

Tokai Pharmaceuticals

(TKAI-NASDAQ)

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

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ARMOR3-SV on Track for Near-Term Initiation

Event

Tokai Pharmaceuticals (TKAI) reported 1Q15 results yesterday and updated progress on key initiatives. The net loss per share was \$0.59, wider than the consensus loss estimate of \$0.31, and the company ended the quarter with \$94.2M. Plans to initiate phase 3 testing of galeterone in castrate resistant prostate cancer patients (n=148) with the androgen receptor splice variant, ARV7 in 2Q15 (ARMOR3-SV) in 2Q15 remain on track. Patient eligibility for the trial will be determined by a circulating tumor cell companion diagnostic under development by Qiagen. Qiagen is on track to complete development of the assay ahead of ARMOR3-SV trial initiation. In 1Q15, the company presented pre-clinical data showing that galeterone inhibits key kinases altering the activity and cellular location of certain transcription factors that are associated with pancreatic ductal adenocarcinoma (PDAC). In pre-clinical PDAC models, galeterone was active but importantly galeterone was able to resensitize tumors to gemcitabine.

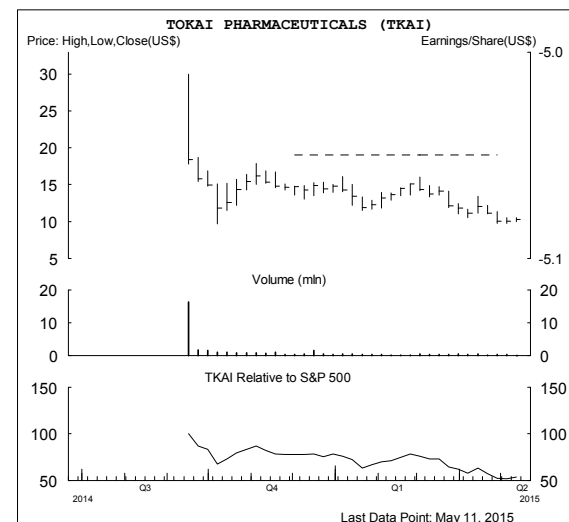
Impact & Analysis

We are reiterating our Outperform rating on the shares of TKAI following review of 1Q15 operating results. Overall, the company remains on track with galeterone development and for near-term initiation of a potential high impact phase 3 study in CRPC. With continued accumulation of evidence suggesting differentiation of activity compared with incumbent brands XTANDI and ZYTIGA, we expect galeterone to emerge from phase 3 with a best-in-class profile, supportive of a \$1B+ opportunity.

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 (12-May) \$11.07 **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
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			11.4x
Shares O/S (mm)	22.4			\$248
Float O/S (mm)	6.5			\$72
Wkly Vol (000s)	1,013			\$18.4
Net Debt (\$mm)	-\$21			na
Yield				0.0%
Price/Book				11.4x
Mkt. Cap (mm)				\$248
Float Cap (mm)				\$72
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

