.3	18.3	22.3	23.3	24.3	25.3	25.4	25.4	25.5	25.5	25.6	25.6	25.7	25.7	0%
Operating EPS	(\$2.17)	(\$4.15)	(\$0.77)	(\$0.65)	(\$0.61)	(\$0.87)	(\$2.91)	(\$2.34)	(\$2.61)	(\$0.21)	\$2.68	\$4.10	\$4.82	\$5.27	\$5.79	\$5.96	\$5.99	\$5.87	\$5.68	10%
Operating EPS Incl 1x Milestones	(\$1.00)	(\$2.62)	(\$0.77)	(\$0.65)	(\$0.61)	(\$0.87)	(\$2.91)	(\$1.44)	(\$2.18)	(\$0.21)	\$2.68	\$4.10	\$4.82	\$5.27	\$5.79	\$5.96	\$5.99	\$5.87	\$5.68	

Source: Leerink Swann and Company Reports



Disclosures Appendix

Analyst Certification

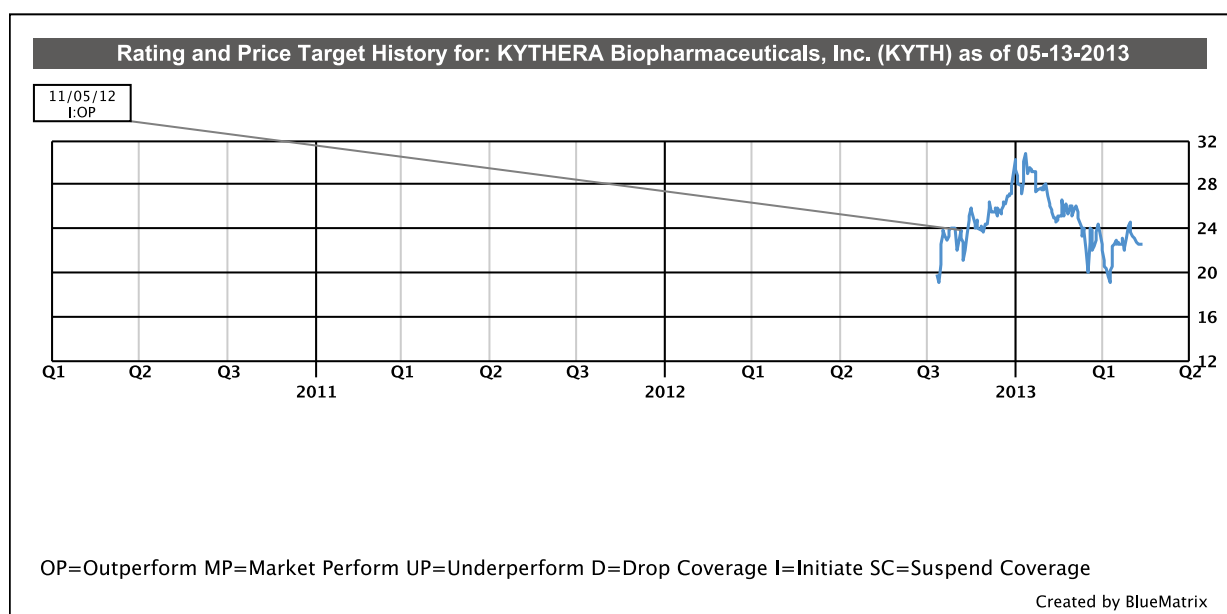
I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Valuation

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

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 (4) disappointing North American Phase III data for ATX-101.





Distribution of Ratings/Investment Banking Services (IB) as of 03/31/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	107	61.14	32	29.91
HOLD [MP]	68	38.86	0	0.00
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.

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

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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.

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