**OUTPERFORM** 

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Reason for report:

**COMPANY UPDATE** 



### KYTHERA BIOPHARMACEUTICALS, INC.

REFINE-1 & REFINE-2 Deliver Big; 4% Dropout Rate a Very Good Sign

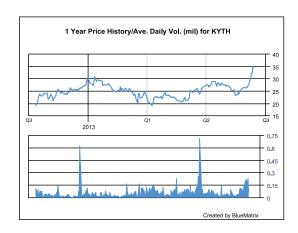
- **Bottom Line**: This evening KYTH announced better-than-expected results for its REFINE-1 and REFINE-2 studies of ATX-101, achieving all primary and secondary efficacy endpoints along with an impressive 4% dropout rate. As a result, we are increasing our DCF valuation from \$34/ shr to \$40/shr and introducing a blended DCF and comparable multiple price target of \$50/shr in the next 12 months, consistent with biotech's 5-6x multiple on 2017E sales which we believe more fully reflects KYTH's strategic value. Conf call 9/17 at 8 am ET; dial in (877) 344-3890 (U.S. and Canada) or (760) 666-3770 (international); conference ID 65266554.
- REFINE-1 & REFINE-2 beat even our high expectations for efficacy. KYTH reported that in REFINE-1, ATX-101 demonstrated a composite 1-grade improvement (70.3% vs. 18.7%, p <0.001), and a composite 2-grade improvement (13.4% vs. 0%, p<0.001); in REFINE-2 the composite 1-grade improvement was (66.9% vs. 22.4%, p <0.001), and the composite 2-grade improvement was (18.7% vs. 3.2%, p<0.001). These response rates exceeded the post-hoc U.S. Ph II and EU Ph III composite 1-grade response rates of 49% and 57%, respectively, and 7.5% and 9.5% for the 2-grade composite. In fact, these efficacy results more closely mirror the results of the open-label safety study reported in December 2012, which showed 1-grade and 2-grade composite changes of 71% & 14%, respectively.
- Four percent dropout rate suggests extremely manageable tolerability profile, consistent with KOL feedback. In line with MEDACorp KOL feedback (click HERE), the tolerability of ATX-101 (for the treatment of submental [double chin] fat reduction) as reflected in the reported low-single-digit dropout rate looks extremely manageable. We expect some additional color on the tolerability and safety profile of ATX-101 in the REFINE studies on tomorrow's conference call and full safety and efficacy results when presented at the American Society for Dermatologic Surgery (ASDS) meeting in Chicago, October 3-6.
- Raising price target from \$34/shr to \$50/shr to reflect strong Ph III results & overall strategic value. We are introducing a new blended comparable/DCF valuation for KYTH to better reflect the company's overall strategic value in specialty dermatology. Consistent with the positive REFINE study results, we are increasing our DCF valuation from \$34/shr to \$40/shr as we reduce our discount rate from 11% to 10%. However, we believe KYTH's strategic value suggests that it could trade for as much as 5.3x 2017 forecasted sales of \$299M, implying a \$74/shr valuation. Using a 70/30 blended DCF/comparable multiple value we get to our \$50/shr price target.

# Key Stats: (NASDAQ:KYTH)

HEALTHCARE EQUITY RESEARCH

S&P 600 Health Care Index: 1,136.50 Price: \$33.53 Price Target: \$50.00 from \$34.00 Methodology: Blended DCF/comparable multiple 52 Week High: \$35.80 52 Week Low: \$14 07 Shares Outstanding (mil): 183 Market Capitalization (mil): \$613.6 Book Value/Share: 0.00 Cash Per Share: \$4.33 Dividend (ann): \$0.00 Dividend Yield: 0.0% Est LT EPS Growth: 8% P/E to LT EPS Growth (FY14): NM

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	0.0A	0.0A			0.0	(\$0.77)A	(\$0.67)A	(\$0.80)	(\$0.91)	(\$3.15)	NM
2014E					\$0.1					(\$2.33)	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 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, and (3) a slower-than-expected launch of ATX-101 in North American and European markets. Our new blended DCF/comparablemultiple price target is \$50/share vs. our prior DCF price target of \$34/shr excluding any potential new indications or off label use outside of the initial indication for treatment of submental fat.

#### **VALUATION**

We value KYTH shares at \$50/share based on our blended DCF/comparable biotech multiple analysis. Our DCF valuation of \$40/shr calculates cash flows through 2025E, applies a 10% discount rate, and assumes a 0% growth rate on the terminal value of KYTH cash flow in 2025E. However, we believe KYTH's strategic value suggests that it could trade for as much as 5.3x 2017 forecasted sales of \$299M (consistent with biotech price/sales multiples of 5-6x sales), implying a \$74/shr valuation. Using a 70/30 blended DCF/comparable multiple value we get to our \$50/shr price target.

