

**US Equity Research**

20 April 2015

**BUY***unchanged***PRICE TARGET** US\$90.00*unchanged*

Price (19-Apr) US\$65.06

Ticker KITE-NASDAQ

52-Week Range (US\$): 21.00 - 89.21  
 Avg Daily Vol (M) : 856.6  
 Shares Out. (M) : 38.3  
 Market Cap (US\$M): 2,494

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).

John Newman, PhD | Canaccord Genuity Inc. (US) | JNewman@canaccordgenuity.com | 212.389.8042

Kevin Dai, PharmD, BCOP | Canaccord Genuity Inc. (US) | kdai@canaccordgenuity.com | 212.389.8043

**Company Update**

## Updates from AACR - TCR technology promising in melanoma/synovial sarcoma, expect HPV update, CART-meso moderate

### NY-ESO-1 TCR data continues to look encouraging, viable approach in melanoma and synovial sarcoma

Dr. Steven Rosenberg (NCI) presented updated data on NY-ESO-1 TCR therapy against melanoma (n=19) and synovial cell sarcoma (n=15), which has demonstrated continued response rates, a positive. Melanoma patients (n=19) had an improvement in ORR of 53% (32% PR, 21% CR) vs. prior results (n=11) ORR of 45% (10% PR, 18% CR, 17% SD), while synovial sarcoma had an ORR of 67% (60% PR, 7% CR) vs. prior results (n=6) and ORR of 67% (all PRs). We find this data very encouraging, particularly since NY-ESO-1 is found in 80% of synovial sarcoma and 25% in melanoma, translating to an addressable market of ~8,000 synovial sarcoma and ~18,500 melanoma patients a year.

### Expect near-term publication for TCR in HPV cancers, may be incremental positive

NCI investigators eluded to an upcoming publication focused on top-line data in HPV cancers with their TCR construct, which could be incrementally positive if efficacy is presented. To date, no clinical data is seen with this target. HPV is the most common viral infection of the reproductive tract, believed to cause 70% of cervical and other urogenital cancers. We believe this is an enormous market place, particularly since HPV is associated with nearly 500,000 new cases of cervical cancer and 9,000 oropharyngeal cancers in the US each year, and eagerly look forward to interim analysis with their technology.

### EGFRVIII CART for GBM development unclear

After speaking with multiple KOLs and investigators, we believe the EGFRVIII CART therapy for glioblastoma multiform is behind in development, as clinician enthusiasm remains lacking for this program. Prior trials with TKIs and other experimental drugs have remained lackluster, particularly since GBM is such a heterogeneous disease with high cross resistance. Importantly, we do not include any value for solid tumors in our valuation, but continue to remain optimistic on KITE's emphasis on their TCR platform.

### Upenn CART-Meso early, clean safety, but no responses

UPenn presented updates on their CART-Meso program (n=6) in mesothelioma, pancreatic, and ovarian carcinoma, which did not show any responses, although the study is early. Four out of six patients showed stable disease, which may suggest some anti-tumor efficacy. We believe UPenn's data is modest at best, but eludes to the fact that safety and efficacy in adoptive T cell therapies may not go hand in hand.

## NY-ESO-1 TCR data continues to look encouraging, viable approach in melanoma and synovial sarcoma

New data was published and reported by Dr. Steven Rosenberg of the NCI, where patients with heavily pretreated metastatic synovial cell sarcoma and melanoma (refractory to standard of care) and whose cancers expressed NY-ESO-1 received autologous TCR-transduced T cells following a lymphodepleting preparative chemotherapy regimen. Although only 15 synovial patients and 19 melanoma patients were discussed in the presentation, a recent publication by Robbins and colleagues had 18 synovial cell sarcomas and 20 melanoma patients (Robbins P et al. Clin Cancer Research. 10.1158). However, response rates between the AACR presentation and the publication were similar and both are an improvement vs. prior NY-ESO-1 publication in 2011, where melanoma patients had an improvement in ORR of 53% (32% PR, 21% CR) vs. prior results (n=11) ORR of 45% (10% PR, 18% CR, 17% SD), while synovial sarcoma had an ORR of 67% (60% PR, 7% CR) vs. prior results (n=6) and ORR of 67% (all PRs). The estimated overall 3- and 5-year survival rates for patients with synovial cell sarcoma were 38% and 14%, respectively, whereas the corresponding estimated survival rates for patients with melanoma were both 33%. Importantly, durations in the melanoma patients that obtained CRs are impressive, with a two patients maintaining this duration for more than 4 years.

