

Tokai Pharmaceuticals, Inc.

Third-Quarter Financials Non-Event; Initiation of ARMOR3-SV Next; Maintain Outperform

On Monday November 10, before markets opened, Tokai reported third-quarter financial results (exhibit 1). The company ended the quarter with \$105.5 million in cash, which included net proceeds of approximately \$97.9 million from the initial public offering; we estimate the current cash should sustain operations into 2017 through the top-line data release of the Phase III ARMOR3-SV study. Net loss for the quarter was \$6.4 million with a per-share loss of \$2.71, versus our estimates of \$6.0 million and \$0.34, respectively; we note that the discrepancy in loss per share is attributed to our estimate for weighted-average number of shares of 17.3 million for the quarter, compared to the 2.4 million shares reported by the company. We updated our model as illustrated in exhibit 1.

Next event: Initiation of the pivotal Phase III ARMOR3-SV study, expected to begin enrollment first half 2015. The Phase III ARMOR3-SV study targets to enroll approximately 170 chemo-naïve mCRPC (metastatic castration-resistant prostate cancer) patients with the AR-V7 splice variant in their AR expression. This mutation has been shown to confer resistance to both Zytiga from Johnson & Johnson (JNJ \$108.23) and Xtandi from Astellas and Medivation (MDVN \$108.95; Outperform). Patients will be randomized 1:1 to either galeterone or Xtandi with progression-free survival (PFS) as the primary endpoint. Top-line data from ARMOR3-SV is expected to be available around year-end 2016.

Development of a companion diagnostic to prospectively identify AR-V7 for study enrollment is prerequisite for the Phase III study start in early 2015, and approval is required for commercialization. Tokai has contracted third parties to finalize and validate an assay to prospectively identify the AR-V7 variant from patient's circulating tumor cells (CTC). Tokai needs to submit an investigational device exemption application (IDE) for the assay to the FDA before start of the Phase III study. This companion diagnostic test will need to be approved by the FDA through its premarket approval or PMA process before commercialization. During the Phase III study, the AR-V7 identification will be conducted by a central laboratory. Tokai expects to screen 1,000 chemo-naïve mCRPC (or M1) patients to identify the target enrollment of 170 patients positive for AR-V7, assuming an approximate 20% prevalence.

Key Catalysts Driving Value in the Next 12-24 Months: 1) further data presentation of galeterone activity in AR mutations and variants at the EORTC, NCI, and AACR Symposium next week; 2) initiation of the pivotal ARMOR3-SV study in chemo-naïve mCRPC patients with AR-V7 in early 2015; and 3) top-line data from ARMOR3-SV by year-end 2016.

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

Y. Katherine Xu, Ph.D.
+1 212 237 2758
kxu@williamblair.com

Please consult pages 3-4 of this report for all disclosures. Analyst certification is on page 3. William Blair & Company, L.L.C. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as a single factor in making an investment decision.

November 10, 2014

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$44.00

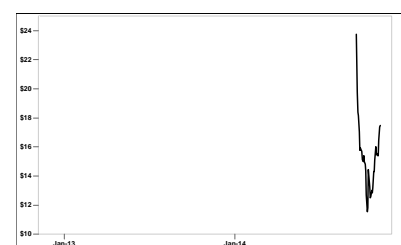
Symbol: TKAI (NASDAQ)
Price: \$16.46 (52-Wk.: \$10-\$30)
Market Value (mil.): \$353
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A\$-0.32	NA
Q2	NA	A\$-0.38	NA
Q3	NA	A\$-2.71	NA
Q4	NA	\$-0.32	NA
FY	\$-3.61	\$-2.77	\$-1.75
CY		\$-2.77	\$-1.75
Sales (mil.)	NA	0	0
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	5
Float (mil.)	5
Average Daily Volume	633,433

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.9
Return on Equity (TTM)	-79.1

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

We maintain our Outperform rating and price target at \$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 year-end 2015.

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.

