

Biotechnology

Kite Pharma

Equity Research

May 6, 2015

Price: \$54.28 (05/4/2015) **Price Target: NA**

OUTPERFORM (1)

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Key Data

Symbol NASDAQ: KITE
Market Cap (MM) \$2,430.3

Quick Take: Company Update

Leading The Way In DLBCL And So Much More

The Cowen Insight

We hosted investor meetings with Dr. Arie Belldegrun (Chairman and CEO) and Dr. David Chang (CMO). Kite remains on-track to generate potentially pivotal data for KTE-C19 in DLBCL during 2016. Through its multiple BD transactions Kite has also significantly broadened its platform and pipeline to become the leader in engineered T cells. We remain at Outperform.

Corporate Mission Is To Become The Leading Producer Of T Cell Therapies...

While much investor attention has been focused on Kite and its competitors' CD19 directed CAR therapies, Kite has guietly assembled what it believes is (1) the best platform from which new CAR/TCR based therapies can be developed and (2) the broadest pipeline of engineered T cell therapies. Kite has worked with the NCI to optimize T cell production methods, completed tech transfer to an external CMO, and is now the only company with an FDA cleared, corporately held CART cell IND (KTE-C19). Kite is also in the process of building commercial scale (5000 patients/ yr capacity) and clinical scale (300 patients/yr capacity) manufacturing facilities in Los Angeles from which to rapidly move promising preclinical product candidates into the clinic and ultimately market without the need for external tech transfer. This will also form a platform to quickly test emerging engineered T cell technologies (e.g. gene editing, switches, etc.) as needed. Through its CRADA with the National Cancer Institute (NCI), Kite has active clinical programs utilizing two CAR constructs (CD19 and EGFRvIII) and four TCR constructs (NY-ESO-1, MAGE A3, MAGE A6, and HPV-16 E6). NCI is also working on additional clinical and preclinical constructs to which Kite has development rights including a mesothelin CAR and HPV-16 E7, SSX2, and personalized neo-antigen TCRs. In addition, Kite has gained access to multiple oncology targets through a 50:50 partnership with Amgen. Finally, the recent acquisition of T Cell Factory (TCF) has given Kite a proprietary high-throughput method for identifying and cloning rare TCR sequences from patient samples. Following this acquisition, Kite possesses many of the leading minds in engineered T cells and immune-therapy as internal employees (Drs. Margo Roberts and Ton Schumacher), collaborators (Dr. Steven Rosenberg), or scientific advisors (Drs. Ron Levy, Toni Ribas, and Owen Witte). Presentations from many of these people will be featured when Kite reviews its platform, pipeline, and future directions at an R&D day in NYC on June 23, 2015.

...And Leverage This To Become The Partner Of Choice

Kite intends to leverage its leading platform (and IP) to become the partner of choice as new T cell modifications prove themselves necessary in the clinic. In January, Amgen partnered with Kite. In return for access to Kite's expertise, Amgen provided Kite with multiple oncology targets and 50% economics on the proposed products. We believe the Amgen partnership in January provides the first validation of this approach. Management described currently proposed T cell modifications such as combination therapies, cytokine secretion, gene editing, suicide genes, and switches as nice theories deserving of study but possessing no clinical data. Due to Please see addendum of this report for important disclosures.

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the often poor translatability of preclinical models to human immune-therapy, Kite plans to generally wait on clinical data before partnering its platform with outside technologies. However, its seminal IP in the CAR space could become important sooner as competitors move towards planned 2016 BLA filings in ALL.

2014 Was And 2015 Is All About Execution

At the time of its 2014 IPO, Kite management outlined a plan to (1) work with NCI to identify an ideal conditioning regimen and cell dose for KTE-C19 in DLBCL, (2) transfer manufacturing outside of NCI to enable multicenter trials and (3) file a corporate IND for KTE-C19 in order to support (4) initiating a potentially pivotal DLBCL trial in H1:15, (5) generating pivotal data in 2016, and (6) potentially gaining FDA approval in 2017. While simultaneously expanding Kite's breadth, management has successfully executed on the first three tasks. Kite's management reports that its tech transfer process has been completed, the FDA has granted an IND, a conditioning regimen and cell dose has been settled, and a potentially pivotal Phase I/II trial protocol is "fully active". Management has completed IRB approval and contract negotiations with at least three clinical trial sites (City of Hope, Moffitt, and Washington University). Kite has also conducted multiple "dummy runs" with these clinical sites and its contract manufacturer (PCT). With these three sites now activated (and MD Anderson to join soon), management expects to dose the first patient in the 6 patient Phase I portion of the trial during Q2:15. This landmark event is expected to be press released. For competitive reasons management does not plan to disclose the conditioning regimen or cell dose until it presents the full Phase I dataset (anticipated for ASH 2015). The Phase I portion is designed to ensure that T cell production outside of NCI is not generating vastly different results. Management intends to progress to the pivotal Phase II portion if grade 3 or greater AEs (primarily CRS) are seen in no more than two of the six Phase I patients. Kite also expects to begin pivotal trials of KTE-C19 in MCL, ALL, and CLL during 2015. Finally, Kite plans to file its first corporate IND for a TCR therapy (likely HPV-16 E6) by YE:15.