Additionally, no toxicities were attributed to the transferred cells, a positive since prior TCR therapies targeting MAGE A3 and other antigens had significant toxicities. We find this very encouraging; reflecting on the positive notion that expression of the NY-ESO-1 antigen is highly restricted to the tumor and not normal tissues, decreasing the risk of safety concerns.

Figure 1: TCR NY-ESO-1 results

Responses to Therapy with NY-ESO-1 TCR				
	Total	PR	CR	OR
	number of patients (duration in months)			
Melanoma	19	6 (32%) (10**, 28, 8, 6+, 3, 3)	4 (21%) (58+, 54+, 28, 40+**)	10 (53%)
Synovial Cell Sarcoma	15	9 (60%) (47+**, 18*, 12**, 10, 8, 7, 5, 4, 3**)	1(7%) (20+)	10 (67%)

\*treated twice  
\*\*plus ALVAC vaccine  
(Robbins et al J Clin Oncol 29:917, 2011; Clin Cancer Res 21:1022,2015)

Source: Rosenberg et al. AACR Presentation

## CART-Meso – clean safety, moderate efficacy

UPenn presented updates on their CART-Meso program, the first CART therapy for solid tumors, although results remain modest. No responses were seen, although 4/6 patients showed stable disease. We believe more time is needed to determine efficacy, as Stable Disease (SD) might translate into prolonged Progression-Free-Survival (PFS) or Overall Survival (OS).

This is a phase I, open label, 3+3 dose escalation study evaluating the effects of CART-Meso in advanced/metastatic disease, particularly epithelial pleural mesothelioma (100% expression), pancreatic ductal adenocarcinoma (100% expression), serous ovarian cancer (85 – 100% expression) and lung adenocarcinomas (50% expression). However, we remind investors that mesothelin is also expressed on normal tissues, particularly in the pleura, peritoneum, and pericardium.

**Figure 2: CART-meso trial design**

Study Summary	
Design	Phase I, Open label 3+3 dose escalation study
Intervention	CART-meso single infusion alone or following lymphodepletion with one flat dose cyclophosphamide
Study Centers	University of Pennsylvania
Number of Subjects	Up to 15–24 evaluable subjects
Evaluable Subject	Infused with target dose of CART-meso product
Study Duration	Approx. 18 months to complete enrollment
Investigational Product	<ul style="list-style-type: none"> <li>CART-meso cells transduced with a lentiviral vector to express anti-mesothelin scFv TCRz-41BB</li> <li>Cyclophosphamide</li> </ul>
Target Dose	<ul style="list-style-type: none"> <li>1–3x10<sup>7</sup> CART/m<sup>2</sup> and 1–3x10<sup>8</sup> CART/m<sup>2</sup></li> <li>Cyclophosphamide 1.5g/m<sup>2</sup></li> </ul>
Dose Notes	<ul style="list-style-type: none"> <li>Lower than the target dose is allowed</li> <li>Dose de-escalation to 1–3x10<sup>6</sup> CART/m<sup>2</sup> is allowed</li> </ul>

