

## US Equity Research

12 May 2015

## BUY

unchanged

PRICE TARGET US\$90.00

unchanged

Price (11-May) US\$55.75

Ticker KITE-NASDAQ

52-Week Range (US\$): 21.00 - 89.21  
 Avg Daily Vol (M) : 880.2  
 Shares Out. (M) : 38.3  
 Market Cap (US\$M): 2,137

FYE Dec	2013A	2014A	2015E
Revenue (US\$M)	0.0	0.0	0.0
EPS Adj&Dil (US\$)	(1.42)	(1.91)	(1.65)

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

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014A	(0.66)	(2.27)	(0.24)	(0.33)
2015E	(0.42)	(0.41)	(0.42)	(0.40)

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

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## Company Update

## Expectations low for EGFRvIII-CART in glioma

## UPenn/NVS EGFRvIII-CART study risky, update at ASGCT

UPenn investigators will present data for three EGFRvIII+ glioblastoma patients treated with EGFRvIII CART at the American Society for Gene and Cell Therapy (ASGCT) May 13-16, but we continue to believe the program in glioma is high risk (see abstract on page 3). The abstract shows that the drug is safe with no evidence of off-tumor toxicity, but we believe efficacy may be sacrificed as a result. We spoke with multiple KOLs/ investigators and carefully examined the literature, resulting in our cautious position. Ultimately, we believe EGFRvIII CART constructs have a low probability of success in gliomas, although we believe CART and TCR technology will be successful in other solid tumors.

## Lower affinity EGFR target may limit efficacy, malignant glioma highly variable

UPenn decided to pursue a lower-affinity single chain variable fragment (scFv) anti-EGFRvIII to minimize potential CART recognition of the EGFRwt protein for safety reasons (Johnson L. *Immunotherapy*. 2015), which may limit efficacy. Because EGFR wild-type (EGFRwt) is expressed in a variety of normal tissues (epithelial tissues), EGFR variant III was chosen in order to minimize off-target toxicity. Importantly cells within this tumor often exhibit significant antigenic heterogeneity, which confounds immunotherapeutic approaches like EGFRvIII-CART designed to target single tumor-specific antigens (multiantigenic therapies may be necessary). Prior EGFRvIII-targeted vaccinations proved this point, where trials in Duke Medical Center showed that the majority of recurrent tumors after vaccination no longer expressed EGFRvIII. Interestingly, Celldex's EGFRvIII vaccine did show an Overall Survival benefit in malignant glioma in Phase 2, but only when combined with Avastin.

## Current preclinical models non-ideal, CNS shows low immunogenicity

Current preclinical models for glioma cells are mainly derived from a modified, overexpressed cell line for EGFRvIII rather than growing glioma cells in a culture, because primary glioma cells often lose EGFRvIII expression in culture. This manipulated tumor model of heightened EGFRvIII expression is likely not representative of the actual disease, where glioma tumors are composed of a heterogeneous cell populations, decreasing the read through from these preclinical data. Also, multiple publications have shown that the CNS has a low immunogenicity, or is "immune privileged," as demonstrated by the absence of antigen presenting cells (APCs) within the brain and lack of draining lymph nodes for T cell infiltration.

## Expect KITE success in other solid tumors, melanoma

We expect positive data for KITE in other solid tumors, such as melanoma, holding long-term upside potential for the stock. Dr. Steven Rosenberg recently presented positive updated data at AACR for NY-ESO-1 TCR therapy against melanoma (n=19) and synovial cell sarcoma (n=15), showing a 53% response rate for melanoma, including a 21% Complete Response rate, and a 67% response rate for synovial sarcoma.

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

## Expectations remain conservative on data for EGFRvIII-CART

Although efficacy data on 3 patients will be presented at ASGCT this Thursday, we continue to believe the results will remain lackluster, although in limited patient numbers. Unlike ASCO or ASH, where companies and institutions will present clinical data they deem to show meaningful clinical efficacy, the American Society of Gene and Cell Therapy program is more focused on research and science in hopes of building on lessons learned in the laboratory or from early clinical data. Investigators will often present early data on safety and current progress, which remains important from an educational standpoint, but may be disappointing or not meaningful from an investor standpoint. Therefore, we do not hold expectations for meaningful clinical efficacy for EGFRvIII-CART in these 3 glioma patients.

We remind investors of the stock weakness for KITE following Novartis' CART-meso data presented by Carl June at AACR. Initially, JUNO, NVS, BLCM, and KITE surged when it was announced that Carl June would present data for CART-meso in solid tumors at AACR, but a significant sell-off occurred when the data showed lack of efficacy (n = 4/6 stable disease). The data were important to investigators and researchers, validating the safety of the CART-meso program, which is important from an early program perspective. However, we believe Wall Street's expectations for these early programs were too high (given the success with CD19 CART in hematology), resulting in weakness after the CART-meso data were presented at AACR. Therefore, we have low expectations for EGFRvIII-CART data at ASGCT in glioma.

