

Tokai Pharmaceuticals

(TKAI-NASDAQ)

Stock Rating: Outperform**Industry Rating:** Outperform

June 2, 2015

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ARMOR-SV3 Could Drive Value Earlier Than Expected

Event

We met with TKAI management during ASCO. TKAI conducted an ARMOR3-SV investigator kick-off meeting immediately prior to ASCO. Investigator enthusiasm for the trial was stated to be high, and some investigators have already identified potential patients. First patients for ARMOR3-SV will be screened in June. TKAI estimates that data from the trial will be available by year-end 2016, but this assumes a 10% prevalence of AR-V7 and with the most recent estimates for AR-V7 prevalence ranging from 14-26%, the timeline may be conservative; a futility analysis is expected to occur mid-2016. Separately, academic investigators presented data from a phase 2 trial of androgen receptor (AR) inhibition in women with triple negative breast cancer (TNBC). The trial enrolled 118 AR+ve patients, 75 of whom were included in the evaluable population defined as having and AR score of 10 or higher. Use of an AR gene expression test, PREDICT AR provided greater discrimination of PFS between responders and non-responders, 16.1 vs. 8.1 weeks in the ITT population and this was magnified in the ~55% of women who had received no or one prior therapy where PFS in the PREDICT AR positive subset was 40 weeks vs. 9 weeks for the negative subset. With respect to OS in the ITT population, women without a PREDICT AR signal lived for 32 weeks vs. not reached (~60% at 12 months) for the positive subset.

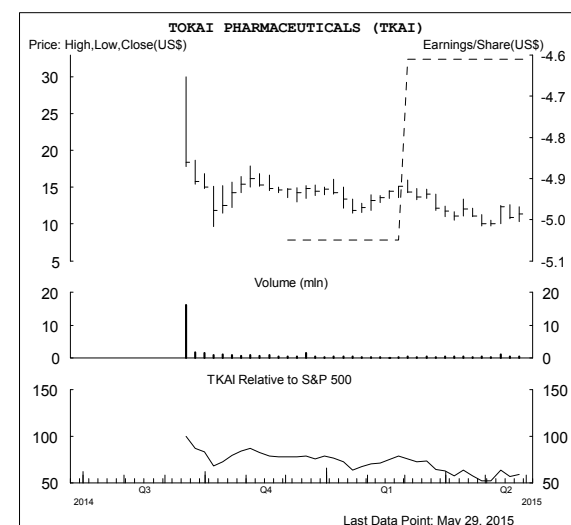
Impact & Analysis

We reiterate our Outperform rating on shares of TKAI following progress toward phase 3 trial initiation in CRPC and on potential expanded opportunity into TNBC highlighted at ASCO. We continue to see a high likelihood of success for galeterone to demonstrate superiority in PFS over XTANDI in patients with ARV7 mutation and believe that timelines to data may not be as extended as the Street thinks. Beyond a differentiated effect on AR degradation we see other novel mechanisms that could support success in TNBC and would view this opportunity as pure option value at present.

Valuation & Recommendation

We arrive at our \$28 price target by applying a 20x multiple to our 2020 EPS estimate of \$3.69 and discounting at 30%. We rate TKAI shares Outperform.

Price (1-Jun) \$11.37 52-Week High \$30.00
Target Price \$28.00 52-Week Low \$9.67

