

Tokai Pharmaceuticals, Inc.

Fourth-Quarter Financials Nonevent; Initiation of ARMOR3-SV Next; Maintain Outperform

On Thursday, March 12, before the markets opened, Tokai reported fourth quarter and full year 2014 financial results (exhibit 1). The company ended the fourth quarter with \$105.3 million in cash, which should sustain operations into 2017 through the top-line data release of the Phase III ARMOR3-SV study, according to our model. Net loss for the quarter was \$6.2 million with a per-share loss of \$0.28, versus our estimates of a \$6.9 million net loss and a loss per share of \$0.32. Net loss for the year was \$23.3 million versus our estimate of \$24.0 million and consensus of \$23.6 million.

The next catalyst is the initiation of the Phase III ARMOR3-SV study, on track for first half 2015, with top-line data expected by the end of 2016. Over the past year, an efficient path to potential approval was identified for galeterone; the niche population to conduct ARMOR3-SV in will be the chemo-naïve, metastatic castration-resistant prostate cancer (mCRPC) patients (or M1 patients) who express a splice variant of the androgen receptor (AR), AR-V7. M1 patients expressing AR-V7 are unresponsive to Xtandi (Astellas and Medivation [MDVN \$129.86; Outperform]) or Zytiga (Johnson & Johnson [JNJ \$99.82]). Although galeterone contains similar mechanisms to those of both drugs, it goes one step further with the additional ability to directly degrade the AR, including the AR-V7 variant.

- **The size of the ARMOR3-SV study is now 148 patients, down from 170 previously.** We note that ARMOR3-SV, with 148 patients, is 90% powered to detect 82% improvement in rPFS for galeterone over Xtandi in M1 patients with the AR-V7 variant. If a stratification factor is added to the design, the study size would be 170. As the company and the FDA jointly decided not to add stratification factors, the study size is now set at 148.
- **Final validation of the ARMOR3-SV companion diagnostic to prospectively identify AR-V7 is on track for first half 2015, and the trial will immediately begin enrollment once the assay is in place.** Tokai recently announced that the company had licensed the AR-V7 assay from The Johns Hopkins University (JHU) and also had entered an agreement with Qiagen (QGEN \$24.61; Market Perform) to create and execute a commercial companion diagnostic assay that would be used in ARMOR3-SV for the identification of patients carrying the AR-V7 variant. Qiagen or its affiliates will run the assays at four trial sites for ARMOR3-SV: two in the United States, one in the EU, and one in Australia. Qiagen is streamlining the assay, as the goal is to get the entire process down to a 48- to 72-hour turnaround time.

Tokai Pharmaceuticals, Inc. is a biopharmaceutical company based in Cambridge, Massachusetts, focused on the development of galeterone and an androgen receptor-degradation platform to address prostate cancer and potentially other hormone-driven cancers.

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March 12, 2015

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$44.00

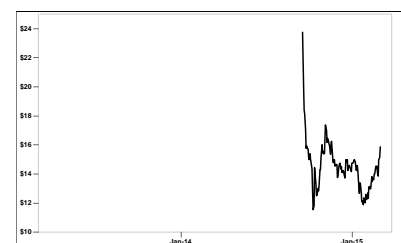
Symbol: TKAI (NASDAQ)
Price: \$14.19 (52-Wk.: \$10-\$30)
Market Value (mil.): \$315
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

		2014A	2015E	2016E
Estimates				
EPS	Q1	\$-0.32	\$-0.30	NA
	Q2	\$-0.38	\$-0.37	NA
	Q3	\$-2.71	\$-0.43	NA
	Q4	\$-0.28	\$-0.50	NA
	FY	\$-3.60	\$-1.61	\$-2.37
	CY		\$-1.61	\$-2.37
Sales (mil.)		0	0	0
Valuation				
FY P/E		NM	NM	NM
CY P/E			NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	2
Float (mil.)	10
Average Daily Volume	101,134

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.7
Return on Equity (TTM)	-79.1

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- **Updates to the Phase II single-arm ARMOR2 study were presented at the EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics in November; these results have helped support the rationale for ARMOR3-SV.** In ARMOR2, galeterone generated a time to PSA progression (TTTP) of 7.3 months in seven M1 AR-V7 patients, versus Xtandi's 1.4 months in 12 patients as reported by Antonarakis et al. (*New England Journal of Medicine* 371:11; 1028-1038; 2014). For rPFS, it is not measured in galeterone-treated patients but was 2.1 months for the 12 Xtandi-treated patients. As TTTP is generally comparable to or shorter than rPFS, it is likely that the rPFS in the seven galeterone-treated patients was longer than 7.3 months. Although the aforementioned data was generated in a very small number of patients, such a sizable differential in rPFS (greater than 7.3 months for galeterone versus 2.1 months for Xtandi) still bodes well for the ARMOR3-SV study, in our opinion. We assign an 85% probability of success to the ARMOR3-SV study.

Key catalysts driving value in the next 12-24 months: 1) Finalization of the companion diagnostic assay for ARMOR3-SV in first half 2015; 2) initiation of the pivotal ARMOR3-SV study in chemo-naïve mCRPC patients with AR-V7 in first half 2015; and 3) top-line data from ARMOR3-SV by the end of 2016.

We maintain our Outperform rating and price target at \$44 (exhibit 2). Our Outperform rating is centered on our belief that Tokai's lead asset, galeterone, will become an essential component of the armamentarium against prostate. We estimate worldwide sales for galeterone will reach \$1.8 billion in the United States and Europe in 2027 in the AR-V7 variant population alone. Assuming an 85% probability of success, our probability-adjusted NPV model suggests a fair value for Tokai shares at \$44 at the end of 2015.

