# J.P.Morgan

## **Kythera Biopharmaceuticals**

### Reiterating OW On Highly Positive Phase III Data

After the close today, Kythera announced that its primary pipeline asset, ATX-101 for aesthetic reduction of submental fat (double chin), met all its primary and secondary endpoints for both the REFINE-1 and REFINE-2 Phase III trials. With positive data now in-hand, we see a very high probability of a 2015 approval for ATX-101 in the US and Europe in what we see as a \$500+ million annual sales opportunity to Kythera. We reiterate our Overweight rating and our raising our price target to \$45 from \$34.

- Phase III data looks solid and very consistent with earlier studies; all primary and secondary endpoints met. REFINE-1 met its primary endpoint with 70.3% of ATX-101 subjects demonstrating simultaneous improvement of at least 1 grade from baseline on CR-SMFRS and PR-SMFRS (vs 18.7% for pbo) and 13.4% demonstrating a 2 grade improvement from baseline (vs 0% pbo), while Refine-2 demonstrated a 66.9% (22.4% for pbo) and 18.7% (3.2% pbo) improvement of at least 1 and 2 grades from baseline, respectively. All primary endpoints were significant with p-values of < 0.001. Secondary endpoints showed statistically significantly reduction in volume of submental region measured through an MRI, as well as a patient reported satisfaction scale (PR-SMFIS).
- Safety data consistent with prior studies. There were no treatment-related serious adverse events, with the most common adverse events being mild to moderate swelling, pain, bruising, numbness and redness. This is consistent with previous studies and we believe supportive of driving broader adoption. Less than 4% of subjects discontinued the study due to adverse events. We will look for additional clarity on the safety and tolerability on ATX-101 on tomorrow's call.
- ATX-101 could address a significant unmet need and large market opportunity. There are currently no approved non-surgical options for the reduction of submental (under-chin) fat and Kythera will target this market with a non-invasive injectable therapy. We see meaningful opportunity for ATX-101 in toxin and filler experienced patients as well as aesthetic naïve patients and over time, see a potentially meaningful off-label market for the product. We estimate annual sales for this product could be \$500 million+.
- Kythera will host a conference call tomorrow at 8:00 AM ET, dial-in 877-344-3890 and conference ID 65266554.

Kythera Biopharmaceuticals, Inc. (KYTH;KYTH US)

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FYE Dec	2011A	2012A	2013E	2014E	2015E
EPS Adjusted (\$)					
Q1 (Mar)	(0.46)	(4.91)	(0.77)A	-	-
Q2 (Jun)	(0.41)	3.21	(0.67)A	-	-
Q3 (Sep)	(1.66)	(11.41)	(0.78)	-	-
Q4 (Dec)	` -	(1.04)	(0.78)	-	-
FY	(7.98)	(2.62)	(2.99)	(0.38)	(1.68)
Bloomberg EPS FY (\$)	-1.00	-4.04	-2.97	-1.41	-1.04
Source: Company data, Bloomb	erg, J.P. Morgan	estimates.			

### Overweight

KYTH, KYTH US

Price: \$33.53

Price Target: \$45.00 Previous: \$34.00

Pharmaceuticals — Major & Specialty

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J.P. Morgan Securities LLC



Company Data	
Price (\$)	33.53
Date Of Price	16 Sep 13
52-week Range (\$)	35.80-14.07
Market Cap (\$ mn)	617.72
Fiscal Year End	Dec
Shares O/S (mn)	18
Price Target (\$)	45.00
Price Target End Date	31-Dec-14

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### Investment Thesis, Valuation and Risks

# **Kythera Biopharmaceuticals** (Overweight; Price Target: \$45.00) **Investment Thesis**

**Maintain Overweight Rating.** Kythera's primary pipeline asset, ATX-101, is in phase 3 development for the aesthetic reduction of submental fat and to us represents a \$500+ million annual sales opportunity. ATX-101 has shown positive and highly consistent results in US phase 2 and European phase 3 trials and we have a high level of confidence in the product's ongoing US phase 3 program.

### **Valuation**

Raising Dec-14 price target to \$45. Our prior Dec-14 price target was \$34. Our discounted cash flow (DCF) analysis leads us to a valuation of \$45/share for KYTH by the end of 2014, assuming the receipt of positive phase 3 data from the ongoing US trials and continued progress toward regulatory filings in the US and EU. We assume Kythera will launch ATX-101 in the US in 2015 and Bayer will launch in the EU around the same time. In addition, we expect Kythera's expense structure to continue to increase through 2030 on an absolute basis but consistently decline as a percentage of revenue through our estimate period.

We estimate a weighted average cost of capital (WACC) of 10.5%, which is consistent with our normal WACC estimates for companies of Kythera's size and development stage due to the risk of the company's business model relative to more established branded pharma companies with commercialized products. We also use a terminal decline of 30% past 2030 as the last patents covering ATX-101 expire in 2030. We use a long-term estimated tax rate of 38% in our analysis given Kythera's US/California domicile.

