

Kite Pharma Reports First Quarter 2016 Financial Results

May 9, 2016 4:55 PM ET

Durable Treatment Effect of KTE-C19 Supported by Updated Patient Follow-up in ZUMA-1 Trial Presented at Annual Meeting of the American Association of Cancer Research (AACR)

Interim Results from Pivotal Phase 2 Portion of KTE-C19 ZUMA-1 Trial Expected in Second Half of 2016, to Support Planned BLA Filing in Late 2016 and Product Launch in 2017

SANTA MONICA, Calif.--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq: KITE), a clinical-stage biopharmaceutical company focused on developing engineered autologous cell therapy (eACT™) products for the treatment of cancer, today provided a corporate update and reported first quarter 2016 financial results for the period ended March 31, 2016.

"Our ZUMA-1 update at AACR last month highlighted the potential of KTE-C19, our breakthrough immunotherapy candidate, to put patients with chemorefractory aggressive non-Hodgkin lymphoma (NHL), a patient population burdened with a short life expectancy and limited treatment options, into a durable complete remission," noted Arie Beldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer. "We remain on track to provide interim data from the pivotal phase 2 portion of ZUMA-1 later this year and plan to submit the KTE-C19 registration filing to the U.S. Food and Drug Administration (FDA) by the end of 2016."

"Our commitment to delivering a breakthrough personalized cell therapy to cancer patients now extends fully to our manufacturing and market planning areas. Validation and qualification activities at our state-of-the-art commercial manufacturing facility are underway. The commercial team is actively evaluating a broad range of market and payor strategies for making KTE-C19 available to patients with a significant unmet need."

First Quarter 2016 and Recent Highlights

- At AACR, reported rapid and durable responses in patients with chemorefractory diffuse large B cell lymphoma treated with KTE-C19 in the phase 1 portion of ZUMA-1.
 - Ongoing complete responses were observed in 3 of 7 patients at 9-month study follow-up (1 patient) and 6-month study follow-up (2 patients).
 - KTE-C19-related adverse events consisted predominantly of cytokine release syndrome and neurotoxicity, which were generally reversible.
- Partnered with Genentech to study KTE-C19 in combination with the checkpoint inhibitor atezolizumab. Kite expects to initiate a Phase 1b/2 combination study in patients with chemorefractory diffuse large B cell lymphoma in the second half of 2016.
- Expanded our clinical and research partnership with the National Cancer Institute (NCI) by entering into a new Cooperative Research and Development Agreement (CRADA) with James (Jim) N. Kochenderfer, M.D., and the NCI's Experimental Transplantation and Immunology Branch.
 - Phase 1 study of human anti-CD19 chimeric antigen receptor for treating B-cell malignancies currently ongoing.
- Also at AACR, William Lu, Ph.D., a collaborator of Kite's at the NCI, reported data from a Phase 1 study of a T cell receptor (TCR) product candidate targeting MAGE-A3 that was advanced under Kite's CRADA with the Surgery Branch at the NCI.
 - Data reported at AACR support Kite's plan to file later this year an investigational new drug (IND) application for a TCR product candidate that targets a MAGE-A3 antigen expressed on solid tumors.
- Entered into a research and license agreement with Leiden University Medical Center in the Netherlands to identify and develop additional TCR product candidates targeting solid tumors that are associated with the human

papillomavirus (HPV) type 16 infection.

- Appointed Tim Moore, a biopharma executive with more than 30 years of global operations experience, as Executive Vice President, Technical Operations, to lead product development, manufacturing, supply chain, quality assurance, and end-to-end process optimization for all aspects of Kite's engineered T cell product candidates.
- Augmented Kite's commercial function, under the leadership of Chief Commercial Officer Shawn Tomasello, with the appointment of an integrated executive team responsible for all aspects of commercial and medical affairs strategy, planning, and analysis for the potential launch of KTE-C19.

First Quarter 2016 Financial Results

- Revenue was \$5.1 million for the first quarter of 2016.
- Research and development expenses were \$34.4 million for the first quarter of 2016, and include \$8.5 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$16.5 million for the first quarter of 2016, and include \$6.4 million of non-cash stock-based compensation expense.
- Net loss was \$43.9 million, or \$0.90 per share, for the first quarter of 2016.
- Non-GAAP net loss for the first quarter of 2016 was \$29.1 million, or \$0.60 per share, which excludes non-cash stock-based compensation of \$14.9 million.
- As of March 31, 2016, Kite had \$577.4 million in cash, cash equivalents, and marketable securities.
- Kite continues to expect the full year 2016 net cash burn to be \$235 to \$250 million dollars, which includes approximately \$20 million in capital expenditures, but excludes any inflows or outflows from business development activities. The estimated full year 2016 net cash burn is primarily driven by an estimated net loss of \$295 to \$310 million, which includes an estimated \$80 million of non-cash stock-based compensation expense.

