

#### Biotechnology

## Kite Pharma

**Equity Research** 

November 10, 2014

Price: \$43.64 (11/6/2014)
Price Target: NA

#### **OUTPERFORM (1)**

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#### **Key Data**

Symbol NASDAQ: KITE
Market Cap (MM) \$1,672.0

Company Quick Take

# Bigger, Broader, Better Than You Might Think

#### The Cowen Insight

We hosted investor meetings with Dr. Arie Belldegrun (Chairman and CEO), Cindy Butitta (COO and CFO), and Dr. David Chang (CMO). The main conclusion from the sessions is that Kite has substantially broadened its development focus for KTE-019 (beyond DLBCL) while it plans for the advancement of additional pipeline candidates and platform technologies. We think KITE is a stock investors need to own.

## **Highlights From Our Meetings Are As Follows:**

## Laying The Groundwork To Become The Leading Player In Engineered T Cells.

Kite is rapidly deploying the capital raised in a June IPO to expand its facilities, management team, and development scope. The company believes it is only a matter of time before engineered T cell therapies (based upon CAR T cells and TCR constructs) become a mainstay of therapy in oncology. While the opportunity for engineered T-cells is likely plenty big to support multiple players, Kite is looking to capitalize on its first mover advantage, academic relationships, and leading IP position with the goal of further advancing its leadership position in the field. Tangible new initiatives include (1) a broader development program for lead candidate KTE-019, (2) the advancement of other CAR and TCR constructs into development, and (3) optimization of platform capabilities to enable the next generation of T cell therapies.

- KTE-019. At the time of Kite's IPO, the company had promised to pursue development of anti-CD19 CAR candidate KTE-019 in a potentially pivotal Phase II trial in diffuse large B-cell lymphoma (DLBCL). The filing of a corporate IND (in December) and start of a trial (Q1:15) in refractory DLBCL are on track. Meanwhile Kite has now made the decision to initiate potentially pivotal Phase II KTE-019 trials in advanced mantle cell lymphoma (H1:15), chronic lymphocytic leukemia (H2:15) and acute lymphocytic leukemia (H2:15).
- 2. Other CARs/TCRs. Following anti-CD19, Kites next tumor antigen target will be NY-ESO-1. Kite will internalize development of an NY-ESO-1 TCR construct currently in Phase II development at the NCI. A prior generation NY-ESO-1 TCR (licensed to AdaptImmune) has demonstrated compelling data in synovial sarcoma, an aggressive tumor type with no approved therapies. Kite believes its murine based construct is at least as good and has already generated responses in the NCI trial. Kite's next CAR candidate is directed against EGFRVIIIa, a target in GBM. Dose escalation in a Phase I trial at the NCI is continuing, though Kite admits responses have yet to be seen. Kite may announce an additional novel cancer antigen target from the NCI in the coming months.
- 3. Platform advancements. Kite believes T cell therapies will be constrained only by the ability to direct them against suitable cancer antigens. The company views its NCI CRADA as an excellent source of new targets, but is also interested in accessing other technologies (i.e. bispecific antibodies) that could expand its CAR repertoire. Additionally, genome editing technologies might be of utility in terms of introducing new functionality into T cells (e.g. the ability to suppress PD-1 expression).

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ASH Likely To Feature CAR T Cells Prominently. We expect T cell immunotherapies to receive much attention at this year's ASH meeting (December 6-9, San Francisco). ASH will feature at least two notable presentations for Kite investors. The company's de facto scientific founder, Dr. Steven Rosenberg will be giving a plenary talk on cell based immunotherapies. We expect the discussion to be broad based (covering multiple CARs and TCR programs) with a potential focus on the role that mutated cancer antigens could play in directing next generation therapies. We remind investors that Kite has access to essentially all of the discoveries coming out of Dr. Rosenberg's lab. A second oral presentation will be given by Dr. James Kochenderfer (Abstract #550), who will provide an update on the NCI's experience with Kite's anti-CD19 CAR in patients with refractory DLBCL. The abstract includes just two newly treated patients beyond the n=28 that were disclosed in Kite's S-1 filing in June. We expect a handful of additional patients to be included at the time of the meeting. In the abstract, 22 of 27 evaluable patients (81%) have responded with 10 patients remaining in CRs for up to 37 months. We believe these data establish a new standard in refractory lymphoma. We expect Dr. Kochenderfer's talk will focus on optimizing the safety/tolerability of anti-CD19 CAR therapy (while retaining strong efficacy). Recall the NCI is now using a third generation protocol which avoids use of IL-2 and includes a reduced dose chemotherapy conditioning regimen. Patients treated using this latest protocol appear to require less supportive care, but still experience some neurologic toxicity.

