

Biotechnology

Price:	\$14.49
Fair Value Estimate:	\$18.00
52-Week Range:	\$9.67 - \$30.00
Market Cap (MM):	\$324
Shr.O/S-Diluted (mm):	22.4
Average Daily Volume:	147,714
Book Value:	\$4.80
Yield:	0.0%
Cash/Share:	\$(3.55)
FCF Yield:	NA
Debt/Cap:	0%

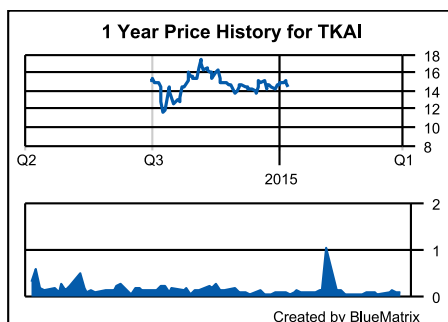
FYE: Dec	2013A	2014E	2015E
EPS:	\$(1.29)A	\$(1.38)E	\$(1.65)E
Prior EPS:		\$(1.20)	\$(1.25)
Consensus	NM	NM	-3.52

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



January 9, 2015

Tokai Pharmaceuticals, Inc.

(TKAI) - BUY

Resume Coverage With Buy, \$18 Fair Value

PORTFOLIO MANAGER BRIEF

We are resuming coverage of Tokai Pharmaceuticals with a Buy rating and YE:2015 fair value of \$18 per share. Tokai is focusing its energies on developing galeterone for the precision treatment of patients with castration resistant prostate cancer (CRPC) that have a specifically altered androgen receptor. Recently, Tokai presented interim data from the galeterone ARMOR2 Phase II trial in CRPC patients that illustrated the strong potential of the company's approach.

ANALYST NOTES

- Galeterone Targets Sizable C-Terminal Loss CRPC Population.** CRPC is a large market with 233,000 patients in the U.S. We estimate that 30,000-plus of these patients have C-terminal loss and no treatment options. Given galeterone's potential in these patients, we estimate that peak worldwide sales for galeterone could exceed \$1.0 billion. Though galeterone could become a blockbuster drug based upon C-terminal loss labeling alone, Tokai is looking at galeterone broader prostate cancer populations.
- Radiographic Progression Free Survival (rPFS) endpoint should benefit.** Since the company is focusing on poorly treated C-terminal loss patients, the FDA has allowed Tokai to utilize radiographic progression free survival (rPFS) as primary endpoint in the pivotal ARMOR3-SV Phase III clinical trial. This gives the company an easier hurdle to obtain approval than an overall survival (OS) endpoint. The trial begins 1H:2015, with top line data late in 2016.
- Recent Incremental Positive Data Seeds Optimism.** Recent positive interim data from the ARMOR2 Phase II clinical trial examining galeterone in castration resistant prostate cancer (CRPC) detail galeterone's potential for patients with C-terminal loss, in particular AR-V7 splice variants. In Part 2 of the trial, 6 of 7 patients identified with C-terminal loss showed maximal reductions of PSA levels of at least 50%.
- Valuation.** We are establishing a year-end 2015 FV of \$18 per share. We come to this FV applying a P/E ratio of 20.0x to our non-GAAP 2019E EPS estimate of \$3.03 and discount back to the end of 2015 by 35%.

GALETERONE OFFERS HOPE FOR HARD TO TREAT CRPC

We are resuming coverage of Tokai Pharmaceuticals with a Buy rating and YE:2015 fair value (FV) of \$18 per share. Tokai is a development stage biopharmaceutical company focused on developing and commercializing unique and proprietary therapies. The company is focusing its energies on developing galeterone for the treatment of prostate cancer and other androgen-driven diseases. Galeterone is a highly selective, multi-targeted, oral small molecule drug candidate that disrupts the androgen receptor pathway. Currently, TKAI is developing galeterone for the precision treatment of patients with castration resistant prostate cancer (CRPC) that have a specifically altered androgen receptor. Recently, Tokai presented interim data from the galeterone ARMOR2 Phase II trial in CRPC patients. The data supports the strong potential for patients with C-terminal loss, in particular those with the AR-V7 variant.