Source: Tanyi et al. AACR Presentation

Figure 3: CART-meso trial design

INCLUSION	EXCLUSION
Advanced/metastatic disease, progressive after prior SOC chemotherapy	HIV, HCV, HBV, HTLV I/II, or other active infections
Age > 18 y.o.	Active autoimmune disease requiring immunosuppressive therapy
ECOG PS 0-1	Clinically significant pericardial effusion; CHF (NY Heart Association Grade II-IV)
Adequate hematologic, renal, and hepatic function	Planned concurrent treatment with systemic high dose corticosteroids
Life expectancy > 3 months	Anticipated need for systemic chemotherapy within 2 weeks of aphaeresis and infusion
Understands experimental nature of therapy	Other active malignancy

Source: Tanyi et al. AACR Presentation

There are key differences in the CART-meso vs. prior CART constructs in leukemia. First, CART-meso is made with a mouse monoclonal antibody, while prior constructs consist of human T-cell activation domains coupled to an anti-protein single-chain variable fragment (scFv). Second, CART-meso binds to mesothelin-expressing cells, while prior therapies bind to CD19 antigens. Finally, CART-meso is immunogenic, meaning that it will have less duration and persistence vs. original CART constructs, which may help with from a safety standpoint. However, both therapies from UPenn still use 4-1BB/CD3 costimulatory domain for responses.

The figure below shows the differences between CART-meso and original CART construct. We would like to point out that for the phase 1 clinical program, the CART-meso is made through a lentiviral transduction system, not electroporation as reported below.



Figure 4: CART-meso vs. CART therapy

CAR Expression Platforms		
	Lenti/Retrovirus	mRNA
Delivery	Viral Transduction	Electroporation
Host genome modification	DNA integration	No
CAR expression	Permanent	Transient
CAR expression level	Promoter	Amount RNA
Proliferation effect on CAR expression, cell function	Maintained	Declined
Anti-tumor effect	Potential long-term (persistence)	Limited window
Toxicity	Potential long-term, unmanageable	Limited window

Source: Tanyi et al. AACR Presentation

The figure below represents the subjects enrolled. All patients were very heavily pretreated, with an average of greater than 6 prior therapies, representing the significant lack of options left for these sick patients.

Figure 5: CART-meso clinical trial - baseline demographics

Subjects Enrolled in Cohort 1.						
	Subject #	Disease	Age	Stage	Prior chemo-therapies/Surgeries	Prior Radiation
1	31213-1-01	MPM	75	IV	6 / 1	Yes
2	31213-1-34	PDA	68	IV	6 / 1	Yes
3	31213-1-66	SOC	54	IV	7 / 2	No
4	31213-1-02	MPM	71	III	4 / 2	No
5	31213-1-67	SOC	50	IIIC	12 / 3	Yes
6	31213-1-35	PDA	68	IV	4 / 1	No

MPM= Malignant Pleural Mesothelioma, PDA=Pancreatic Ductal Adenocarcinoma, SOC= Serous Ovarian Carcinoma

Source: Tanyi et al. AACR Presentation

The side effects for this therapy remained moderate, with only a few incidences of grade 3 and 3 toxicity, which includes elevated LFT, leukocytosis, DIC...etc (see figure below). However, there were no reports of cytokine release syndrome or infusion reactions, demonstrating the relative safety of this platform.

Figure 6: CART-meso side effects

Primary Endpoint: Safety Data						
Related AEs as March 30, 2015						
Subject	AE grade					Total
	1	2	3	4	5	
31213-1-01	8	1				9
31213-1-02	3	0	1			4
31213-1-34	10	7	17 *	2 *		37
31213-1-66	19	3	2			24
31213-1-67	1					1
31213-1-35	5	1				6
Total	46	12	20	2		81

