KITE PHARMA, INC.

FORM 8-K
(Current report filing)

Filed 05/08/17 for the Period Ending 05/08/17

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

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

FORM 8-K

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

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

Kite Pharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36508**	**27-1524986**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2225 Colorado Avenue **Santa Monica, California**	**90404**
(Address of principal executive offices)	**(Zip Code)**

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

Not Applicable
(Former name or former address, if changed since last report.)

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2017, Kite Pharma, Inc. ("Kite") announced its financial results for the first quarter ended March 31, 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 May 8, 2017.

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: May 8, 2017

KITE PHARMA, INC.
(Registrant)

By: /s/ Paul Jenkinson
Name: Paul Jenkinson
Title: Chief Financial Officer

EXHIBIT INDEX

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

Kite Reports First Quarter Financial Results

- Completed Submission of Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Kite's CAR-T Therapy, Axicabtagene Ciloleucel, in Patients with Aggressive Non-Hodgkin Lymphoma (NHL)
- Initiated Two New Clinical Studies as Part of an Expanded KTE-C19 Development Program
- Advanced Additional New Cell Therapy Candidates Toward Clinical Study in 2017
- Expanded Cell Therapy Account Management Capabilities in Anticipation of Potential Approval and Launch of Axicabtagene Ciloleucel
- Completed $409.7 Million Follow-On Offering of Common Stock
- Conference Call to Be Held Today at 5:30 AM PDT / 8:30 AM EDT

SANTA MONICA, Calif. May 8, 2017 - Kite Pharma, Inc. (Nasdaq:KITE), a cell therapy company, today reported first quarter 2017 financial results and provided a corporate update for the period ended March 31, 2017.

"Kite is intensely focused on bringing axicabtagene ciloleucel to market in 2017. Our preparation for the potential commercialization of the first CAR-T therapy in aggressive non-Hodgkin lymphoma began two years ago. With the team and infrastructure we now have in place, we are confident in our readiness to deliver upon potential approval in the U.S. and expect to file for approval in Europe in the third quarter of this year," said Arie Belldegrun, M.D., FACS, Chairman, President, and Chief Executive Officer of Kite. "We are also keeping an eye toward future growth with additional indications across the KTE-C19 program and development of earlier stage product candidates, including KITE-585, which we believe has the potential to become the next significant opportunity for Kite."

First Quarter 2017 Financial Results

- Revenues were $9.8 million for the first quarter of 2017.
- Research and development expenses were $65.9 million for the first quarter of 2017, which includes $12.7 million of non-cash stock-based compensation expense.
- General and administrative expenses were $35.8 million for the first quarter of 2017, which includes $11.4 million of non-cash stock-based compensation expense.
- Net loss was $90.4 million, or $1.74 per share, for the first quarter of 2017.
- Non-GAAP net loss for the first quarter of 2017 was $66.3 million, or $1.28 per share, excluding non-cash stock-based compensation expense of $24.1 million.
- As of March 31, 2017, Kite had $804.0 million in cash, cash equivalents, and marketable securities. A public offering of common stock generated approximately $409.7 million in gross proceeds to Kite. In addition, Kite received a $50 million upfront payment related to its strategic collaboration with Daiichi Sankyo.

2017 Financial Guidance

- Kite continues to expect the full year 2017 net cash burn to be between $325 million and $340 million. This guidance assumes GAAP operating expenses to be between $490 million and $515 million, which includes approximately $135 million in non-cash stock based compensation expense. Kite expects 2017 total operating expenses to consist of approximately 60 percent Research and Development and approximately 40 percent General and Administrative.

First Quarter 2017 and Recent Highlights

Axicabtagene Ciloleucel/KTE-C19 Progress

- Presented positive topline results from the primary analysis of the ZUMA-1 study of axicabtagene ciloleucel in patients with aggressive non-Hodgkin lymphoma (NHL) at the 2017 American Association of Cancer Research annual meeting. Data included the 99 percent success rate in the manufacturing of clinical product patient dose from a single apheresis for the multi-center ZUMA-1 clinical trial.
- Completed the submission of a Biologics License Application (BLA) to the FDA for axicabtagene ciloleucel in patients with aggressive NHL.
- Initiated ZUMA-5 study of axicabtagene ciloleucel in patients with follicular NHL.
- Initiated ZUMA-9 study to provide patients access to axicabtagene ciloleucel during the regulatory review period.

