

Biotechnology

Price:	\$15.13
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$339
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	86,574
Book Value:	\$4.80
Yield:	0.0%
Cash/Share:	\$(3.55)
FCF Yield:	NA
Debt/Cap:	0%

FYE: Dec	2013A	2014E	2015E
EPS:	\$(1.29)A	\$(1.38)E	\$(1.65)E
Prior EPS:		NC	NC
Consensus	NM	NM	-2.99

Quarterly EPS:

Q1	--	--	\$(0.40)E
Q2	--	--	\$(0.41)E
Q3	--	\$(0.39)A	\$(0.42)E
Q4	--	\$(0.31)E	\$(0.43)E

Quarterly Revenue (M):

Q1	\$0A	\$0A	\$0E
Q2	\$0A	\$0A	\$0E
Q3	\$0A	\$0A	\$0E
Q4	\$0A	\$0E	\$0E
Year:	\$0A	\$0E	\$0E



March 2, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

ARMOR3-SV Design Presented AT ASCO GU, Trial Initiation 1H:2015

PORTFOLIO MANAGER BRIEF

At the ASCO GU meeting, Tokai presented a poster that examined the design and rationale for the ARMOR3-SV Phase III clinical trial that will examine galeterone for the treatment of CRPC in patients with the AR-V7 variant. The presentation supports our contention that the Phase III trial is on track to begin in 1H:2015. Some concerns emerged in January after Tokai selected a companion diagnostic for the trial that perhaps the initiation would be delayed. This clearly is not the case. We maintain our Buy rating and \$18 fair value estimate.

ANALYST NOTES

- **ARMOR3-SV Trial Remains On Track.** At the American Society of Oncology Genitourinary Cancers Symposium (ASCO GU), Tokai conducted a continuing medical education (CME) course as well as presented a poster (Abstract 259), that examined the design of the Phase III ARMOR3-SV Phase III clinical trial that examines galeterone for the treatment of advanced castration-resistant prostate cancer (CRPC) patients with the AR-V7 variant. The presentations are notable in that they support the contention we made in our February 2 note that fears of a delay in connection with the January announcement of an agreement with Johns Hopkins for a companion diagnostic for use in the study were unwarranted. In that note, we indicated our believe that the timing of the announcement was in line with our expectation and that Tokai and its partner Qiagen have the trial on track to begin on schedule in 1H:2015.
- **ARMOR3-SV Compares Galeterone to XTANDI in AR-V7 Patients.** The ARMOR3-SV Phase III trial will examine galeterone versus XTANDI (enzalutamide) in the treatment of progressive metastatic (M1) CRPC in patients which have the AR-V7 variant. An estimated 12-30% of overall CRPC patients have C-terminal loss, of which the AR-V7 variant is the most frequent. The study will enroll 148 patients randomized between the two drugs. The primary endpoint--determined in partnership with the FDA--is radiographic progression free survival (rPFS). The allowance of this endpoint by the FDA as opposed to requiring a tougher overall survival (OS) endpoint is a significant benefit. It also indicates the gravity of the problem in treating C-terminal loss patients. Secondary endpoints include OS and time to cytotoxic therapy. Top line data from this trial is expected YE:2016.
- **Johns Hopkins Selected As Partner For Diagnostic.** On January 12, Tokai Pharmaceuticals announced that they entered into an agreement with Johns

Hopkins University regarding the development of a diagnostic that will determine the AR-V7 status of patients with castration-resistant prostate cancer (CRPC). As part of the agreement, Tokai acquired the exclusive worldwide rights to utilize the assay. The companion diagnostic would be used in conjunction with the company's drug candidate galeterone and is a key part of the Phase III ARMOR3-SV trial. The timing of this announcement was in line with our expectation.

- Galeterone Could Have Advantage In C-Terminal Loss Patients. AR-V7 variant patients come from a category of CRPC patients who have C-terminal loss at the end of the ligand binding domain of the androgen receptor (AR). CRPC patients with C-terminal loss are not effectively treated with currently approved therapies, including Zytiga (abiraterone acetate) and Xtandi (enzalutamide). Phase II data from the ARMOR2 trial showed a benefit for the drug in these patients, pointing toward potential for the Phase III ARMOR3-SV trial.

Company Description

Tokai Pharmaceuticals biopharmaceutical company, focuses on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally-driven diseases. Its lead drug candidate includes galeterone, an oral small molecule drug candidate, which is about to enter a Phase III clinical study for the treatment of castration resistant prostate cancer.

IMPORTANT DISCLOSURES

Research Analyst Certification

I, David Lebowitz, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Tokai Pharmaceuticals, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Tokai Pharmaceuticals, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Tokai Pharmaceuticals, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Tokai Pharmaceuticals, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

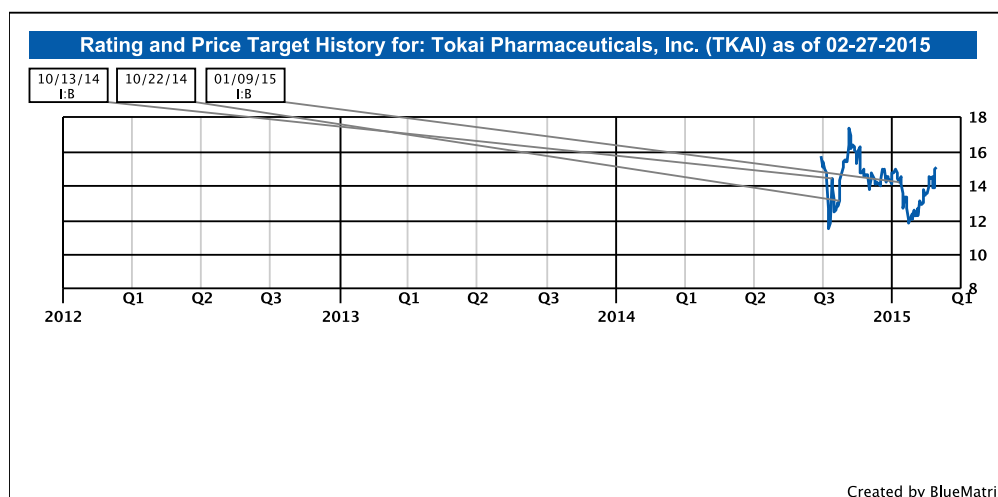
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 12/31/14

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	138	51.30	15	10.87

NEUTRAL [N]	131	48.70	5	3.82
SELL [S]	0	0.00	0	0.00

*Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.

Other Disclosures

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