

Tokai Pharmaceuticals

(TKAI-NASDAQ)

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

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Well-Positioned for Success in CRPC

Event

Tokai Pharmaceuticals (TKAI) today announced that it has entered into an agreement with The Johns Hopkins University on the development of a companion diagnostic to determine the AR-V7 status of patients with castration-resistant prostate cancer (CRPC) for use with the company's lead product candidate, galeterone. Under this agreement, TKAI has obtained an exclusive, global license to patent applications and know-how covering an assay that has been used to determine the AR-V7 status of patients. Recall that The Johns Hopkins University has conducted a prospective trial demonstrating that AR-V7 is associated with poor responsiveness to ZYTIGA and XTANDI. In addition, TKAI announced that it has entered into an agreement with Qiagen under which Qiagen will develop a noninvasive companion diagnostic for use with galeterone. TKAI remains on track to initiate in 1H15 the phase 3 ARMOR3-SV study of first-line galeterone versus XTANDI in metastatic CRPC patients with the AR-V7 splice variant.

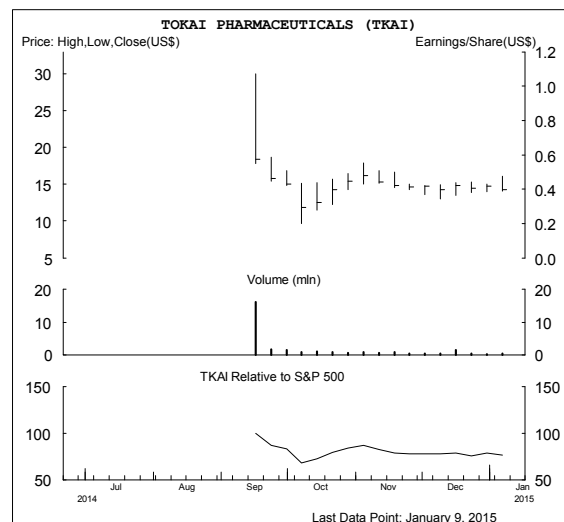
Impact & Analysis

We are maintaining our Outperform rating on the shares of TKAI following the update on ARV7 mutation testing. With an estimated 12% of CRPC patients with ARV7 mutation and roughly two-thirds of patients failing XTANDI/ZYTIGA with ARV7 mutation, we believe that non-invasive identification of these patients will be critical to success. We continue to view galeterone as a differentiated drug in the CRPC space with a favorably handicapped ARMOR3 study in ARV7 patients that have limited response to comparator XTANDI and high response to galeterone.

Valuation & Recommendation

We arrive at our \$28 price target by applying a 20x multiple to our 2020 EPS estimate of \$4.25 and discounting at 30%. We rate TKAI shares Outperform.

Price (12-Jan) \$14.58 **52-Week High** \$30.00
Target Price \$28.00 **52-Week Low** \$9.67

