

June 24, 2015

Tokai Pharmaceuticals, Inc.

Pivotal ARMOR3-SV Study Initiated; Top-Line Data Expected by the End of 2016; Maintain Outperform

On Wednesday, June 24, before the markets opened, Tokai announced the initiation of the ARMOR3-SV pivotal Phase III clinical trial of galeterone in chemo-naïve patients with metastatic castration-resistant prostate cancer (mCRPC) who harbor the AR-V7 androgen receptor splice variant. We note that the initiation occurred in the second quarter, as was guided by management. The multinational Phase III ARMOR3-SV study is registered at 110 clinical sites throughout the United States, Australia, Canada, and Western Europe. More than 15 sites have been opened in the United States, with sites opening in Canada and the United Kingdom in June. Additional sites are due to open in the coming months. Study investigators will begin screening patients for entry in July.

- Design of the ARMOR3-SV trial.** ARMOR3-SV is a Phase III, randomized, double-blind, multicenter, active controlled study of galeterone versus Xtandi in 148 men with chemo-naïve mCRPC (or the M1 setting). Patients eligible to participate in this study must express the AR-V7 splice variant. 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 with the 148 patient target enrollment, ARMOR3-SV is 90% powered to detect 82% improvement in rPFS for galeterone over Xtandi.
- The initiation of ARMOR3-SV marks an important milestone achieved and starts the clock. Management continues to expect top-line data by the end of 2016. Enrollment speed would partly depend on the prevalence of AR-V7 in the M1 population.** In literature the prevalence of the AR-V7 variant ranges from the low teens to over 30%. The company conservatively assumes 10% prevalence and is prepared to screen 1,500 patients for the target enrollment of 148.
- The initiation of ARMOR3-SV was contingent upon the validation and completion of the companion diagnostic to screen patients for the AR-V7 splice variant, which is now deployed globally.** Partner Qiagen (QGEN \$24.75; Market Perform) has finalized the components of the companion diagnostic and is now ready for global deployment. 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.
- We note that there will be a futility analysis in ARMOR3-SV when 50% of events have occurred, which management estimates will happen in the first half of 2016.** The blinded analysis will not include a look at efficacy. The analysis will provide better visibility into enrollment progress and timing of top-line data release, which management estimates to be by the end of 2016.

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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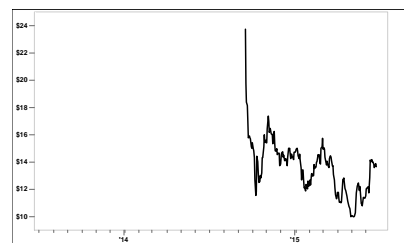
Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$44.00
Symbol: TKAI (NASDAQ)
Price: \$13.82 (52-Wk.: \$10-\$30)
Market Value (mil.): \$311
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2014A	2015E	2016E
Estimates			
EPS 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.)	2
Average Daily Volume	88,288

Financial Data (FactSet)	
Book Value Per Share (MRQ)	4.1
Return on Equity (TTM)	-34.9

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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- **AR-V7 screening could become standard of care, supported by the rising popularity of precision medicine.** If ARMOR3-SV is successful, it is likely that AR-V7 screening becomes standard of care in metastatic patients when selecting treatment options, in our opinion, and the next step would be to push galeterone earlier into the treatment paradigm. Moreover, payers may push testing for AR-V7 as part of standard of care to streamline diagnosis and proper treatment and avoid paying for expensive drugs that may not work.

Key Catalysts Driving Value in the Next 12-24 Months: 1) data presentation at the European Society for Medical Oncology (ESMO) in September 2015; 2) the planned futility analysis in ARMOR3-SV in first half 2016; and 3) top-line data from ARMOR3-SV by the end of 2016.

We maintain our Outperform rating and price target of \$44 (exhibit 1). Our Outperform rating is centered on our belief that Tokai's lead asset, galeterone, will become an essential component of the armamentarium against prostate cancer. We estimate 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 NPV model suggests a fair value for Tokai shares at \$44.

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, 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	98.6%
Subtotal						\$984,638	\$43.17	98.6%
Net Cash at mid-year 2016						\$21,659	\$0.95	2.2%
Net Present Value of additional Gain (Loss)*						(\$8,000)	(\$0.35)	(0.8%)
Sum-of-Parts Fair Value						\$998,297	\$43.77	100.0%

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

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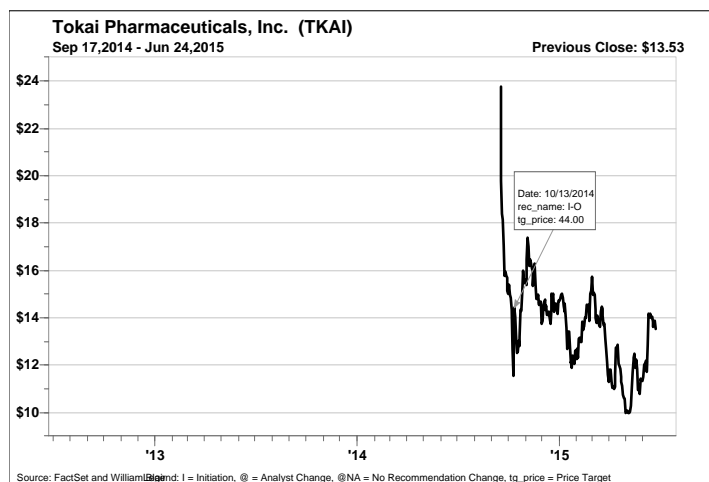
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DOW JONES: 18,144.07

S&P 500: 2,124.20

NASDAQ: 5,160.09



Current Rating Distribution (as of 05/31/15)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	14
Market Perform (Hold)	33	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

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