2016 Will Be A Year Of Data In Liquid And Solid Tumors

The Phase II portion of the initial pivotal KTE-C19 trial will utilize ~25 sites to enroll a 72 patient DLBCL cohort (cohort 1) and a 40 patient PMBCL and TFL cohort (cohort 2). The primary endpoint of the trial is ORR and a potentially pivotal efficacy analysis will be conducted on the first 50 DLBCL patients (H2:16). Kite believes historical data indicates a <20% ORR and 4-5month mOS would be expected. Therefore, an ORR of at least 40% with a mOS of at least 6 months is expected to be approvable. If the interim analysis is successful, Kite expects to file for a BLA by YE:16. As a result, approval for KTE-C19 in DLBCL could come in 2017. Kite's partner NCI has also dosed patients in clinical trials for multiple Kite owned engineered T cell constructs in solid tumors. These include an (1) EGFRvIII specific CAR for glioblastoma and head and neck cancers (2) NY-ESO-1 TCR for urothelial carcinoma, sarcoma, and NSCLC, (3) HPV-16 E6 TCR in anal, cervical, and head and neck cancers (4) MAGE A3/A6 TCR and (5) MAGE A3 TCR both for NSCLC, breast, gastric, ovarian, pancreatic, and prostate cancers. Data from all five solid tumor programs is expected to be presented in 2016. Kite appeared particularly excited by the HPV-16 E6 program. This excitement stems from HPV's central role in ~5% of all cancers and HPV antigen expression being restricted to tumor cells. Importantly, management cautions that Penn/NVS's recent mesothelin CAR T cell presentation is far from definitive for the solid tumor opportunity. First, Kite believes the patient cohort is too small to draw significant conclusions from. Second and likely far more important, the researchers did not utilize a conditioning regimen. Kite/NCI's extensive work on conditioning regimens with the CD19 product have demonstrated that conditioning intensity can impact efficacy. In

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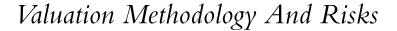
addition, the only publicly disclosed responses from engineered T cell therapy in solid tumors (NY-ESO-1 TCR) utilized a preconditioning regimen.

Building For The Future With T Cell Factory And Neo-Antigens

Emerging clinical data from TIL and checkpoint therapies indicates that a major correlate of efficacy in immune-therapy is the presence of T cells that recognize tumor neo-antigens. As a result, Dr. Steven Rosenberg used his plenary presentation at ASH 2014 to present an initial proof of concept and set the goal of commercializing engineered TCR therapies for a patient's specific neo-antigens. We initially thought this goal was admirable but a long way from becoming practical. Dr. Chang admits that his initial reaction over a year ago was much the same. However, Kite revealed that Dr. Rosenberg is currently able to conduct the neo-antigen sequencing, TCR isolation, and T cell production processes within 10 weeks. Through the recent acquisition of T cell Factory (TCF) and its high throughput TCR screening technology, as well as other streamlining efforts, Dr. Chang believes Kite and NCI can shorten the process to 6 weeks in the near future. He believes this timeframe is commercially viable. TCF will be leveraged to fill out Kite's TCR pipeline with neo-antigen (including KRAS) products as well as TCRs specific for cancer testis antigen and viral antigens from oncogenic viruses.

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Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

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Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Kite Pharma is unprofitable, has no approved products, and will likely need to raise additional capital from the public markets prior to turning profitable. There is limited clinical trial experience on lead candidate KTE-C19, and eACT's more broadly. Moreover, KTE-C19 faces a number of clinical, regulatory, and commercial hurdles prior to becoming successful, and projecting any future sales for KTE-C19 is inherently difficult.

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Stocks Mentioned In Important Disclosures

Ticker	Company Name
KITE	Kite Pharma

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	450	58.67%	103	22.89%
Hold (b)	302	39.37%	8	2.65%
Sell (c)	15	1.96%	0	0.00%

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Kite Pharma Rating History as of 05/04/2015

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Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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