We have applied a 90% probability of success to ATX-101 gaining approval in the US and EU, which is consistent with probabilities of success for other products with positive phase 3 data and potential for filing in multiple jurisdictions.

### Risks to Rating and Price Target

Risks to the downside include: 1) clinical risk from ongoing US phase 3 trials; 2) regulatory risk from FDA and EMA review of ATX-101 following submission; 3) commercial and partnership risk with ATX-101 potentially launching into the US and EU markets and 4) financing risk on any development delays for ATX-101.



## **Kythera Biopharmaceuticals: Summary of Financials**

Income Statement - Annual	FY12A	FY13E	FY14E	FY15E	Income Statement - Quarterly	1Q13A	2Q13A	3Q13E	4Q13E
Revenues	20	0	39	21	Revenues	0A	0A	0	0
Cost of products sold	(2)	0	(4)	(2)	Cost of products sold	0A	0A	0	0
Gross profit	18	0	35	18	Gross profit	0A	0A	0	0
SG&A	(11)	(16)	(25)	(40)	SG&A	(4)A	(4)A	(4)	(4)
R&D	(43)	(38)	(15)	(8)	R&D	(10)A	A(8)	(10)	(10)
Operating income	(36)	(53)	(5)	(29)	Operating income	(14)A	(12)A	(14)	(14)
Net interest (income) / expense	(1)	(2)	(2)	(2)	Net interest (income) / expense	(0)A	(1)A	(0)	(0)
Other income / (expense)	0	0	0	0	Other income / (expense)	0A	0A	0	0
Pretax income	(37)	(55)	(7)	(31)	Pretax income	(14)A	(12)A	(14)	(14)
Income taxes	0	0	0	0	Income taxes	0A	0A	0	0
Net income - recurring	(37)	(55)	(7)	(31)	Net income - recurring	(14)A	(12)A	(14)	(14)
Diluted shares outstanding	14	18	19	19	Diluted shares outstanding	18A	18A	18	18
EPS - excluding non-recurring	(2.62)	(2.99)	(0.38)	(1.68)	EPS - excluding non-recurring	(0.77)A	(0.67)A	(0.78)	(0.78)
EPS - recurring	(2.62)	(2.99)	(0.38)	(1.68)	EPS - recurring	(0.77)A	(0.67)A	(0.78)	(0.78)
Balance Sheet and Cash Flow Data	FY12A	FY13E	FY14E	FY15E	Ratio Analysis	FY12A	FY13E	FY14E	FY15E
Cash and cash equivalents	79	10	40	9	Sales growth	51.6%	(100.0%)	-	(47.3%)
Short Term Investment	-	-	-	-	EBIT growth	231.3%	48.9%	(90.8%)	495.6%
Accounts receivable	0	0	7	8	EPS growth - recurring	(67.2%)	14.4%	(87.3%)	342.4%
Inventories	0	0	0	0					
Other current assets	8	8	8	8	Gross margin	90.2%	-	90.0%	89.4%
Current assets	88	18	54	26	EBIT margin	(182.5%)	-	(12.6%)	(142.0%)
PP&E	0	0	0	1					
Total assets	96	25	62	33	Tax rate	0.0%	0.0%	0.0%	0.0%
					Net Profit Margin	(186.9%)	-	(18.0%)	(152.4%)
Total debt	3	18	25	25					
Total liabilities	27	40	48	47					
Shareholders' equity	69	17	14	(13)					
Net income (including charges)	(37)	(55)	(7)	(31)					
D&A	1	0	0	0					
Change in working capital	(1)	(2)	(7)	(3)					
Other	4	2	2	2					
Cash flow from operations	(33)	(55)	(12)	(33)					
Capex	(0)	(0)	(0)	(0)					
Free cash flow	(32)	(54)	(10)	(31)					
Cash flow from investing activities	(0)	(33)	32	(0)					
Cash flow from financing activities	78	19	10	2					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

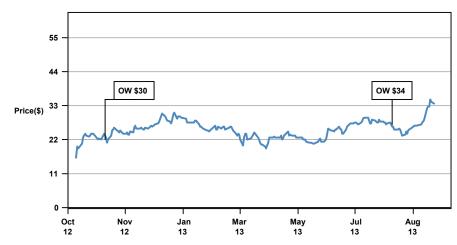
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### Kythera Biopharmaceuticals (KYTH, KYTH US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
05-Nov-12	OW	22.11	30.00
06-Aug-13	OW	26.96	34.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Nov 05, 2012.

The chart(s) show J.P. Morgan's continuing coverage of the stocks; the current analysts may or may not have covered it over the entire period.

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