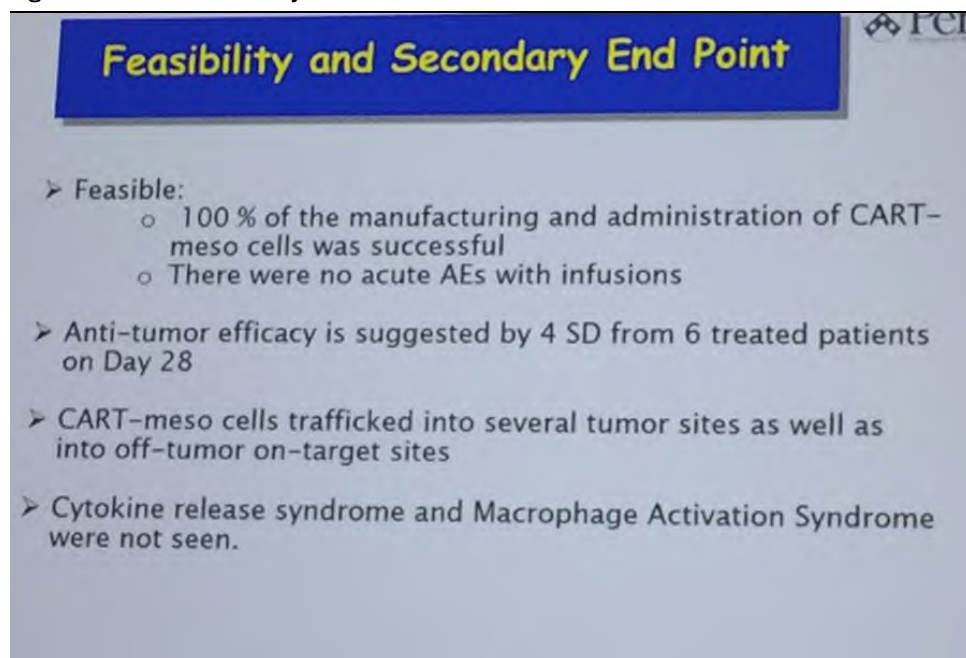
\* DLT #1

- No acute adverse event with infusion
- Grade 3 and 4 AEs: elevated LTs, leukocytosis, DIC, tachycardia, dyspnea, hypotension, skin rash, fatigue, ascites, peritonitis, sepsis, portal vein hypertension, acute kidney injury, anemia, pleural effusion, tachypnea .

Source: Tanyi et al. AACR Presentation

However, no efficacy was seen at day 28, with only stable disease seen in 4 out of 6 patients. We believe that it is too early to assess the value of CART-Meso, since current data remain modest at best. Although there are no significant side effects, no efficacy was seen either, reflecting on the theory that side effects and efficacy may go hand in hand.