- **Significant global market opportunity in lead indications.** CRPC is a large market with 233,000 patients in the U.S. We estimate peak worldwide sales for galeterone could exceed \$1.0 billion, despite conservatively assuming use in only ARV7 splice variants. Though, galeterone could become a blockbuster drug based upon C-terminal loss labeling alone, Tokai is looking at galeterone broader prostate cancer populations.
- **Radiographic Progression Free Survival (rPFS) endpoint should benefit.** Since the company is focusing on poorly treated C-terminal loss patients, the FDA has allowed Tokai to utilize radiographic progression free survival (rPFS) as primary endpoint in the pivotal ARMOR3-SV Phase III clinical trial. This gives the company an easier hurdle to obtain approval than an overall survival (OS) endpoint. The trial begins 1H:2015, with top line data late in 2016.
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Valuation. We are initiating coverage on Vertex with a Neutral rating and a year-end 2015 FV of \$18 per share. We establish this FV applying a P/E ratio of 20.0x to our 2019E EPS estimate of \$3.03 and discount back to the end of 2015 by 35%. This target price establishes 26% upside from current levels. Additionally for a company with a mid-to-late stage cancer therapeutic, Tokai appears undervalued on an enterprise value basis (Figure 1).

Figure 1. Tokai Comps

Company	Ticker	Price 01/08/15	Shares Out	Mkt Cap (000,000s)	Enterprise Value (000,000s)
OncoMed Pharmaceuticals, Inc.	OMED	25.75	29.8	768.2	520.3
Array BioPharma Inc.	ARRY	4.73	132.0	624.2	618.7
Progenics Pharmaceuticals, Inc.	PGNX	7.18	69.6	499.4	412.0
Geron Corporation	GERN	3.21	157.2	504.6	378.0
Spectrum Pharmaceuticals, Inc.	SPPI	7.10	65.8	466.9	414.4
Exelixis, Inc.	EXEL	1.79	195.2	349.4	403.2
Endocyte, Inc.	ECYT	6.07	41.7	253.2	124.6
Mean					
Median					
Tokai Pharmaceuticals, Inc.	TKAI	14.49	22.4	324.3	218.9

Source: Janney Montgomery Scott

As a validation of our relative value based FV, we conducted a discounted cash flow analysis (DCF). In the analysis, we forecast free cash flow to the firm through 2025, adding 2026 as the terminal growth year. Then we discounted this to the end of 2015 by 25% annually. The DCF brings us to an equity value of \$431 million. Applying our end of 2015 share count estimate of 22.7 million, we come to a YE:2015 price of \$19 per share (Figure 2).

Figure 2. Vertex DCF Sensitivity Analysis

Discounted Cash Flow Sensitivity Analysis						
Value of Equity						
WACC		Terminal Growth				
		4.0%	4.5%	5.0%	5.5%	6.0%
	15.0%	1,429,907	1,479,456	1,533,959	1,594,199	1,661,132
	20.0%	735,408	750,486	766,568	783,760	802,179
	25.0%	418,868	424,642	430,706	437,080	443,789
	30.0%	249,702	252,235	254,869	257,611	260,467
	35.0%	150,090	151,308	152,566	153,867	155,213
Price Per Share						
WACC		Terminal Growth				
		4.0%	4.5%	5.0%	5.5%	6.0%
	15.0%	\$63.04	\$65.23	\$67.63	\$70.29	\$73.24
	20.0%	\$32.42	\$33.09	\$33.80	\$34.56	\$35.37
	25.0%	\$18.47	\$18.72	\$18.99	\$19.27	\$19.57
	30.0%	\$11.01	\$11.12	\$11.24	\$11.36	\$11.48
	35.0%	\$6.62	\$6.67	\$6.73	\$6.78	\$6.84

Source: Janney Montgomery Scott

Investment Risks. Downside risks to our fair value include risks that are typical of development stage biotechnology companies. This includes the potential for weak data from the galeterone clinical program, as well as any delays or unexpected challenges in the regulatory/clinical process. The potential for any unforeseen litigation—such as intellectual property (IP) challenges. The inability to obtain the necessary financing required to fund operations including the future development of galeterone. The inability to find an adequate partner(s) that might be necessary for the future development and commercialization of galeterone.

GALETERONE: A MULTI-FACTORIAL APPROACH TO CRPC

Galeterone is a unique molecule in the colorectal cancer world. Unlike market leading therapies abiraterone acetate or Zytiga (Janssen) and enzalutamide or Xtandi (Astellas & Medivation), which both utilize one primary mechanism to combat the disease, galeterone utilizes three separate mechanisms. Treatment of this disease focuses on disrupting the androgen receptor signaling pathway. Galeterone seeks to disrupt the synthesis of androgen by inhibiting CYP17 like Zytiga. It also an androgen receptor antagonist like Xtandi. Lastly, the drug is unique in that it contributes to androgen receptor degradation. Furthermore, the Phase II ARMOR2 study shows galeterone to have activity in treating patients with C-terminal loss, particularly the AR-V7 splice variant. Neither Zytiga nor Xtandi can be effectively used in these patients giving these patients limited treatment options.