Changes

Annual EPS

2015E -\$0.84 to -\$1.35

2016E -\$0.74 to -\$0.86

Quarterly EPS

Q2/15E -\$0.21 to -\$0.25

Q3/15E -\$0.21 to -\$0.25

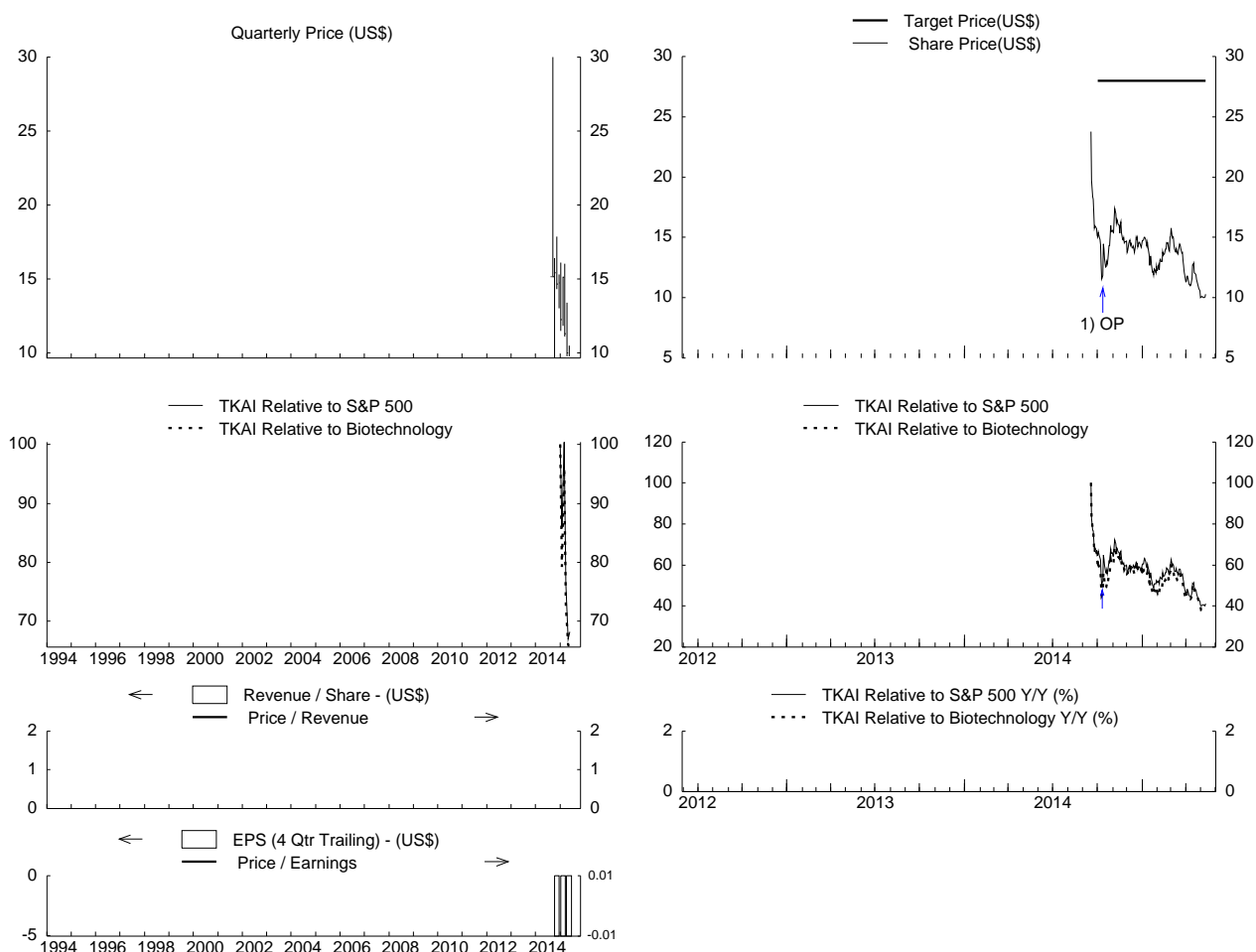
Q4/15E -\$0.21 to -\$0.25

Exhibit 1: TKAI Income Statement 2015E-2020E

INCOME STATEMENT (\$M)	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
REVENUES										
Product Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 72.4	\$ 344.1
Collaboration Revenue	-	-	-	-	-	-	-	-	-	-
Sponsored Research and Other Revenue	-	-	-	-	-	-	-	-	-	-
TOTAL REVENUES	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 72.4	\$ 344.1
EXPENSES (GAAP)										
Cost of Goods Sold (COGS)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 7.2	\$ 32.7
R&D Expense	10.6	4.2	4.2	4.2	23.2	17.6	18.4	24.5	28.0	32.0
SG&A Expense	2.7	1.5	1.5	1.5	7.2	6.8	7.6	8.0	20.0	33.0
Other	-	-	-	-	-	-	-	-	-	-
TOTAL EXPENSES	13.3	5.7	5.7	5.7	30.4	24.4	26.0	32.5	55.2	97.7
Operating Income	(13.3)	(5.7)	(5.7)	(5.7)	(30.4)	(24.4)	(26.0)	(32.5)	17.1	246.4
Depreciation and amortization	-	-	-	-	-	-	-	-	-	-
EBIT	(13.3)	(5.7)	(5.7)	(5.7)	(30.4)	(24.4)	(26.0)	(32.5)	17.1	246.4
Interest and other income	0.0	-	-	-	0.0	-	-	-	-	-
Interest and other expense	-	-	-	-	-	-	-	-	-	-
Other Income (Expense)	-	-	-	-	-	-	-	-	-	-
Interest and Other Income (Expense)	0.0	-	-	-	0.0	-	-	-	-	-
Pre-Tax Income	(13.3)	(5.7)	(5.7)	(5.7)	(30.4)	(24.4)	(26.0)	(32.5)	17.1	246.4
Income Taxes	-	-	-	-	-	-	-	-	-	51.7
Net Income (GAAP)	(13.3)	(5.7)	(5.7)	(5.7)	(30.4)	(24.4)	(26.0)	(32.5)	17.1	194.7
EPS (GAAP) (basic)	\$ (0.59)	\$ (0.25)	\$ (0.25)	\$ (0.25)	\$ (1.35)	\$ (0.86)	\$ (0.71)	\$ (0.82)	\$ 0.30	\$ 3.68
EPS (GAAP) (diluted)	\$ (0.59)	\$ (0.25)	\$ (0.25)	\$ (0.25)	\$ (1.35)	\$ (0.86)	\$ (0.71)	\$ (0.82)	\$ 0.30	\$ 3.69
Total of Reconciliation Items	-	-	-	-	-	-	-	-	-	-
Net Income (Non-GAAP)	\$ (13.3)	\$ (5.7)	\$ (5.7)	\$ (5.7)	\$ (30.4)	\$ (24.4)	\$ (26.0)	\$ (32.5)	\$ 17.1	\$ 194.7
Impact of Adjustments to EPS	-	-	-	-	-	-	-	-	-	-
EPS (Non-GAAP) (basic)	\$ (0.59)	\$ (0.25)	\$ (0.25)	\$ (0.25)	\$ (1.35)	\$ (0.86)	\$ (0.71)	\$ (0.82)	\$ 0.30	\$ 3.68
EPS (Non-GAAP) (diluted)	\$ (0.59)	\$ (0.25)	\$ (0.25)	\$ (0.25)	\$ (1.35)	\$ (0.86)	\$ (0.71)	\$ (0.82)	\$ 0.30	\$ 3.69
Weighted average shares outstanding (basic)	22.4	22.4	22.6	22.8	22.6	28.3	36.8	39.8	48.4	52.7
Weighted average shares outstanding (diluted)	22.4	22.4	22.6	22.8	22.6	28.3	36.8	39.7	48.3	52.6

Source: Company reports and BMO Capital Markets

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*	-5.05	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 Q4/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (May 11, 2015): \$10.29
 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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