## **US Equity Research**

5 January 2015

#### **BUY**

unchanged

#### PRICE TARGET US\$90.00个

from US\$51.00

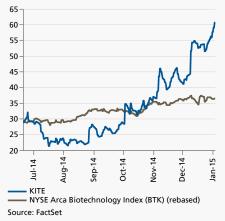
Price (5-Jan) US\$69.75 Ticker KITE-NASDAO

52-Week Range (US\$): 21.00 - 61.59
Avg Daily Vol (M): 588.8
Shares Out. (M): 38.3
Market Cap (US\$M): 2,674

FYE Dec	2013A	2014E	2015E
Revenue (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(1.42)	(1.70)	(1.30)

Quarterly Revenue	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	0.0A	0.0A	0.0A	0.0
2015E	0.0	0.0	0.0	0.0

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	(0.66)A	(2.27)A	(0.24)A	(0.23)
2015E	(0.33)	(0.33)	(0.33)	(0.32)



Kite Pharma is focused on development of novel cancer immunotherapy using engineered autologous cell therapy (eACT).

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# **Raising Target Price**

# Raising target to \$90 on strong outlook for 2015

## Two-way collaboration with Amgen - new antigens, stronger solid tumor development

Under the alliance between the two companies, Amgen will contribute cancer targets to KITE in identifying new indications, mainly for their CART therapy, which we believe will focus heavily on solid tumors as well as additional hematologic cancers. Interestingly, the collaboration allows for either party to receive milestones and royalties from the company taking the antigen into clinical development. Additionally, we believe that any indication of positive efficacy for CART or TCR technology in solid tumors would be a major plus for KITE shares, as we currently do not include any value for solid tumor indications in our model.

## Antigen identification critical going forward for the evolution for CART

CD19 has emerged as the lead antigen in B-cell tumors, but we believe additional antigens will be identified and validated, including CD123 in AML and others in solid tumors beyond intracellular antigens like NY-ESO and MAGE. Importantly, the collaboration with Amgen allows for use of 3<sup>rd</sup> generation CAR-T constructs, as well as constructs targeting multiple antigens, which we believe will be more efficacious in solid tumors. In addition, other competitors in the space are testing CAR-T constructs that edit out the PD-1 gene and may boost efficacy further.

#### Expect 4 pivotal studies in 2015 for various heme cancers

Kite plans on launching 4 pivotal studies in various hematologic cancers in 2015, which we expect to be in DLBCL, ALL, CLL, or MCL/FL, each of which should serve as a pivotal study and facilitate filing with FDA assuming positive efficacy and safety data. Importantly, KITE is leading the field in development of CAR-T therapy for DLBCL, the largest single hematological indication being studied. Although KITE has not yet disclosed clinical trial designs, we believe that response rate data and progression data should be sufficient for FDA approval.

# Market Cap disparity vs. Juno favors upside for Kite

Kite is currently valued at ~\$2.7B, compared to ~\$4.3B for Juno, despite Kite's leading indication (DLBCL) representing a market opportunity 2-3x larger than Juno's lead indication (ALL). Also, KITE is only ~36% owned by institutions, whereas we believe JUNO is largely owned by institutions following its recent IPO. We would expect ownership for KITE to shift heavily towards institutions during 2015, which should push shares higher, adding to any positive effect from clinical data readouts during the year.

## Raising price target to \$90 from \$51, reiterate BUY rating

We are raising our PT to \$90 given the recent positive clinical data at ASH of improved durable response in DLBCL and the collaborative alliance with Amgen. We raise our probability adjustment for DLBCL (45%) and other indications (30%) to 70% for DLBCL, 65% for ALL, and 60% for CLL, FL, and MCL. We also included the \$200M cash raise into our valuation to achieve a \$90 PT, though this value could be higher if data in solid tumors are presented in 2015. If we were to assume 100% probability of approval for all indications, our price target would be ~\$131.

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## **CART against CD123 for AML**

AML remains a very difficult to treat disease due to various molecular mutations, making this an extremely heterogeneous disease. Because AML cells frequently overexpress CD33 and CD123, these antigens could be a valuable target for CART therapy. According to recent publications by Pizzitola et al., CD123 may prove to be a very interesting target as this antigen is only expressed in AML cells, while CD33 is commonly found in normal hematopoietic stem cells. Preclinical data already validates that modified T cells, using the cytokine-induced killer (CIK) cells, demonstrated specific AML killing with the CD123 antigen target with low effect on normal hematopoietic stem cells (Pizzitola I et al. Leukemia. 2014).