Castration Resistant Prostate Cancer: A Primer

Prostate Cancer is the most commonly diagnosed solid tumor malignancy in the US and is the second leading cause of cancer death in American men. The American Cancer Society estimates that there will be approximately 233,000 new cases diagnosed each year, resulting in 29,000 patient deaths.

The growth and survival of prostate cancer tumor cells depends primarily on the functioning androgen receptor signaling pathway. Androgens are the male sexual hormones including testosterone, 5-alpha-dihydrotestosterone (DHT), androstenediol, androsterone, as well as others. In a patient with this disease, androgens have a detrimental impact in that they encourage tumor growth. Treatment of these patients targets this pathway as the primary approach to disrupt and hopefully eliminate the tumor.

The first line treatment for these patients focuses on reducing the production of testosterone. This utilizes medical castration (not surgical castration). Approaches to medical castration include the use of estrogen, luteinizing hormone-releasing hormone (LHRH) agonists, LHRH antagonist and anti-androgens, among other approaches. For many patients, medical castration provides benefit. However, almost all patients treated will eventually become castration resistant and begin to see disease progression.

After patients become castration resistant, they progress to second line therapy, which includes FDA approved drugs such as market leaders Zytiga & Xtandi.

Zytiga. The drug—which is marketed by Janssen—is used in combination with prednisone to treat metastatic CRPC patients. The drug’s mechanism disrupts the androgen receptor signaling pathway by inhibiting the enzyme CYP17. Suppressing the production of CYP17 disrupts the overall pathway and leads to reduced testosterone. Zytiga is the leading drug for the treatment of CRPC and it achieved \$1.7 billion in sales in 2013.

Xtandi. This drug—which was developed by Medivation—also disrupts the androgen receptor signaling pathway. Xtandi is a receptor antagonist that functions by blocking the ability for testosterone to bind to the androgen receptor rather than to reduce the levels of the hormone itself. Xtandi is the second leading drug for the treatment of CRPC, reaching \$445 million of sales in 2013

Galeterone Uses a Three Pronged Mechanism

Both Zytiga and Xtandi use a single mechanism to fight the disease. While this allows them to be effective treatments in the 2nd line population, they are not effective in patients with C-terminal loss. Galeterone combines a testosterone suppressing mechanism similar to Zytiga and with a receptor antagonist mechanism similar to Xtandi and adds on a unique receptor degradation mechanism that could allow the drug to be a highly effective therapy. Perhaps more important, however, is that the drug has demonstrated the potential for being effective in the 12%-30% of patients with C-terminal loss. In addition, galeterone appears to have an improved safety profile versus the

ARMOR2 Trial. The ARMOR2 trial was initiated in December 2012 as an open label Phase II study. It was a two part study, with Part 1 establishing dose in 25 patients and

Part 2 (currently ongoing) designed to examine the safety and efficacy of the 2,550 mg/day dose of the drug in 108 patients coming from one of the following groups: non metastatic-CRPC treatment-naïve patients, metastatic CRPC treatment-naïve patients, Zytiga-refractory patients and Xtandi-refractory patients.

Tokai recently updated the interim galeterone data from this ongoing trial at the EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in an oral presentation in November. The interim data includes data from 107 evaluable patients who were treated with the 2,550 mg/day dose. At this announcement, 85% of patients achieved a maximal reduction of PSA levels of at least 30% (PSA30) and 77% achieved a maximal reduction of 50% (PSA50). In a 60 patient sub-segment that included 60 patients with either non-metastatic or metastatic treatment naïve CRPC patients, 83% achieved PSA30 and 70% PSA50.

Despite the quality of the data from the broad treatment population in the trial, it is patients with the splice receptor variant AR-V7 that was most intriguing. Zytiga and Xtandi are not effective in these patients; however, in seven treatment-naïve CRPC patients with C-terminal loss six had maximal PSA reductions of 50%. The one patient that failed to show a reduction had to discontinue treatment early due to an adverse event considered unrelated to galeterone. Median time to PSA progression in these patients according to the Prostate Cancer Working Group 2 (PCWGR) criteria was 7.3 months.

