

Tokai Pharmaceuticals

(TKAI-NASDAQ)

Stock Rating: Outperform
Stock Price: US\$15.38
Target Price: US\$28.00

November 19, 2014
Biotechnology

Jim Birchenough, M.D. 415-591-2129
BMO Capital Markets Corp
jim.birchenough@bmo.com

Chuck Whitesell / Nick Abbott, PhD / Yanan Zhu, PhD
BMO Capital Markets Corp.
212-885-4120 / 206-542-2492 / 415-591-2141
charles.whitesell@bmo.com / nicholas.abbott@bmo.com /
yanan.zhu@bmo.com

Positive Update on ARV7 Response Duration

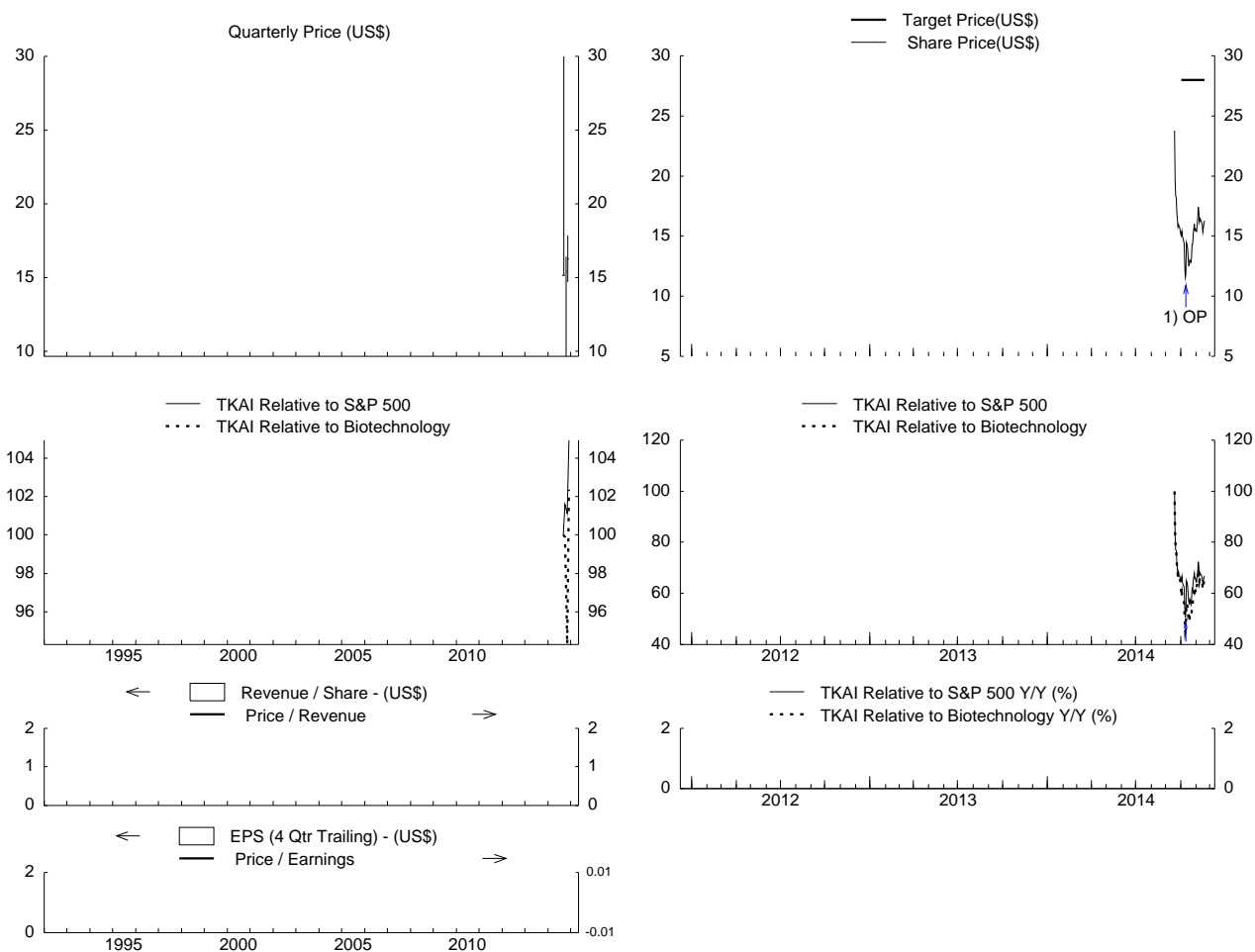
We are attending the ENA14 meeting in Barcelona where, earlier today, Tokai pharma presented updated results from ARMOR2, a trial evaluating 12-week treatment of galeterone, a first-in-class triple androgen receptor inhibitor in castrate-resistant prostate cancer (CRPC). In seven treatment-naïve subjects with the c terminal androgen receptor loss, including ARV7 identified from circulating tumor cells (CTC), six have shown maximal PSA reductions of 50% or greater with an immature median PFS of 7.3 months; the seventh patient discontinued galeterone with a non-drug-related AE approximately six weeks after initiating therapy. Of the six responders, four elected to continue treatment at the end of 12 weeks and time on treatment in the extension phase ranges from 155 to >334 days as of 10/14/14, with several responses ongoing and an immature PFS of 7.3 months. As previously noted, best response in untreated metastatic CRPC (PSA 50 after 12 weeks of treatment) was 72% while in 46 subjects failing 9-11 months of XTANDI or ZYTIGA, best ORR ranged from 47-50%. In 1H15, TKAI will initiate ARMOR3-SV, <170 subjects with metastatic CRPC progressing on androgen deprivation therapy, but XTANDI or ZYTIGA and chemotherapy naïve, and with ARV7 detected in CTC will be randomized to XTANDI (160 mg/d) or galeterone (2550mg/d) with radiographic PFS the primary endpoint.

