

Equity Research

October 13, 2014

**Price: \$32.56** (10/10/2014)

**Price Target: NA**

**OUTPERFORM (1)**

**Eric Schmidt, Ph.D.**

646.562.1345  
eric.schmidt@cowen.com

**Marc Frahm, Ph.D.**

646.562.1394  
marc.frahm@cowen.com

**Key Data**

Symbol	NASDAQ: KITE
Market Cap (MM)	\$1,247.5

Company Quick Take

## *CD19 CAR Highly Active In ALL Too*

### The Cowen Insight

The Lancet published data from NCI's ongoing CD19 CAR T cell trial in r/rALL. NCI has observed a 70% CR rate with 60% of patients achieving a MRD-negative response. Although ALL is not Kite's initial focus (Kite expects to begin its potentially registrational PI/II DLBCL trial in Q1:15), the data provides additional excitement around the use of its CD19 CAR in highly refractory tumors.

**The News:** This morning, The Lancet published a manuscript providing an update on the NCI's ongoing Phase I trial of CD19 CAR T cells in pediatric and young adults with relapsed/refractory ALL. As of the June 20, 2014 data cutoff, 20 ALL patients had been assigned to receive  $1 \times 10^6$  or  $3 \times 10^6$  cells/kg. 18 patients received the protocol assigned dose. In the two remaining patients, insufficient T cells to administer the full assigned dose were generated. As a result, these patients received  $2.8 \times 10^4$  and  $4.8 \times 10^5$  cells/kg respectively. Among all 20 ALL patients, 14 (70%) achieved a complete response. 12 patients (60%) achieved a minimal residual disease (MRD)-negative complete response. In addition, 10 of the MRD-negative patients proceeded to a hematopoietic stem-cell transplant (HSCT) and have subsequently remained disease free for a median of 10 months. Two patients with MRD-negative CRs were deemed ineligible for HSCT. These patients ultimately relapsed at 3 and 5 months respectively. The CAR T cell therapy was associated with multiple toxicities, although all were reversible. Three (14%) patients experienced grade 4 cytokine release syndrome (CRS). Grade 3 fever, hypokalemia, neutropenia, CRS, and dysphasia were experienced by nine (43%), nine (43%), eight (38%), three (14%), and one (5%) patient(s) respectively. Finally, in patients experiencing a CR, CAR T cells rapidly expanded but generally disappeared by approximately day 68 allowing for the return of normal B cells.

**Our Take:** The data published in The Lancet demonstrates activity outside of DLBCL, Kite's lead CD19 CAR indication. While cross-trial comparisons are difficult given small patient numbers, varying treatment protocols, and patient profiles (which include MRD-negative responses prior to CAR therapy), Kite's ALL efficacy data appears directionally lower than either Juno or Novartis' data using competing CD19 CAR constructs. On the other hand, Kite's safety may be marginally better. No treatment related deaths occurred in the NCI trial, but CD19 negative relapses were observed. All three companies have observed ALL relapses in the absence of subsequent HSCT. Therefore, we believe CD19 CARs are best viewed as a bridge to transplant rather than an independent cure for ALL. While Kite may be modestly behind Juno and/or Novartis within ALL, this is not Kite's primary indication. Meanwhile, Kite is the clinical leader within DLBCL where it is achieving cures independent of HSCT. Additionally, Kite's leading IP position in the CAR space may allow it to monetize its competitors' products.

**Our Thesis:** Kite is a pioneer in the use of engineered Autologous T Cell Therapy (eACT), a personalized approach that directs a patient's immune system to fight

**Please see addendum of this report for important disclosures.**

his or her cancer. KTE-C19 is expected to enter a multicenter PI/II trial in 3rd-line DLBCL in early 2015. If data from this single-arm trial are compelling, it might support accelerated FDA approval. Trials for KTE-C19 in 2nd-line DLBCL and other refractory lymphomas/leukemias, as well as for eACT's targeting EGFRvIII, MAGE-A3, NY-ESO-1, and SSX2, are in planning. Kite is financed into 2017 and through multiple potential value creating milestones. We believe lead candidate KTE-C19 has sales potential in excess of \$1B in refractory Diffuse Large B Cell Lymphoma (DLBCL). We expect development progress on KTE-C19 and other eACTs to drive outperformance in KITE shares.

# *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.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon a 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 it there are any good methodologies for assigning a specific target price to such stocks.

# Addendum

## Stocks Mentioned In Important Disclosures

Ticker	Company Name
KITE	Kite Pharma

## Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

## Important Disclosures

Cowen and Company, LLC and or its affiliates make a market in the stock of Kite Pharma securities.

