

June 26, 2015

HEALTHCARE/BIOTECHNOLOGY

Stock Rating:
OUTPERFORM

12-18 mo. Price Target	\$38.00
TKAI - NASDAQ	\$14.16

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	\$30.00-\$9.67
Shares Outstanding	22.4M
Float	6.6M
Market Capitalization	\$317.4M
Avg. Daily Trading Volume	107,205
Dividend/Div Yield	NA/NM
Book Value	NA
Fiscal Year Ends	Dec
2015E ROE	NA
LT Debt	NA
Preferred	NA
Common Equity	NA
Convertible Available	No

Trading range is as of 9/23/14 IPO.

EPS Diluted	Q1	Q2	Q3	Q4	Year	Mult.
2014A	NA	NA	(2.71)	(0.28)	(3.60)	NM
2015E	(0.30)	(0.34)	(0.47)	(0.51)	(1.62)	NM
2016E	--	--	--	--	(2.15)	NM

Tokai Pharmaceuticals, Inc.

Phase III ARMOR3-SV Trial Initiated, Updating Model

SUMMARY

Recently TKAI announced the initiation of the phase III ARMOR3 trial which met management's 1H15 guidance. The components of the companion diagnostic test of the AR-V7 assay have been finalized by its collaborator, Qiagen (QGEN). The trial expects to start screening patients in July after the central labs are trained. Final data from the trial is expected by YE16. We continue to view the ARMOR3 trial as having a high probability of success based on a clear MOA, promising efficacy seen in the ARMOR2 trial, and Xtandi's lack of efficacy in AR-V7+ mCRPC patients. We also update the financials in this note.

KEY POINTS

- **Phase III trial design is favorable with short follow-up.** The ARMOR3 trial is the first biomarker guided pivotal trial in CRPC. The FDA's buy-in on using rPFS (rather than OS) as the primary endpoint allows the company to run a relatively small trial with short follow-up time. Final data is expected by YE16.
- **We view ARMOR3 trial as having a high probability of success.** We project a 75% probability of success based on clear MOA, promising efficacy seen in the ARMOR2 trial, and Xtandi's lack of efficacy in AR-V7+ mCRPC patients.
- **Companion diagnostic test has been finalized.** Currently technology transfers (from Johns Hopkins University to Qiagen and central labs) are underway. Once the training of global central laboratories is completed, the ARMOR3 trial will start screening eligible AR-V7+ patients in July 2015.
- **Updating model.** TKAI ended 1Q15 with \$94.2M in cash & equivalents which should be sufficient to fund operations into 2017 after the readout of the ARMOR3 trial. Our new EPS estimates are \$(2.44) and \$(2.19) for 2015 and 2016 vs. prior \$(1.62) and \$(2.15) as we increased R&D expenses based on 1Q15 results.

Stock Price Performance



Company Description

Tokai Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company, focuses on developing novel proprietary therapies for the treatment of prostate cancer and other hormonally driven diseases in the US.

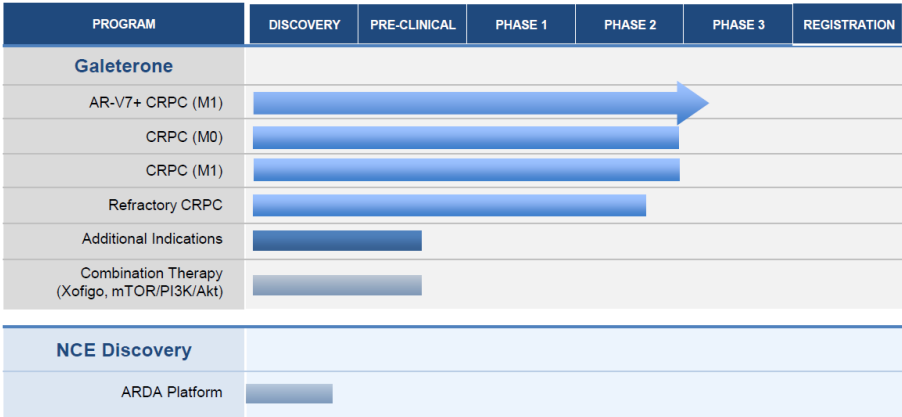
Oppenheimer & Co. Inc. does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. See "Important Disclosures and Certifications" section at the end of this report for important disclosures, including potential conflicts of interest. See "Price Target Calculation" and "Key Risks to Price Target" sections at the end of this report, where applicable.

