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Biotechnology

August 13, 2015

# Tokai Pharmaceuticals, Inc. (TKAI) - BUY

## ARMOR3-SV Phase III CRPC Trial Initiated in Multiple Clinical Centers

| | |
|---|---|
| Price: | $11.83 |
| Fair Value Estimate: | $18.00 |
| 52-Week Range: | $9.67 - $30.00 |
| Market Cap (MM): | $265 |
| Shr.O/S-Diluted (mm): | 22.4 |
| Average Daily Volume: | 141,216 |
| Book Value: | $3.69 |
| Yield: | 0.0% |
| FCF Yield: | NA |

| FYE: Dec | 2013A | 2014A | 2015E |
|---|---|---|---|
| EPS: | $(1.29)A | $(3.60)A | $(1.88)E |
| Prior EPS: | | | $(2.09) |
| Consensus | NM | NM | -2.36 |

| Quarterly EPS: | | | |
|---|---|---|---|
| Q1 | -- | -- | $(0.59)A |
| Q2 | -- | -- | $(0.40)A |
| Q3 | -- | $(0.39)A | $(0.43)E |
| Q4 | -- | $(0.28)A | $(0.45)E |

| Quarterly Revenue (M): | | | |
|---|---|---|---|
| Q1 | $0A | $0A | $0A |
| Q2 | $0A | $0A | $0A |
| Q3 | $0A | $0A | $0E |
| Q4 | $0A | $0A | $0E |
| Year: | $0A | $0A | $0E |


### PORTFOLIO MANAGER BRIEF

Last evening, Tokai reported 2Q:2015 earnings highlighting the initiation of the Phase III ARMOR3-SV trial evaluating galeterone in AR-V7 CRPC patients. The company reported trial initiation at 30 clinical centers in North America and EU. Tokai has established a companion diagnostic in partnership with Qiagen to reliably detect AR-V7 mutation and anticipates screening of eligible patients in 3Q. As of 2Q:2015, Tokai has $83.2 million in cash, enough to fund the company through YE: 2016. We reiterate our BUY rating with $18 fair value.

### ANALYST NOTES

- Successful Initiation of Phase III Trial in Multiple Centers Highlight of 2Q Earnings Report. Tokai reported 2Q earnings and highlighted the initiation of the ARMOR3-SV Phase III trial investigating galeterone in patients with castration resistant prostate cancer (CRPC) with the AR-V7 variant. Tokai reported a net loss of $9.0 million, due to increase in operational expenses. The 34% y/y increase in R&D spend came from Phase III trial start-up costs and clinical trial assay development, and the 107% increase in SG&A expenses was due to increased headcount, patent costs, and other expenses. Following the recent initiation of the Phase III ARMOR3-SV, the company is confident of funding operations through YE:2016 with the $83.2 million it currently has on the books.
- Tokai Initiates ARMOR3-SV Phase III Trial in 2Q as Anticipated. In June 2015, keeping in line with prior guidance, Tokai announced the initiation of ARMOR3-SV, the pivotal Phase III trial investigating galeterone as a treatment for mCRPC patients with the AR-V7 variant. Tokai reported that the trial has been initiated at 30 clinical centers in the United States, Canada, and the United Kingdom and that regulatory approvals to begin the trial have been obtained in Belgium, France, and Spain. Simultaneously, the companion diagnostic assay which has been developed in collaboration with Qiagen to reliably detect the AR-V7 variant carrying CRPC patients is being implemented at the global central laboratories. Following completion of the necessary training to run the assay, company anticipates screening of eligible patients to begin this quarter.
- Phase III Investigates Galeterone in mCRPC Patients and is Supported by Strong Phase II Data. The Phase III trial is designed to investigate galeterone versus Xtandi in CRPC AR-V7 patients. Phase II data from the ARMOR2 trial showed that galeterone was efficacious in the treatment of a subgroup of CRPC


RESEARCH ANALYST CERTIFICATIONS AND IMPORTANT DISCLOSURES ARE ON PAGES 4 - 5 OF THIS REPORT

patients with the AR-V7 variant of the androgen receptor. These patients are not effectively treated with 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 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 cytoxic 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.