Strategic Collaborations

- Entered a strategic collaboration with Daiichi Sankyo to develop and commercialize axicabtagene ciloleucel in Japan.
- Established a joint venture with Fosun Pharma to develop and commercialize T-cell therapies, including axicabtagene ciloleucel, in China.

Pipeline Expansion

- Cleared an investigational new drug (IND) application for KITE-718, a T cell receptor (TCR) cell therapy candidate that targets MAGE-A3/A6 antigens expressed on solid tumors.

Commercial Preparation

- Started recruitment and training of cell therapy account managers to support customer service and logistical coordination.

Additional 2017 Clinical Milestones

KTE-C19 and axicabtagene ciloleucel

- Submit marketing authorization application (MAA) to the European Medicines Authority (EMA) for axicabtagene ciloleucel in aggressive NHL in the third quarter of 2017.
- Availability of preliminary 12-month follow-up data from ZUMA-1 study of axicabtagene ciloleucel in patients with aggressive NHL.
- Availability of preliminary follow-up Phase 1 data from ZUMA-3 and ZUMA-4 studies of pediatric and adult acute lymphoblastic leukemia, respectively.
- Advance ZUMA-3 and ZUMA-4 studies into Phase 2.
- Availability of preliminary data from ZUMA-6 combination study of axicabtagene ciloleucel and atezolizumab PD-L1 checkpoint inhibitor in aggressive NHL.

Cell Therapy Pipeline

- Initiate Phase 1 study of KITE-718 in patients with solid tumors in the second quarter of 2017.
- File IND for KITE-585, a CAR T cell therapy candidate that targets BCMA for the treatment of multiple myeloma in the third quarter of 2017.

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 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 . Sign up to follow @KitePharma on Twitter at 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, submitting an MAA to the EMA for axicabtagene ciloleucel, and researching and developing additional product candidates, including KITE-718 and KITE-585, and meeting the additional 2017 clinical milestones, and Kite's 2017 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, 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 44658201. 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.
CONSOLIDATED BALANCE SHEETS
(In thousands)

	MARCH 31, 2017 (unaudited)	DECEMBER 31, 2016
ASSETS		
Current assets		
Cash, cash equivalents, and marketable securities	$ 804,028	$ 414,422
Prepaid expenses and other current assets	15,200	12,974
Total current assets	819,228	427,396
Restricted cash and investments	17,883	10,669
Property and equipment, net	46,241	44,409
Intangible assets and goodwill, net	30,873	31,398
Other assets	9,518	10,432
Total assets	$ 923,743	$ 524,304
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 13,214	$ 10,660
Accrued expenses and other current liabilities	26,492	29,482
Deferred revenue	39,886	15,000
Total current liabilities	79,592	55,142
Deferred revenue, less current portion	38,177	19,779
Contingent consideration	14,575	14,218
Other non-current liabilities	11,301	7,195
Total liabilities	143,645	96,334
Total stockholders' equity	780,098	427,970
Total liabilities and stockholders' equity	$ 923,743	$ 524,304

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

	THREE MONTHS ENDED MARCH 31,	
	2017	2016
Revenues	$ 9,836	$ 5,127
Operating expenses:		
Research and development	65,906	34,414
General and administrative	35,842	16,683
Total operating expenses	101,748	51,097
Loss from operations	(91,912)	(45,970)
Interest income	1,028	816
Interest expense	(4)	—
Other income (expense)	428	29
Loss before income taxes	(90,460)	(45,125)
Benefit from income taxes	61	1,209
Net loss	$ (90,399)	$ (43,916)
Net loss per share, basic and diluted	$ (1.74)	$ (0.90)
Weighted-average shares outstanding, basic and diluted	51,840	48,832

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 MARCH 31,	
	2017	2016
Net loss - GAAP	$ (90,399)	$ (43,916)
Adjustments:		
Non-cash stock-based compensation expense	24,076	14,864
Net loss - Non-GAAP	$ (66,323)	$ (29,052)
Net loss per share, basic and diluted - GAAP	$ (1.74)	$ (0.90)
Adjustments:		
Non-cash stock-based compensation expense per share	0.46	0.30
Net loss per share, basic and diluted - Non-GAAP	$ (1.28)	$ (0.60)
Weighted average common shares outstanding, basic and diluted	51,840	48,832

KITE CONTACT:

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