# CART against mesothelin (CARTmeso cells) for solid tumors

The UPenn group published an interesting article recently, discussing the CART therapy targeting mesothelin. This approach is designed to circumvent off target toxicities seen with historical CARTs against solid tumors due to normal tissue expression of these antigens. Known as the CARTmeso cells, which combines CART therapy with the mesothelin as its antigen, this combination allowed the CARTmeso cells to persist transiently and attack specific metastatic solid tumor sites (Beatty GL et al. Cancer Immunol Res. 2014). These data, validated by preclinical trials, may represent an interesting opportunity for CAR-T in solid tumors.

# **CART** against various antigens for multiple myeloma (MM)

To date, there are two ongoing clinical trials using CART therapy for multiple myeloma. one targeting kappa immunoglobulin light chain (Baylor College) and another using an anti-CD138, which we believe could be viable options for the Kite/Amgen collaboration. Both antigens are interesting, since immunoglobulin light chains are commonly expressed on MM cells while high CD138 is correlated with high disease burden in MM patients. Additionally, other clinical antigen targets, including BCMA, CS1, Lewis Y antigen, and CD38 are in pre-clinical testing, though data are too early to define any efficacy (Garfall A et al. Discovery Medicine. 2014).



Figure 1: Kite income statement

(\$000's) [FY - DEC] Revenues	<u>2012 A</u>	<u>2013A</u>	<u>1Q14A</u>	2Q14A	3Q14A	4Q14E	<u>2014E</u>	<u>2015E</u>	<u>2016E</u>	<u>2017E</u>	<u>2018E</u>	<u>2019E</u>	2020E
CAR T													
US			_	_	-	_		_	_	263,453	795,983	1,176,814	1,255,539
Ex-US			_	_	-	_		_	_	179,806	516,481	800,327	1,031,009
Ex-US roy alty			-	-	-	-		-	-	26,971	77,472	120,049	154,651
Total revenues							-		-	290,423	873,455	1,296,863	1,410,191
Income Statement (\$000's)	2012 A	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<u> </u>	<u> zorza</u>	2010/4	19(1-1/1)	25(147)	<u>041-91</u>	<u> 1011E</u>	<del></del>	20102					
Total revenues	•	-	•	•	•	•	• •	•	•	290,423	873,455	1,296,863	1,410,191
Cost of goods sold	-	-	-	-	-	-	-	-	-	52,691	159,197	235,363	251,108
Gross profit	•					•	•	-	•	237,733	714,259	1,061,500	1,159,083
Operating expenses													
Research and Development	1,802	5,071	2,062	7,424	5,716	5,773	20,975	39,619	40,412	50,515	63,144	78,929	98,662
SG&A	770	1,339	1,070	3,668	3,385	3,419	11,542	14,021	14,722	14,869	15,464	16,082	16,726
Depreciation and amortization	9	17	30	48			78	-					
Total Operating Expense	2,581	6,427	3,162	11,140	9,101	9,192	32,595	53,640	55,134	65,384	78,607	95,012	115,387
Depreciation and amortization	9	17	30	48			78	-					
EBITDA	(2,572)	(6,410)	(3,132)	(11,092)	(9,101)	(9,192)	(32,517)	(53,640)	(55, 134)	172,349	635,651	966,489	1,043,695
Operating income (EBIT)	(2,581)	(6,427)	(3,162)	(11,140)	(9,101)	(9,192)	(32,595)	(53,640)	(55,134)	172,349	635,651	966,489	1,043,695
Non-operating Interest income	36	52		47	61	290	398	809	714	1,769	6,034	13,578	23,019
Other income/interest expense	(27)	13	21	(6,266)	(11)								
Pre-tax income (EBT)	(2,571)	(6,362)	(3,141)	(17,359)	(9,051)	(8,902)	(32,197)	(52,832)	(54,419)	174,118	641,685	980,066	1,066,715
Provision for Income Taxes	_	_	_	_	_	-		_	_	64,424	237,423	362,625	394,684
Net Income	(2,571)	(6,362)	(3,141)	(17,359)	(9,051)	(8,902)	(38,454)	(52,832)	(54,419)	109,694	404,262	617,442	672,030
Preferred Dividends	,	1,436	557	532	, , ,	, , ,	, , ,	,	, , ,		•	,	,
Net Income to Common Shareholders	(2,571)	(7,797)	(3,698)	(17,891)									
Adjustments to Net income	(7:3)	(,,,,,	(3,334)	( , , , , ,									
GAAP EPS	(0.48)	(1.42)	(0.66)	(2.27)	(\$0.24)	(\$0.23)	(\$1.70)	(\$1.30)	(\$1.29)	\$2.34	\$7.70	\$10.50	\$10.21
Adjusted EPS excl options expense								•					
Diluted Weighted Average Shares	5,314,214	5,473,384	5,571,499	7,890,029	38,330,026	38,713,326	22,626,220	10,668,708	42,196,368	46,864,399	52,488,127	58,786,703	65,841,107

