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# Tokai Pharmaceuticals, Inc.

## Second-Quarter Financials a Nonevent; Patient Screening in ARMOR3-SV to Begin this Quarter; Maintain Outperform Rating

On Wednesday, August 12, after the markets closed, Tokai reported second-quarter financial results (exhibit 1). **The company ended the second quarter with $83.2 million in cash, which should sustain operations into 2017 and past the expected top-line data release of the Phase III ARMOR3-SV study around the end of 2016, according to our model.** The net loss for the quarter was $9.0 million, versus our estimate of $11.4 million and consensus of $12.8 million. The per share loss was $0.40, better than our estimate of a $0.51 loss and consensus of a $0.57 loss. The smaller-than-expected loss was due to a significant decrease in R&D spending in second quarter compared with the first quarter; first-quarter R&D spending contained a one-time payment to collaborator Qiagen (QGEN $27.55; Market Perform) for development of the diagnostic assay being used in the ARMOR3-SV clinical trial. We expect R&D spending to increase in the coming quarters as ARMOR3-SV gets underway.

**In the second quarter, Tokai initiated the pivotal Phase III ARMOR3-SV study by opening 30 clinical sites and deploying the AR-V7 diagnostic assay at three central reference laboratories; top-line data continues to be expected by the end of 2016.** Galeterone's strategy to market is to obtain approval in the niche population of chemo-naïve, metastatic castration-resistant prostate cancer (mCRPC) patients (or M1 patients) who express a splice variant of the androgen receptor (AR), AR-V7. M1 patients expressing AR-V7 are unresponsive to Xtandi (Astellas and Medivation [MDVN $98.95; Outperform]) or Zytiga (Johnson & Johnson [JNJ $98.71]). Although galeterone contains similar mechanisms to those of both drugs, it goes one step further with the additional ability to directly degrade the AR, including the AR-V7 variant.

- ***The final design for ARMOR3-SV was presented at the 2015 American Society of Clinical Oncology (ASCO) Conference (May 29-June 2, in Chicago).*** ARMOR3-SV is a Phase III, randomized, double-blind, multicenter, active controlled study of galeterone versus Xtandi in 148 men with chemo-naïve mCRPC. Patients eligible to participate in this study must express the AR-V7 splice variant; an assay to determine the presence of AR-V7 has been validated. The primary endpoint is radiographic progression-free survival (rPFS), and secondary endpoints include overall survival, time to cytotoxic therapy, and skeletal-related events. We note that with a 148-patient target enrollment, ARMOR3-SV is 90% powered to detect 82% improvement in rPFS for galeterone over Xtandi.
- ***ARMOR3-SV has now been initiated at 30 sites in the United States, Canada, and the United Kingdom.*** The company expects to open sites in Belgium, France, and Spain in the near future.
- ***The assay to detect the presence of the AR-V7 splice variant in circulating tumor cells (CTCs) has been successfully developed and validated by collaborator Qiagen and was implemented at three reference labs to prepare for imminent patient screening.*** Training is underway at designated central laboratories to run the assays. The company expects to complete the training at the central laboratories in third quarter and begin screening patients into the trial shortly thereafter.

Tokai Pharmaceuticals, Inc. is focused on the development of galeterone and an androgen receptor-degradation platform to address prostate cancer and potentially other hormone-driven cancers.

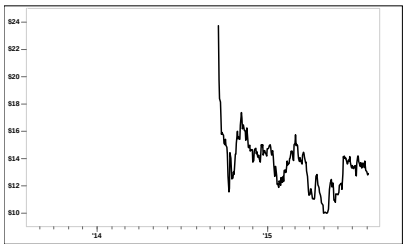
| | |
|---|---|
| Stock Rating: | **Outperform** |
| Company Profile: | **Aggressive Growth** |
| Price Target: | $44.00 |
| Symbol: | TKAI (NASDAQ) |
| Price: | $11.83 (52-Wk.: $10-$30) |
| Market Value (mil.): | $258 |
| Fiscal Year End: | December |
| Long-Term EPS Growth Rate: | NA |
| Dividend/Yield: | None |

| | 2014A | 2015E | 2016E |
|---|---|---|---|
| **Estimates** | | | |
| EPS Q1 | $-0.32 | A$-0.59 | NA |
| Q2 | $-0.38 | $-0.40 | NA |
| Q3 | $-2.71 | $-0.53 | NA |
| Q4 | $-0.28 | $-0.55 | NA |
| FY | $-3.60 | $-2.07 | $-2.34 |
| CY | | $-2.07 | $-2.34 |
| Sales (mil.) | 0 | 0 | 0 |
| **Valuation** | | | |
| FY P/E | NM | NM | NM |
| CY P/E | | NM | NM |

| **Trading Data (FactSet)** | |
|---|---|
| Shares Outstanding (mil.) | 22 |
| Float (mil.) | 2 |
| Average Daily Volume | 116,166 |

| **Financial Data (FactSet)** | |
|---|---|
| Book Value Per Share (MRQ) | 4.1 |
| Return on Equity (TTM) | -34.9 |

