William Blair

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Tokai Pharmaceuticals, Inc.

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

On Tuesday, May 12, before the markets opened, Tokai reported first-quarter financial results (exhibit 1). **The company ended the fourth quarter with $94.2 million in cash, which should sustain operations into 2017 and past the date of the top-line data release of the Phase III ARMOR3-SV study near the end of 2016, according to our model.** Net loss for the quarter was $13.2 million, versus our estimate of $6.8 million and consensus of $7.5 million. Loss per share for the quarter was $0.59, versus our estimate of $0.30 and consensus of $0.33. The greater-than-expected loss was due to an increase in research-and-development (R&D) spending of 178% over fourth quarter 2014, which included increased expenses related to manufacturing optimization and validation studies for galeterone and the costs of developing the companion diagnostic, including a one-time payment for the exclusive right to the circulating tumor cells (CTC) enrichment technology to collaborator Qiagen (QGEN $24.47; Market Perform).

The next catalyst is the initiation of the Phase III ARMOR3-SV study, on track to begin this quarter, with top-line data still expected by the end of 2016. Over the past year, an efficient path to potential approval was identified for galeterone; the niche population for the ARMOR3-SV trial 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 $124.24; Outperform]) or Zytiga (Johnson and Johnson [JNJ $100.47]). 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 final protocol design for ARMOR3-SV was presented at the 2015 Genitourinary Cancers Symposium (ASCO-GU) in February.*** ARMOR3-SV is a Phase III, randomized, double-blind, multicenter, active-controlled study of galeterone versus Xtandi in 148 men with chemo-naïve mCRPC. Patients eligible to participate in this study must express the AR-V7 splice variant; an assay to determine the presence of AR-V7 variant is in the final stages of validation and should be available before ARMOR3-SV begins. The primary endpoint is radiographic progression-free survival (rPFS), and secondary endpoints include overall survival, time to cytotoxic therapy, and skeletal-related events. We note that the 148-patient target enrollment ARMOR3-SV is 90% powered to detect 82% improvement in rPFS for galeterone over Xtandi.
- ***Final validation of the ARMOR3-SV companion diagnostic to prospectively identify AR-V7 is on track for second quarter 2015, and the trial will immediately begin enrollment once the assay is in place.*** Tokai licensed the AR-V7 assay from The Johns Hopkins University (JHU) and also had entered into an agreement with Qiagen 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 European Union, and one in Australia. Qiagen is streamlining the assay since 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.

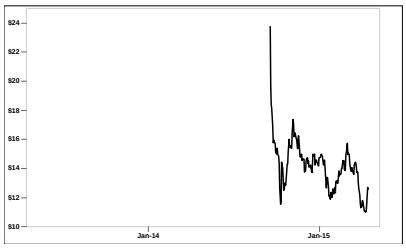
Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$44.00
Symbol:	TKAI (NASDAQ)
Price:	$11.07 (52-Wk.: $10-$30)
Market Value (mil.):	$231
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

		2014A	2015E	2016E
Estimates				
EPS	Q1	$-0.32	A$-0.59	NA
	Q2	$-0.38	$-0.51	NA
	Q3	$-2.71	$-0.52	NA
	Q4	$-0.28	$-0.54	NA
	FY	$-3.60	$-2.16	$-2.30
	CY		$-2.16	$-2.30
Sales (mil.)		0	0	0
Valuation				
FY P/E		NM	NM	NM
CY P/E			NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	22
Float (mil.)	10
Average Daily Volume	63,735

Financial Data (FactSet)	
Book Value Per Share (MRQ)	4.6
Return on Equity (TTM)	-34.9

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

Also in the first quarter, preclinical data from the University of Maryland was presented at the 2015 American Association for Cancer Research (AACR) Annual Meeting (April 18-22, Philadelphia), demonstrating that galeterone and novel androgen receptor degrading agents (ARDA) can inhibit pancreatic cancer cell survival. These studies, performed in vitro, showed that galeterone and related analogs were effective at inhibiting the growth, proliferation, colony formation, migration, and invasion of human pancreatic ductal adenocarcinoma cells. These effects were seen in both gemcitabine-naïve and gemcitabine-resistant cell lines. Together, these results suggest that galeterone and related compounds may have wider applicability beyond prostate cancer and support the strength of Tokai's ARDA discovery platform.

Key Catalysts Driving Value in the Next 12-24 Months: 1) initiation of the pivotal ARMOR3-SV study in chemo-naïve mCRPC patients with AR-V7 in second quarter 2015; and 2) top-line data from ARMOR3-SV by the end of 2016.

