

# KITE PHARMA, INC.

## **FORM 8-K** (Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

Address	2225 COLORADO AVENUE SANTA MONICA, CA 90404
Telephone	(310) 824-9999
CIK	0001510580
Symbol	KITE
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of Earliest Event Reported): August 8, 2017**

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**Kite Pharma, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36508**  
(Commission  
File Number)

**27-1524986**  
(I.R.S. Employer  
Identification No.)

**2225 Colorado Avenue**  
**Santa Monica, California**  
(Address of principal executive offices)

**90404**  
(Zip Code)

**Registrant's telephone number, including area code: (310) 824-9999**

**Not Applicable**

(Former name or former address, if changed since last report.)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02 Results of Operations and Financial Condition.**

On August 8, 2017, Kite Pharma, Inc. (“Kite”) announced its financial results for the second quarter ended June 30, 2017 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by Kite under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

The following exhibit is filed as part of this Current Report:

99.1 Press Release of Kite, dated August 8, 2017.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 8, 2017

KITE PHARMA, INC.  
(Registrant)

By:           /s/ Paul Jenkinson          

Name: Paul Jenkinson

Title: Chief Financial Officer

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**EXHIBIT INDEX**

Exhibit Number	Description
99.1	Press Release of Kite, dated August 8, 2017.

## Kite Reports Second Quarter 2017 Financial Results

- Filed Industry’s First CAR-T Marketing Authorization Application in Europe for Axicabtagene Ciloleucel for Potential EU Approval and Launch in 2018
- Submitted Investigational New Drug Application for KITE-585, a CAR-T Candidate that Targets BCMA in Multiple Myeloma
- Conference Call Today at 5:30 AM PDT / 8:30 AM EDT

SANTA MONICA, Calif., August 8, 2017—Kite Pharma, Inc. (Nasdaq:KITE), a leading cell therapy company, today reported second quarter 2017 financial results and provided a corporate update for the period ended June 30, 2017.

“We’ve continued to make significant progress on key clinical and commercial milestones in the last six months alone,” said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer of Kite. “With the anticipated events on the horizon for the remainder of 2017, the potential for CAR-T to become one of the most powerful anti-cancer agents for certain patients may finally be realized.”

### Second Quarter 2017 Financial Results

- Revenue was \$10.1 million for the second quarter of 2017.
- Research and development expenses were \$70.9 million for the second quarter of 2017, including \$13.1 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$41.1 million for the second quarter of 2017, including \$12.1 million of non-cash stock-based compensation expense.
- Net loss was \$109.8 million, or \$1.94 per share, for the second quarter of 2017.
- Non-GAAP net loss for the second quarter of 2017 was \$84.7 million, or \$1.50 per share, excluding non-cash stock-based compensation expense of \$25.2 million.
- As of June 30, 2017, Kite had \$781.1 million in cash, cash equivalents, and marketable securities.

### Recent Highlights

#### *Axicabtagene Ciloleucel (axi-cel) Regulatory and Clinical Development*

- The submission of axi-cel to the U.S. Food and Drug Administration (FDA) remains under review with a PDUFA Action Date of November 29, 2017.
- Submitted a Marketing Authorization Application to the European Medicines Agency (EMA) for axi-cel as a treatment for patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL), transformed follicular lymphoma (TFL), and primary mediastinal B-cell lymphoma (PMBCL) who are ineligible for autologous stem cell transplant. This application represents the first chimeric antigen receptor (CAR) T-cell therapy submitted to the EMA.
- Patients are now being treated in ZUMA-5, the Phase 2 trial of axi-cel in indolent B-Cell Non-Hodgkin lymphoma.
- Patients in the European Union (EU) are now being treated with axi-cel. Kite is currently enrolling adult patients with relapsed/refractory DLBCL, PMBCL and TFL in certain EU medical centers.
- A publication from researchers at the National Cancer Institute reported complete remissions up to 56+ months in patients with chemorefractory aggressive non-Hodgkin’s lymphoma (NHL) after receiving anti-CD19 CAR T-cells in a clinical trial.

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### *KTE-C19 Development*

- At the 2017 American Society of Clinical Oncology annual meeting, Kite reported 73 percent minimum residual disease (MRD) negative complete remission rate in an updated analysis of the Phase 1 ZUMA-3 trial of KTE-C19 in adults with high burden relapsed/refractory acute lymphoblastic leukemia (ALL). Adverse events included cytokine release syndrome and neurologic events, and were generally reversible.

### *CAR-T Pipeline*

- Submitted an investigational new drug (IND) application for KITE-585, a CAR-T therapy candidate that targets BCMA expressed in multiple myeloma.

### *TCR Pipeline*

- Opened a Phase 1 clinical trial of KITE-718, a T-cell receptor (TCR) cell therapy candidate that targets MAGE A3/A6 antigen expressed in solid tumors, including non-small cell lung cancer, bladder cancer and head and neck cancer.

### *Axi-cel Commercial Preparation*

- Completed recruitment and training of cell therapy account managers to support customer service and logistical coordination.
- Conducted test runs of technical operations for ordering, scheduling, processing and shipment of cell therapy product at key major medical institutions in preparation for potential approval and launch.

