

Biotechnology

Price:	\$11.37
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$255
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	82,618
Book Value:	\$4.81
Yield:	0.0%
Cash/Share:	\$(3.26)
FCF Yield:	NA
Debt/Cap:	0%

FYE: Dec	2013A	2014A	2015E
EPS:	\$(1.29)A	\$(3.60)A	\$(2.09)E
Prior EPS:			NC
Consensus	NM	NM	-2.00

Quarterly EPS:

Q1	--	--	\$(0.59)A
Q2	--	--	\$(0.49)E
Q3	--	\$(0.39)A	\$(0.50)E
Q4	--	\$(0.28)A	\$(0.51)E

Quarterly Revenue (M):

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



June 1, 2015

Tokai Pharmaceuticals, Inc. (TKAI) - BUY

ARMOR3-SV Phase III for Galeterone in CRPC on Track to Start in Near-Term

PORTFOLIO MANAGER BRIEF

At 2015 ASCO Meeting, Tokai reported details of the Phase III ARMOR3-SV trial investigating galeterone as a treatment for patients with the AR-V7 variant of mCRPC. The Phase III study follows a Phase II trial, which demonstrated that galeterone was more efficacious in CRPC patients with the AR-V7 C-terminal loss variant. In an exclusive partnership with JHU and Qiagen, the company has developed an assay to detect AR-V7 levels in CTCs. Tokai remains on track to initiate the trial before the end of the quarter.

ANALYST NOTES

- Tokai Set to Initiate Phase III Trials for Galeterone in Metastatic Castration Resistant Prostate Cancer (mCRPC) in 2Q:2015. ARMOR3-SV is a Phase III clinical trial comparing galeterone with enzalutamide in patients with AR splice variant-7 (AR-V7) mRNA mCRPC. Set to begin in the coming weeks, the study is expected to enroll 148 mCRPC patients who will be randomized to receive either galeterone (2550 mg/day) or enzalutamide (160 mg/day). The primary endpoint of the trial will be radiographic progression free survival (rPFS). Patients will also be evaluated for overall survival, time to cytotoxic therapy, symptomatic skeletal results, safety, PSA50, time to PSA progression, time to ECOG deterioration, and best overall response by RECIST 1.1.
- Tokai Developing Galeterone for the Treatment of CRPC with C-Terminal Loss. The current leading therapies for CRPC, Zytiga and Xtandi, work by disrupting androgen receptor (AR) signaling pathway either by antagonizing AR (Xtandi) or disrupting the synthesis of androgen (Zytiga). Galeterone is a unique molecule in the colorectal cancer world as it disrupts the pathway by antagonizing AR, disrupting synthesis of androgen and also by contributing to androgen receptor degradation. An estimated 12-30% of CRPC patients have a C-terminal loss in their androgen receptor, of which the AR-V7 is the most frequent and do not respond to Zytiga and Xtandi treatment, leaving these patients with limited treatment options. Tokai is investigating galeterone as a treatment option for CRPC patients with C-terminal deletions including the AR-V7 variant.
- Phase II Data from ARMOR2 Trial Provides Clinical Rationale for Phase III Study. The ARMOR2 Phase II was an open-label, 2-part trial investigating galeterone as a treatment of patients with castration-resistant prostate cancer (CRPC), including those who were abiraterone or enzalutamide refractory. Initial data

analysis showed that the results from the treatment of the broad population were positive, with 77% of pretreated and 70% of treatment naïve CRPC patients achieving PSA50. Retrospective analysis of patients from the trial indicated that treatment of patients with the AR-V7 variant showed maximal PSA50 reductions in six out of seven patients (86%), despite Zytiga and Xtandi being ineffective in this group. Median time to PSA progression in these patients was 7.3 months. These data support the strong potential for galeterone treatment of AR-V7 CRPC patients.

- Partnership with Johns Hopkins and Qiagen to Develop Companion Diagnostic Essential for Phase III Program. Following research from Johns Hopkins University (JHU) indicating that AR-V7 positive patients responded much better to chemotherapy than to hormone treatment, Tokai partnered with JHU to develop a companion diagnostic to determine the AR-V7 status of CRPC patients. This diagnostic is being developed using Qiagen's acquired technology, which uses RT-PCR on CTCs obtained via a blood draw to detect AR-V7 positive patients. Tokai and Qiagen expanded the exclusive agreement for the development and commercialization of an AR-V7 companion diagnostic for use with galeterone, incorporating Qiagen's newly acquired CTC enrichment technology. This agreement brings in a partner with a leading portfolio of liquid biopsy solutions to ensure the time line for the 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.

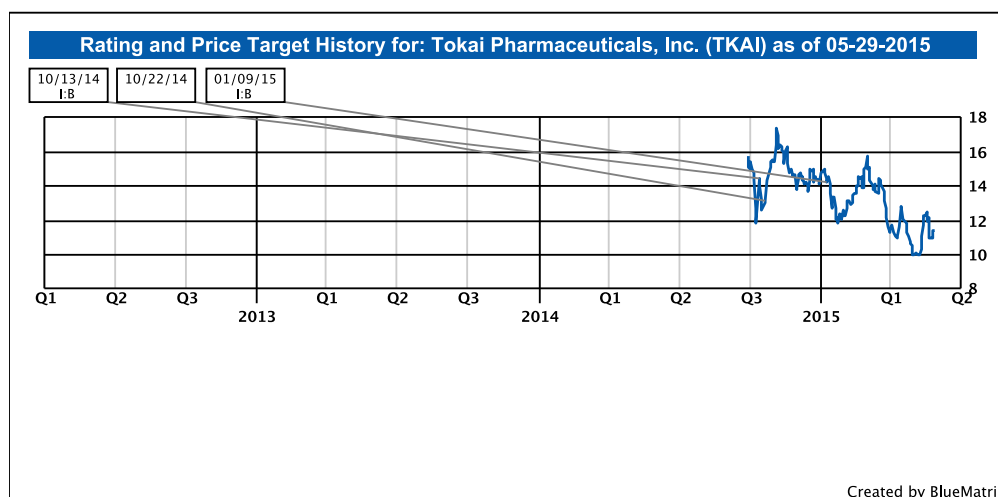
Definition of Ratings

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 3/31/15

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	140	50.36	21	15.00

NEUTRAL [N]	137	49.28	14	10.22
SELL [S]	1	0.36	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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