Upcoming Catalysts

- ✓ Potential to initiate the phase III ARMOR3 trial in frontline M1 CRPC patients with detectable AR-V7 in CTC (1H15)
- Potential to report top line data from the pivotal phase III ARMOR3 trial of galeterone in patients with AR-V7+ tumors (2H16)
- Potential business development activities for galeterone (TBD)

Pipeline Programs

Exhibit 1. TKAI Programs



Source: Company reports

Financial Models

Tokai Pharmaceuticals, Inc.												
Income Statement & Financial Projections												
(Figures in thousands, except per share items)												
	2012A	2013A	1H14A	3Q14A	4Q14A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E
Revenue												
Operating expenses:												
Research and development	7,370	12,201	7,948	2,825	3,804	14,577	10,559	11,087	11,420	10,500	43,566	39,209
General and administrative	2,279	3,548	2,829	3,599	2,457	8,885	2,741	2,850	2,950	3,000	11,541	12,118
Total operating expenses	9,649	15,749	10,777	6,424	6,261	23,462	13,300	13,937	14,370	13,500	55,107	51,327
Loss from operations	(9,649)	(15,749)	(10,777)	(6,424)	(6,261)	(23,462)	(13,300)	(13,937)	(14,370)	(13,500)	(55,107)	(51,327)
Other income		24	79	34	53	166	40	43	34	30	147	100
Net loss and comprehensive loss	(9,649)	(15,725)	(10,698)	(6,390)	(6,208)	(23,296)	(13,260)	(13,894)	(14,336)	(13,470)	(54,960)	(51,227)
Accretion of redeemable convertible preferred stock to redemption value	(34)	(94)										
Net loss attributable to common stockholders	(9,683)	(15,819)	(10,698)	(6,390)	(6,208)	(23,296)	(13,260)	(13,894)	(14,336)	(13,470)	(54,960)	(51,227)
EPS, basic and diluted	(\$31.1)	(\$38.0)	(\$2.05)	(\$2.71)	(\$0.28)	(\$3.60)	\$ (0.59)	\$ (0.62)	\$ (0.63)	\$ (0.59)	\$ (2.44)	\$ (2.19)
Common shares outstanding, basic and diluted	311,474.0	416,037.0	5,215	2,357	22,329	6,469	22,384	22,496	22,609	22,722	22,553	23,403

Source: Company Reports & Oppenheimer & Co. Research

Investment Thesis

TKAI's flagship compound galeterone addresses a clear unmet medical need in prostate cancer, i.e., patients with tumor-expressing androgen receptor (AR) split variants (in particular, AR-V7) for whom recently approved novel agents such as Zytiga and Xtandi are not expected to work potentially due to the loss of ligand binding domain (LBD). We view TKAI as a highly favorable biotech name, given a clear pathway for approval, a high probability of phase III success, large market opportunity and no foreseeable competition.

Price Target Calculation

Our 12- to 18-month price target of \$38 is primarily based on the risk-adjusted NPV of galeterone of ~\$923M (~\$38/share). We project galeterone 2023 US sales of \$1.2B and ex-US sales of ~\$748M (royalty rate of ~20% in ex-US sales). We use a typical biotech revenue multiple of 5x, royalty multiple of 10x, a probability of success of 75%, discount rate of 30% (which reflects the development stage of the company) to derive the risk-adjusted NPV of galeterone.

