

Kythera Biopharmaceuticals

Updating Model Post 1Q Results; Remain OW Ahead Of ATX-101 Data In 2H/13

Kythera reported 1Q operating results after the close today and provided an update on the development timelines for its primary asset, ATX-101 for the reduction of submental fat. We continue to believe ATX-101 represents a potential \$500+ million annual sales opportunity for Kythera and we have a high level of confidence in a successful phase III outcome for the company in the second half of 2013 based on positive and highly consistent results from US phase II and European phase III trials.

- **Topline results delayed three months.** Kythera now expects to report topline results for the North America phase III studies in late 3Q/early 4Q 2013. This is roughly 3 months later than our prior expectations as Kythera will maintain the blind of its studies until after the final patient safety visit rather than the final patient efficacy visit. This change in timing appears to be completely based on updated guidelines from the FDA following the implementation of PDUFA V.
- **European filing later in year; timing tied to US safety.** Kythera confirmed that the timing of the European filing for ATX-101 is tied to the availability of additional safety data from the US Phase III studies. While the two European pivotal studies are complete, Bayer, Kythera's partner, is waiting for the full safety data from the North American studies to include in the package. Along these lines, we now expect a European filing closer to yearend 2013.
- **ATX-101 could successfully address a significant unmet need in facial aesthetics.** 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 a meaningful opportunity for ATX-101 to initially target the estimated 2 million unique patients in the US who currently receive a toxin and/or dermal filler with a longer term opportunity to address the estimated 10 million individuals who would be physically and financially appropriate for the treatment. A survey we conducted last year confirmed a high level of interest in the product in both opportunities and also highlighted a number of off-label opportunities for ATX-101.

Kythera Biopharmaceuticals, Inc. (KYTH;KYTH US)

FYE Dec	2011A	2012A	2013E	2013E	2014E	2014E	2015E	2015E
			(Prev)	(Curr)	(Prev)	(Curr)	(Prev)	(Curr)
EPS Adjusted (\$)								
Q1 (Mar)	(0.46)	(4.91)	-	(0.77)A	-	-	-	-
Q2 (Jun)	(0.41)	3.21	-	(0.82)	-	-	-	-
Q3 (Sep)	(1.66)	(11.41)	-	(0.84)	-	-	-	-
Q4 (Dec)	-	(1.04)	-	(0.69)	-	-	-	-
FY	(7.98)	(2.62)	-	(3.12)	-	(0.35)	-	(1.14)
Bloomberg EPS FY (\$)	-1.00	-4.04	-	-2.86	-	-1.13	-	-0.88

Source: Company data, Bloomberg, J.P. Morgan estimates.

See page 6 for analyst certification and important disclosures.

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Overweight

KYTH, KYTH US

Price: \$22.59

Price Target: \$30.00

Pharmaceuticals — Major & Specialty

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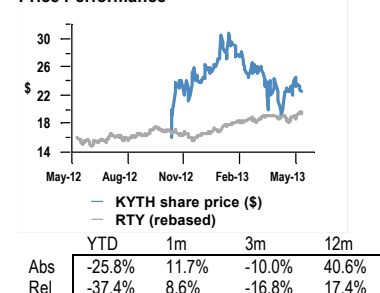
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Price Performance



Company Data

Price (\$)	22.59
Date Of Price	13 May 13
52-week Range (\$)	31.93-14.07
Market Cap (\$ mn)	414.19
Fiscal Year End	Dec
Shares O/S (mn)	18
Price Target (\$)	30.00
Price Target End Date	31-Dec-13

Changes to Our Estimates

Figure 1: Changes to Kythera Revenue and EPS Estimates

Kythera Period	EPS			Revenue (\$ thousands)		
	Revised	Prior	Difference	Revised	Prior	Difference
2Q/13E	(\$0.82)	(\$0.83)	\$0.01	\$0	\$0	\$0
3Q/13E	(\$0.84)	(\$0.72)	(\$0.12)	\$0	\$0	\$0
4Q/13E	(\$0.69)	(\$0.66)	(\$0.03)	\$0	\$0	\$0
2013E	(\$3.12)	(\$3.15)	\$0.03	\$0	\$0	\$0
2014E	(\$0.35)	(\$0.19)	(\$0.16)	\$39,000	\$38,000	\$1,000
2015E	(\$1.14)	(\$1.14)	\$0.00	\$34,253	\$34,253	\$0
2016E	\$0.54	\$0.57	(\$0.03)	\$79,916	\$79,916	\$0

Source: J.P. Morgan estimates.

