

Equity Research

March 3, 2015

Price: \$64.12 (03/2/2015)

Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: KITE
Market Cap (MM)	\$2,682.6

Quick Take: Company Update

Kite Continues To Rise

The Cowen Insight

In conjunction with our 35th Annual Healthcare Conference we hosted an investor luncheon with senior management of Kite Pharma. Kite is rapidly expanding on the preclinical, clinical and manufacturing fronts in order to support a projected 2017 commercial launch of its first CAR T product. We remain convinced that Kite is a leader in engineered T cells and reiterate our Outperform rating.

Below are the highlights from our investor lunch with Kite's CEO Arie Belldegrun, COO Cynthia Butitta, and CMO David Chang.

KTE-C19 Corporate IND Is Now Active

Kite filed a corporate IND for its lead CD19 directed CAR T cell product, KTE-C19, in December 2014 and reports that the FDA has allowed its response period to pass and the IND is now active. Therefore, Kite holds the first corporate IND on a CAR T cell product candidate. Kite has transitioned clinical trial manufacturing of KTE-C19 from the National Cancer Institute (NCI) to a third party contract manufacturer. As part of this process Kite has performed multiple *ex vivo* comparability studies including analysis of transduction efficiency and *in vitro* cytokine responses following antigenic stimulation. The *in vivo* comparability will be confirmed with a small ~6 patient Phase I run-in portion of the potentially pivotal Phase I/II DLBCL trial due to enroll its first patient in H1:15. Management indicated that an announcement of the first patient treated under the corporate IND could come around the ASCO meeting. Following the confirmation of comparable acute safety signals between the NCI and Kite manufacturing processes, the trial will progress to an ~72 patient Phase II portion. A potentially registrational interim analysis is planned following the first 50 patients. The Phase II portion will utilize a yet to be defined chemotherapy conditioning regimen. Management believes that the previously reported "high dose" and "low dose" pretreatment regimens have successfully established bookends for an efficacy/safety tradeoff with the ideal regimen possibly somewhere in between. Data currently being accumulated at the NCI will be used to establish the exact dose, which should be settled soon. Shortly after the DLBCL Phase II cohort begins enrollment, management plans to open a 40 patient potentially pivotal PMBCL and TFL Phase II cohort (H1:15). Additional potentially pivotal Phase II trials in CLL and ALL are planned to begin during H2:15.

Manufacturing Scale Up Underway

Kite reports that its contract manufacturer is capable of producing clinical trial material for all planned trials. However, as insurance and to allow for further pipeline expansion Kite recently signed a lease on an internal manufacturing facility in Santa Monica. This clinical trial supply facility is expected to be online this year. Kite is also in the process of building out a commercial supply facility near LAX. This facility will contain 43K sq. ft. of manufacturing space with the ability to expand a further 17K sq. ft. Kite believes this facility will be capable of supplying engineered T cells to 4,000 patients annually. The facility build-out is expected to be completed by mid-2016, Please see addendum of this report for important disclosures.

allowing for an H2:16 FDA inspection and building approval alongside KTE-C19's initial product approval (projected for 2017). Finally, Kite plans to establish a European presence around YE:15. The rate limiting step to this is the negotiation of a supply agreement with an EU GMP manufacturing provider.

NCI CRADA Tripling In Size

Yesterday Kite announced the signing of a revised and expanded CRADA with the National Cancer Institute (NCI). In total, across the CRADA's many programs funding will triple from a quarterly research budget of \$250K to \$750K. The NCI's Dr. Steven Rosenberg gave a plenary talk at ASH 2014 highlighting emerging work at the NCI to link the discovery of patient specific cancer neo-antigens, the identification of relevant CAR/TCR sequences, and ultimately the engineering of autologous T cells expressing these CAR/TCRs for infusion into the patient. We highlighted this development in our December ([KITE Flying Into New Horizons In Personalized Oncology](#)) note. Management indicates that the current NCI neo-antigen process can generate an infusible neo-antigen specific engineered T cell in a timeframe measured in months meaning it is not yet "ready for primetime". However, Kite reports that the primary focus of the Rosenberg lab is shortening this process to make it commercially feasible. Kite management believes the process can be shortened to a matter of weeks and will ultimately become a source of major value. Kite reports that the existing process as well as planned refinements present numerous opportunities for patents. These patents could include the use of tandem minigenes in the initial neo-antigen identification process. The expansion of the CRADA will also include additional antigen targets on both the CAR and TCR sides of the business. Management reports that 6 TCRs (NY-ESO-1, HPV E6, HPV E7, MAGE A3/A6, MAGE A3, and SSX2) are either currently in the clinic or set to begin trials imminently. While multiple trials using these TCRs as well as an EGFRvIII CAR are ongoing with accumulated efficacy data, management is deferring to Dr. Rosenberg and the NCI regarding data publication timelines. Management expects updates on the CD19 NCI trials over the course of 2015, but dissuaded investors from thinking ASCO would feature any data from other CAR T or TCR programs.

Amgen Deal Reinforces Our Belief In Kite's IP Position

Kite signed a major collaboration with Amgen in January 2015. This collaboration gives Kite access to multiple Amgen targets and in return Amgen gained access to Kite's IP portfolio. Kite reports that Amgen performed a thorough IP due diligence process and that upon confirming Kite's controlling IP position (primarily the Eshhar patent) agreed to grant Kite >50% economics. We believe these economics are beyond the industry norm for early stage assets and are consistent with Amgen believing CAR commercialization requires access to Kite's IP. We also note that Amgen's IP lawyers have a stellar track record in major IP disputes (e.g. Epogen vs. Transkaryotic, Enbrel vs. Ariad, and Neupogen vs. Roche).

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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Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
KITE	Kite Pharma

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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

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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

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 12/31/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.50%	109	23.64%
Hold (b)	288	37.80%	14	4.86%
Sell (c)	13	1.71%	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 03/02/2015

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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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