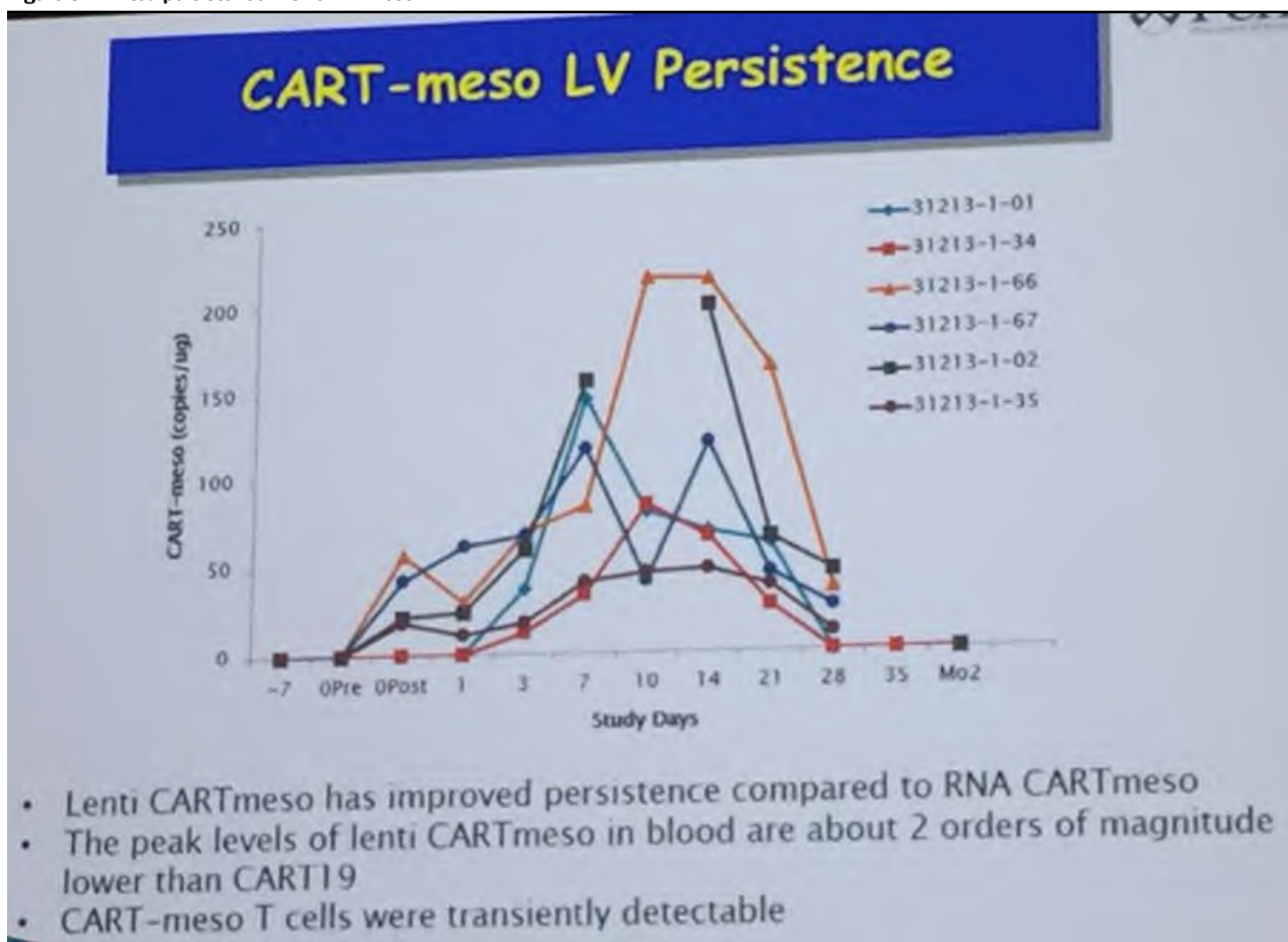
**Figure 7: CART-meso efficacy**



Source: Tanyi et al. AACR Presentation

As expected, CART-meso T cells were detected but did not persist as long as the original CD19 CART constructs. Dr. Tariyi believes this is due to the immunogenic construct from a mouse anti-body, which eliminates the CART-meso out of the systemic system quickly.

