

Tokai Pharmaceuticals

(TKAI-NASDAQ)

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

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Galeterone on Track for ARMOR3 Initiation

Event

Tokai Pharmaceuticals reported 4Q14 operating results in a news release late last week. Net loss per share was (\$0.28) vs. (\$0.34) consensus, and TKAI ended 2014 with \$105.3 mm in cash, sufficient into 2017. With the primary focus on the company's androgen receptor (AR)-targeting product candidate galeterone, TKAI reported that it remains on track to initiate the phase 3 ARMOR-SV study in patients with castration-resistant prostate cancer (CRPC) with AR splice variants in 1H15, and that the company is completing the development of the AR-V7 clinical trial assay (partnered with Qiagen) and clinical trial center start-up. Top-line data for ARMOR-SV are expected in late 2016.

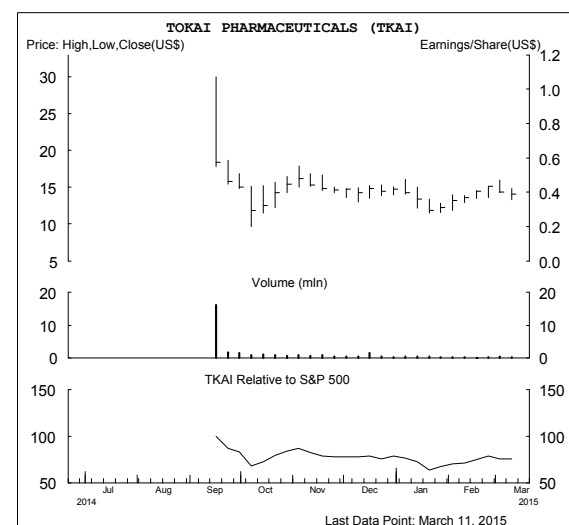
Impact & Analysis

We reiterate our Outperform rating on shares of TKAI following review of 4Q14 operating results. We continue to view lead product galeterone as a highly differentiated, best-in-class androgen blocker in CRPC and expect ARMOR3-PC to establish superiority over XTANDI in patients with splice variant mutations and typically resistant to available therapy. We expect ARMOR2 update to support durable activity in splice variant patients and further de-risk product development.

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 (13-Mar) \$13.69 **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	-\$0.84	-\$0.74
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	-\$23	-\$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	-\$0.21	-\$0.21	-\$0.21	-\$0.21
Dividend	\$0.00			
Book Value	\$0.90			
Shares O/S (mm)	22.3			
Float O/S (mm)	6.5			
Wkly Vol (000s)	1,267			
Net Debt (\$mm)	-\$21			
Yield				0.0%
Price/Book				15.7x
Mkt. Cap (mm)				\$314
Float Cap (mm)				\$92
Wkly \$ Vol (mm)				\$23.6
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: TOKAI PHARMACEUTICALS INC (US\$)
2014E: -\$3.52; 2015E: -\$1.47; 2016E: -\$1.76

Changes

Annual EPS

2016E na to -\$0.74

Quarterly EPS

Q1/15E na to -\$0.21

Q2/15E na to -\$0.21

Q3/15E na to -\$0.21

Q4/15E na to -\$0.21

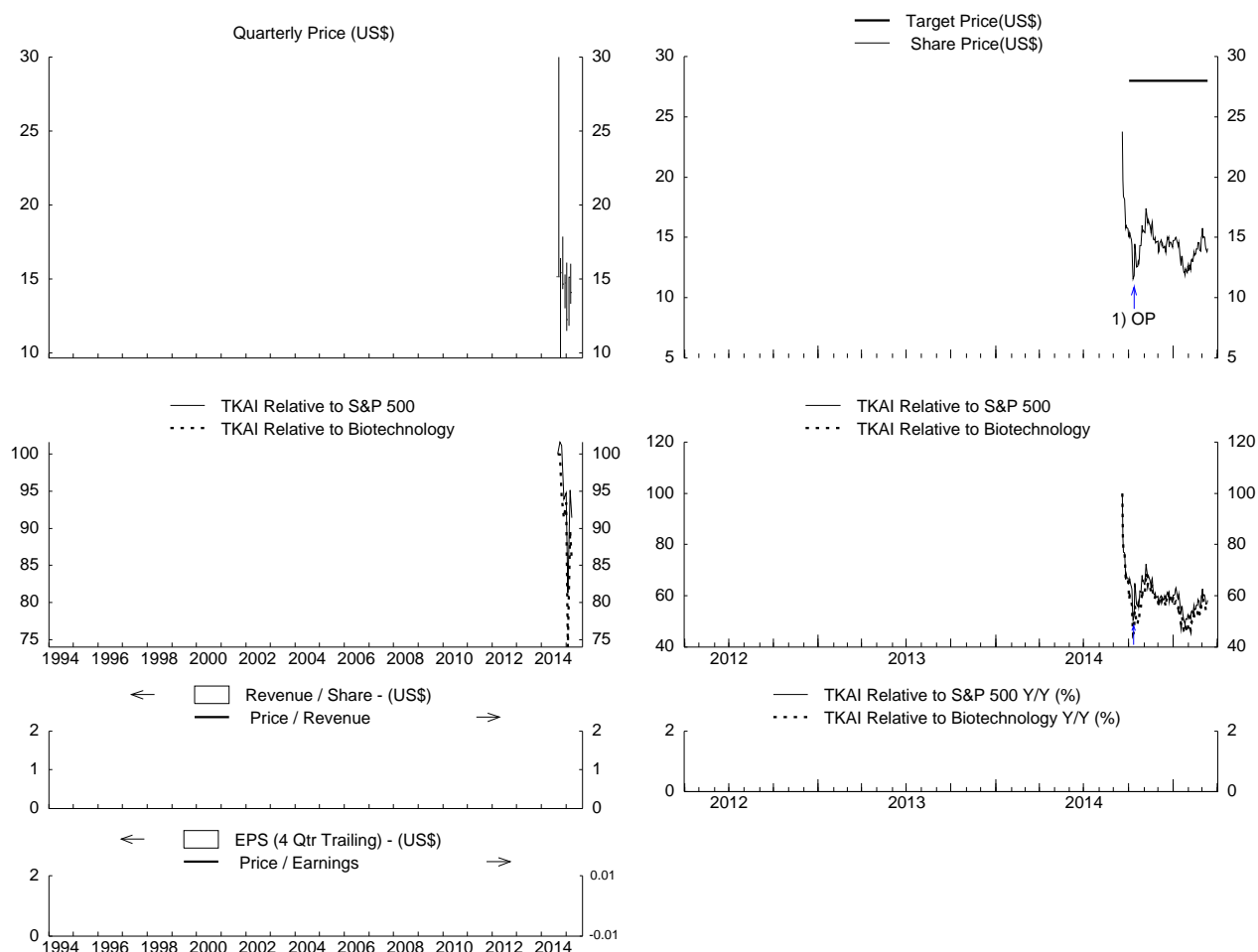
Exhibit 1: TKAI Income Statement 2014A-2020E

