USA | Healthcare | Biotechnology

May 18, 2015

# **Jefferies**

# Kite Pharma (КІТЕ)

# Q1: First Patient Expected To Dose With KTE-C19 This Quarter

## **Key Takeaway**

KITE announced after market close on Friday with an in-line quarter and provided clinical updates with the first patient expected to dose with KTE-C19 (CD19 CAR-T) this quarter and would be on track to deliver pivotal data in diffuse large B-cell lymphoma (DLBCL) in 2016. The first pt would be part of a pilot trial of a handful of pts before initiating pivotal studies in Q4. The company also is on track to initiate add'l studies in other lymphomas/ leukemias.

**Update On KTE-C19:** The company expects to initiate a pilot study with KTE-C19, a CD19 CAR-T in DLBCL this quarter with pivotal trial initiating in Q4. The first cohort of the pivotal trial will enroll DLBCL patients (n=72) and the second cohort will enroll PMBCL and FL patients (n = 40). The 1 EP is ORR with data expected in 2016. KITE also plans to initiate trials in acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL) in 2015. We estimate risk-adj peak sales of \$526M in DLBCL with additional indications generating riskadj peak sale of \$559M. We also believe KITE's IP position remains unrecognized with the '465 Eshhar patent possibly having a dominant position over all single-chain CARs, and may lead to potential royalties to KITE.

Looking Beyond KTE-C19: Given the multiple competitive programs focused on CD19 CAR-T, investors are also focused on other pipeline development programs. KITE plans to have TCR data (thru NCI) in 2016 with a potential start of TCR clinical trials in 2016. Recall, NCI has currently five ongoing trials with various targets with KITE having rights to the following cancer antigen targets - NY-ESO1 and HPV-16 E6. NCI has initiated a trial in 2014 targeting enrollment of up to 61 patients with HPV-16 positive cancers that express the E6 oncoprotein. The NCI also has an ongoing trial in 22 patients with melanoma that express ESO. We should have data from both programs in 2016 and supporting a potential company-sponsored trial.

Q1 Financials: KITE reported Q1 revenues of \$2.9M v. IEF est. of \$60M and GAAP EPS of (\$0.36) vs. JEF est of \$1.07 and cons of (\$0.29). Cash and equivs were \$428.5M as of end-Q1.

Our PT of \$83 (vs. prev \$84) is DCF-based. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

USD	Prev.	2014A	Prev.	2015E	Prev.	2016E	Prev.	2017E
Rev. (MM)		0.0	60.0	2.9		0.0		134.7
EV/Rev				NM				13.0x
EPS								
Mar		(0.66)	1.07	(0.36)A				
Jun		(2.27)	(0.35)	(0.46)				
Sep		(0.24)	(0.42)	(0.52)				
Dec		(0.33)	(0.52)	(0.64)				
FY Dec		(1.91)	(0.22)	(1.97)	(1.64)	(2.11)	1.06	0.65
FY P/E		NM		NM		NM		77.0x

## BUY

Price target \$83.00 (from \$84.00) Price \$50.02

Financial Summary	
Net Debt (MM):	(\$428.5)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$428.5
Cash/Share:	\$10.10
Cash (MM):	\$428.5
Marilan Bata	
Market Data	
52 Week Range:	\$89.21 - \$21.00
Total Entprs. Value (MM):	\$1 <i>,7</i> 47.4
Market Cap. (MM):	\$2 <i>,</i> 175.9
Shares Out. (MM):	43.5
Float (MM):	27.4
Avg. Daily Vol.:	1,183,764

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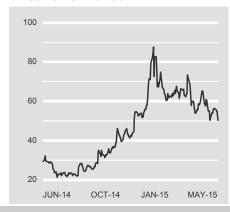
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### **Price Performance**



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## **Valuation**

We arrive at our \$83 (v. prev \$84) PT based on a DCF valuation model, which assumes a WACC of 11%, terminal growth rate of 0% and outstanding shares of 44.6 million, driven by sales of KTE-C19. We assume market entry for KTE-C19 for third-line refractory diffuse large B-cell lymphoma (DLBCL) in 2017 based on accelerated approval on a positive data package from its pivotal Phase I/IIb trial. We estimate total U.S. peak sales of KTE-C19 of \$2.7 billion (risk-unadjusted) by 2028 for multiple potential indications in hematology. Applying a 40% discount rate to reflect the risk associated with this asset, we estimate peak sales of \$1.6 billion by 2028.