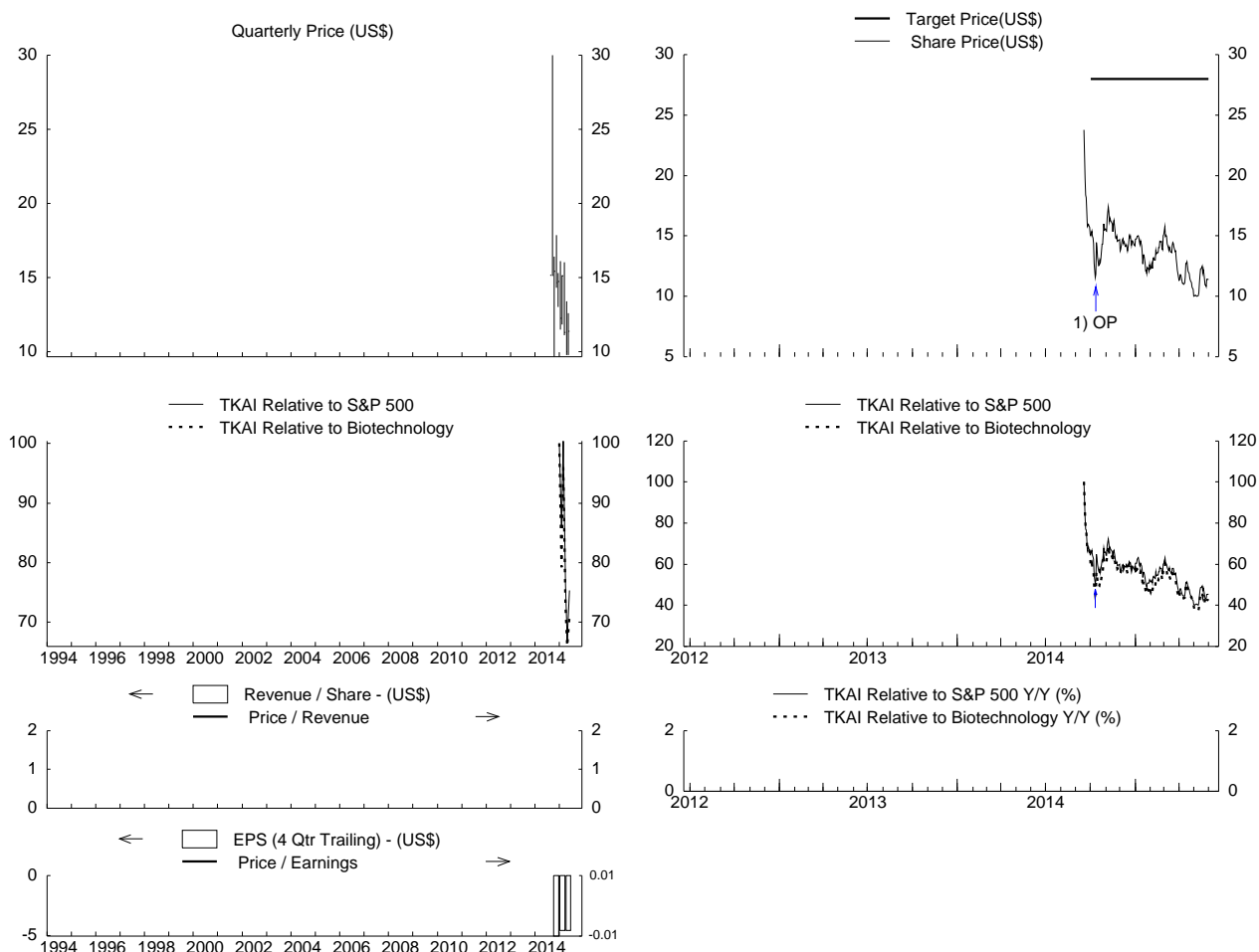


(FY-Dec.)	2013A	2014A	2015E	2016E
EPS	-\$3.63	-\$3.60	-\$1.35	-\$0.86
P/E			na	na
CFPS	na	na	na	na
P/CFPS			na	na
Rev. (\$mm)	\$0	\$0	\$0	\$0
EV (\$mm)	na	\$256	\$256	\$256
EBITDA (\$mm)	-\$16	-\$23	-\$30	-\$24
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014A	-\$1.03	-\$1.03	-\$2.71	-\$0.28
2015E	-\$0.59a	-\$0.25	-\$0.25	-\$0.25
Dividend	\$0.00			
Book Value	\$0.90			
Shares O/S (mm)	22.4			
Float O/S (mm)	6.5			
Wkly Vol (000s)	1,002			
Net Debt (\$mm)	-\$21			
Yield				0.0%
Price/Book				12.6x
Mkt. Cap (mm)				\$255
Float Cap (mm)				\$74
Wkly \$ Vol (mm)				\$17.9
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: TOKAI PHARMACEUTICALS INC (US\$)
2015E: -\$2.00; 2016E: -\$1.95

TOKAI PHARMACEUTICALS (TKAI)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %
2014	-3.60	na na	0.00	0.0 0.0	0	-2.5	-11.9 -3.8	
Range*		na na		0.0 0.0			-11.9 -3.8	
Current*	-4.61	na	0.00	0.0	0	0.9	12.6	na

TKAI - Rating as of 16-Sep-14 = NR

Date	Rating Change	Share Price
1 10-Oct-14	NR to OP	\$11.82

* Current EPS is the 4 Quarter Trailing to Q1/2015.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (May 29, 2015): \$ND
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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Methodology and Risks to Price Target/Valuation

Methodology: We arrive at our price target by applying a 20x multiple to our 2020E EPS of \$3.69 discounted 30%.

Risks: There are a number of risks associated with investment in biotechnology companies. These risks include, but are not limited to, risk of clinical trial delay or failure, adverse regulatory decisions including product non-approval, unanticipated adverse effects of drugs which may result in removal from market, risk of manufacturing difficulties, capital market risk which may impair the ability to fund product discovery, research, regulatory filing, manufacture and/or commercialization, risk in attaining and retaining appropriate development or commercial partners, lower-than-expected product adoption, difficulties in gaining appropriate reimbursement for products from payors, unforeseen generic and branded competition, risk to patents being invalidated, and failure to meet earnings and revenue expectations.

Distribution of Ratings (March 31, 2015)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	43.7%	18.6%	58.2%	42.7%	55.5%	54.1%
Hold	Market Perform	51.4%	10.4%	38.5%	52.1%	41.9%	40.5%
Sell	Underperform	4.9%	9.4%	3.3%	5.2%	2.6%	5.5%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis

Und = Underperform - Forecast to underperform the analyst's coverage universe on a total return basis

(S) = speculative investment;

NR = No rating at this time;

R = Restricted – Dissemination of research is currently restricted.

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