INCOME STATEMENT (\$M)	2014A	1Q15E	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)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 32.7
R&D Expense	14.6	4.2	4.2	4.2	4.2	16.8	17.6	18.4	24.5	28.0	32.0
SG&A Expense	8.9	1.5	1.5	1.5	1.5	6.0	6.8	7.6	8.0	20.0	33.0
Other	-	-	-	-	-	-	-	-	-	-	-
TOTAL EXPENSES	23.5	5.7	5.7	5.7	5.7	22.8	24.4	26.0	32.5	55.2	97.7
Operating Income	(22.6)	(5.7)	(5.7)	(5.7)	(5.7)	(22.8)	(24.4)	(26.0)	(32.5)	17.1	246.4
Depreciation and amortization	-	-	-	-	-	-	-	-	-	-	-
EBIT	(22.6)	(5.7)	(5.7)	(5.7)	(5.7)	(22.8)	(24.4)	(26.0)	(32.5)	17.1	246.4
Interest and other income	-	-	-	-	-	-	-	-	-	-	-
Interest and other expense	-	-	-	-	-	-	-	-	-	-	-
Other Income (Expense)	0.2	-	-	-	-	-	-	-	-	-	-
Interest and Other Income (Expense)	0.2	-	-	-	-	-	-	-	-	-	-
Pre-Tax Income	(23.3)	(5.7)	(5.7)	(5.7)	(5.7)	(22.8)	(24.4)	(26.0)	(32.5)	17.1	246.4
Income Taxes	-	-	-	-	-	-	-	-	-	-	-
Net Income (GAAP)	\$ (23.3)	\$ (5.7)	\$ (5.7)	\$ (5.7)	\$ (5.7)	\$ (22.8)	\$ (24.4)	\$ (26.0)	\$ (32.5)	\$ 17.1	\$ 246.4
EPS (GAAP) (basic)	\$ (3.60)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.84)	\$ (0.74)	\$ (0.63)	\$ (0.73)	\$ 0.28	\$ 4.25
EPS (GAAP) (diluted)	\$ (3.60)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.84)	\$ (0.74)	\$ (0.63)	\$ (0.73)	\$ 0.28	\$ 4.25
Total of Reconciliation Items	1.2	-	-	-	-	-	-	-	-	-	-
Net Income (Non-GAAP)	\$ (21.3)	\$ (5.7)	\$ (5.7)	\$ (5.7)	\$ (5.7)	\$ (22.8)	\$ (24.4)	\$ (26.0)	\$ (32.5)	\$ 17.1	\$ 246.4
Impact of Adjustments to EPS	0.50	-	-	-	-	-	-	-	-	-	-
EPS (Non-GAAP) (basic)	\$ (4.51)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.84)	\$ (0.74)	\$ (0.63)	\$ (0.73)	\$ 0.28	\$ 4.25
EPS (Non-GAAP) (diluted)	\$ (4.51)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.21)	\$ (0.84)	\$ (0.74)	\$ (0.63)	\$ (0.73)	\$ 0.28	\$ 4.25
Weighted average shares outstanding (basic)	6.5	27.3	27.3	27.3	27.6	27.5	33.4	42.1	45.2	53.9	58.4
Weighted average shares outstanding (diluted)	6.5	27.3	27.3	27.6	27.9	27.5	33.4	42.1	45.1	53.8	58.3

Source: Company reports and BMO Capital Markets

Companies mentioned (priced as of the close on March 13, 2015):
Qiagen (QGEN, \$24.84, 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 %	TKAI - Rating as of 16-Sep-14 = NR		
Range*:		na na		NC			>15 >15		Date	Rating Change	Share Price
Current*	ND	na	0.00	0.0	na	0.9	16.8	na	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 (March 11, 2015): \$14.09
 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 \$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.

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Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	43.4%	16.2%	60.6%	42.6%	51.7%	55.6%
Hold	Market Perform	52.6%	8.1%	36.6%	53.0%	45.8%	39.5%
Sell	Underperform	3.9%	8.3%	2.8%	4.5%	2.5%	4.9%

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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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