**Exhibit 1: DCF sensitivity analysis** 

Equity Value Price/Share						
\$4,853.9	\$108.77					
\$4,213.7	\$94.43					
\$3,683.1	\$82.54					
\$3,240.7	\$72.62					
\$2,869.8	\$64.31					

Source: Jefferies estimates

## Risks

**Clinical Failure:** As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

**Regulatory Failure:** The FDA could determine the Biologic Licensing Application is inadequate for KTE-C19 for DLBCL and could delay approval. KITE is under the assumption that an ORR >50% with a duration of response >6 months in patients from a single-arm trial will be sufficient for accelerated approval, but the FDA could decide that is inadequate. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

**Commercial Failure:** We currently assume peak sales for KTE-C19 of \$1.0 billion in the U.S. (risk adjusted) and royalty revenue of \$92 million (risk-adjusted) on EU sales by 2028. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

**Manufacturing Risks:** KITE relies on its eACT process to manufacture its CAR-T products, and involves 1) harvesting T-cells from the patient's blood, 2) genetically engineering the T-cells to express cancer-specific receptors, and 3) increasing the number of engineered T-cells and 4) infusing the modified T-cells back into the patient. Assuming approval, KITE will require reliable commercial supplies for the materials used to manufacture and process its eACT-based candidates. KITE will need a consistent and reliable process, while limiting contamination risks, for manufacturing these candidates for the approved patient population. Any supply or manufacturing disruption could negatively impact KTE-C19 supply and sales.

**Competitive Risks:** Other companies are rapidly developing CAR-T product candidates in various stages of clinical development for hematological malignancies that may compete with KTE-C19. If any of these product candidates have an improved therapeutic profile over KTE-C19 and is approved, KTE-C19's growth trajectory in the marketplace, even if approved, could be adversely impacted.

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**Financing Risks:** We expect KITE to have adequate cash to support the KTE-C19 launch in 2017, and we do not currently model any equity financing. However, KITE may need additional dilutive financing to fund the potential U.S. launch of KTE-C19 and its R&D programs in additional indications.

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#### **Exhibit 2: KITE Income Statement**

# Kite Pharma, Inc.

#### **Income Statement**

(All values in \$MM except EPS and average shares) 2012A 2013A 2014A 2015E 2016E 2017E 2018E 2019E 2020E 2021E 2022E 2023E 1QA 2QE 3QE 4QE FΥ Revenue: 0.0 0.0 0.0 109.7 446.8 8.808 10412 1276.5 1368.7 1448.4 CD19 CAR-T U.S. Sales 0.0 0.0 0.0 0.0 0.0 0.0 CD19 CAR-T EU Royalty 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 11.1 52.1 99.2 128.3 Amgen collaboration revenues 29 25.0 25.0 25.0 75.0 75.0 75.0 Total revenue, net 0.0 0.0 0.0 0.0 0.0 0.0 0.0 134.7 471.8 833.8 1,077.2 1,403.6 1,542.9 1,651.8 Costs and expenses: 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 1117 202.2 260.3 306.4 314.8 318.7 Cost of goods sold Research & development 1.8 5.1 23.1 9.3 10.0 12.8 17.9 50.0 52.5 55.1 57.8 60.7 62.5 64.4 66.4 68.3 Selling, general & administrative 13.6 10.0 10.5 39.2 76.3 Total operating expenses 2.6 6.4 36.7 18.4 19.5 22.8 28.4 89.1 94.0 99.1 235.6 335.5 399.1 450.9 463.6 471.9 Income (loss) from operations (2.6) (6.4) (36.7) (15.6) (19.5)(22.8) (28.4) (86.3) (94.0) 35.6 236.2 498.2 678.1 952.7 1,079.2 1,179.8 Other income (expense): Miscellaneous (expense) income 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 Interest income 0.0 0.1 0.4 0.5 0.0 0.0 0.0 0.5 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 (0.0)(0.0)(6.3)(0.0)0.0 0.0 0.0 (0.0)0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 (0.0) (0.6) 0.0 0.0 0.0 (10.0) (1.4) (94.0) Net profit (loss) before income taxes (2.6) (7.9)(43.1) (15.1)(19.5) (22.8)(28.4)(85.7) 29.6 236.2 498.2 668.1 952.7 1,079.2 1,179.8 333.5 377.7 412.9 0.0 0.0 0.0 0.0 49.8 66.8 Income tax expense (benefit) (0.0)0.0 0.0 0.0 0.0 0.0 0.0 Income tax (%) 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 0.0% 10.0% 10.0% 35.0% 35.0% 35.0% Net Income (GAAP) (2.6)(7.8)(43.7)(15.1)(20.0)(22.8)(28.4)(86.3)(94.0)29.6 236.2 448.4 601.3 619.3 701.5 766.9 Adjusted Items (Non-GAAP) 0.0 0.0 16.1 6.7 4.0 4.0 4.0 18.7 16.0 16.0 16.0 20.0 22.0 23.0 24.0 25.0 Stock options 0.0 6.1 0.0 0.0 0.0 0.0 0.0 Other 0.0 0.0 0.0 0.0 0.0 Net Income (Non-GAAP) (78.0)791.9 (2.6) (6.4) (21.4) (8.4) (16.0) (18.8) (24.4) (67.6) 45.6 252.2 468.4 623.3 642.3 725.5 (0.49) 0.65 15.01 EPS. GAAP (1.43)(1.91)(0.36)(0.46)(0.52)(0.64)(1.97)(2.11)5.11 9.50 12.49 12.61 14.01 43.3 44.0 45.4 46.3 47.2 48.1 49.1 51.1 Diluted shares 5.3 5.5 22.8 42.5 43.3 44.0 44.6 43.6 44.5 45.4 46.3 47.2 48.1 49.1 50.1 51.1 (0.49)(0.22)(0.94)(0.20)(0.55)(1.75) 1.01 5.45 9.93 12.95 13.08 14.49 15.50 EPS, Non-GAAP (0.37)(0.43)(1.54)5.4 44.5 46.3 47.2 51.1 Basic shares 29.2 22.8 42.5 43.3 44.0 44.6 43.6 45.4 48.1 49.1 Diluted shares 5.4 29.2 22.8 42.5 43.3 44.0 44.6 43.6 44.5 45.4 46.3 47.2 48.1 49.1 50.1 51.1