### *Intellectual Property*

- Favorable outcome at the United States Patent and Trademark Office (USPTO) in an *ex parte* reexamination of Kite's seminal Eshhar '465 CAR-T patent (U.S. Patent No. 7,741,465) that confirmed the patentability of its amended claims. The Eshhar '465 patent term continues to June 2027, not including certain potential extensions.

## **Second Half 2017 Milestones**

### *Axi-cel*

- Commercial launch of axi-cel in the United States, if approved.
- One year follow-up data from ZUMA-1 study of axi-cel in patients with aggressive NHL.
- Preliminary data from ZUMA-6 combination study of axi-cel and atezolizumab (PD-L1 checkpoint inhibitor) in refractory DLBCL.

### *KTE-C19*

- Preliminary follow-up Phase 1 data from ZUMA-3 and ZUMA-4 studies of pediatric and adult ALL, respectively.
- Advance ZUMA-3 and ZUMA-4 studies into Phase 2.

### *KITE-585*

- Initiate Phase 1 KITE-585 trial in multiple myeloma.

## **About Kite**

Kite is a biopharmaceutical company engaged in the development of innovative cancer immunotherapies with a goal of providing rapid, long-term durable response and eliminating the burden of chronic care. The company is focused on chimeric antigen receptor (CAR) and T cell

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receptor (TCR) engineered cell therapies designed to empower the immune system's ability to recognize and kill tumors. Kite is based in Santa Monica, CA. For more information on Kite, please visit [www.kitepharma.com](http://www.kitepharma.com). Sign up to follow @KitePharma on Twitter at [www.twitter.com/kitepharma](https://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 regulatory approval based on the studies of axicabtagene ciloleucel, commercially launching axicabtagene ciloleucel, advancing additional product candidates, including KTE-C19, KITE-718 and KITE-585, and meeting the second half 2017 milestones, and Kite's ability to maintain intellectual property protection. 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 June 30, 2017. 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 5:30 AM Pacific Time (8:30 AM Eastern 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 45253546. The webcast will be made available on the Company's website at [www.kitepharma.com](http://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)

	<u>JUNE 30, 2017</u>	<u>DECEMBER</u>
	<u>(UNAUDITED)</u>	<u>31, 2016</u>
<b>ASSETS</b>		
Current assets		
Cash, cash equivalents, and marketable securities	\$ 781,111	\$ 414,422
Prepaid expenses and other current assets	17,169	12,974
Total current assets	798,280	427,396
Property and equipment, net	49,722	44,409
Intangibles assets and goodwill, net	31,921	31,398
Other assets	27,190	21,101
Total assets	<u>\$ 907,113</u>	<u>\$ 524,304</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 15,803	\$ 10,660
Deferred revenue	30,570	29,482
Accrued expenses and other current liabilities	42,191	15,000
Total current liabilities	88,564	55,142
Deferred revenue, less current portion	78,354	19,779
Contingent consideration	15,450	14,218
Other non-current liabilities	15,491	7,195
Total liabilities	197,859	96,334
Total stockholders' equity	709,254	427,970
Total liabilities and stockholders' equity	<u>\$ 907,113</u>	<u>\$ 524,304</u>

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

	<b>THREE MONTHS ENDED</b>		<b>SIX MONTHS ENDED</b>	
	<b>JUNE 30,</b>		<b>JUNE 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Revenue	\$ 10,052	\$ 4,795	\$ 19,888	\$ 9,922
Operating expenses:				
Research and development	70,870	47,356	136,777	81,771
General and administrative	41,101	23,713	76,466	40,395
Total operating expenses	111,971	71,069	213,243	122,166
Loss from operations	(101,919)	(66,274)	(193,355)	(112,244)
Total other income (expense)	(1,144)	920	(170)	1,766
Income tax (provision) benefit	(6,759)	1,080	(6,698)	2,289
<b>Net loss</b>	<b>\$ (109,822)</b>	<b>\$ (64,274)</b>	<b>\$ (200,223)</b>	<b>\$ (108,189)</b>
Net loss per share, basic and diluted	\$ (1.94)	\$ (1.31)	\$ (3.69)	\$ (2.21)
Weighted-average shares outstanding, basic and diluted	56,663	49,157	54,264	48,877

**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)**

	<b>THREE</b>		<b>SIX MONTHS ENDED</b>	
	<b>MONTHS ENDED</b>		<b>MONTHS ENDED</b>	
	<b>JUNE 30,</b>		<b>JUNE 30,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Net loss—GAAP	\$(109,822)	\$(64,274)	\$(200,223)	\$(108,189)
Adjustments:				
Non-cash stock-based compensation expense	25,163	19,758	49,241	34,622
Net loss—Non-GAAP	<u>\$ (84,659)</u>	<u>\$ (44,516)</u>	<u>\$ (150,982)</u>	<u>\$ (73,567)</u>
Net loss per share, basic and diluted—GAAP	\$ (1.94)	\$ (1.31)	\$ (3.69)	\$ (2.21)
Adjustments:				
Non-cash stock-based compensation expense per share	0.44	0.40	0.91	0.71
Net loss per share, basic and diluted—Non-GAAP	<u>\$ (1.50)</u>	<u>\$ (0.91)</u>	<u>\$ (2.78)</u>	<u>\$ (1.50)</u>
Weighted-average shares outstanding, basic and diluted	<u>56,663</u>	<u>49,157</u>	<u>54,264</u>	<u>48,877</u>

KITE CONTACT:

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