Source: Canaccord Genuity Estimates



Figure 2: Kite Valuation

Product	Peak Sales/Royalty (\$MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value (\$MM)	Value / Share
KTE-C19								
US								
DLBCL US	\$691	2020	\$3,002	10/1/2017	2.7	70%	\$1,568	\$40
CLL US	\$83	2021	\$337	10/1/2018	3.7	60%	\$135	\$3
ALL US	\$195	2021	\$976	10/1/2018	3.7	65%	\$425	\$11
FL US	\$165	2021	\$738	10/1/2018	3.7	60%	\$297	\$8
MCL US	\$164	2021	\$734	10/2/2018	3.7	60%	\$295	\$8
US - total	\$1,298	2020	\$5,788	10/1/2018	3.7	60%	\$2,328	\$70
Ex-US								
DLBCL royalty Ex-US	\$53	2020	\$499	6/1/2018	3.4	70%	\$243	\$6
CLL royalty Ex-US	\$6	2021	\$55	6/1/2019	4.4	60%	\$21	\$1
ALL royalty Ex-US	\$15	2021	\$140	6/1/2019	4.4	65%	\$57	\$1
FL royalty Ex-US	\$13	2021	\$108	6/2/2019	4.4	60%	\$40	\$1
MCL royalty Ex-US	\$12	2021	\$107	6/3/2019	4.4	60%	\$40	\$1
Ex-US - royalty - total	\$99	2020	\$977	6/1/2018	3.4	60%	\$407	\$10
Total Product Value							\$3,129	\$80
Cash							\$400	\$10.3
Total Equity Value							\$3,529	\$90
Shares Outstanding (MM)							39	

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	5%
Discount Rate	11%

Source: Canaccord Genuity Estimates



# Appendix: Important Disclosures

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#### **Target Price / Valuation Methodology:**

Kite Pharma - KITE:

Our target price is \$90 based on a probability adjusted NPV valuation.

## Risks to achieving Target Price / Valuation:

Kite Pharma - KITE:

Although NCI is conducting a phase 1-2a trial of anti-CD19 CAR T-cell therapy, KITE's KTE-C19 trial has not begun. Any delays or significant negative results from NCI's clinical trials could negatively affect Kite's IND application and delay the timing to start their own phase 1-2 clinical trial. KITE is highly dependent on the third parties for R&D and early clinical testing of CAR and TCR product candidates. These collaborations related to the intellectual property licensed from the NIH relating to product candidates targeting the EGFRvIII antigen, the SSX2 antigen and the NY-ESO-1 antigen and from Cabaret for intellectual property relating to KTE-C19. The differences in manufacturing compared to NCI may render the product incomparable, particularly with respect to clinical trials, which could negatively affect our valuation. Although plans for manufacturing and processing is based on current approach undertaken by the NCI, the company cannot ensure that even minor changes in the product process will not result in significantly different T-cells that may not have similar efficacy or toxicity. KTE-C19 could fail in clinical studies, resulting in significant downside to our price target and shares of the stock. Kite faces significant competition from other biotechnology and pharmaceutical companies in the space of immunotherapy, including Novartis, Juno, Bluebird, Cellectis and Adaptimmune, as well as companies developing novel targeted therapies for cancer.

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### Global Stock Ratings (as of 01/05/15)

Rating	Coverage	e Universe	IB Clients		
	#	%	%		
Buy	656	61.31%	33.54%		
Hold	319	29.81%	12.85%		
Sell	43	4.02%	0%		
Speculative Buy	52	4.86%	63.46%		
	1070*	100.0%			

<sup>\*</sup>Total includes stocks that are Under Review

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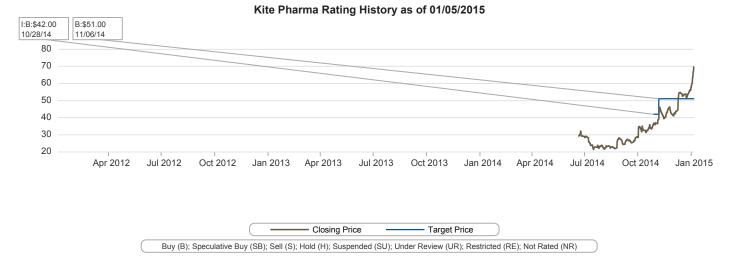
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