**Two-Year Price Performance Chart**




Sources: FactSet, William Blair & Company estimates

- ***We expect a futility analysis in ARMOR3-SV when 50% of events have occurred, which management estimates will happen in first half 2016. We expect the interim analysis to act as the next catalyst to Tokai shares.*** The blinded analysis will not include a look at efficacy. The analysis will give better visibility into when top-line data will be reported, which management estimates to be by the end of 2016.

- ***AR-V7 screening could become standard of care, supported by the rising popularity of precision medicine.*** If ARMOR3-SV is successful, it is likely that AR-V7 screening becomes standard of care in metastatic patients when selecting treatment options, in our opinion, and the next step would be to push galeterone earlier into the treatment paradigm. Moreover, payers may push testing for AR-V7 into becoming a first step in the standard of care so as to streamline diagnosis and proper treatment and avoid paying for expensive drugs that may not work.

**Key Catalysts Driving Value in the Next 12-24 Months:** 1) Start of patient screening in pivotal Phase III ARMOR3-SV trial in third quarter 2015; 2) futility analysis in ARMOR3-SV in first half 2016; and 3) top-line data from ARMOR3-SV by the end of 2016.

**We maintain our Outperform rating and reiterate our price target of $44 (exhibit 2). Our Outperform rating is centered on our belief that Tokai's lead asset, galeterone, will become an essential component of the armamentarium against prostate.** We estimate worldwide sales for galeterone will reach $1.8 billion in the United States and Europe in 2027 in the AR-V7 variant population alone. Assuming an 85% probability of success, our probability-adjusted NPV model suggests a fair value for Tokai shares at $44 at mid-2016, with $43 assigned to the value of galeterone in the United States and Europe and about $1 of net cash.

Key risks to our Outperform rating and price target include: 1) clinical risk of the Phase III program; 2) regulatory risk related to receiving approval for galeterone in the United States and Europe; 3) development and approval of the companion diagnostic; 4) reimbursement risk; and 5) financing risk.

Exhibits 1 and 2 are shown on the following pages.

**Exhibit 1**
**Tokai Pharmaceuticals**
**Income Statemement**
(dollars in thousands)

| Tokai Pharmaceuticals | 2012 | 2013 | 2014 | 2015 | | | | | 2016 | 2017 |
|---|---|---|---|---|---|---|---|---|---|---|
| Income Statement | | | FY:14A | Q1A | Q2A | Q3E | Q4E | FY:15E | FY:16E | FY:17E |
| **Revenues** | | | | | | | | | | |
| Galeterone | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 |
| License revenue | | | - | - | - | - | - | - | - | - |
| Collaboration revenue | | | - | - | - | - | - | - | - | - |
| **Total Revenues** | **$0** | **$0** | **-** | **-** | **-** | **-** | **-** | **-** | **-** | **-** |
| **Expenses** | | | | | | | | | | |
| COGS | | | - | - | - | - | - | - | - | - |
| R&D expense | 7,370 | 12,201 | 14,577 | 10,559 | 5,855 | 8,532 | 8,703 | 33,649 | 35,645 | 21,281 |
| SG&A expense | 2,279 | 3,548 | 8,885 | 2,741 | 3,127 | 3,440 | 3,784 | 13,091 | 17,781 | 52,858 |
| **Total Operating Expenses** | 9,649 | 15,749 | 23,462 | 13,300 | 8,982 | 11,972 | 12,486 | 46,740 | 53,425 | 74,138 |
| **Operating income** | (9,649) | ($15,749) | (23,462) | (13,300) | (8,982) | (11,972) | (12,486) | (46,740) | (53,425) | (74,138) |
| Finance income | | - | - | - | - | 59 | 49 | 108 | 70 | (87) |
| Finance costs | | | - | - | - | - | - | - | - | - |
| Other (expense) income, net | | 24 | 166 | 40 | 25 | - | - | 65 | - | - |
| **Total other Income (expense)** | (9,649) | (15,725) | (23,296) | (13,260) | (8,957) | (11,913) | (12,437) | (46,567) | (53,355) | (74,226) |
| Pretax income/(loss) | (9,649) | (15,725) | (23,296) | (13,260) | (8,957) | (11,913) | (12,437) | (46,567) | (53,355) | (74,226) |
| Other comprehensive gain/(loss) | - | - | - | - | - | - | - | - | - | - |
| Amortization of deemed dividend | - | - | - | - | - | - | - | - | - | - |
| Accretion to redemption value of redeemable convertible preferred stock | (34) | (34) | - | - | - | - | - | - | - | - |
| Provision for income taxes/(income) | | | - | - | - | - | - | - | - | - |
| **Net Income/(Loss)** | **($9,683)** | **($15,759)** | **($23,296)** | **($13,260)** | **($8,957)** | **($11,913)** | **($12,437)** | **($46,567)** | **($53,355)** | **($74,226)** |
| **Total comprehensive loss** | **($9,683)** | **($15,759)** | **($23,296)** | **($13,260)** | **($8,957)** | **($11,913)** | **($12,437)** | **($46,567)** | **($53,355)** | **($74,226)** |
| **GAAP EPS** | **($2.97)** | **($3.62)** | **($3.60)** | **($0.59)** | **($0.40)** | **($0.53)** | **($0.55)** | **($2.07)** | **($2.34)** | **($2.97)** |
| Weighted average shares outstanding, diluted | 3,261 | 4,356 | 6,469 | 22,384 | 22,422 | 22,497 | 22,572 | 22,469 | 22,822 | 24,972 |

