Kite Pharma Reports Third Quarter 2016 Financial Results

November 9, 2016 2:50 PM ET

- Company Announces Plans to Initiate a Rolling Submission of the Biologics License Application for KTE-C19 with the U.S. Food and Drug Administration for an Expanded Indication of Aggressive Non-Hodgkin Lymphoma in December 2016 with a Targeted Completion in Q1 2017
- Potential Approval and Commercial Launch of KTE-C19 Expected in 2017
- Conference Call to Be Held Today at 8:30 a.m. Pacific Time/11:30 a.m. Eastern Time

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 reported financial results for the third quarter 2016 and recent business highlights.

Kite also announced that it has met with the U.S. Food and Drug Administration (FDA) to discuss the company's plans to submit the Biologics License Application (BLA) for KTE-C19. Kite currently intends to file for the broader label of aggressive non-Hodgkin lymphoma, which includes chemorefractory diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL). The BLA submission will be based on the primary analysis of the ZUMA-1 pivotal trial. Kite plans to initiate the rolling submission of the BLA for accelerated approval of KTE-C19 by the end of December 2016 with a targeted completion by the end of the first quarter 2017 and a potential approval and commercial launch of KTE-C19 in 2017.

"We are making history with each step we take toward bringing engineered T-cell therapy to patients. We are very pleased with the outcome from our productive discussions with the FDA and their willingness to partner with us to advance this innovative therapy," said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer. "We will focus on initiating and finalizing the submission based on the FDA feedback and look ahead to the potential approval of KTE-C19 in 2017."

Third Quarter 2016 and Recent Highlights

- Reported positive topline results from the pre-planned interim analysis in the KTE-C19 ZUMA-1 pivotal trial in patients with aggressive non-Hodgkin lymphoma, which includes chemorefractory DLBCL (n=51), and TFL and PMBCL (n=11). The study met the pre-specified response endpoint with an objective response rate of 76 percent in DLBCL (Cohort 1). Thirty nine percent of patients maintained complete response at three-month follow up. Grade 3 or higher cytokine release syndrome (CRS) and neurological toxicity was observed in 18 percent and 34 percent of patients, respectively. Treatment emergent Grade 5 events were observed in 3 percent of patients.
- Reported ongoing complete responses in three of seven patients at the 12-month follow-up in the Phase 1 portion of the ZUMA-1 study of KTE-C19 in chemorefractory DLBCL at the European Society for Medical Oncology (ESMO).
- Announced planned oral and poster presentations of KTE-C19 clinical and manufacturing data at the 2016 annual meeting of the American Society of Hematology. The presentations will include additional clinical data from the interim analysis of the ZUMA-1 pivotal trial as well as clinical and manufacturing data from the ZUMA-3 and ZUMA-4 clinical studies in adult acute lymphoblastic leukemia (ALL) and pediatric ALL, respectively. Preliminary results from a clinical study of a fully human anti-CD19 chimeric antigen receptor (CAR) conducted at the National Cancer Institute will also be shared in an oral presentation.
- Initiated patient enrollment in a Phase 1b/2 combination study of KTE-C19 and atezolizumab, Genentech's anti-PD-L1 monoclonal antibody. This is the first combination study of an anti-CD19 engineered CAR T-cell and a checkpoint inhibitor.

- At the Kite investor day on October 18, 2016:
  - Detailed manufacturing and commercial preparations for potential KTE-C19 commercial launch;
  - Outlined KTE-C19 expansion studies with the potential to deliver six additional indications in B-cell malignancies;
  - Announced the expansion of Kite's T-cell receptor (TCR) and CAR T development pipeline with four new INDs planned in the 2016-2018 timeframe; and
  - Presented "T cells 2.0" next-generation cell programming technologies to realize the full potential of engineered T-cell therapy.
- Licensed multiple neoantigen directed TCR product candidates to treat solid tumors expressing mutated KRAS antigens from the National Institutes of Health.

