

Biotechnology

Price:	\$11.07
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$248
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	58,177
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:			\$(1.65)
Consensus	NM	NM	-1.70

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



May 13, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

ARMOR3-SV Trial Start Imminent

PORTFOLIO MANAGER BRIEF

Tokai is set to begin the Phase III ARMOR3-SV trial evaluating galeterone patients with castration resistant prostate cancer (CRPC) who have the AR-V7 mutation before the end of the quarter. Over the past year, Tokai presented strong data from the ARMOR2 trial in CRPC patients. As of 1Q:2015, Tokai has \$94.1 million in cash, enough to fund the company through data by YE:2016. We reiterate our BUY rating with \$18 fair value.

ANALYST NOTES

- Tokai Reports 1Q:2015, Strong Balance Sheet to Support Phase III Trial. Tokai reported 1Q:2015 earnings of (0.59). The company is beginning to ramp expenses for the anticipated Phase III ARMOR3-SV trial examining galeterone versus Xtandi in patients with C-terminal loss. R&D took a step up in the quarter in part due to one-time fees relating to the diagnostic as well as preparations for the study. At the end of the quarter, Tokai has \$94.1 million on the books. This should be enough to fund operations through data by YE:2016.
- Tokai Phase III Galeterone CRPC Trial to Initiate 2Q:2015. Phase II data from the ARMOR2 trial showed that galeterone was efficacious in the treatment of a subgroup of CRPC patients characterized by the AR-V7 variant of the C-terminal loss. These patients are not effectively treated with currently approved therapies including Zytiga and Xtandi. Following the ARMOR2 trial, Tokai designed Phase III ARMOR3-SV trial to investigate galeterone versus Xtandi (enzalutamide) in 148 treatment naive CRPV patients with the AR-V7 variant. The primary endpoint of the trial--which was determined in collaboration with the FDA--is radiographic progression free survival (rPFS). This offers the company a lower hurdle for success than if an Overall Survival (OS) benefit had been required as the primary endpoint. Secondary endpoints include OS and time to cytotoxic therapy.
- 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.

- Galeterone and Novel Analogs Demonstrate Anti-proliferative Activity in Human Pancreatic Adenocarcinoma Cells. In April 2015, Tokai presented pre-clinical data from the laboratory of Vincent Njar at UMD School of Medicine at AACR in Philadelphia. The pre-clinical study showed that Tokai's lead drug candidate galeterone and its novel analogs (androgen receptor degrading agents, ARDAs) showed anti-proliferative activity in human pancreatic adenocarcinoma (PDAC) cells. The drugs were evaluated for said activity in both gemcitabine-naïve and gemcitabine-resistant cell lines. Galeterone and its analogs not only demonstrated anti-proliferative activity in these cell lines but also showed synergistic activity with gemcitabine (gem), the standard therapy for pancreatic cancer.

May 13, 2015

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

	<u>1Q:14A</u>	<u>2Q:14A</u>	<u>3Q:14A</u>	<u>4Q:14A</u>	<u>2014A</u>	<u>1Q:15A</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	\$0
Research & Development % Annual Growth	7,948	7,948	2,825	3,804	22,525	10,559 32.9%	8,000 0.7%	8,000 183.2%	8,000 110.3%	34,559 53.4%	32,000 -7.4%	32,000 0.0%
Selling, General & Administrative % Annual Growth	2,829	2,829	3,599	2,457	11,714	2,741 -3.1%	3,000 6.0%	3,250 -9.7%	3,500 42.5%	12,491 6.6%	14,000 12.1%	15,000 7.1%
Other	0	0	0	0	0	0	0	0	0	0	0	0
Operating Expenses	10,777	10,777	6,424	6,261	34,239	13,300	11,000	11,250	11,500	47,050	46,000	47,000
Operating Profit	(\$10,777)	(\$10,777)	(\$6,424)	(\$6,261)	(\$34,239)	(\$13,300)	(\$11,000)	(\$11,250)	(\$11,500)	(\$47,050)	(\$46,000)	(\$47,000)
Other Income (Expense)	79	79	34	53	245	40	30	30	30	130	120	120
Net Income	(\$10,698)	(\$10,698)	(\$6,390)	(\$6,208)	(\$33,994)	(\$13,260)	(\$10,970)	(\$11,220)	(\$11,470)	(\$46,920)	(\$45,880)	(\$46,880)
Earnings Per Share (Basic)	(\$0.70)	(\$0.70)	(\$0.39)	(\$0.28)	(\$5.25)	(\$0.59)	(\$0.49)	(\$0.50)	(\$0.51)	(\$2.09)	(\$2.02)	(\$2.05)
Earnings Per Share (Fully Diluted)	(\$0.70)	(\$0.70)	(\$0.39)	(\$0.28)	(\$5.25)	(\$0.59)	(\$0.49)	(\$0.50)	(\$0.51)	(\$2.09)	(\$2.02)	(\$2.05)
Shares Outstanding (Basic)	15,358	15,358	16,531	22,400	6,469	22,384	22,440	22,496	22,553	22,468	22,694	22,921
Shares Outstanding (Fully Diluted)	15,358	15,358	16,531	22,400	6,469	22,384	22,440	22,496	22,553	22,468	22,694	22,921

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.

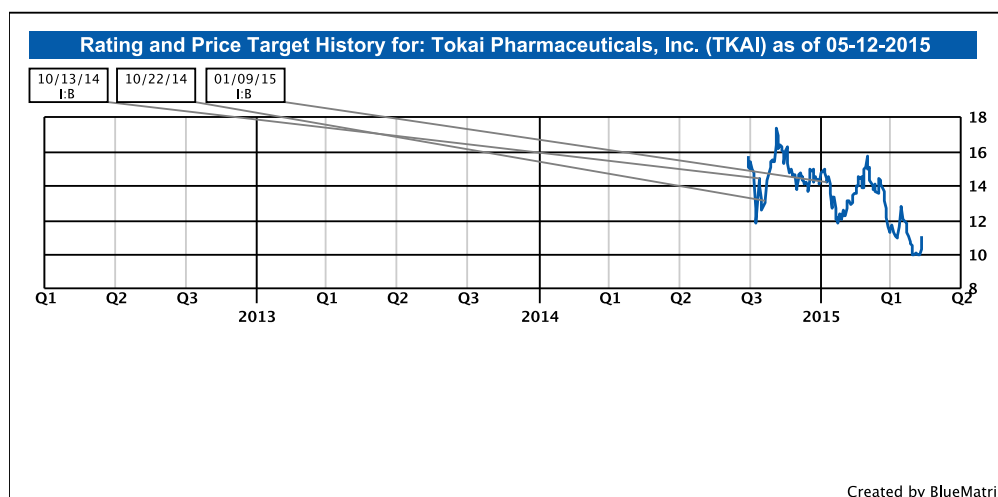
Definition of Ratings

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 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

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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