Figure 8: Limited persistence with CART-meso

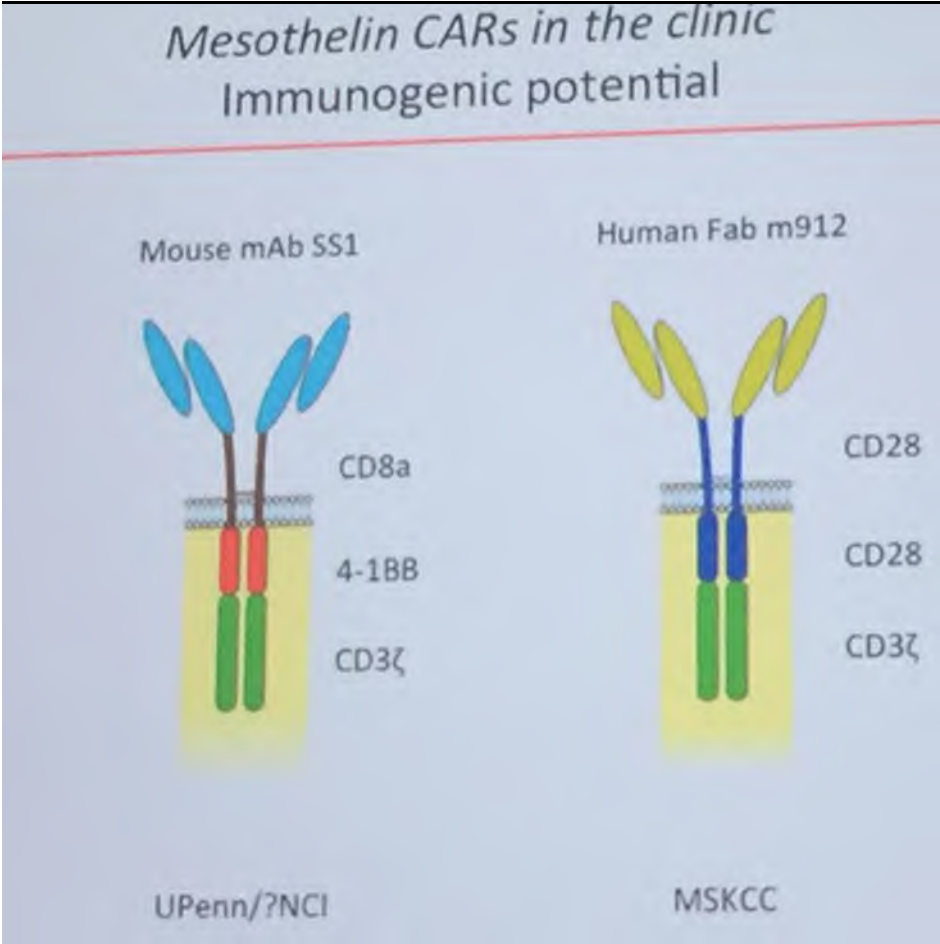


Source: Tanyi et al. AACR Presentaiton

In conclusion, mesothelin targeted CARTs may be efficacious, although initial data did not show tumor responses. Although not seen in the UPenn group, we are still concerned with off tumor toxicity, especially since mesothelin is found in normal tissues. Additionally, due to the potential immunogenicity of the construct due to its origins in mice, we wonder about potential challenges long-term in humans. We believe this may be addressed by MSKCC, where their mesothelin CAR construct is fully humanized vs. UPenn's murine CAR. Additionally, MSKCC is incorporating a suicide gene into their CART-meso model with CASP9, which we believe is interesting since this adds an additional layer of safety. We find the current data early and interesting, but maintain cautious optimism for this CART mesothelin technology.