Investment Thesis, Valuation and Risks

Kythera Biopharmaceuticals *(Overweight; Price Target: \$30.00)*

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

Maintain Dec-13 price target of \$30. Our discounted cash flow (DCF) analysis leads us to a valuation of \$30/share for KYTH by the end of 2013, 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 12%, 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 75% probability of success to ATX-101 gaining approval in the US and EU, which is consistent with probabilities of success for other products with initial 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.

Figure 2: Kythera Financial Model

\$ in millions

thousands USD							Mar 2013	Jun 2013	Sep 2013	Dec 2013								
Fiscal year ends December 31	FY 2007A	FY 2008A	FY 2009A	FY 2010A	FY 2011A	FY 2012A	1QA	2QE	3QE	4QE	FY 2013E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Income Statement																		
Revenue	-	-	-	-	-	-	-	-	-	-	-	-	33,255	75,930	132,739	204,991	298,552	365,729
License/royalty income	-	-	-	4,488	12,985	19,687	-	-	-	-	-	39,000	998	3,986	17,964	20,374	26,273	35,110
Total revenue	-	-	-	4,488	12,985	19,687	-	-	-	-	-	39,000	34,253	79,916	150,703	225,366	324,825	400,839
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	-	3,326	7,593	13,274	20,499	29,855	36,573
Sublicense expense	-	-	-	411	1,188	1,936	-	-	-	-	-	3,900	299	1,196	5,389	6,112	7,882	10,533
Total cost of revenue	-	-	-	411	1,188	1,936	-	-	-	-	-	3,900	3,625	8,789	18,663	26,611	37,737	47,106
Gross profit	-	-	-	4,077	11,797	17,751	-	-	-	-	-	35,100	30,628	71,127	132,040	198,754	287,088	353,733
R&D	9,012	15,672	9,823	14,842	15,766	43,183	10,034	10,000	10,000	7,500	37,534	15,000	8,000	8,000	8,000	8,000	8,000	8,000
SG&A	3,232	4,522	4,930	6,785	6,879	10,503	3,725	3,750	4,000	4,000	15,475	25,000	40,936	52,541	69,841	90,442	120,510	139,052
Total operating expense	12,244	20,194	14,753	21,627	22,645	53,686	13,759	13,750	14,000	11,500	53,009	40,000	48,936	60,541	77,841	98,442	128,510	147,052
Income (loss) from operations (EBIT)	(12,244)	(20,194)	(14,753)	(17,550)	(10,848)	(35,935)	(13,759)	(13,750)	(14,000)	(11,500)	(53,009)	(4,900)	(18,308)	10,586	54,199	100,312	158,578	206,682
Warrant & other interest income (expense)	810	457	(7)	589	(304)	(861)	(367)	(319)	(314)	(309)	(1,308)	(1,180)	(1,388)	-	-	-	-	-
Other income	-	-	-	930	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total other income (expense)	810	457	(7)	1,519	(304)	(861)	(367)	(319)	(314)	(309)	(1,308)	(1,180)	(1,388)	-	-	-	-	-
Earnings (loss) before tax (EBT)	(11,434)	(19,737)	(14,760)	(16,031)	(11,152)	(36,796)	(14,126)	(14,069)	(14,314)	(11,809)	(54,317)	(6,080)	(19,697)	10,586	54,199	100,312	158,578	206,682
Income tax (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	529	2,710	15,047	55,502	78,539
NET INCOME	(11,434)	(19,737)	(14,760)	(16,031)	(11,152)	(36,796)	(14,126)	(14,069)	(14,314)	(11,809)	(54,317)	(6,080)	(19,697)	10,057	51,489	85,265	103,075	128,143
EPS	(8.53)	(14.62)	(10.85)	(11.64)	(7.98)	(2.62)	(0.77)	(0.82)	(0.84)	(0.69)	(3.12)	(0.35)	(1.14)	0.54	2.72	4.44	5.28	6.44
Basic shares outstanding	1,341	1,350	1,360	1,377	1,398	14,058	18,335	17,056	17,077	17,094	17,390	17,194	17,316	17,468	17,662	17,908	18,230	18,597
FD shares outstanding	1,341	1,350	1,360	1,377	1,398	14,058	18,335	18,356	18,377	18,394	18,365	18,494	18,616	18,768	18,962	19,208	19,530	19,897
Margins																		
Gross product margin													90%	90%	90%	90%	90%	90%
Gross sublicense margin												90%	70%	70%	70%	70%	70%	70%
Gross margin													89%	89%	88%	88%	88%	88%
R&D													24%	11%	6%	4%	3%	2%
SG&A													123%	69%	53%	44%	40%	38%
Opex													147%	80%	59%	48%	43%	40%
Operating margin													-55%	14%	41%	49%	53%	57%
Pretax margin													-59%	14%	41%	49%	53%	57%
Tax rate														5%	5%	15%	35%	38%