Key risks to our Outperform rating and price target include: 1) clinical risk of the Phase III program; 2) regulatory risk related to receiving approval for galeterone in the United States and Europe; 3) development and approval of the companion diagnostic; 4) reimbursement risk; and 5) financing risk.

Exhibit 1
Tokai Pharmaceuticals
Income Statement
(dollars in thousands)

Tokai Pharmaceuticals	2012	2013	2014					2015	2016
Income Statement			Q1A	Q2A	Q3A	Q4A	FY:14A		
Revenues									
Galeterone	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
License revenue	-	-	-	-	-	-	-	-	-
Collaboration revenue	-	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	-	-	-	-	-	-	-
Expenses									
COGS	-	-	-	-	-	-	-	-	-
R&D expense	7,370	12,201	3,748	4,200	2,825	3,804	14,577	23,985	36,905
SG&A expense	2,279	3,548	1,129	1,700	3,599	2,457	8,885	12,543	17,530
Total Operating Expenses	9,649	15,749	4,877	5,900	6,424	6,261	23,462	36,528	54,435
Operating income	(9,649)	(\$15,749)	(4,877)	(5,900)	(6,424)	(6,261)	(23,462)	(36,528)	(54,435)
Finance income	-	-	-	-	-	-	-	377	208
Finance costs	-	-	-	-	-	-	-	-	-
Other (expense) income, net	24	79	34	53	166	-	-	-	-
Total other Income (expense)	(9,649)	(15,725)	(4,877)	(5,821)	(6,390)	(6,208)	(23,296)	(36,151)	(54,227)
Pretax income/(loss)	(9,649)	(15,725)	(4,877)	(5,821)	(6,390)	(6,208)	(23,296)	(36,151)	(54,227)
Other comprehensive gain/(loss)	-	-	-	-	-	-	-	-	-
Amortization of deemed dividend	-	-	-	-	-	-	-	-	-
Accretion to redemption value of redeemable convertible preferred stock	(34)	(34)	-	-	-	-	-	-	-
Provision for income taxes/(income)	-	-	-	-	-	-	-	-	-
Net Income/(Loss)	(\$9,683)	(\$15,759)	(\$4,877)	(\$5,821)	(\$6,390)	(\$6,208)	(\$23,296)	(\$36,151)	(\$54,227)
Total comprehensive loss	(\$9,683)	(\$15,759)	(\$4,877)	(\$5,821)	(\$6,390)	(\$6,208)	(\$23,296)	(\$36,151)	(\$54,227)
GAAP EPS	(\$2.97)	(\$3.62)	(\$0.94)	(\$1.12)	(\$2.71)	(\$0.28)	(\$3.60)	(\$1.61)	(\$2.37)
Weighted average shares outstanding, diluted	3,261	4,356	5,215	5,215	2,357	22,329	6,469	22,516	22,879

Sources: Tokai Pharmaceuticals and William Blair & Company, L.L.C. estimates

Exhibit 2
Tokai Pharmaceuticals, Inc.
Sum-of-the-Parts Fair Value
(dollars in thousands, except shares)

Drug	Peak Sales	Stage of Development	Estimated Launch Date	Probability of Commercialization	Percentage of Sales to Company	Probability-Adjusted NPV	Value per Share	Percentage of Fair Value
Galeterone	\$ 1,814,414	Pre-Phase III	H1:2018	85%	100% US; 25% ex-US	\$929,987	\$41.10	93.7%
Subtotal						\$929,987	\$41.10	93.7%
Net Cash at year-end 2015						\$70,624	\$3.12	7.1%
Net Present Value of additional Gain (Loss)*						(\$8,000)	(\$0.35)	(0.8%)
Sum-of-Parts Fair Value						\$992,611	\$43.86	100.0%

Sources: William Blair & Company, L.L.C. estimates

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William Blair is a market maker in the security of Tokai Pharmaceuticals, Inc.

William Blair intends to seek investment banking compensation in the next three months from Tokai Pharmaceuticals, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Tokai Pharmaceuticals, Inc.

Additional information is available upon request.

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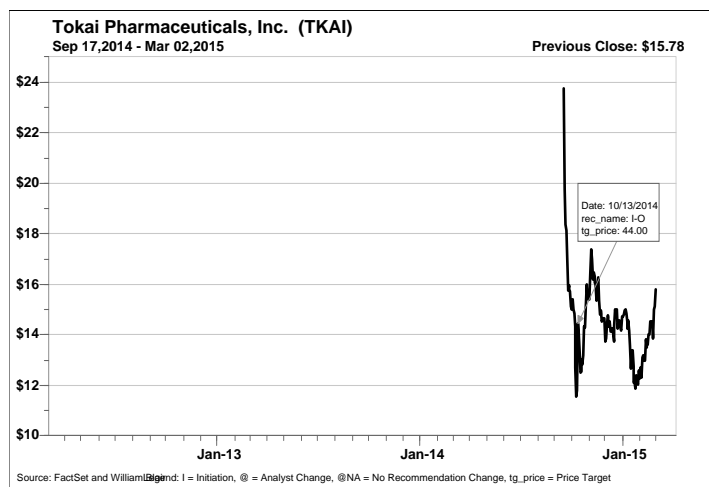
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DOW JONES: 17,635.39

S&P 500: 2,040.24

NASDAQ: 4,849.94



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
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Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

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