Our View:

- Duration of response in patients with ARV7 mutation is impressive with 7+ months PFS, well beyond the 2-3 months seen with approved agents in this indication.
- Updated PFS data should serve to favorably handicap likelihood of phase 3 success in ARMOR3 where galeterone will be compared head to head vs. XTANDI.
- With category sales of close to \$4 billion we believe that an ARV7 mutation rate of 12% to 30% should support a meaningful opportunity for galeterone and significant upside potential for TKAI shares.

Please refer to pages 2 to 5 for Important Disclosures, including the Analyst's Certification.

TOKAI PHARMACEUTICALS (TKAI)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %	TKAI - Rating as of 16-Sep-14 = NR		
Range*:		na na		NC			>15 >15		Date	Rating Change	Share Price
Current*	ND	na	0.00	0.0	na	0.9	17.1	na	1 10-Oct-14	NR to OP	\$11.82

* Current EPS is the 4 Quarter Trailing to Q3/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (November 18, 2014): \$16.27
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

IMPORTANT DISCLOSURES**Analyst's Certification**

I, Jim Birchenough, M.D., hereby certify that the views expressed in this report accurately reflect my personal views about the subject securities or issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Analysts who prepared this report are compensated based upon (among other factors) the overall profitability of BMO Capital Markets and their affiliates, which includes the overall profitability of investment banking services. Compensation for research is based on effectiveness in generating new ideas and in communication of ideas to clients, performance of recommendations, accuracy of earnings estimates, and service to clients.

Analysts employed by BMO Nesbitt Burns Inc. and/or BMO Capital Markets Limited are not registered as research analysts with FINRA (exception: Alex Arfaei). These analysts may not be associated persons of BMO Capital Markets Corp. and therefore may not be subject to the NASD Rule 2711 and NYSE Rule 472 restrictions on communications with a subject company, public appearances and trading securities held by a research analyst account.

Company Specific Disclosure

Disclosure 1: BMO Capital Markets has undertaken an underwriting liability with respect to this issuer within the past 12 months.

Disclosure 2: BMO Capital Markets has provided investment banking services with respect to this issuer within the past 12 months.

Disclosure 3: BMO Capital Markets has managed or co-managed a public offering of securities with respect to this issuer within the past 12 months.

Disclosure 4: BMO Capital Markets or an affiliate has received compensation for investment banking services from this issuer within the past 12 months.

Disclosure 6: This issuer is a client (or was a client) of BMO NB, BMO Capital Markets Corp., BMO CM Ltd. or an affiliate within the past 12 months: Investment Banking Services.

Disclosure 9: BMO Capital Markets makes a market in this security.