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

Kythera Biopharmaceuticals: Summary of Financials

Income Statement - Annual	FY12A	FY13E	FY14E	FY15E	Income Statement - Quarterly	1Q13A	2Q13E	3Q13E	4Q13E
Revenues	20	0	39	34	Revenues	0A	0	0	0
Cost of products sold	(2)	0	(4)	(4)	Cost of products sold	0A	0	0	0
Gross profit	18	0	35	31	Gross profit	0A	0	0	0
SG&A	(11)	(15)	(25)	(41)	SG&A	(4)A	(4)	(4)	(4)
R&D	(43)	(38)	(15)	(8)	R&D	(10)A	(10)	(10)	(8)
Operating income	(36)	(53)	(5)	(18)	Operating income	(14)A	(14)	(14)	(12)
Net interest (income) / expense	(1)	(1)	(1)	(1)	Net interest (income) / expense	(0)A	(0)	(0)	(0)
Other income / (expense)	0	0	0	0	Other income / (expense)	0A	0	0	0
Pretax income	(37)	(54)	(6)	(20)	Pretax income	(14)A	(14)	(14)	(12)
Income taxes	0	0	0	0	Income taxes	0A	0	0	0
Net income - recurring	(37)	(54)	(6)	(20)	Net income - recurring	(14)A	(14)	(14)	(12)
Diluted shares outstanding	14	18	18	19	Diluted shares outstanding	18A	18	18	18
EPS - excluding non-recurring	(2.62)	(3.12)	(0.35)	(1.14)	EPS - excluding non-recurring	(0.77)A	(0.82)	(0.84)	(0.69)
EPS - recurring	(2.62)	(3.12)	(0.35)	(1.14)	EPS - recurring	(0.77)A	(0.82)	(0.84)	(0.69)
Balance Sheet and Cash Flow Data	FY12A	FY13E	FY14E	FY15E	Ratio Analysis	FY12A	FY13E	FY14E	FY15E
Cash and cash equivalents	79	3	25	8	Sales growth	51.6%	(100.0%)	-	(12.2%)
Short Term Investment	-	-	-	-	EBIT growth	231.3%	47.5%	(90.8%)	273.6%
Accounts receivable	0	0	7	6	EPS growth - recurring	(67.2%)	19.3%	(88.7%)	221.7%
Inventories	0	0	0	1					
Other current assets	8	8	8	8	Gross margin	90.2%	-	90.0%	89.4%
Current assets	88	10	39	22	EBIT margin	(182.5%)	-	(12.6%)	(53.5%)
PP&E	0	0	0	1					
Total assets	96	18	47	30	Tax rate	0.0%	0.0%	0.0%	0.0%
					Net Profit Margin	(186.9%)	-	(15.6%)	(57.5%)
Total debt	3	9	8	8					
Total liabilities	27	32	31	30					
Shareholders' equity	69	18	16	0					
Net income (including charges)	(37)	(54)	(6)	(20)					
D&A	1	0	0	0					
Change in working capital	(1)	(2)	(7)	(1)					
Other	4	2	2	2					
Cash flow from operations	(33)	(54)	(11)	(19)					
Capex	(0)	(0)	(0)	(0)					
Free cash flow	(32)	(53)	(10)	(18)					
Cash flow from investing activities	(0)	(33)	32	(0)					
Cash flow from financing activities	78	11	1	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



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

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