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

| | 2014A | 1Q:15A | 2Q:15A | 3Q:15E | 4Q:15E | 2015E | 2016E | 2017E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenue** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** |
| Research & Development | 22,525 | 10,559 | 5,855 | 6,500 | 6,750 | 29,664 | 29,500 | 31,000 |
| *% Annual Growth* | | *32.9%* | *-26.3%* | *130.1%* | *77.4%* | *31.7%* | *-0.6%* | *5.1%* |
| Selling, General & Administrative | 11,714 | 2,741 | 3,127 | 3,250 | 3,500 | 12,618 | 14,000 | 15,000 |
| *% Annual Growth* | | *-3.1%* | *10.5%* | *-9.7%* | *42.5%* | *7.7%* | *11.0%* | *7.1%* |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Operating Expenses | 34,239 | 13,300 | 8,982 | 9,750 | 10,250 | 42,282 | 43,500 | 46,000 |
| **Operating Profit** | **($34,239)** | **($13,300)** | **($8,982)** | **($9,750)** | **($10,250)** | **($42,282)** | **($43,500)** | **($46,000)** |
| Other Income (Expense) | 245 | 40 | 25 | 30 | 30 | 125 | 120 | 120 |
| **Net Income** | **($33,994)** | **($13,260)** | **($8,957)** | **($9,720)** | **($10,220)** | **($42,157)** | **($43,380)** | **($45,880)** |
| | | | | | | | | |
| **Earnings Per Share (Basic)** | **($5.25)** | **($0.59)** | **($0.40)** | **($0.43)** | **($0.45)** | **($1.88)** | **($1.91)** | **($2.00)** |
| **Earnings Per Share (Fully Diluted)** | **($5.25)** | **($0.59)** | **($0.40)** | **($0.43)** | **($0.45)** | **($1.88)** | **($1.91)** | **($2.00)** |
| Shares Outstanting (Basic) | 6,469 | 22,384 | 22,422 | 22,489 | 22,556 | 22,463 | 22,726 | 22,953 |
| Shares Outstanting (Fully Diluted) | 6,469 | 22,384 | 22,422 | 22,489 | 22,556 | 22,463 | 22,726 | 22,953 |

*Source: Janney Montgomery Scott, Company Reports*



RESEARCH ANALYST CERTIFICATIONS AND IMPORTANT DISCLOSURES ARE ON PAGES 4 - 5 OF THIS REPORT

## 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.

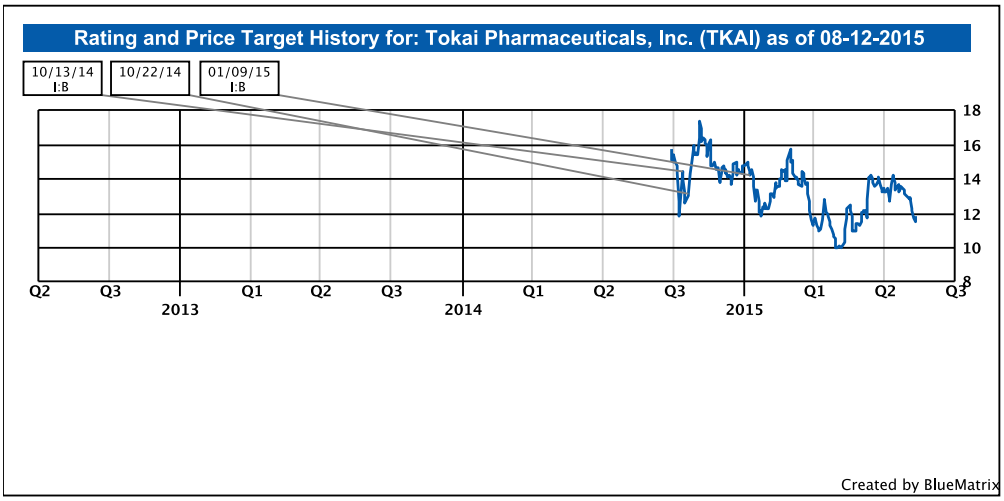
## Definition of Ratings

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 6/30/15

| | | | IB Serv./Past 12 Mos.* | |
|---|---|---|---|---|
| **Rating** | **Count** | **Percent** | **Count** | **Percent** |
| **BUY [B]** | 112 | 54.34 | 31 | 27.68 |

| | | | | |
|---|---|---|---|---|
| **NEUTRAL [N]** | 94 | 45.63 | 13 | 13.83 |
| **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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