ARMOR3-SV. Based on this data, the company will initiate the ARMOR3-SV Phase III open label trial in AR-V7 positive patients. These patients will be randomized to take either galeterone or Xtandi. The trial will be powered to detect an 82% increase in median radiographic progression-free survival (rPFS) in 170 patients treated previously with Zytiga, Xtandi or other anti-androgen therapies. The secondary endpoints will be overall survival, skeletal-related events and time to cytotoxic therapy.

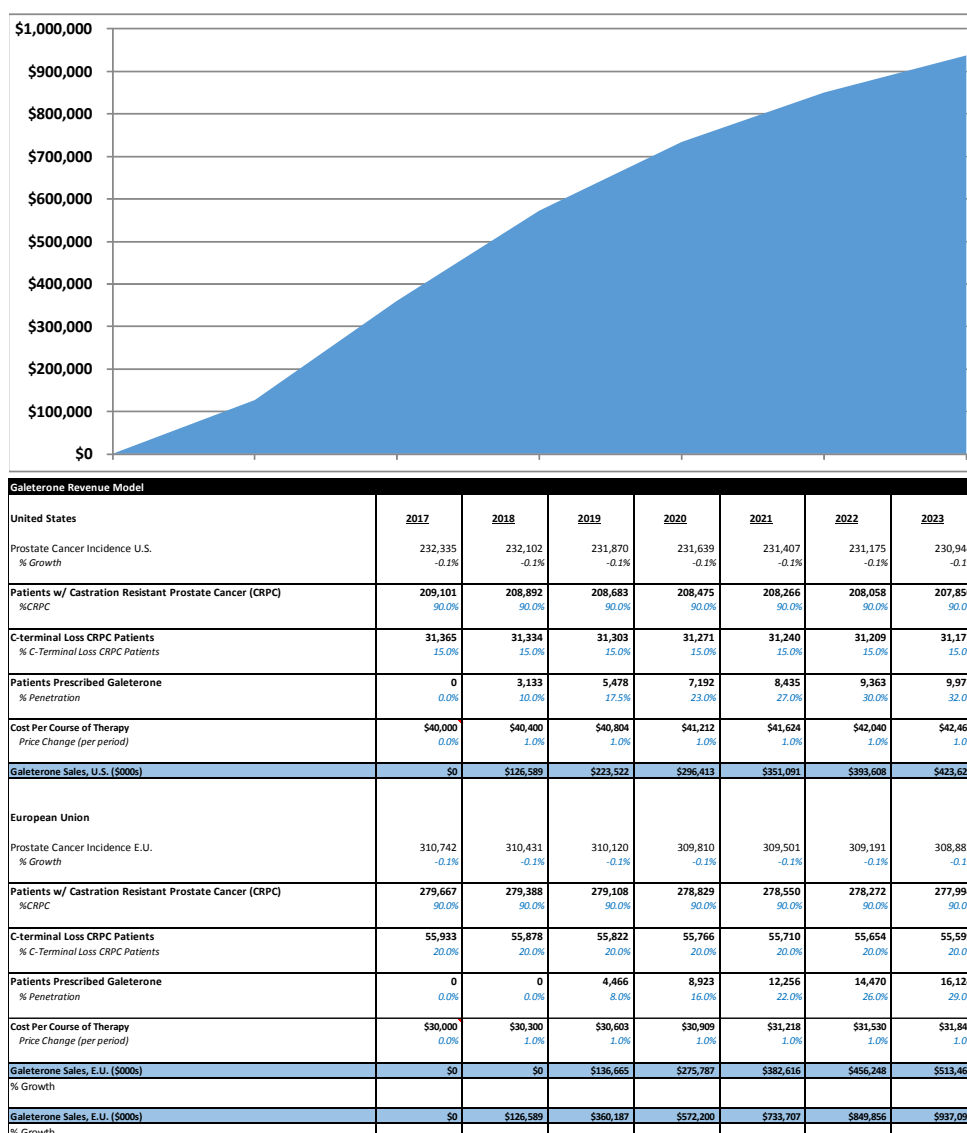
The FDA granting the go ahead to initiate a pivotal Phase III trial with rPFS in a relatively small 170 patient population represents a departure that could allow Tokai to avoid pitfalls that have befallen other players in the CRPC space. Overall survival is a tough endpoint in a population that relapses or is refractory after anti-androgen therapy. This gives a lower bar for galeterone to get FDA approval. The intriguing nature of the C-terminal loss data and the FDA's inclination toward more population specific therapies has paved the way for this approach.