Exhibit 1
Tokai Pharmaceuticals
Income Statement
(dollars in thousands)

Tokai Pharmaceuticals	2012	2013	2014					2015	2016
Income Statement			Q1A	Q2A	Q3A	Q4E	FY:14E		
Revenues									
Galeterone	\$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	3,748	4,200	2,825	3,108	13,881	19,593	30,148
SG&A expense	2,279	3,548	1,129	1,700	3,599	3,779	10,207	19,292	26,961
Total Operating Expenses	9,649	15,749	4,877	5,900	6,424	6,886	24,087	38,885	57,110
Operating income	(9,649)	(\$15,749)	(4,877)	(5,900)	(6,424)	(6,886)	(24,087)	(38,885)	(57,110)
Finance income	-	-	-	-	-	-	-	347	168
Finance costs	-	-	-	-	-	-	-	-	-
Other (expense) income, net	-	24	-	79	34	-	113	-	-
Total other income (expense)	(9,649)	(15,725)	(4,877)	(5,821)	(6,390)	(6,886)	(23,974)	(38,539)	(56,942)
Pretax income/(loss)	(9,649)	(15,725)	(4,877)	(5,821)	(6,390)	(6,886)	(23,974)	(38,539)	(56,942)
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)	(\$4,877)	(\$5,821)	(\$6,390)	(\$6,886)	(\$23,974)	(\$38,539)	(\$56,942)
Total comprehensive loss	(\$9,683)	(\$15,759)	(\$4,877)	(\$5,821)	(\$6,390)	(\$6,886)	(\$23,974)	(\$38,539)	(\$56,942)
GAAP EPS	(\$2.97)	(\$3.62)	(\$0.93)	(\$1.12)	(\$2.71)	(\$0.32)	(\$2.77)	(\$1.75)	(\$2.55)
Weighted average shares outstanding, diluted	3,261	4,356	5,218	5,218	2,357	21,800	8,647	21,988	22,350

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	\$923,238	\$41.78	94.5%
Subtotal						\$923,238	\$41.78	94.5%
Net Cash at year-end 2015						\$61,539	\$2.78	6.3%
Net Present Value of additional Gain (Loss)*						(\$8,000)	(\$0.36)	(0.8%)
Sum-of-Parts Fair Value						\$976,778	\$44.20	100.0%

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

IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for Tokai Pharmaceuticals, Inc. within the prior 12 months.

William Blair is a market maker in the security of Tokai Pharmaceuticals, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from Tokai Pharmaceuticals, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Tokai Pharmaceuticals, Inc.

Additional information is available upon request.

This report is available in electronic form to registered users via R*Docs™ at www.rdocs.com or www.williamblair.com.

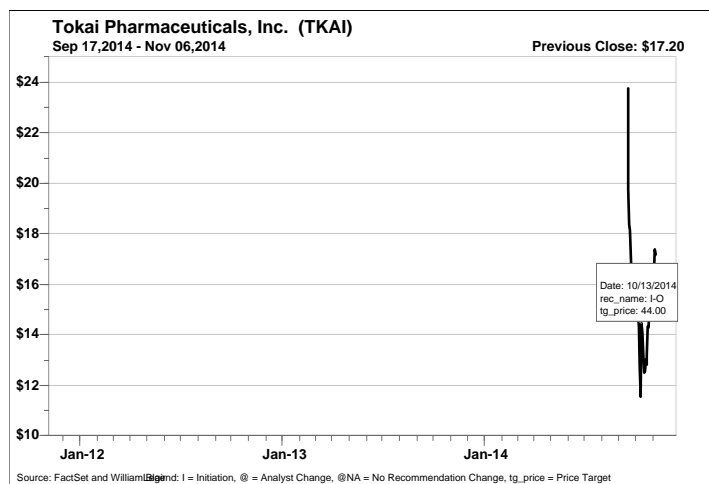
Please contact us at +1 800 621 0687 or consult williamblair.com/Research-and-Insights/Equity-Research/Coverage.aspx for all disclosures.

Y. Katherine Xu attests that 1) all of the views expressed in this research report accurately reflect his/her personal views about any and all of the securities and companies covered by this report, and 2) no part of his/her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed by him/her in this report. We seek to update our research as appropriate, but various regulations may prohibit us from doing so. Other than certain periodical industry reports, the majority of reports are published at irregular intervals as deemed appropriate by the analyst.

DOW JONES: 17,573.93

S&P 500: 2,031.92

NASDAQ: 4,632.53



Current Rating Distribution (as of 10/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	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.

The compensation of the research analyst is based on a variety of factors, including performance of his or her stock recommendations; contributions to all of the firm's departments, including asset management, corporate finance, institutional sales, and retail brokerage; firm profitability; and competitive factors.

