

# Tokai Pharmaceuticals

(TKAI-NASDAQ)

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

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## ASCO Abstract Highlights Potential Broader Opportunity for Galeterone

### Event

TKAI competitor MDVN will present data at ASCO supporting the use of androgen receptor (AR) inhibition in a subset of triple negative breast cancer patients. In addition to determination of AR by IHC, investigators devised an AR-related gene signature (Dx). Per the abstract, of the 404 samples tested, 79% had detectable AR by IHC, which was present at a high level (>10%) in 55% and 118 patients were treated. In the evaluable subset, over half the patients received XTANDI as either a first- or second-line treatment and mPFS in these subjects was 32 weeks for the Dx+ve cohort vs. 9 weeks for the Dx-ve cohort. The authors note that this is the largest trial of an AR inhibitor in TNBC to date and that AR inhibition has activity in an AR-related gene signature subset, which was observed in 47% of patients tested. The authors suggest that AR inhibition could be an alternative to chemotherapy in selected TNBC patients.

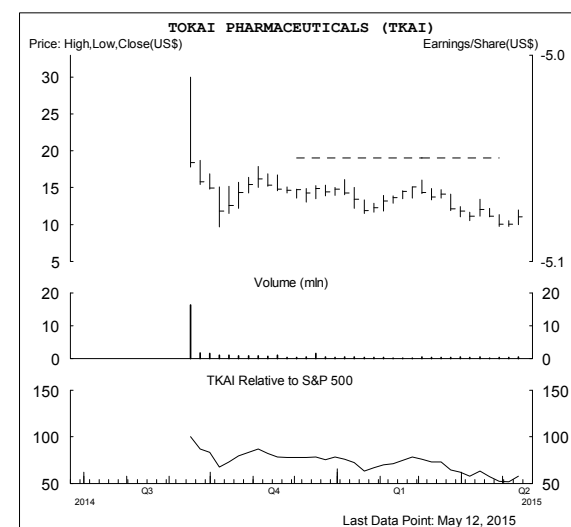
### Impact & Analysis

We are reiterating our Outperform rating on shares of TKAI following review of ASCO abstracts and in consideration of a potential larger opportunity for novel AR inhibitor galeterone beyond CRPC in TNBC. We continue to view galeterone as a highly differentiated AR inhibitor, with both activity in patients with ARV7 mutation, not typically responsive to market leaders ZYTIGA and XTANDI, as well as recently discovered synergies with leading breast cancer therapeutics HERCEPTIN and Taxotere. We expect near-term initiation of a phase 3 study of galeterone in CRPC patients with ARV7 mutation and expect galeterone to emerge as a best-in-class drug for CRPC and now potentially TNBC.

### 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 (13-May)** \$11.74 **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			0.0%
Book Value	\$0.90			13.0x
Shares O/S (mm)	22.4			Mkt. Cap (mm)
Float O/S (mm)	6.5			\$263
Wkly Vol (000s)	1,013			Float Cap (mm)
Net Debt (\$mm)	-\$21			\$76
				Wkly \$ Vol (mm)
				\$18.4
				Next Rep. Date
				na

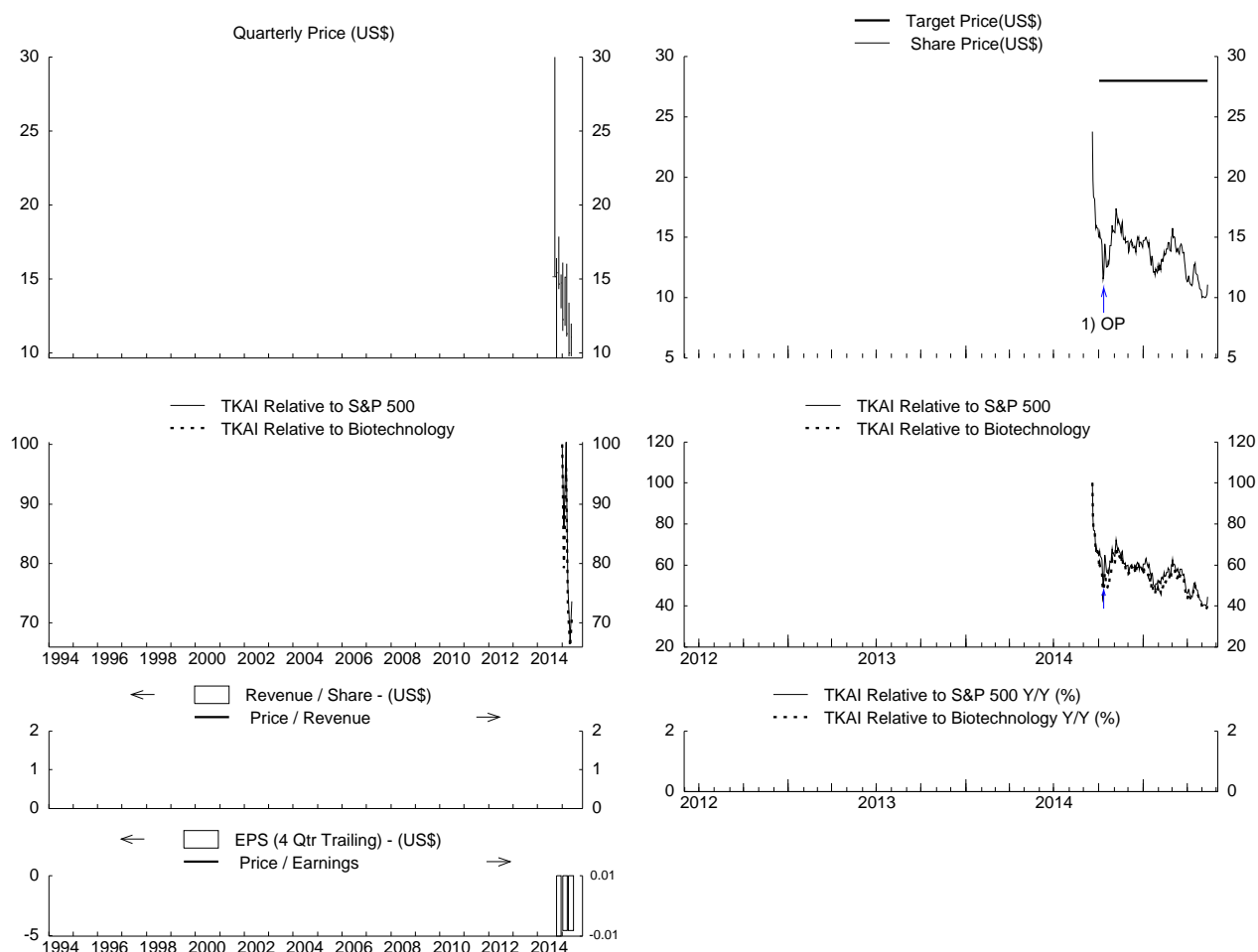
Notes: All values in US\$

First Call Mean Estimates: TOKAI PHARMACEUTICALS INC (US\$)  
2015E: -\$1.40; 2016E: -\$1.67

**Companies mentioned (priced as of the close on May 13, 2015):**

Medivation (MDVN, \$122.65, Not Rated)

## 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	11.1	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 12, 2015): \$11.07  
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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**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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(S) = speculative investment;

NR = No rating at this time;

R = Restricted – Dissemination of research is currently restricted.

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