This trial is set to initiate in 1H:2015, with top line data would likely be available YE:2016. We expect the company will submit an NDA to the FDA in 2017 and an approval likely 2018. We have European approval coming in 2019. Our timelines are most conservative and earlier approval would provide upside to our estimates.

Galeterone Offers Billion Dollar-Plus Opportunity

Based on the nature of the Phase III ARMOR3-SV trial, which targets AR-V7 C-terminal loss patients, the initial label for galeterone would focus on this population. As an estimated between 12% and 30% of refractory and relapse patients have splice variants. We estimate that the initial label would open the drug's use in 30,000-plus patients. In itself, this would present an intriguing revenue opportunity. We forecast worldwide galeterone sales in C-terminal loss patients of \$127 million in 2018, growing to \$937 million by 2021E.

Figure 2. Galeterone Revenue Model



Source: Janney Montgomery Scott

MANAGEMENT

Jodie Morrison, President and Chief Executive Officer. Ms. Morrison has served as President and Chief Executive Officer at Tokai and as a member of the board of directors since March 2013. Prior to her appointment, Ms. Morrison served as both the company's Chief Operating Officer and Head of Clinical Affairs over the seven preceding years. Throughout her tenure at Tokai, Ms. Morrison has led the company's operational management and galeterone prostate cancer development program. Prior to joining Tokai, Ms. Morrison was director of clinical operations and medical affairs at Dyax Corporation. During her tenure at Dyax, she built and led the clinical development teams for Kalbitor (hereditary angioedema) and DX-88 (cardiothoracic surgery), and oversaw the Kalbitor clinical trials that ultimately led to its marketing approval. Prior to joining Dyax, she held clinical management positions at both Curis, Inc. and at Diacrin, Inc.

Lee Kalowski, Chief Financial Officer. Mr. Kalowski has served as Chief Financial Officer at Tokai since September 2014. Prior to joining Tokai, he served as a vice president in global biotechnology equity research at Credit Suisse. In this role, Mr. Kalowski served as a Senior Research Analyst covering the biotechnology industry, including numerous companies globally in the prostate cancer therapeutic area. Prior to Credit Suisse, Mr. Kalowski worked at Johnson & Johnson in mergers & acquisitions in the pharmaceutical group, where he was involved in the analysis and execution of several completed transactions, and in global pharmaceutical equity research at Sanford C. Bernstein and Prudential Equity Group.

John McBride, Chief Operating Officer. Mr. McBride has served as Chief Operating Officer at Tokai since February 2014. Prior to joining Tokai, he founded and served as president of Alliance Life Science Advisors, Inc., a consulting firm focused on assisting life science companies with strategic planning, business development and financing projects. Prior to that, Mr. McBride served as executive vice president and chief operating officer of Gloucester Pharmaceuticals, Inc. where he was responsible for the company's business development, finance, administrative and manufacturing functions. He has also served as global head of oncology licensing at Pharmacia Corporation; executive vice president, business operations and chief financial officer at CytoTherapeutics, Inc.; vice president, business development and treasurer at Phytera, Inc.; vice president, commercial development at Sparta Pharmaceuticals, Inc.; and vice president, business development at U.S. Bioscience, Inc.

Karen Ferrante, M.D., Head of R&D and Chief Medical Officer. Ms. Ferrante has served as head of research and development and chief medical officer at Tokai since April 2014. Prior to Tokai, she served as oncology therapeutic area head for Takeda Pharmaceuticals and Takeda Cambridge, USA site head. Prior to that, Ms. Ferrante held senior positions at Millennium Pharmaceuticals and its parent company, Takeda Pharmaceuticals including her role as chief medical officer and a head of R&D for Millennium, The Takeda Oncology Company. From 1999 to 2007, she held positions of increasing responsibility at Pfizer Global Research & Development, culminating as vice president and therapeutic area clinical leader in oncology development. Ms. Ferrante began her career in the pharmaceutical industry as associate director of clinical oncology at Bristol-Myers Squibb Company. For more than a decade prior, she was at the New England Deaconess Hospital in Boston (Beth Israel Deaconess), where she completed her internship and residency in internal medicine followed by her fellowship in hematology and oncology. While at the Beth Israel Deaconess Hospital, she served as instructor, clinical instructor and clinical fellow in medicine at the Harvard Medical School. Karen has been an author of a number of peer-reviewed papers in the field of oncology, an active participant in academic and professional associations and symposia, is the holder of several patents and serves as a member of the board of Progenics Pharmaceuticals.