About Kite Pharma

Kite Pharma, Inc., is a clinical-stage biopharmaceutical company engaged in the development of novel cancer immunotherapy products, with a primary focus on engineered autologous cell therapy (eACT™) designed to restore the immune system's ability to recognize and eradicate tumors. Kite is based in Santa Monica, CA. For more information on Kite Pharma, please visit www.kitepharma.com. Sign up to follow @KitePharma on Twitter at <http://www.twitter.com/kitepharma>.

Kite Pharma, Inc. Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the ability and timing of obtaining interim KTE-C19 data, filing a Biologics License Application with the FDA, obtaining regulatory approval based on the studies of KTE-C19, commercially launching KTE-C19, initiating the Phase 1b/2 combination study and filing an IND application for a TCR product candidate that targets a MAGE-A3 antigen, expectations regarding the clinical effectiveness and safety of KTE-C19, the ability and willingness of the NCI to continue research and development activities pursuant to the CRADAs, and Kite's 2016 financial guidance. Various factors may cause differences between Kite's expectations and actual results as discussed in greater detail in Kite's filings with the Securities and Exchange Commission, including without limitation in its Form 10-Q for the quarter ended March 31, 2016. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Kite assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Conference Call and Webcast Details

Kite will host a live conference call and webcast today at 4:30PM Eastern Time (1:30PM Pacific Time) to discuss financial results and provide a business update. To access the live conference call by telephone, please dial (877) 301-8565 (U.S.) or (678) 562-4240 (International). The conference ID number for the live call is 89570152. The webcast will be made available on the Company's website at www.kitepharma.com under the Investors tab in the Events and Presentations section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

KITE PHARMA, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands)

	MARCH 31, 2016 (unaudited)	DECEMBER 31, 2015
ASSETS		
Current assets		
Cash, cash equivalents, and marketable securities	\$ 577,421	\$ 614,722
Prepaid expenses and other current assets	15,066	16,371
Total current assets	592,487	631,093
Property and equipment, net	40,462	30,116
Intangible assets and goodwill, net	37,167	36,740
Other assets	9,135	10,014
Total assets	\$ 679,251	\$ 707,963
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 9,614	\$ 8,049
Deferred revenue	16,250	16,333
Accrued expenses and other current liabilities	11,272	11,787
Total current liabilities	37,136	36,169
Deferred revenue, less current portion	28,900	32,176
Contingent consideration	16,869	16,080
Other non-current liabilities	6,950	7,778
Total liabilities	89,855	92,203
Total stockholders' equity	589,396	615,760
Total liabilities and stockholders' equity	\$ 679,251	\$ 707,963

KITE PHARMA, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share amounts) (unaudited)

THREE MONTHS ENDED	
MARCH 31,	
2016	2015

Revenue:		
Revenue	\$ 5,127	\$ 2,881
Operating expenses:		
Research and development	34,414	9,260
General and administrative	16,494	9,171
Total operating expenses	<u>50,908</u>	<u>18,431</u>
Loss from operations	(45,781)	(15,550)
Other income (expense):		
Interest income	816	466
Interest expense	(126)	(4)
Other expense	(34)	-
Total other income	<u>656</u>	<u>462</u>
Benefit from income taxes	1,209	-
Net loss	<u>\$ (43,916)</u>	<u>\$ (15,088)</u>
Net loss per share, basic and diluted	<u>\$ (0.90)</u>	<u>\$ (0.36)</u>
Weighted-average shares outstanding, basic and diluted	<u>48,832</u>	<u>42,466</u>

Note Regarding Use of Non-GAAP Financial Measures

Kite provides non-GAAP net loss and non-GAAP net loss per share that include adjustments to GAAP figures. These adjustments to GAAP net loss exclude non-cash stock-based compensation expense. Kite believes that these non-GAAP financial measures, when considered together with the GAAP figures, can enhance an overall understanding of Kite's financial performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of Kite's operating results. In addition, these non-GAAP financial measures are among the indicators Kite's management uses for planning purposes and measuring Kite's performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. The non-GAAP financial measures used by Kite may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies. Please refer below for a reconciliation of these non-GAAP financial measures to the comparable GAAP financial measures.

KITE PHARMA, INC.
Reconciliation of GAAP to Non-GAAP Net Loss
(In thousands, except per share amounts)
(unaudited)

	THREE MONTHS ENDED	
	MARCH 31,	
	2016	2015
Net loss - GAAP	\$ (43,916)	\$ (15,088)
Adjustments:		
Non-cash stock-based compensation expense	<u>14,864</u>	<u>6,677</u>
Net loss - Non-GAAP	<u>\$ (29,052)</u>	<u>\$ (8,411)</u>
Net loss per share, basic and diluted - GAAP	\$ (0.90)	\$ (0.36)

Adjustments:

Non-cash stock-based compensation expense per share	0.30	0.16
Net loss per share, basic and diluted - Non-GAAP	\$ (0.60)	\$ (0.20)
Weighted average common shares outstanding, basic and diluted	48,832	42,466

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