### **RISKS TO VALUATION**

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

Kythera - Quarterly Income Statement Analysis 2011-2025E

(\$ in Millions, Except EPS)																				
(Year Ended December 31)	2011	2012	1Q13	2Q13	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	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	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	7.8	11.0	13.2	42.0	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	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	4.0	3.8	3.5	15.0	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	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)	(11.7)	(14.8)	(16.7)	(57.0)	(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	-4.6%	31.5%	37.2%	41.0%	40.9%	42.2%	42.6%	42.5%	42.4%	42.4%	4%								
Interest Income	0.0	0.0	0.0	0.0	0.1	0.1	0.4	0.1	0.6	0.2	0.0	0.1	0.4	0.9	1.5	2.2	2.9	3.7	4.5	NM
Warrant and Other Interest Exp/Inc, Net	(0.3)	(0.9)	0.0	(0.6)	(0.1)	(0.1)	(8.0)	(0.4)	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	NM
Other Income	0.0	0.0	(0.4)	0.0	0.0	0.0	(0.4)	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
Non-Operating Items	(0.3)	(0.9)	(0.4)	(0.5)	(0.0)	(0.0)	(0.9)	(0.4)	0.4	0.2	0.0	0.1	0.4	0.9	1.5	2.2	2.9	3.7	4.5	NM
Pre-tax Income	(24.1)	(56.5)	(14.1)	(12.3)	(14.8)	(16.7)	(57.9)	(52.3)	(60.8)	(5.2)	94.2	144.4	188.5	206.6	227.6	234.5	236.3	232.1	225.1	12%
% of Sales	NM	-4.4%	31.5%	37.3%	41.1%	41.1%	42.5%	43.0%	43.1%	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%	16.2%	25.0%	32.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	10%
Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	15.2	36.1	60.3	72.3	79.7	82.1	82.7	81.2	78.8	23%
Net Income	(24.1)	(56.5)	(14.1)	(12.3)	(14.8)	(16.7)	(57.9)	(52.3)	(60.8)	(5.2)	78.9	108.3	128.2	134.3	148.0	152.4	153.6	150.9	146.3	8%
Net Income Incl 1x Milestones	(11.2)	(36.8)	(14.1)	(12.3)	(14.8)	(16.7)	(57.9)	(32.3)	(50.8)	(5.2)	78.9	108.3	128.2	134.3	148.0	152.4	153.6	150.9	146.3	,
% of Sales	NM	-4.4%	26.4%	28.0%	27.9%	26.7%	27.6%	28.0%	28.0%	28.0%	28.1%	1%								
Average Shares Outstanding	11.1	14.0	18.3	18.4	18.4	18.4	18.4	22.4	23.4	24.4	25.4	25.5	25.5	25.6	25.6	25.7	25.7	25.8	25.8	0%
Operating EPS	(\$2.17)	(\$4.15)	(\$0.77)	(\$0.67)	(\$0.80)	(\$0.91)	(\$3.15)	(\$2.33)	(\$2.60)	(\$0.21)	\$3.10	\$4.25	\$5.02	\$5.25	\$5.77	\$5.94	\$5.97	\$5.85	\$5.67	8%
Operating EPS Incl 1x Milestones	(\$1.00)	(\$2.62)	(\$0.77)	(\$0.67)	(\$0.80)	(\$0.91)	(\$3.15)	(\$1.44)	(\$2.17)	(\$0.21)	\$3.10	\$4.25	\$5.02	\$5.25	\$5.77	\$5.94	\$5.97	\$5.85	\$5.67	- 70
	(45)	(+)	(+5)	,40.0.)	(40.00)	(+0.0.)	,400)	(*)	(*)	,40.2.)	40	¥0	40.0-	40.20	<b>40</b>	<b>40.0</b> .	40.0.	40.00	<b>70.0.</b>	

Source: Leerink Swann and Company Reports



# **Disclosures Appendix Analyst Certification**

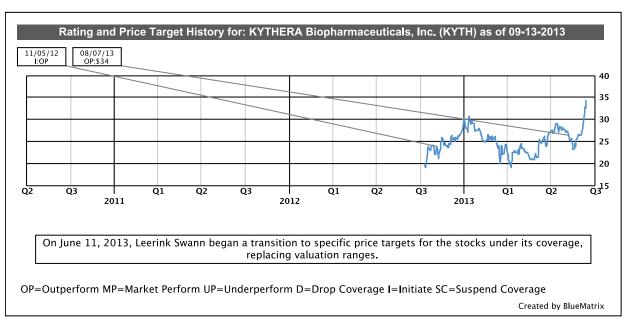
I, Seamus Fernandez, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### **Valuation**

We value KYTH shares at \$50/share based on our blended DCF/comparable biotech multiple analysis. Our DCF valuation of \$40/shr calculates cash flows through 2025E, applies a 10% discount rate, and assumes a 0% growth rate on the terminal value of KYTH cash flow in 2025E. However, we believe KYTH's strategic value suggests that it could trade for as much as 5.3x 2017 forecasted sales of \$299M (consistent with biotech price/sales multiples of 5-6x sales), implying a \$74/shr valuation. Using a 70/30 blended DCF/comparable multiple value we get to our \$50/shr price target.

### **Risks to Valuation**

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





	Distribution of Ratings/Investment Bank	ing Services (IE	,	erv./Past 12 Mos.
Rating	Count	Percent	Count	Percent
BUY [OP] HOLD [MP]	103 61	62.80 37.20	30	29.00 3.00
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.

<u>Market Perform (Hold/Neutral):</u> We expect this stock to perform in line with its benchmark over the next 12 months.

<u>Underperform (Sell):</u> 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**

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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.

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