January 9, 2015

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

	1H:14A	3Q:14A	4Q:14E	2014E	1Q:15E	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E
Galeterone											
Other											
Total Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Research & Development	7,948	2,825	3,500	14,273	5,500	5,750	6,000	6,250	23,500	26,000	26,000
% of Revenue							112.4%	78.6%	64.6%	10.6%	0.0%
% Annual Growth											
Selling, General & Administrative	2,829	3,599	3,500	9,928	3,500	3,500	3,500	3,500	14,000	14,000	15,000
% of Revenue							-2.8%	0.0%	41.0%	0.0%	7.1%
% Annual Growth											
Other	0	0	0	0	0	0	0	0	0	0	0
Operating Expenses	10,777	6,424	7,000	24,201	9,000	9,250	9,500	9,750	37,500	40,000	41,000
Operating Profit	(\$10,777)	(\$6,424)	(\$7,000)	(\$24,201)	(\$9,000)	(\$9,250)	(\$9,500)	(\$9,750)	(\$37,500)	(\$40,000)	(\$41,000)
Other Income (Expense)	79	34	30	143	30	30	30	30	120	120	120
Pretax Profit	(\$10,698)	(\$6,390)	(\$6,970)	(\$24,058)	(\$8,970)	(\$9,220)	(\$9,470)	(\$9,720)	(\$37,380)	(\$39,880)	(\$40,880)
Income Tax											
Effective Tax Rate											
Net Income	(\$10,698)	(\$6,390)	(\$6,970)	(\$24,058)	(\$8,970)	(\$9,220)	(\$9,470)	(\$9,720)	(\$37,380)	(\$39,880)	(\$40,880)
Earnings Per Share (Basic)	(\$0.70)	(\$0.39)	(\$0.31)	(\$1.38)	(\$0.40)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.65)	(\$1.72)	(\$1.75)
Earnings Per Share (Fully Diluted)	(\$0.70)	(\$0.39)	(\$0.31)	(\$1.38)	(\$0.40)	(\$0.41)	(\$0.42)	(\$0.43)	(\$1.65)	(\$1.72)	(\$1.75)
Shares Outstanding (Basic)	15,358	16,531	22,400	17,412	22,512	22,625	22,738	22,851	22,681	23,138	23,370
Shares Outstanding (Fully Diluted)	15,358	16,531	22,400	17,412	22,512	22,625	22,738	22,851	22,681	23,138	23,370
% Sequential Growth					0.5%	0.5%	0.5%	0.5%		2.0%	1.0%

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.

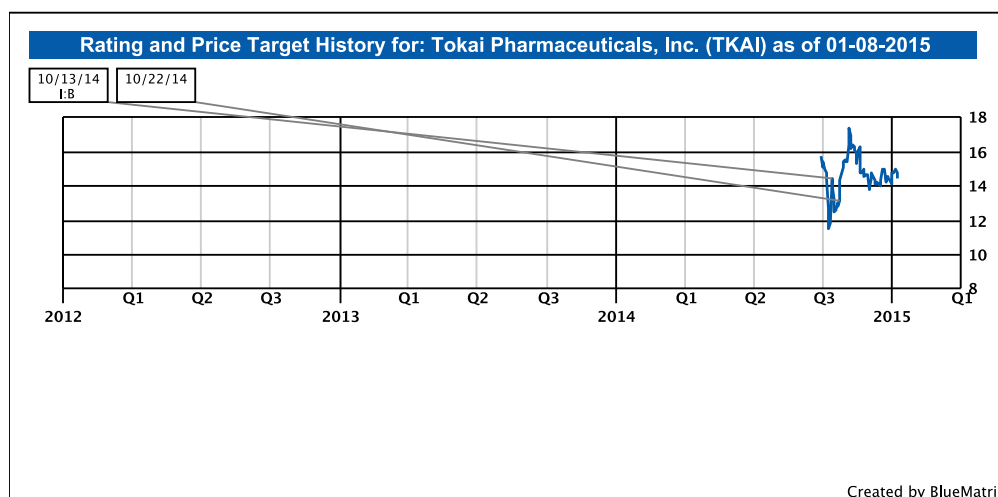
Definition of Ratings

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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