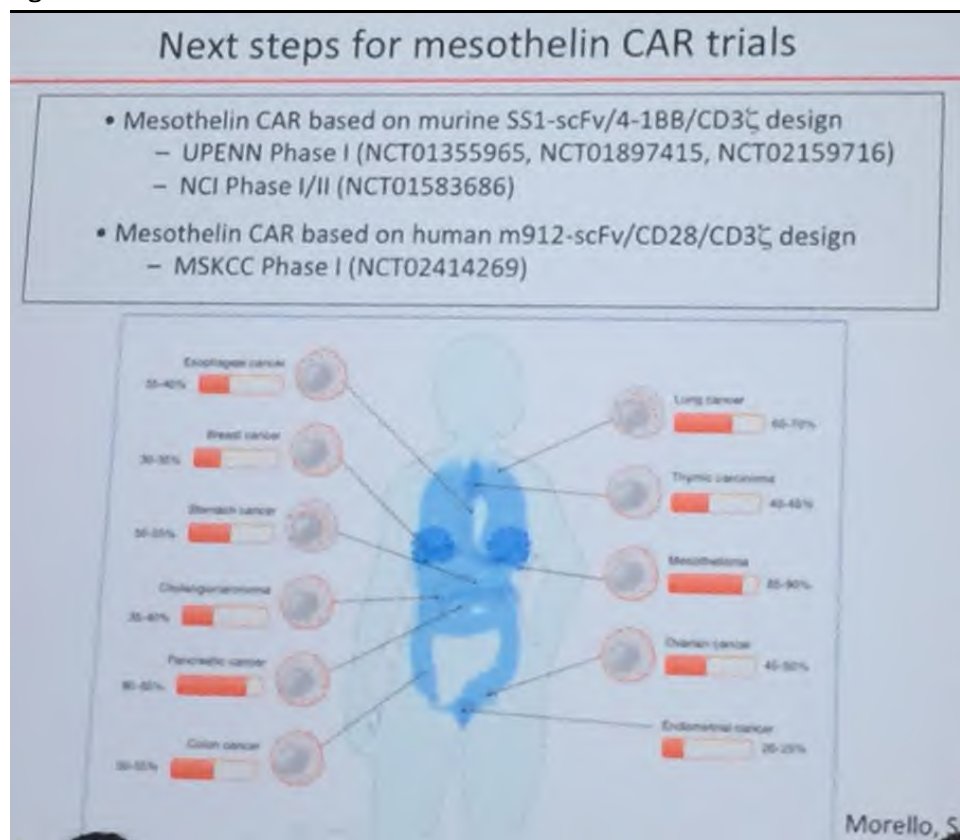


Figure 9: CART-meso landscape



Source: Saladin et al. AACR Presentation

Figure 10: Future for CART-meso



Source: Saladin et al. AACR Presentation

Figure 11: KITE income statement

(\$000's) [FY - DEC]	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenues</b>											
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 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>											
	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
<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>	<b>36,658</b>	<b>17,388</b>	<b>17,442</b>	<b>17,616</b>	<b>17,793</b>	<b>70,239</b>	<b>72,308</b>	<b>84,806</b>	<b>101,077</b>	<b>121,219</b>	<b>146,192</b>
<b>EBITDA</b>	<b>(36,658)</b>	<b>(17,388)</b>	<b>(17,442)</b>	<b>(17,616)</b>	<b>(17,793)</b>	<b>(70,239)</b>	<b>(72,308)</b>	<b>152,927</b>	<b>613,181</b>	<b>940,281</b>	<b>1,012,891</b>
<b>Operating income (EBIT)</b>	<b>(36,658)</b>	<b>(17,388)</b>	<b>(17,442)</b>	<b>(17,616)</b>	<b>(17,793)</b>	<b>(70,239)</b>	<b>(72,308)</b>	<b>152,927</b>	<b>613,181</b>	<b>940,281</b>	<b>1,012,891</b>
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>	<b>(42,569)</b>	<b>(16,630)</b>	<b>(16,747)</b>	<b>(16,990)</b>	<b>(17,161)</b>	<b>(67,528)</b>	<b>(69,958)</b>	<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>	<b>(42,569)</b>	<b>(16,630)</b>	<b>(16,747)</b>	<b>(16,990)</b>	<b>(17,161)</b>	<b>(67,528)</b>	<b>(69,958)</b>	<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>	<b>(43,658)</b>										
<b>Adjustments to Net income</b>											
<b>GAAP EPS</b>	<b>(\$1.91)</b>	<b>(\$0.42)</b>	<b>(\$0.41)</b>	<b>(\$0.42)</b>	<b>(\$0.40)</b>	<b>(\$1.65)</b>	<b>(\$1.65)</b>	<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 12: 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	\$2,879	10/1/2017	2.5	70%	\$1,552	\$40
CLL US	\$83	2021	\$314	10/1/2018	3.5	60%	\$130	\$3
ALL US	\$195	2021	\$957	10/1/2018	3.5	65%	\$430	\$11
FL US	\$165	2021	\$718	10/1/2018	3.5	60%	\$298	\$8
MCL US	\$164	2021	\$713	10/2/2018	3.5	60%	\$296	\$8
<b>US - total</b>	<b>\$1,298</b>	<b>2020</b>	<b>\$5,581</b>	<b>10/1/2018</b>	<b>3.5</b>	<b>60%</b>	<b>\$2,318</b>	<b>\$69</b>
Ex-US								
DLBCL royalty Ex-US	\$53	2020	\$501	6/1/2018	3.1	70%	\$252	\$6
CLL royalty Ex-US	\$6	2021	\$56	6/1/2019	4.1	60%	\$22	\$1
ALL royalty Ex-US	\$15	2021	\$140	6/1/2019	4.1	65%	\$59	\$2
FL royalty Ex-US	\$13	2021	\$108	6/2/2019	4.1	60%	\$42	\$1
MCL royalty Ex-US	\$12	2021	\$108	6/3/2019	4.1	60%	\$42	\$1
<b>Ex-US - royalty - total</b>	<b>\$99</b>	<b>2020</b>	<b>\$981</b>	<b>6/1/2018</b>	<b>3.1</b>	<b>60%</b>	<b>\$422</b>	<b>\$11</b>
<b>Total Product Value</b>							<b>\$3,129</b>	<b>\$80</b>
Cash							\$400	\$10.3
<b>Total Equity Value</b>							<b>\$3,529</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