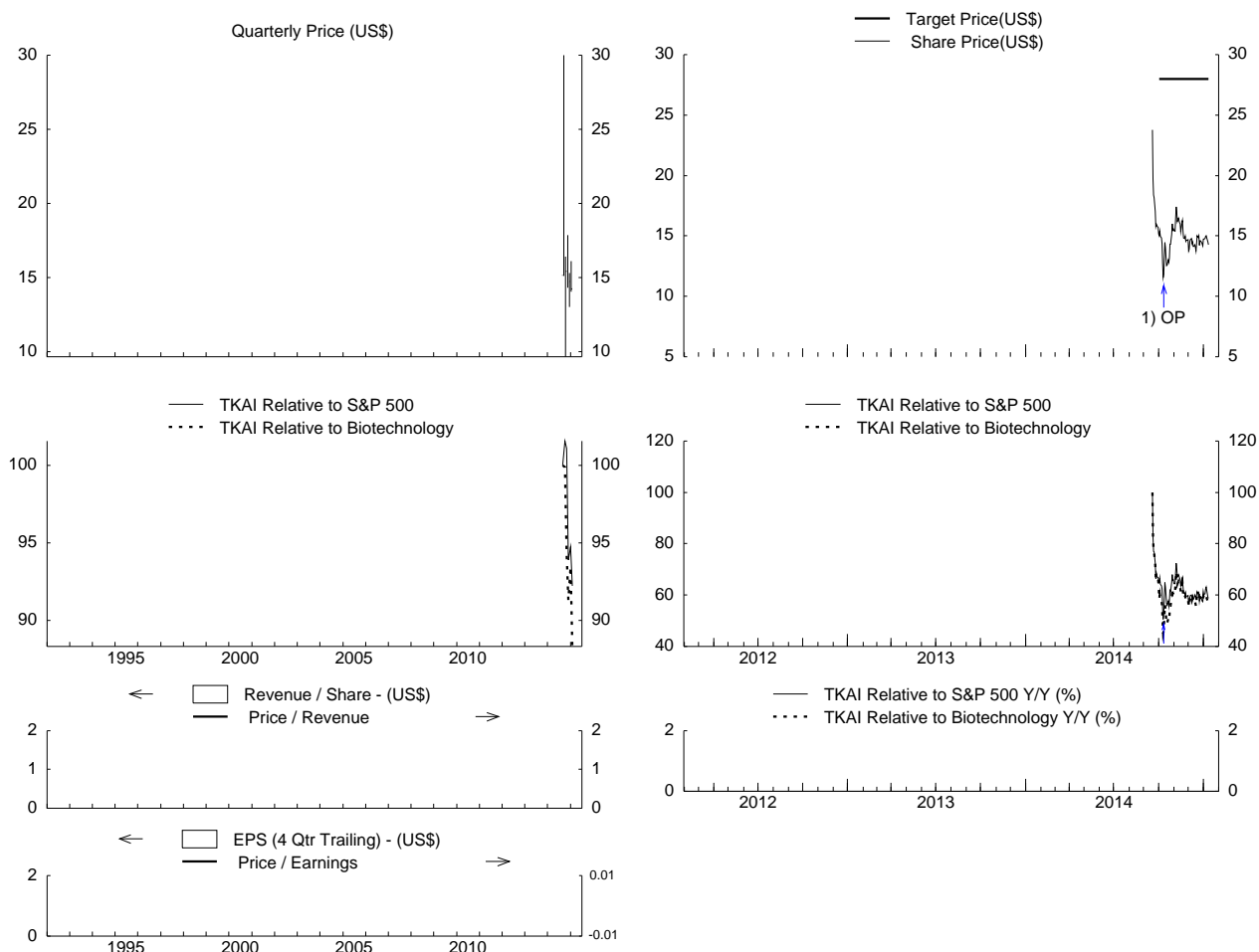


(FY-Dec.)	2013A	2014E	2015E	2016E
EPS	-\$3.63	-\$5.01	-\$0.84	na
P/E		na	na	na
CFPS	na	na	na	na
P/CFPS		na	na	na
Rev. (\$mm)	\$0	\$0	\$0	na
EV (\$mm)	na	\$256	\$256	na
EBITDA (\$mm)	-\$16	-\$22	-\$23	na
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2013A	na	na	na	na
2014E	-\$1.03a	-\$1.03a	-\$2.71a	-\$0.25
2015E	na	na	na	na
Dividend	\$0.00			0.0%
Book Value	\$0.90			16.2x
Shares O/S (mm)	21.8			Mkt. Cap (mm)
Float O/S (mm)	6.5			\$318
Wkly Vol (000s)	1,730			Float Cap (mm)
Net Debt (\$mm)	-\$21			\$95
				Wkly \$ Vol (mm)
				\$33.0
				Next Rep. Date
				na

Notes: All values in US\$

First Call Mean Estimates: TOKAI PHARMACEUTICALS INC (US\$)
2014E: -\$2.99; 2015E: -\$1.47; 2016E: -\$1.76

TOKAI PHARMACEUTICALS (TKAI)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %
Range*		na na		NC			>15 >15	
Current*	ND	na	0.00	0.0	na	0.9	16.4	

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 Q3/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (January 9, 2015): \$14.25
 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 \$4.25 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 (September 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	44.3%	18.0%	60.3%	43.9%	56.5%	56.0%
Hold	Market Perform	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

* 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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