Third Quarter 2016 Financial Results

- Revenue was $7.3 million for the third quarter of 2016.
- Research and development expenses were $57.3 million for the third quarter of 2016, and includes $8.9 million of non-cash stock-based compensation expense.
- General and administrative expenses were $25.0 million for the third quarter of 2016, and includes $10.3 million of non-cash stock-based compensation expense.
- Net loss attributable to common stockholders was $73.9 million, or $1.49 per share, for the third quarter of 2016.
- Non-GAAP net loss attributable to common stockholders for the third quarter of 2016 was $54.7 million, or $1.10 per share, which excludes non-cash stock-based compensation expense of $19.3 million.
- Cash burn for the third quarter was $54.0 million. It is expected that the company's cash, cash equivalents, and marketable securities of $477.1 million as of September 30, 2016 will be sufficient to fund its current operations, including planned clinical development programs, through the first half of 2018.

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.

Cautionary Note on 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," "expected," "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 KTE-C19 data, initiating and completing a submission of the BLA for KTE-C19 with the FDA, obtaining regulatory approval based on the studies of KTE-C19, commercially launching KTE-C19, researching and developing additional product candidates, expectations regarding the clinical effectiveness and safety of KTE-C19 and the sufficiency of Kite's cash, cash equivalents and marketable securities. 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 September 30, 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 11:30 AM Eastern Time (8:30 AM Pacific Time) to discuss financial results and provide a business update. To access the live conference call by telephone, please dial (888) 771-4371 (U.S.) or (847) 585-4405 (International). The conference ID number for the live call is 43463182. 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)

	SEPTEMBER 30, 2016 (unaudited)	DECEMBER 31, 2015
ASSETS		
Current assets		
Cash, cash equivalents, and marketable securities	$ 477,119	$ 614,722
Prepaid expenses and other current assets	13,988	16,371
Total current assets	491,107	631,093
Property and equipment, net	43,548	30,116
Intangible assets and goodwill, net	34,546	36,740
Other assets	15,316	10,014
Total assets	$ 584,517	$ 707,963
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 11,293	$ 8,049
Deferred revenue	15,083	16,333
Accrued expenses and other current liabilities	20,979	11,787
Total current liabilities	47,355	36,169
Deferred revenue, less current portion	22,461	32,176
Contingent consideration	14,797	16,080
Other non-current liabilities	5,551	7,778
Total liabilities	90,164	92,203
Total stockholders' equity	494,353	615,760
Total liabilities and stockholders' equity	$ 584,517	$ 707,963

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

(unaudited)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2016	2015	2016	2015
Revenue:				
Revenue	$ 7,341	$ 5,087	$ 17,263	$ 12,371
Operating expenses:				
Research and development	57,262	21,727	139,033	47,576
General and administrative	25,032	11,135	65,046	30,080
Total operating expenses	82,294	32,862	204,079	77,656
Loss from operations	(74,953)	(27,775)	(186,816)	(65,285)
Other income (expense):				
Interest income	942	342	2,712	1,307
Interest expense	(196)	(451)	(519)	(456)
Other income (expense)	(31)	(49)	(94)	521
Total other income	715	(158)	2,099	1,372
Benefit from income taxes	292	491	2,582	491
Net loss	$ (73,946)	$ (27,442)	$ (182,135)	$ (63,422)
Net loss per share, basic and diluted	$ (1.49)	$ (0.63)	$ (3.72)	$ (1.47)
Weighted-average shares outstanding, basic and diluted	49,625	43,818	48,915	43,172

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 U.S. Generally Accepted Accounting Principles (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 SEPTEMBER 30,

	2016	2015
Net loss - GAAP	$ (73,946)	$ (27,442)
Adjustments:		
Non-cash stock-based compensation expense	19,262	10,845
Net loss - Non-GAAP	$ (54,684)	$ (16,597)
Net loss per share, basic and diluted - GAAP	$ (1.49)	$ (0.63)
Adjustments:		
Non-cash stock-based compensation expense per share	0.39	0.25
Net loss per share, basic and diluted - Non-GAAP	$ (1.10)	$ (0.38)
Weighted average common shares outstanding, basic and diluted	49,625	43,818

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