Methodology and Risks to Price Target/Valuation

Methodology: We arrive at our price target by applying a 20x multiple to our 2020E EPS of \$4.25 discounted 30%.

Risks: There are a number of risks associated with investment in biotechnology companies. These risks include, but are not limited to, risk of clinical trial delay or failure, adverse regulatory decisions including product non-approval, unanticipated adverse effects of drugs which may result in removal from market, risk of manufacturing difficulties, capital market risk which may impair the ability to fund product discovery, research, regulatory filing, manufacture and/or commercialization, risk in attaining and retaining appropriate development or commercial partners, lower-than-expected product adoption, difficulties in gaining appropriate reimbursement for products from payors, unforeseen generic and branded competition, risk to patents being invalidated, and failure to meet earnings and revenue expectations.

Distribution of Ratings (September 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	44.3%	18.0%	60.3%	43.9%	56.5%	56.0%
Hold	Market Perform	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage within ratings category.

*** Reflects rating distribution of all companies from which BMO Capital Markets Corp. has received compensation for Investment Banking services as percentage of Investment Banking clients.

**** Reflects rating distribution of all companies covered by BMO Capital Markets equity research analysts.

***** Reflects rating distribution of all companies from which BMO Capital Markets has received compensation for Investment Banking services as percentage of Investment Banking clients.

Rating and Sector Key (as of April 5, 2013):

We use the following ratings system definitions:

OP = Outperform - Forecast to outperform the analyst's coverage universe on a total return basis

Mkt = Market Perform - Forecast to perform roughly in line with the analyst's coverage universe on a total return basis

Und = Underperform - Forecast to underperform the analyst's coverage universe on a total return basis

(S) = speculative investment;

NR = No rating at this time;

R = Restricted – Dissemination of research is currently restricted.

BMO Capital Markets' seven Top 15 lists guide investors to our best ideas according to different objectives (CDN Large Cap, CDN Small Cap, US Large Cap, US Small Cap, Income, CDN Quant, and US Quant have replaced the Top Pick rating).

Prior BMO Capital Markets Ratings System (January 4, 2010–April 5, 2013):

http://researchglobal.bmocapitalmarkets.com/documents/2013/prior_rating_system.pdf

Other Important Disclosures

For Other Important Disclosures on the stocks discussed in this report, please go to http://researchglobal.bmocapitalmarkets.com/Public/Company_Disclosure_Public.aspx or write to Editorial Department, BMO Capital Markets, 3 Times Square, New York, NY 10036 or Editorial Department, BMO Capital Markets, 1 First Canadian Place, Toronto, Ontario, M5X 1H3.

Dissemination of Research

BMO Capital Markets Equity Research is available via our website <https://research-ca.bmocapitalmarkets.com/Public/Secure/Login.aspx?ReturnUrl=/Member/Home/ResearchHome.aspx>

Institutional clients may also receive our research via Thomson Reuters, Bloomberg, FactSet, and Capital IQ.

Research reports and other commentary are required to be simultaneously disseminated internally and externally to our clients.

Conflict Statement

A general description of how BMO Financial Group identifies and manages conflicts of interest is contained in our public facing policy for managing conflicts of interest in connection with investment research which is available at http://researchglobal.bmocapitalmarkets.com/Public/Conflict_Statement_Public.aspx

General Disclaimer

"BMO Capital Markets" is a trade name used by the BMO Investment Banking Group, which includes the wholesale arm of Bank of Montreal and its subsidiaries BMO Nesbitt Burns Inc., BMO Capital Markets Limited in the U.K. and BMO Capital Markets Corp. in the U.S. BMO Nesbitt Burns Inc., BMO Capital Markets Limited and BMO Capital Markets Corp are affiliates. Bank of Montreal or its subsidiaries ("BMO Financial Group") has lending arrangements with, or provide other remunerated services to, many issuers covered by BMO Capital Markets. The opinions, estimates and projections contained in this report are those of BMO Capital Markets as of the date of this report and are subject to change without notice. BMO Capital Markets endeavours to ensure that the contents have been compiled or derived from sources that we believe are reliable and contain information and opinions that are accurate and complete. However, BMO Capital Markets makes no representation or warranty, express or implied, in respect thereof, takes no responsibility for any errors and omissions contained herein and accepts no liability whatsoever for any loss arising from any use of, or reliance on, this report or its contents. Information may be available to BMO Capital Markets or its affiliates that is not reflected in this report. The information in this report is not intended to be used as the primary basis of investment decisions, and because of individual client objectives, should not be construed as advice designed to meet the particular investment needs of any investor. This material is for information purposes only and is not an offer to sell or the solicitation of an offer to buy any security. BMO Capital Markets or its affiliates will buy from or sell to customers the securities of issuers mentioned in this report on a principal basis. BMO Capital Markets or its affiliates, officers, directors or employees have a long or short position in many of the securities discussed herein, related securities or in options, futures or other derivative instruments based thereon. The reader should assume that BMO Capital Markets or its affiliates may have a conflict of interest and should not rely solely on this report in evaluating whether or not to buy or sell securities of issuers discussed herein.