Sources: Tokai Pharmaceuticals and William Blair & Company, L.L.C. estimates

**Exhibit 2**
**Tokai Pharmaceuticals, Inc.**
**Sum-of-the-Parts Fair Value**
(dollars in thousands, except shares)

| Drug | Peak Sales | Stage of Development | Estimated Launch Date | Probability of Commercialization | Percentage of Sales to Company | Probability-Adjusted NPV | Value per Share | Percentage of Fair Value |
|---|---|---|---|---|---|---|---|---|
| **Galeterone** | $ 1,814,414 | Pre-Phase III | H1:2018 | 85% | 100% US; 25% ex-US | $984,245 | $43.22 | 97.3% |
| **Subtotal** | | | | | | **$984,245** | **$43.22** | **97.3%** |
| **Net Cash at mid-year 2016** | | | | | | $35,468 | $1.56 | 3.5% |
| **Net Present Value of additional Gain (Loss)*** | | | | | | ($8,000) | ($0.35) | (0.8%) |
| **Sum-of-Parts Fair Value** | | | | | | **$1,011,713** | **$44.43** | **100.0%** |

Sources: William Blair & Company, L.L.C. estimates

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William Blair or an affiliate expects to receive or intends to seek compensation for investment banking services from Tokai Pharmaceuticals, Inc. within the next three months.

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Additional information is available upon request.

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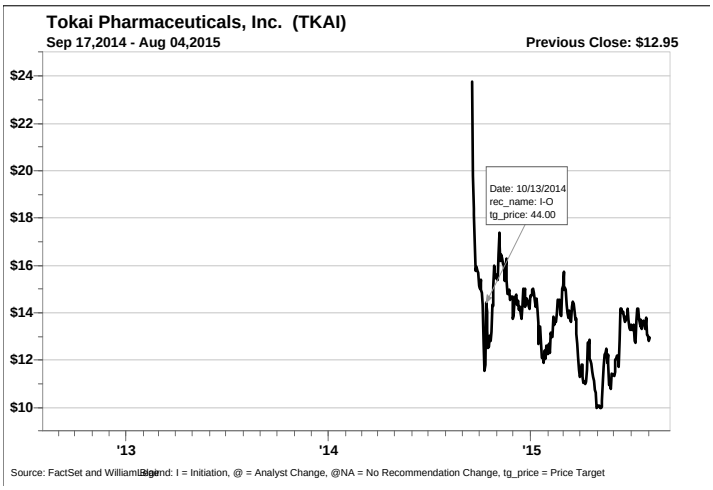
DOW JONES: 17,402.84
S&P 500: 2,084.07
NASDAQ: 5,036.79




**Current Rating Distribution (as of 07/31/15)**

| Coverage Universe | Percent | Inv. Banking Relationships* | Percent |
|---|---|---|---|
| Outperform (Buy) | 66 | Outperform (Buy) | 16 |
| Market Perform (Hold) | 32 | Market Perform (Hold) | 3 |
| Underperform (Sell) | 2 | Underperform (Sell) | 0 |

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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