KTE-019 Trial Design in DLBCL Coming Into Focus. As noted above, Kite is on track to file its corporate IND in December, and initiate a potentially pivotal Phase I/II trial on KTE-019 for DLBCL in Q1:15. The Phase I portion of the trial will include 5-10 patients with the goal of refining a couple of treatment parameters (cell count, chemo regimen). The Phase II portion of the trial will enroll 72 DLBCL patients across 20-25 sites. The trial will enroll a second cohort of patients (n=40) with PMBCL and TFL in order to maintain population homogeneity and provide for a broader label across multiple lymphoma subtypes. Kite notes much investigator interest in the trial, and believes enrollment will be rapid (~12 months). The primary endpoint will be response rate and duration. The FDA has not set a specific target for efficacy, though management believes durable CR rates >50% would provide compelling evidence of efficacy and could support either full or accelerated approval in late 2016. The trial will include the ability to retreat patients upon relapse. We believe KTE-019 has \$1B+ U.S. potential in refractory DLCBL.

Optimization Of Manufacturing Continues. Management views the collection, preparation, transduction, and cultivation of T cells as the most important factor underlying success in the engineered T cell marketplace. Kite notes that its "platform technology" is really that of a "T cell factory", into which any number of cassettes targeting an array of cancer antigens (either CARs or TCRs) can be introduced. As such, Kite believes its ability to handle T cells will prove far more important to its success than any specific CAR or TCR construct. The company notes that it has the advantage of NCl's 20+ years of experience in manipulating T cells. Over that period of time, the NCl has tried multiple different approaches (including CD3/CD28 beads) as part of the long, gradual evolution into its current protocol. Kite has further tweaked the NCl's process (converting it to a partially closed system, removing human serum) and is very pleased with its attributes. These include the industry's shortest processing time (6-8 days) and a simple, straightforward protocol (no requirement for CD3/CD28 beads for T cell purification/expansion) that is capable of producing T cells with reproducible release characteristics.

**How Best To Maximize Kite's IP Advantage.** Kite's founders were early to appreciate the potential of CARs, and took pains to consolidate much of the

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intellectual property in the space. Kite's exclusive license to the Eshhar patent provides it with claims on any CAR that expresses a single chain antibody on its surface. Management believes that others in the field recognize the importance of the Eshhar patent, but perhaps not at what Kite believes is its true value. Kite does not think it is reasonable to use the Eshhar patent to block competitors from developing potentially disruptive cancer therapies, but believes it can extract much value. We believe one of the most important decisions facing management is how best to maximize this IP advantage. Kite seemingly will not be short on cash resources, but could benefit from a partnership in other ways (access to ex-U.S. clinical/regulatory expertise, product rights to novel CAR or TCR constructs). Management also believes that its leading IP position makes it the partner of choice for companies with technologies (antibody developers, genome editors) that can enable next generation CAR therapies.

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# Valuation Methodology And Risks

## **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.

#### **Investment Risks**

## **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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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

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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

Neutral (2): Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

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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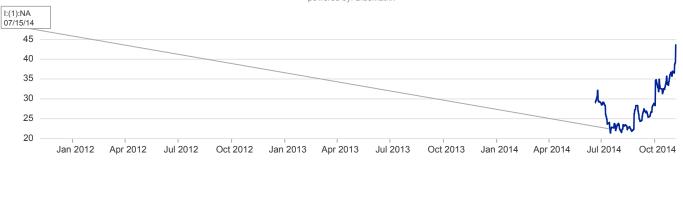
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## Kite Pharma Rating History as of 11/06/2014

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## Legend for Price Chart:

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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

Target Price

Closing Price

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