OTHER IMPORTANT DISCLOSURES

Stock ratings, price targets, and valuation methodologies: William Blair & Company, L.L.C. uses a three-point system to rate stocks. Individual ratings and price targets (where used) reflect the expected performance of the stock relative to the broader market (generally the S&P 500, unless otherwise indicated) over the next 12 months. The assessment of expected performance is a function of near-, intermediate-, and long-term company fundamentals, industry outlook, confidence in earnings estimates, valuation (and our valuation methodology), and other factors. Outperform (O) – stock expected to outperform the broader market over the next 12 months; Market Perform (M) – stock expected to perform approximately in line with the broader market over the next 12 months; Underperform (U) – stock expected to underperform the broader market over the next 12 months; not rated (NR) – the stock is not currently rated. The valuation methodologies used to determine price targets (where used) include (but are not limited to) price-to-earnings multiple (P/E), relative P/E (compared with the relevant market), P/E-to-growth-rate (PEG) ratio, market capitalization/revenue multiple, enterprise value/EBITDA ratio, discounted cash flow, and others.

Company Profile: The William Blair research philosophy is focused on quality growth companies. Growth companies by their nature tend to be more volatile than the overall stock market. Company profile is a fundamental assessment, over a longer-term horizon, of the business risk of the company relative to the broader William Blair universe. Factors assessed include: 1) durability and strength of franchise (management strength and track record, market leadership, distinctive capabilities); 2) financial profile (earnings growth rate/consistency, cash flow generation, return on investment, balance sheet, accounting); 3) other factors such as sector or industry conditions, economic environment, confidence in long-term growth prospects, etc. Established Growth (E) – Fundamental risk is lower relative to the broader William Blair universe; Core Growth (C) – Fundamental risk is approximately in line with the broader William Blair universe; Aggressive Growth (A) – Fundamental risk is higher relative to the broader William Blair universe.

The ratings, price targets (where used), valuation methodologies, and company profile assessments reflect the opinion of the individual analyst and are subject to change at any time.

Our salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies—to our clients and our trading desks—that are contrary to opinions expressed in this research. Certain outstanding reports may contain discussions or investment opinions relating to securities, financial instruments and/or issuers that are no longer current. Always refer to the most recent report on a company or issuer before making an investment decision. Our asset management and trading desks may make investment decisions that are inconsistent with recommendations or views expressed in this report. We will from time to time have long or short positions in, act as principal in, and buy or sell the securities referred to in this report. Our research is disseminated primarily electronically, and in some instances in printed form. Electronic research is simultaneously available to all clients. This research is for our clients only. No part of this material may be copied or duplicated in any form by any means or redistributed without the prior written consent of William Blair & Company, L.L.C.

THIS IS NOT IN ANY SENSE A SOLICITATION OR OFFER OF THE PURCHASE OR SALE OF SECURITIES. THE FACTUAL STATEMENTS HEREIN HAVE BEEN TAKEN FROM SOURCES WE BELIEVE TO BE RELIABLE, BUT SUCH STATEMENTS ARE MADE WITHOUT ANY REPRESENTATION AS TO ACCURACY OR COMPLETENESS OR OTHERWISE. OPINIONS EXPRESSED ARE OUR OWN UNLESS OTHERWISE STATED. PRICES SHOWN ARE APPROXIMATE.

THIS MATERIAL HAS BEEN APPROVED FOR DISTRIBUTION IN THE UNITED KINGDOM BY WILLIAM BLAIR INTERNATIONAL, LIMITED, REGULATED BY THE FINANCIAL CONDUCT AUTHORITY (FCA), AND IS DIRECTED ONLY AT, AND IS ONLY MADE AVAILABLE TO, PERSONS FALLING WITHIN COB 3.5 AND 3.6 OF THE FCA HANDBOOK (BEING “ELIGIBLE COUNTERPARTIES” AND “PROFESSIONAL CLIENTS”). THIS DOCUMENT IS NOT TO BE DISTRIBUTED OR PASSED ON TO ANY “RETAIL CLIENTS.” NO PERSONS OTHER THAN PERSONS TO WHOM THIS DOCUMENT IS DIRECTED SHOULD RELY ON IT OR ITS CONTENTS OR USE IT AS THE BASIS TO MAKE AN INVESTMENT DECISION.

“William Blair” and “R*Docs” are registered trademarks of William Blair & Company, L.L.C. Copyright 2014, William Blair & Company, L.L.C. All rights reserved.