We maintain our Outperform rating and reiterate our price target of $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 project that 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 net present value (NPV) model suggests a fair value for Tokai shares of $44 at midyear 2016, with $43 assigned to the value of galeterone in the United States and Europe and roughly $1 of net cash.

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.

Our exhibits are included on the following pages.

Exhibit 1
Tokai Pharmaceuticals
Income Statemement
(dollars in thousands)

Tokai Pharmaceuticals	2012	2013	2014	2015					2016
Income Statement			FY:14A	Q1A	Q2E	Q3E	Q4E	FY:15E	FY:16E
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	14,577	10,559	8,447	8,532	8,702	36,240	35,643
SG&A expense	2,279	3,548	8,885	2,741	3,015	3,317	3,648	12,721	17,144
Total Operating Expenses	9,649	15,749	23,462	13,300	11,462	11,848	12,351	48,961	52,788
Operating income	(9,649)	($15,749)	(23,462)	(13,300)	(11,462)	(11,848)	(12,351)	(48,961)	(52,788)
Finance income		-	-	-	94	83	71	248	161
Finance costs			-	-	-	-	-	-	-
Other (expense) income, net		24	166	40	-	-	-	40	-
Total other Income (expense)	(9,649)	(15,725)	(23,296)	(13,260)	(11,368)	(11,766)	(12,279)	(48,673)	(52,627)
Pretax income/(loss)	(9,649)	(15,725)	(23,296)	(13,260)	(11,368)	(11,766)	(12,279)	(48,673)	(52,627)
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)**	**($23,296)**	**($13,260)**	**($11,368)**	**($11,766)**	**($12,279)**	**($48,673)**	**($52,627)**
Total comprehensive loss	**($9,683)**	**($15,759)**	**($23,296)**	**($13,260)**	**($11,368)**	**($11,766)**	**($12,279)**	**($48,673)**	**($52,627)**
GAAP EPS	**($2.97)**	**($3.62)**	**($3.60)**	**($0.59)**	**($0.51)**	**($0.52)**	**($0.54)**	**($2.16)**	**($2.30)**
Weighted average shares outstanding, diluted	3,261	4,356	6,469	22,384	22,459	22,534	22,609	22,497	22,859

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	$984,638	$43.17	97.4%
Subtotal						**$984,638**	**$43.17**	**97.4%**
Net Cash at mid-year 2016						$34,044	$1.49	3.4%
Net Present Value of additional Gain (Loss)*						($8,000)	($0.35)	(0.8%)
Sum-of-Parts Fair Value						**$1,010,682**	**$44.31**	**100.0%**

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

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William Blair or an affiliate expects to receive or intends to seek compensation for investment banking services from Tokai Pharmaceuticals, Inc. within the next three months.

William Blair or an affiliate received compensation for investment banking services from Tokai Pharmaceuticals, Inc. within the last 12 months. Tokai Pharmaceuticals, Inc. is or was, within the last 12 months, an investment banking client of William Blair & Company and/or one or more of its affiliates.

Additional information is available upon request.

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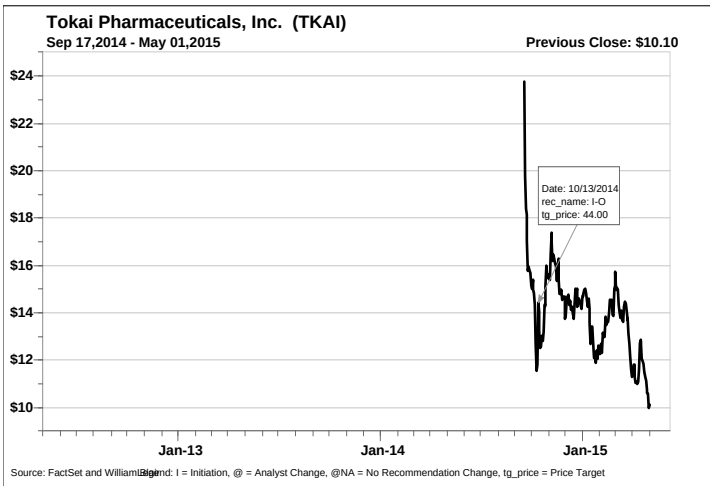
DOW JONES: 18,105.17
S&P 500: 2,105.33
NASDAQ: 4,993.57



Current Rating Distribution (as of 04/30/15)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	14
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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