Figure 1: EGFRvIII-CART in Glioma at ASGCT

Thursday, May 14, 2015

Scientific Symposium 201

8:00 AM - 10:00 AM

Clinical Trials Spotlight

Empire D

Co-Chair(s)

Laurence JN Cooper, MD, PhD

Stephen J. Russell, MD, PhD

Speaker(s)

Marcela V. Maus, MD, PhD

**C-12: Pilot Study of T Cells Redirected to EGFRvIII with a Chimeric Antigen Receptor in Patients with EGFRvIII+ Glioblastoma**

We have initiated a first-in-human pilot study of intravenous delivery of autologous T cells re-directed to the EGFR variant III mutation by means of a lentiviral vector encoding a chimeric antigen receptor (CAR). We report preliminary results on the first three patients we have treated. To date, we have found that infusion of CART-EGFRvIII cells is safe, without evidence of off-tumor toxicity such as cross-reactivity to wild type EGFR. No clinical or laboratory signs of systemic cytokine release syndrome have been observed. All three patients have had significant expansion of CART-EGFRvIII cells as measured by flow cytometry and quantitative PCR in peripheral blood samples, despite the use of steroids in two out of three patients. Updated response data as measured by MRI will be presented.

Source: ASGCT Session Guide

ABSTRACT:

**C-12: Pilot Study of T Cells Redirected to EGFRvIII with a Chimeric Antigen Receptor in Patients with EGFRvIII+ Glioblastoma**

We have initiated a first-in-human pilot study of intravenous delivery of autologous T cells re-directed to the EGFR variant III mutation by means of a lentiviral vector encoding a chimeric antigen receptor (CAR). We report preliminary results on the first three patients we have treated. To date, we have found that infusion of CART-EGFRvIII cells is safe, without evidence of off-tumor toxicity such as cross-reactivity to wild type EGFR. No clinical or laboratory signs of systemic cytokine release syndrome have been observed. All three patients have had significant expansion of CART-EGFRvIII cells as measured by flow cytometry and quantitative PCR in peripheral blood samples, despite the use of steroids in two out of three patients. Updated response data as measured by MRI will be presented.

Figure 2: KITE income statement

(\$000's) [FY - DEC]	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenues</b>											
<b>CAR T</b>											
US	-	-	-	-	-	-	-	263,453	795,983	1,176,814	1,255,539
Ex-US	-	-	-	-	-	-	-	179,806	516,481	800,327	1,031,009
Ex-US royalty	-	-	-	-	-	-	-	26,971	77,472	120,049	154,651
<b>Total revenues</b>	-	-	-	-	-	-	-	<b>290,423</b>	<b>873,455</b>	<b>1,296,863</b>	<b>1,410,191</b>
<b>Income Statement (\$000's)</b>											
<b>Total revenues</b>	✓ -	-	-	-	-	-	-	<b>290,423</b>	<b>873,455</b>	<b>1,296,863</b>	<b>1,410,191</b>
Cost of goods sold	-	-	-	-	-	-	-	52,691	159,197	235,363	251,108
<b>Gross profit</b>	-	-	-	-	-	-	-	<b>237,733</b>	<b>714,259</b>	<b>1,061,500</b>	<b>1,159,083</b>
<b>Operating expenses</b>											
Research and Development	✓ 23,089	11,936	11,936	12,055	12,175	48,102	49,064	61,329	76,662	95,827	119,784
SG&A	✓ 13,569	5,452	5,506	5,562	5,617	22,137	23,244	23,477	24,416	25,392	26,408
Depreciation and amortization	264					-					
<b>Total Operating Expense</b>	✓ 36,658	17,388	17,442	17,616	17,793	70,239	72,308	<b>84,806</b>	<b>101,077</b>	<b>121,219</b>	<b>146,192</b>
<b>EBITDA</b>	✓ (36,658)	(17,388)	(17,442)	(17,616)	(17,793)	(70,239)	(72,308)	152,927	613,181	940,281	1,012,891
<b>Operating income (EBIT)</b>	✓ (36,658)	(17,388)	(17,442)	(17,616)	(17,793)	(70,239)	(72,308)	152,927	613,181	940,281	1,012,891
Non-operating Interest income	✓ 358	757	696	626	631	2,711	2,350	3,195	7,271	14,595	23,777
Other income/interest expense	✓ (6,269)										
<b>Pre-tax income (EBT)</b>	(42,569)	(16,630)	(16,747)	(16,990)	(17,161)	(67,528)	(69,958)	<b>156,122</b>	<b>620,452</b>	<b>954,876</b>	<b>1,036,668</b>
Provision for Income Taxes	✓ -	-	-	-	-	-	-	57,765	229,567	353,304	383,567
<b>Net Income</b>	✓ (42,569)	(16,630)	(16,747)	(16,990)	(17,161)	(67,528)	(69,958)	<b>98,357</b>	<b>390,885</b>	<b>601,572</b>	<b>653,101</b>
Preferred Dividends	✓ 1,089										
<b>Net Income to Common Shareholders</b>	(43,658)										
Adjustments to Net income											
<b>GAAP EPS</b>	(\$1.91)	(\$0.42)	(\$0.41)	(\$0.42)	(\$0.40)	(\$1.65)	(\$1.65)	<b>\$2.09</b>	<b>\$7.40</b>	<b>\$10.17</b>	<b>\$9.86</b>
<b>Adjusted EPS excl options expense</b>											
Diluted Weighted Average Shares	22,822,204	39,739,141	40,533,924	40,939,263	42,491,513	40,925,960	42,458,765	47,145,164	52,802,584	59,138,894	66,235,561