### Analyst Certification

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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.

### Distribution of Ratings:

#### Global Stock Ratings (as of 04/20/15)

Rating	Coverage Universe		IB Clients
	#	%	%
Buy	581	58.63%	33.22%
Hold	326	32.90%	18.10%
Sell	40	4.04%	2.50%
Speculative Buy	44	4.44%	59.09%
	991*	100.0%	

\*Total includes stocks that are Under Review

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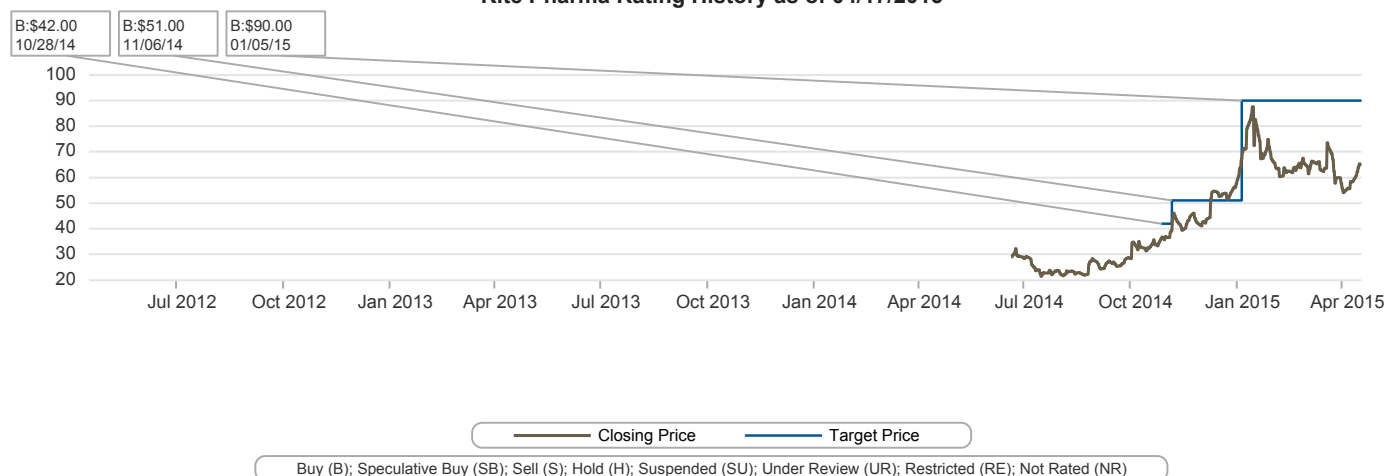
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**Kite Pharma Rating History as of 04/17/2015**



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