Source: Jefferies estimates, company data

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**Exhibit 5: KITE DCF Analysis** 

# Kite Pharma, Inc.

# **Discounted Cash Flow Analysis**

(All values in \$MM)	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Sales	0.0	0.0	0.0	2.9	0.0	134.7	471.8	833.8	1,077.2	1,403.6	1,542.9	1,651.8
Operating Expenses	7.7	9.4	36.7	89.1	94.0	99.1	235.6	335.5	399.1	450.9	463.6	471.9
EBIT	(7.7)	(9.4)	(36.7)	(86.3)	(94.0)	35.6	236.2	498.2	678.1	952.7	1079.2	1179.8
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	49.8	66.8	333.5	377.7	412.9
EBIAT	(7.7)	(9.4)	(36.7)	(86.3)	(94.0)	35.6	236.2	448.4	611.3	619.3	701.5	766.9
(+):Depreciation	0.0	0.0	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
(+):FAS-123 Options	3.4	5.5	16.1	18.7	16.0	16.0	16.0	20.0	22.0	23.0	24.0	25.0
(-): Capital expenditures	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(-): Changes in working capital	0.0	0.0	2.9	4.3	4.2	1.9	4.2	4.2	4.2	4.2	4.2	4.2
Unlevered free cash flow	(4.3)	(3.9)	(23.1)	(71.6)	(81.9)	50.0	248.3	464.4	629.4	638.3	721.5	787.9

Source: Jefferies estimates, company data

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# **Company Description**

Kite Pharma, Inc. operates as a clinical stage biotechnology company which engages in the development of novel cancer immunotherapeutic products with focus on engineered autologous T cell therapeutics targeted to different tumor types. In addition, the company is advancing a novel therapeutic cancer vaccine aimed to trigger potent and specific immunity against multiple epithelial cancers, which has the potential to complement its eACT programs.

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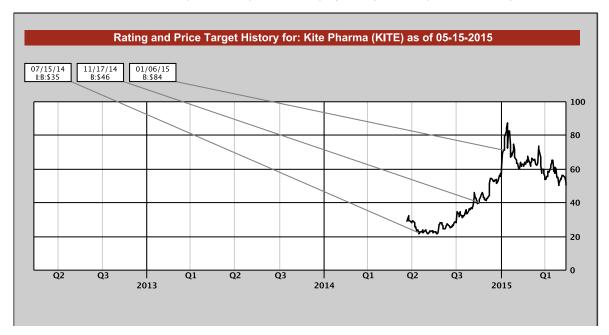
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