Key Risks to Price Target

We view clinical risks associated with galeterone as the main risk for TKAI. Other risks include regulatory risks, financing risk, and commercialization risk.

Stock prices of other companies mentioned in this report (as of 6/25/15):

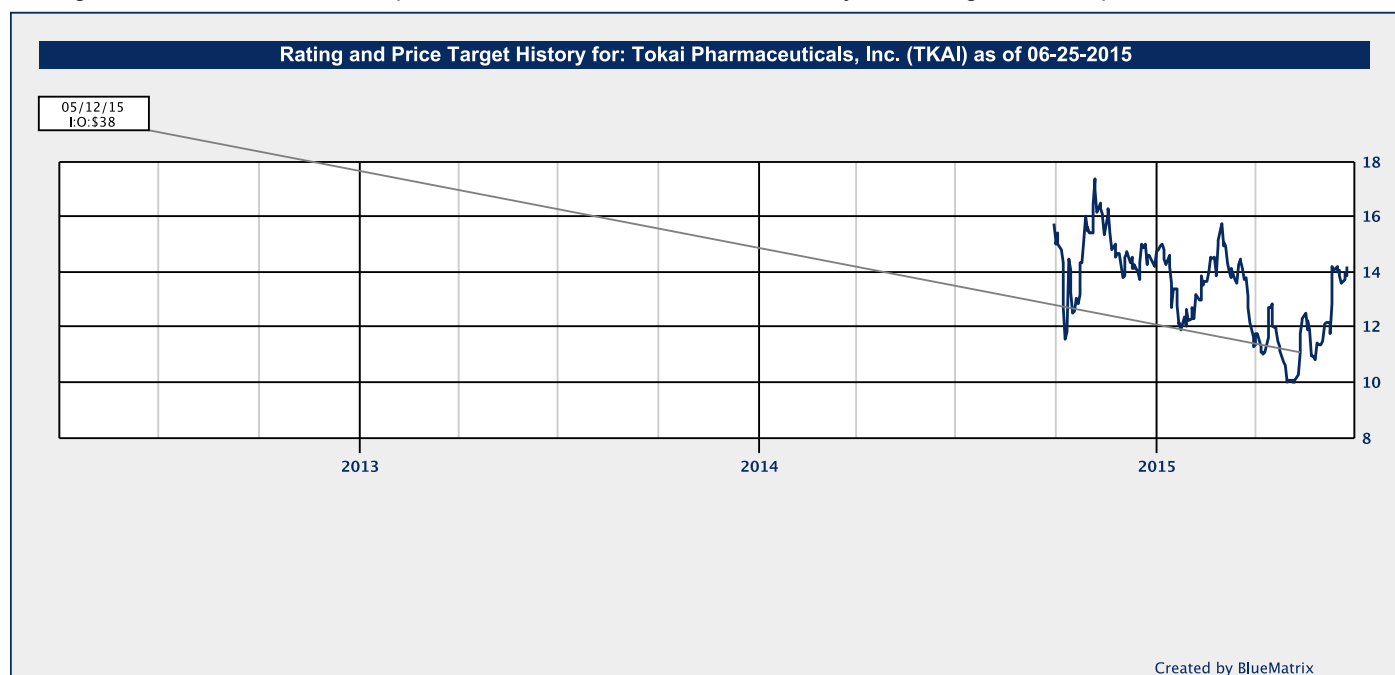
Qiagen (QGEN-NYSE, \$24.76, Not Covered)

Important Disclosures and Certifications

Analyst Certification - The author certifies that this research report accurately states his/her personal views about the subject securities, which are reflected in the ratings as well as in the substance of this report. The author certifies that no part of his/her compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this research report.