Kite Pharma has been client(s) of Cowen and Company, LLC in the past 12 months.

Kite Pharma is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Kite Pharma.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Kite Pharma within the past twelve months.

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients. Individual compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions.

## Disclaimer

This research is for our clients only. Our research is disseminated primarily electronically and, in some cases, in printed form. Research distributed electronically is available simultaneously to all Cowen and Company, LLC clients. All published research can be obtained on the Firm's client website, <https://cowenlibrary.bluematrix.com/client/library.jsp>.

Further information on any of the above securities may be obtained from our offices. This report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice.

For important disclosures regarding the companies that are the subject of this research report, please contact Compliance Department, Cowen and Company, LLC, 599 Lexington Avenue, 20th Floor, New York, NY 10022. In addition, the same important disclosures, with the exception of the valuation methods and risks, are available on the Firm's disclosure website at <https://cowen.bluematrix.com/sellside/Disclosures.action>.

**Price Targets:** Cowen and Company, LLC assigns price targets on all covered companies unless noted otherwise. The price target for an issuer's stock represents the value that the analyst reasonably expects the stock to reach over a performance period of twelve months. The price targets in this report should be considered in the context of all prior published Cowen and Company, LLC research reports (including the disclosures in any such report or on the Firm's disclosure website), which may or may not include price targets, as well as developments relating to the issuer, its industry and the financial markets. For price target valuation methodology and risks associated with the achievement of any given price target, please see the analyst's research report publishing such targets.

**Notice to UK Investors:** This publication is produced by Cowen and Company, LLC which is regulated in the United States by FINRA. It is to be communicated only to persons of a kind described in Articles 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. It must not be further transmitted to any other person without our consent.

### Copyright, User Agreement and other general information related to this report

© 2014 Cowen and Company, LLC. Member NYSE, FINRA and SIPC. All rights reserved. This research report is prepared for the exclusive use of Cowen clients and may not be reproduced, displayed, modified, distributed, transmitted or disclosed, in whole or in part, or in any form or manner, to others outside your organization without the express prior written consent of Cowen. Cowen research reports are distributed simultaneously to all clients eligible to receive such research reports. Any unauthorized use or disclosure is prohibited. Receipt and/or review of this research constitutes your agreement not to reproduce, display, modify, distribute, transmit, or disclose to others outside your organization the contents, opinions, conclusion, or information contained in this report (including any investment recommendations, estimates or price targets). All Cowen trademarks displayed in this report are owned by Cowen and may not be used without its prior written consent.

**Cowen and Company, LLC. New York** (646) 562-1000 **Boston** (617) 946-3700 **San Francisco** (415) 646-7200 **Chicago** (312) 577-2240 **Cleveland** (440) 331-3531 **Atlanta** (866) 544-7009 **London** (affiliate) 44-207-071-7500

### COWEN AND COMPANY RATING DEFINITIONS

#### Cowen and Company Rating System effective May 25, 2013

**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

**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

#### Cowen Securities, formerly known as Dahlgren Rose & Company, Rating System until May 25, 2013

**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

**Sell** – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

**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

## Cowen And Company Rating Definitions

### Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

### Kite Pharma Rating History as of 10/10/2014

powered by: BlueMatrix



#### 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

## Points Of Contact

### Reaching Cowen

#### Main U.S. Locations

**New York**

599 Lexington Avenue  
New York, NY 10022  
646.562.1000  
800.221.5616

**Boston**

Two International Place  
Boston, MA 02110  
617.946.3700  
800.343.7068

**Cleveland**

20006 Detroit Road  
Suite 100  
Rocky River, OH 44116  
440.331.3531

**San Francisco**

555 California Street, 5th Floor  
San Francisco, CA 94104  
415.646.7200  
800.858.9316

**Atlanta**

3399 Peachtree Road NE  
Suite 417  
Atlanta, GA 30326  
866.544.7009

**Chicago**

181 West Madison Street  
Suite 1925  
Chicago, IL 60602  
312.577.2240

#### International Locations

**Cowen International  
Limited****London**

1 Snowden Street - 11th Floor  
London EC2A 2DQ  
United Kingdom  
44.20.7071.7500

**Cowen and Company (Asia)  
Limited****Hong Kong**

Suite 1401 Henley Building  
No. 5 Queens Road Central  
Central, Hong Kong  
852 3752 2333



@CowenResearch



Cowen and Company