

Biotechnology

Price:	\$14.09
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$316
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	87,445
Book Value:	\$4.81
Yield:	0.0%
Cash/Share:	\$4.70
FCF Yield:	NA
Debt/Cap:	0%

FYE: Dec	2013A	2014A	2015E
EPS:	\$(1.29)A	\$(3.60)A	\$(1.65)E
Prior EPS:		\$(1.38)	NC
Consensus	NM	NM	-2.99

Quarterly EPS:

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

Quarterly Revenue (M):

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



March 12, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

Galeterone Phase III Trial On Track for 1H:2015 Start

PORTFOLIO MANAGER BRIEF

Tokai is developing galeterone for the treatment of CRPC patients with AR-V7 variant. Over the past year, Tokai presented strong data from the ARMOR2 trial in CRPC patients. The company is on track to initiate the ARMOR3-SV Phase III trial in CRPC patients with the AR-V7 variant in 1H:2015. As of YE:2014, Tokai has \$105 million in cash, enough to fund the company through data by YE:2016 and into 2017. We reiterate our BUY rating with \$18 fair value.

ANALYST NOTES

- **ARMOR3-SV Trial Remains on Track.** Tokai and partner Qiagen are on track to initiate the Phase III ARMOR3-SV clinical trial to evaluate galeterone versus XTANDI (enzalutamide) in the treatment of progressive metastatic (M1) CRPC in patients with the ARV7 variant. 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. The trial is on track to begin on schedule in 1H:2015 and top line data from this trial is expected YE:2016.
- **Encouraging Interim Results from Ongoing ARMOR2 Trial.** The ARMOR2 Phase II trial investigates galeterone for treatment of castration-resistant prostate cancer (CRPC), with special focus on the AR-V7 variant. At the AACR Symposium on Molecular Targets and Cancer Therapeutics in November 2014, Tokai presented updated interim results from ARMOR2 Phase II trial. While the results from the treatment of the broad population were positive, with 77% of pretreated and 70% of treatment naïve CRPC patients achieving PSA50, treatment of patients with the AR-V7 variant showed maximal PSA50 reductions in six out of seven patients, 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.
- **Johns Hopkins Selected As Partner For Diagnostic.** Early in 2015, Tokai 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 CRPC for the ARMOR3-SV trial. As part of the agreement, Tokai acquired the exclusive worldwide rights to utilize the assay.

March 12, 2015

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PROFIT & LOSS STATEMENT (in thousands, except share data)

	<u>1H:14A</u>	<u>3Q:14A</u>	<u>4Q:14A</u>	<u>2014A</u>	<u>1Q:15E</u>	<u>2Q:15E</u>	<u>3Q:15E</u>	<u>4Q:15E</u>	<u>2015E</u>	<u>2016E</u>	<u>2017E</u>
Total Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
% Annual Growth											
Research & Development	7,948	2,825	3,804	14,577	5,500	5,750	6,000	6,250	23,500	26,000	26,000
% of Revenue											
% Annual Growth							112.4%	64.3%	61.2%	10.6%	0.0%
Selling, General & Administrative	2,829	3,599	2,457	8,885	3,500	3,500	3,500	3,500	14,000	14,000	15,000
% of Revenue											
% Annual Growth							-2.8%	42.5%	57.6%	0.0%	7.1%
Other	0	0	0	0	0	0	0	0	0	0	0
Operating Expenses	10,777	6,424	6,261	23,462	9,000	9,250	9,500	9,750	37,500	40,000	41,000
Operating Profit	(\$10,777)	(\$6,424)	(\$6,261)	(\$23,462)	(\$9,000)	(\$9,250)	(\$9,500)	(\$9,750)	(\$37,500)	(\$40,000)	(\$41,000)
Other Income (Expense)	79	34	53	166	30	30	30	30	120	120	120
Net Income	(\$10,698)	(\$6,390)	(\$6,208)	(\$23,296)	(\$8,970)	(\$9,220)	(\$9,470)	(\$9,720)	(\$37,380)	(\$39,880)	(\$40,880)
Earnings Per Share (Basic)	(\$0.70)	(\$0.39)	(\$0.28)	(\$3.60)	(\$0.40)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.65)	(\$1.72)	(\$1.75)
Earnings Per Share (Fully Diluted)	(\$0.70)	(\$0.39)	(\$0.28)	(\$3.60)	(\$0.40)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.65)	(\$1.72)	(\$1.75)
Shares Outstanding (Basic)	15,358	16,531	22,400	6,469	22,512	22,625	22,738	22,851	22,681	23,138	23,370
Shares Outstanding (Fully Diluted)	15,358	16,531	22,400	6,469	22,512	22,625	22,738	22,851	22,681	23,138	23,370

Source: Janney Montgomery Scott, Company Reports

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.

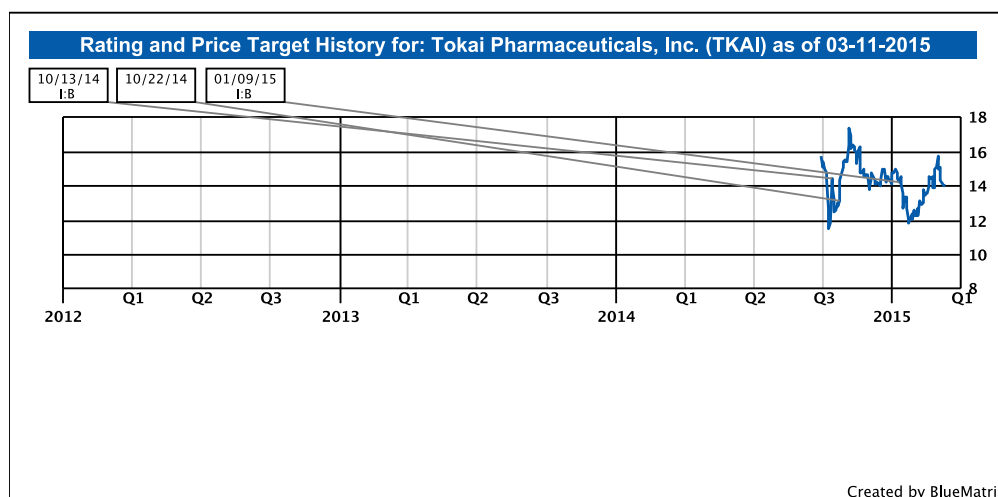
Definition of Ratings

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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