Additional Matters

To Canadian Residents: BMO Nesbitt Burns Inc. furnishes this report to Canadian residents and accepts responsibility for the contents herein subject to the terms set out above. Any Canadian person wishing to effect transactions in any of the securities included in this report should do so through BMO Nesbitt Burns Inc.

The following applies if this research was prepared in whole or in part by Andrew Breichmanas, Iain Reid, Tony Robson, David Round, Edward Sterck or Brendan Warn: This research is not prepared subject to Canadian disclosure requirements. This research is prepared by BMO Capital Markets Limited and subject to the regulations of the Financial Conduct Authority (FCA) in the United Kingdom. FCA regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 5% or more of the equity of the issuer. Canadian regulations require that a firm providing research disclose its ownership interest in the issuer that is the subject of the research if it and its affiliates own 1% or more of the equity of the issuer that is the subject of the research. Therefore BMO Capital Markets Limited will disclose its and its affiliates' ownership interest in the subject issuer only if such ownership exceeds 5% of the equity of the issuer.

To U.S. Residents: BMO Capital Markets Corp. furnishes this report to U.S. residents and accepts responsibility for the contents herein, except to the extent that it refers to securities of Bank of Montreal. Any U.S. person wishing to effect transactions in any security discussed herein should do so through BMO Capital Markets Corp.

To U.K. Residents: In the UK this document is published by BMO Capital Markets Limited which is authorised and regulated by the Financial Conduct Authority. The contents hereof are intended solely for the use of, and may only be issued or passed on to, (I) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (II) high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together referred to as "relevant persons"). The contents hereof are not intended for the use of and may not be issued or passed on to retail clients.

Unauthorized reproduction, distribution, transmission or publication without the prior written consent of BMO Capital Markets is strictly prohibited.

[Click here](#) for data vendor disclosures when referenced within a BMO Capital Markets research document.

ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

BMO Financial Group (NYSE, TSX: BMO) is an integrated financial services provider offering a range of retail banking, wealth management, and investment and corporate banking products. BMO serves Canadian retail clients through BMO Bank of Montreal and BMO Nesbitt Burns. In the United States, personal and commercial banking clients are served by BMO Harris Bank N.A., (Member FDIC). Investment and corporate banking services are provided in Canada and the US through BMO Capital Markets.

BMO Capital Markets is a trade name used by BMO Financial Group for the wholesale banking businesses of Bank of Montreal, BMO Harris Bank N.A. (Member FDIC), BMO Ireland Plc, and Bank of Montreal (China) Co. Limited and the institutional broker dealer businesses of BMO Capital Markets Corp. (Member SIPC), and BMO Capital Markets GKST Inc. (Member SIPC) in the U.S., BMO Nesbitt Burns Inc. (Member Canadian Investor Protection Fund) in Canada, Europe and Asia, BMO Capital Markets Limited in Europe and Australia and BMO Advisors Private Limited in India. "Nesbitt Burns" is a registered trademark of BMO Nesbitt Burns Corporation Limited, used under license. "BMO Capital Markets" is a trademark of Bank of Montreal, used under license. "BMO (M-Bar roundel symbol)" is a registered trademark of Bank of Montreal, used under license.

® Registered trademark of Bank of Montreal in the United States, Canada and elsewhere.
TM Trademark Bank of Montreal

©COPYRIGHT 2014 BMO CAPITAL MARKETS CORP

A member of BMO  Financial Group
