

Biotechnology

Price:	\$13.61
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$305
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	84,812
Book Value:	\$4.81
Yield:	0.0%
Cash/Share:	\$(3.55)
FCF Yield:	NA
Debt/Cap:	0%

FYE: Dec	2013A	2014A	2015E
EPS:	\$(1.29)A	\$(3.60)A	\$(1.65)E
Prior EPS:			NC
Consensus	NM	NM	-1.40

Quarterly EPS:

Q1	 	\$(0.40)E
Q2	 	\$(0.41)E
Q3	 \$(0.39)A	\$(0.42)E
Q4	 \$(0.28)A	\$(0.43)E

Quarterly Revenue (M):

01	\$0A	\$0A	\$0E
Q2	\$0A	\$0A	\$0E
Q3	\$0A	\$0A	\$0E
Q4	\$0A	\$0A	\$0E
Year:	\$0A	\$0A	\$0E



March 17, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

Tokai Licenses Exclusive Rights for Diagnostic; Phase III On Track For 1H:2015

PORTFOLIO MANAGER BRIEF

Tokai and Qiagen announced an expansion of the agreement for the development of the companion diagnostic for detecting castration-resistant prostate cancer with AR-V7 variant to be used with galeterone. This expansion gives Tokai the exclusive right to incorporate its newly acquired circulating tumor cell (CTC) enrichment technology for the development of the diagnostic . The Phase III ARMOR3-SV trial in this population is on track for 1H: 2015. We maintain our BUY rating an \$18 fair value estimate.

ANALYST NOTES

- Galeterone Could Have Advantage In C-Terminal Loss Patients. Tokai
 Pharmaceuticals is developing galeterone as a treatment for patients with
 castration-resistant prostate cancer with a C-terminal loss, particularly the AR V7 variant. 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.
- Johns Hopkins Partners Exclusively with Tokai For AR-V7 Diagnostic. Research
 from Johns Hopkins indicated that AR-V7 positive patients responded much
 better to chemotherapy than to hormone treatment, suggesting that expression
 of AR-V7 in CTCs may be a potential marker for guiding therapy choice in
 metastatic CRPC. In order to target these patients, it is important to be able
 to detect patients with the AR-V7 variant. To this effect, Tokai entered into an
 agreement with Johns Hopkins University to develop a companion diagnostic
 that will determine the AR-V7 status of the patients with CRPC.
- Companion Diagnostic utilizes Qiagen's CTC Enrichment Technology. The
 companion diagnostic assay for use with galeterone was developed by Johns
 Hopkins University using Qiagen's newly acquired technology, which enables use
 of non-invasive blood tests to analyze circulating tumor cells (CTC). The assay
 utilizes a blood draw followed by CTC isolation and RT-PCR AR-V7 determination
 to detect AR-V7 positive patients. While the assay was exclusively licensed
 to Tokai in January 2015, Tokai and Qiagen expanded the agreement for the
 development and commercialization of an AR-V7 companion diagnostic for

- use with galeterone, incorporating Qiagen's newly acquired CTC enrichment technology.
- <u>Diagnostic Essential Component of Phase III Program.</u> The ARMOR3-SV Phase III clinical trial is being designed to investigate galeterone in C-terminal loss CRPC patients, particularly AR-V7 patients and would benefit immensely from the companion diagnostic assay. The expanded agreement between Qiagen and Tokai give exclusive rights to Tokai for use of the AR-V7 diagnostic, team Tokai with a partner with a leading portfolio of liquid biopsy solutions to help commercialize and ensure the time line for the trial which is set to being in 1H: 2015.
- <u>Tokai is developing its lead asset</u>, <u>galeterone</u>, for the treatment of prostate cancers that target C-terminal loss splice variants, which can cause resistance to other marketed therapies. We view <u>galeterone</u> as a first-in-class and best-in-class, Phase III-ready therapy that can offer the potential for improved efficacy and safety over currently marketed products, ease of use, broad utility, and importantly, potential for lower risk of resistance

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.

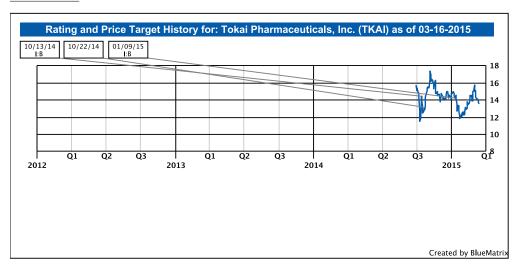
<u>Definition of Ratings</u>

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

		_	ID Selv./Fast 12 Wos.		
Rating	Count	Percent	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

Janney Montgomery Scott LLC, is a U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the New York Stock Exchange, the Financial Industry Regulatory Authority and the Securities Investor Protection Corp.

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