Potential Conflicts of Interest:

Equity research analysts employed by Oppenheimer & Co. Inc. are compensated from revenues generated by the firm including the Oppenheimer & Co. Inc. Investment Banking Department. Research analysts do not receive compensation based upon revenues from specific investment banking transactions. Oppenheimer & Co. Inc. generally prohibits any research analyst and any member of his or her household from executing trades in the securities of a company that such research analyst covers. Additionally, Oppenheimer & Co. Inc. generally prohibits any research analyst from serving as an officer, director or advisory board member of a company that such analyst covers. In addition to 1% ownership positions in covered companies that are required to be specifically disclosed in this report, Oppenheimer & Co. Inc. may have a long position of less than 1% or a short position or deal as principal in the securities discussed herein, related securities or in options, futures or other derivative instruments based thereon. Recipients of this report are advised that any or all of the foregoing arrangements, as well as more specific disclosures set forth below, may at times give rise to potential conflicts of interest.



All price targets displayed in the chart above are for a 12- to- 18-month period. Prior to March 30, 2004, Oppenheimer & Co. Inc. used 6-, 12-, 12- to 18-, and 12- to 24-month price targets and ranges. For more information about target price histories, please write to Oppenheimer & Co. Inc., 85 Broad Street, New York, NY 10004, Attention: Equity Research Department, Business Manager.

Oppenheimer & Co. Inc. Rating System as of January 14th, 2008:

Outperform(O) - Stock expected to outperform the S&P 500 within the next 12-18 months.

Perform (P) - Stock expected to perform in line with the S&P 500 within the next 12-18 months.

Underperform (U) - Stock expected to underperform the S&P 500 within the next 12-18 months.

Not Rated (NR) - Oppenheimer & Co. Inc. does not maintain coverage of the stock or is restricted from doing so due to a potential conflict of interest.

Oppenheimer & Co. Inc. Rating System prior to January 14th, 2008:

Buy - anticipates appreciation of 10% or more within the next 12 months, and/or a total return of 10% including dividend payments, and/or the ability of the shares to perform better than the leading stock market averages or stocks within its particular industry sector.

Neutral - anticipates that the shares will trade at or near their current price and generally in line with the leading market averages due to a perceived absence of strong dynamics that would cause volatility either to the upside or downside, and/or will perform less well than higher rated companies within its peer group. Our readers should be aware that when a rating change occurs to Neutral from Buy, aggressive trading accounts might decide to liquidate their positions to employ the funds elsewhere.

Sell - anticipates that the shares will depreciate 10% or more in price within the next 12 months, due to fundamental weakness perceived in the company or for valuation reasons, or are expected to perform significantly worse than equities within the peer group.

Distribution of Ratings/IB Services Firmwide				
Rating	Count	IB Serv/Past 12 Mos.		Count
		Percent	Percent	
OUTPERFORM [O]	343	57.65		149
PERFORM [P]	245	41.18		88
UNDERPERFORM [U]	7	1.18		2

Although the investment recommendations within the three-tiered, relative stock rating system utilized by Oppenheimer & Co. Inc. do not correlate to buy, hold and sell recommendations, for the purposes of complying with FINRA rules, Oppenheimer & Co. Inc. has assigned buy ratings to securities rated Outperform, hold ratings to securities rated Perform, and sell ratings to securities rated Underperform.

Additional Information Available

Please log on to <http://www.opco.com> or write to Oppenheimer & Co. Inc., 85 Broad Street, New York, NY 10004, Attention: Equity Research Department, Business Manager.