Source: Company Reports, Canaccord Genuity estimates

Figure 3: KITE valuation

Product	Peak Sales/Royalty (\$MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value (\$MM)	Value / Share
<b>KTE-C19</b>								
US								
DLBCL US	\$691	2020	\$2,854	10/1/2017	2.4	70%	\$1,545	\$40
CLL US	\$83	2021	\$311	10/1/2018	3.4	60%	\$130	\$3
ALL US	\$195	2021	\$948	10/1/2018	3.4	65%	\$428	\$11
FL US	\$165	2021	\$711	10/1/2018	3.4	60%	\$297	\$8
MCL US	\$164	2021	\$707	10/2/2018	3.4	60%	\$295	\$8
<b>US - total</b>	<b>\$1,298</b>	<b>2020</b>	<b>\$5,531</b>	<b>10/1/2018</b>	<b>3.4</b>	<b>60%</b>	<b>\$2,306</b>	<b>\$69</b>
Ex-US								
DLBCL royalty Ex-US	\$53	2020	\$496	6/1/2018	3.1	70%	\$250	\$6
CLL royalty Ex-US	\$6	2021	\$55	6/1/2019	4.1	60%	\$21	\$1
ALL royalty Ex-US	\$15	2021	\$139	6/1/2019	4.1	65%	\$59	\$2
FL royalty Ex-US	\$13	2021	\$107	6/2/2019	4.1	60%	\$42	\$1
MCL royalty Ex-US	\$12	2021	\$107	6/3/2019	4.1	60%	\$41	\$1
<b>Ex-US - royalty - total</b>	<b>\$99</b>	<b>2020</b>	<b>\$973</b>	<b>6/1/2018</b>	<b>3.1</b>	<b>60%</b>	<b>\$420</b>	<b>\$11</b>
<b>Total Product Value</b>							<b>\$3,114</b>	<b>\$80</b>
Cash							\$400	\$10.3
<b>Total Equity Value</b>							<b>\$3,514</b>	<b>\$90</b>
Shares Outstanding (MM)							39	

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

Source: Company Reports, 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 05/12/15)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	577	57.99%	32.24%
Hold	335	33.67%	16.12%
Sell	38	3.82%	2.63%
Speculative Buy	45	4.52%	55.56%
	995*	100.0%	

\*Total includes stocks that are Under Review

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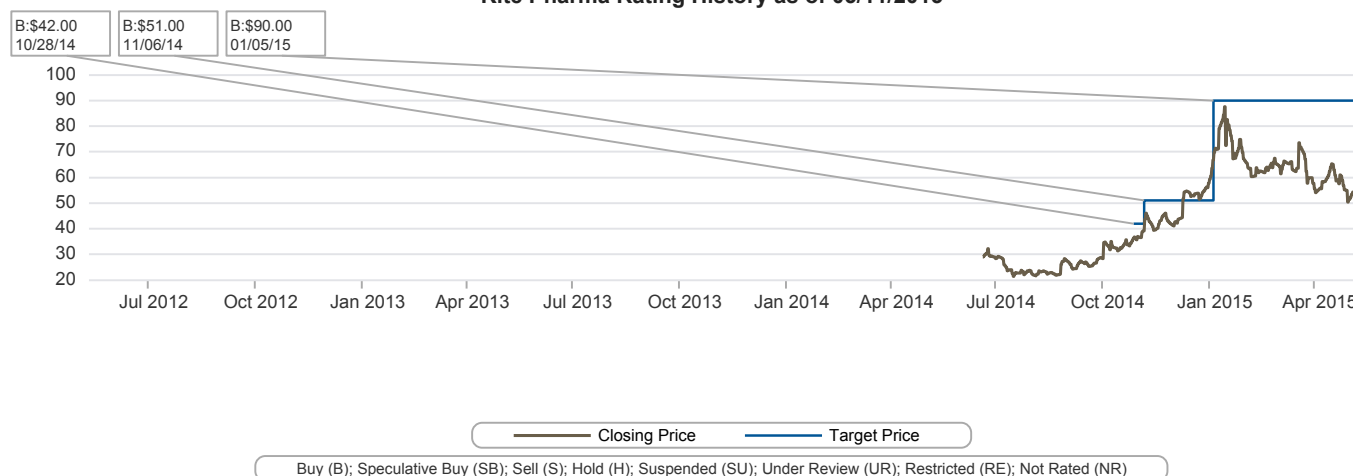
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**Kite Pharma Rating History as of 05/11/2015**



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