

Tokai Pharmaceuticals

(TKAI-NASDAQ)

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

June 24, 2015

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ARMOR3-SV Initiation Sets Stage for Superiority Over XTANDI

Event

Tokai Pharmaceuticals announced today the initiation of the phase 3 ARMOR3-SV trial of galeterone in AR-V7 positive metastatic castration-resistant prostate cancer (mCRPC), with top-line data expected by year-end 2016. The ARMOR3-SV study has been initiated at more than 15 sites in the U.S., with site initiations in Canada and the U.K. expected later this month and additional site initiations in North America, Western Europe, and Australia in coming months. TKAI also noted that an AR-V7 clinical trial assay has been optimized for global use by partner Qiagen and that training of the global central laboratories is underway. Recall that the ARMOR3-SV study is designed to compare galeterone with Medivation (MDVN)'s XTANDI (enzalutamide) in 148 mCRPC treatment-naïve patients whose prostate tumors express the AR-V7 splice variant, the most common form of androgen receptor (AR) C-terminal loss. As noted in our last note (following management meeting at ASCO), TKAI assumes a relatively conservative 10% prevalence of AR-V7 in estimating the study timeline, while most recent estimates for AR-V7 prevalence ranged from 14-26%.

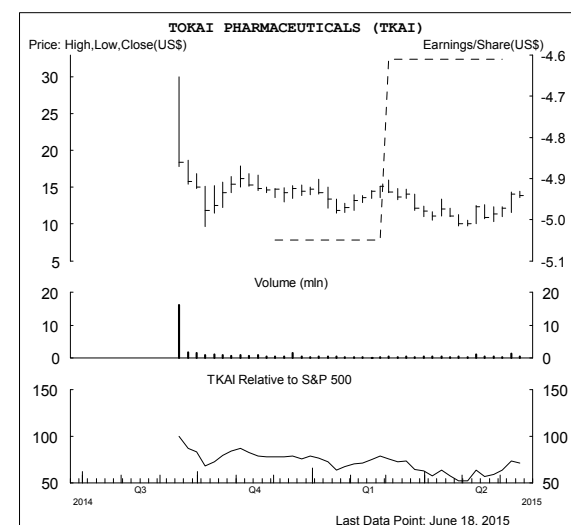
Impact & Analysis

We reiterate our Outperform rating on shares of TKAI following initiation of the ARMOR3-SV trial of galeterone in AR-V7 positive mCRPC. With highly differentiated activity in AR-V7 positive patients, we view the head-to-head study with XTANDI as close to a placebo controlled trial and see a high likelihood of success. Superiority over XTANDI in AR-V7 positive patients could support a \$1B+ opportunity in second/third line treatment, with roughly two-thirds of patients failing current therapy expressing the mutation.

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 (23-Jun) \$13.89 **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			15.4x
Shares O/S (mm)	22.4			Mkt. Cap (mm)
Float O/S (mm)	6.5			\$311
Wkly Vol (000s)	976			Float Cap (mm)
Net Debt (\$mm)	-\$21			\$90
				Wkly \$ Vol (mm)
				\$17.2
				Next Rep. Date
				na

Notes: All values in US\$

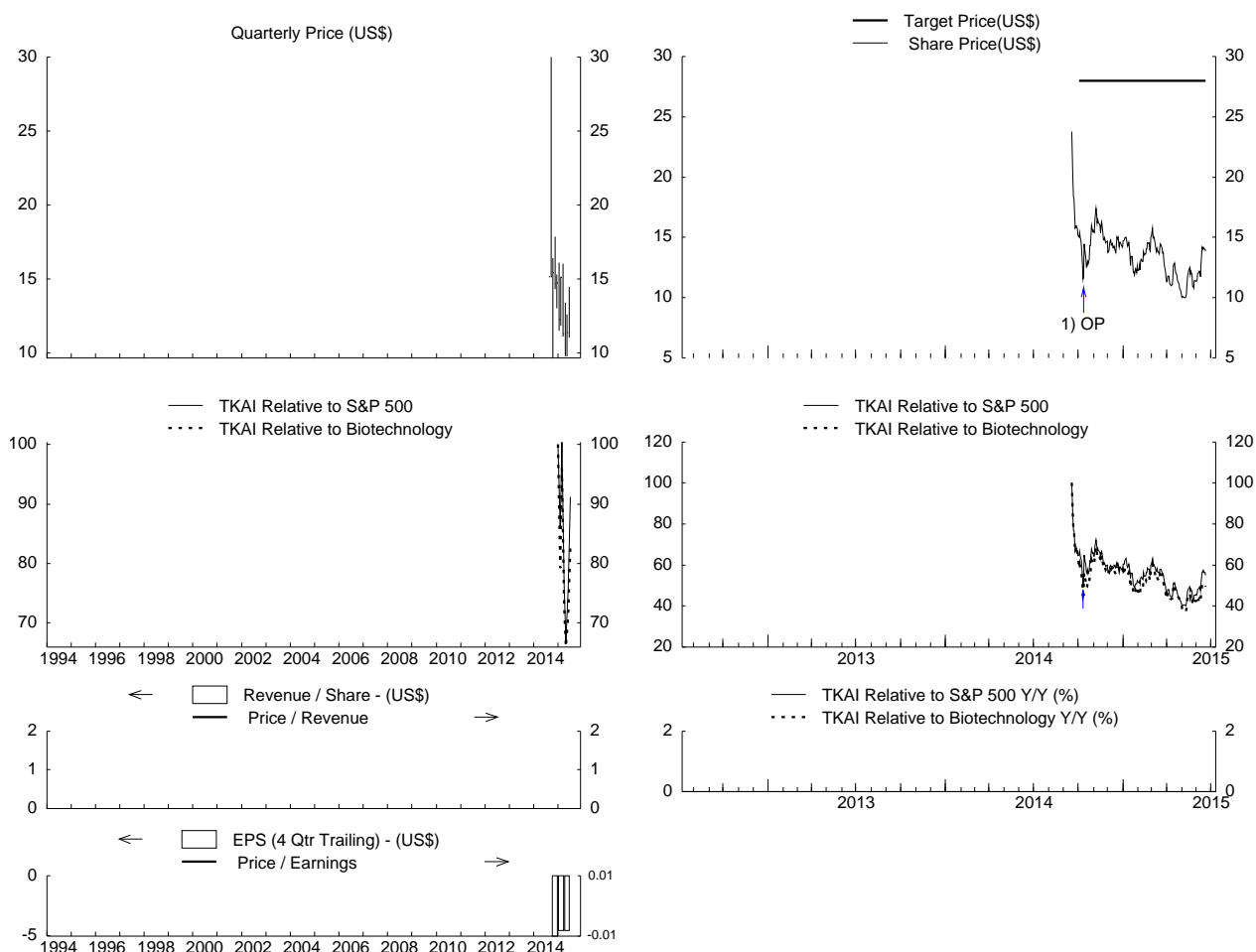
First Call Mean Estimates: TOKAI PHARMACEUTICALS INC (US\$)
2015E: -\$2.00; 2016E: -\$1.95

Companies mentioned (priced as of the close on June 23, 2015):

Medivation (MDVN, \$116.06, Not Rated)

Qiagen (QGEN, \$24.95, 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	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 (June 18, 2015): \$13.85
 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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OP = Outperform - Forecast to outperform the analyst's coverage universe on a total return basis

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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