Other Disclosures

This report is issued and approved for distribution by Oppenheimer & Co. Inc. Oppenheimer & Co. Inc. transacts business on all principal exchanges and is a member of SIPC. This report is provided, for informational purposes only, to institutional and retail investor clients of Oppenheimer & Co. Inc. and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such offer or solicitation would be prohibited. The securities mentioned in this report may not be suitable for all types of investors. This report does not take into account the investment objectives, financial situation or specific needs of any particular client of Oppenheimer & Co. Inc. Recipients should consider this report as only a single factor in making an investment decision and should not rely solely on investment recommendations contained herein, if any, as a substitution for the exercise of independent judgment of the merits and risks of investments. The analyst writing the report is not a person or company with actual, implied or apparent authority to act on behalf of any issuer mentioned in the report. Before making an investment decision with respect to any security recommended in this report, the recipient should consider whether such recommendation is appropriate given the recipient's particular investment needs, objectives and financial circumstances. We recommend that investors independently evaluate particular investments and strategies, and encourage investors to seek the advice of a financial advisor. Oppenheimer & Co. Inc. will not treat non-client recipients as its clients solely by virtue of their receiving this report. Past performance is not a guarantee of future results, and no representation or warranty, express or implied, is made regarding future performance of any security mentioned in this report. The price of the securities mentioned in this report and the income they produce may fluctuate and/or be adversely affected by exchange rates, and investors may realize losses on investments in such securities, including the loss of investment principal. Oppenheimer & Co. Inc. accepts no liability for any loss arising from the use of information contained in this report, except to the extent that liability may arise under specific statutes or regulations applicable to Oppenheimer & Co. Inc. All information, opinions and statistical data contained in this report were obtained or derived from public sources believed to be reliable, but Oppenheimer & Co. Inc. does not represent that any such information, opinion or statistical data is accurate or complete (with the exception of information contained in the Important Disclosures section of this report provided by Oppenheimer & Co. Inc. or individual research analysts), and they should not be relied upon as such. All estimates, opinions and recommendations expressed herein constitute judgments as of the date of this report and are subject to change without notice. Nothing in this report constitutes legal,

accounting or tax advice. Since the levels and bases of taxation can change, any reference in this report to the impact of taxation should not be construed as offering tax advice on the tax consequences of investments. As with any investment having potential tax implications, clients should consult with their own independent tax adviser. This report may provide addresses of, or contain hyperlinks to, Internet web sites. Oppenheimer & Co. Inc. has not reviewed the linked Internet web site of any third party and takes no responsibility for the contents thereof. Each such address or hyperlink is provided solely for the recipient's convenience and information, and the content of linked third party web sites is not in any way incorporated into this document. Recipients who choose to access such third-party web sites or follow such hyperlinks do so at their own risk.

This research is distributed in the UK and elsewhere throughout Europe, as third party research by Oppenheimer Europe Ltd, which is authorized and regulated by the Financial Conduct Authority (FCA). This research is for information purposes only and is not to be construed as a solicitation or an offer to purchase or sell investments or related financial instruments. This research is for distribution only to persons who are eligible counterparties or professional clients and is exempt from the general restrictions in section 21 of the Financial Services and Markets Act 2000 on the communication of invitations or inducements to engage in investment activity on the grounds that it is being distributed in the UK only to persons of a kind described in Article 19(5) (Investment Professionals) and 49(2) High Net Worth companies, unincorporated associations etc.) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended). It is not intended to be distributed or passed on, directly or indirectly, to any other class of persons. In particular, this material is not for distribution to, and should not be relied upon by, retail clients, as defined under the rules of the FCA. Neither the FCA's protection rules nor compensation scheme may be applied.

Distribution in Hong Kong: This report is prepared for professional investors and is being distributed in Hong Kong by Oppenheimer Investments Asia Limited (OIAL) to persons whose business involves the acquisition, disposal or holding of securities, whether as principal or agent. OIAL, an affiliate of Oppenheimer & Co. Inc., is regulated by the Securities and Futures Commission for the conduct of dealing in securities, advising on securities, and advising on Corporate Finance. For professional investors in Hong Kong, please contact researchasia@opco.com for all matters and queries relating to this report. This report or any portion hereof may not be reprinted, sold, or redistributed without the written consent of Oppenheimer & Co. Inc.

This report or any portion hereof may not be reprinted, sold, or redistributed without the written consent of Oppenheimer & Co. Inc. Copyright © Oppenheimer & Co. Inc. 2015.