

XENCOR INC

FORM 8-K (Current report filing)

Filed 05/09/17 for the Period Ending 05/09/17

Address	111 WEST LEMON AVE MONROVIA, CA 91016
Telephone	626-305-5900
CIK	0001326732
Symbol	XNCR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 9, 2017**

XENCOR, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of incorporation)

001-36182
(Commission File No.)

20-1622502
(IRS Employer Identification No.)

**111 West Lemon Avenue
Monrovia, California 91016**
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(626) 305-5900**

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 (see General Instruction A.2. below):

- 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 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 9, 2017, we announced our financial results for the quarter ended March 31, 2017 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information herein and in the exhibit hereto is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 9, 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 9, 2017

XENCOR, INC.

By: /s/ Bassil I. Dahiyat, Ph.D.
Bassil I. Dahiyat, Ph.D.
President and Chief Executive Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 9, 2017.



Xencor Reports First Quarter 2017 Financial Results

— Phase 1 Data from Subcutaneous Administration Trial of XmAb®5871 Support Biweekly Dosing —
 — Management to Host Conference Call Today at 4:30 p.m. ET —

MONROVIA, Calif., May 9, 2017 — Xencor, Inc. (NASDAQ: XNCR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune diseases, asthma and allergic diseases and cancer, today reported financial results for the first quarter ended March 31, 2017 and provided a review of business and clinical highlights.

“We have been focused on advancing our clinical development pipeline across the breadth of our portfolio,” said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. “Today, we are pleased to announce data from our Phase 1 trial of subcutaneously administered XmAb5871, which support use of this formulation as a simpler, more flexible treatment option for patients and doctors. We look forward to further advancing our XmAb5871 program in the months ahead, with topline data from our ongoing Phase 2 study in IgG4-Related Disease and additional clarity on the clinical and regulatory path forward expected this year. Also in the quarter, we initiated our Phase 1 study of XmAb®13676 in non-Hodgkin lymphoma and chronic lymphocytic leukemia, and continued to enroll patients in our Phase 1 study of XmAb®14045 in acute myeloid leukemia.”

Recent Business Highlights and Anticipated Upcoming Milestones

XmAb5871: XmAb5871 is a first-in-class monoclonal antibody that targets CD19 with its variable domain, and uses Xencor’s XmAb immune inhibitor Fc domain to target FcγRIIb, a receptor that inhibits B-cell function. XmAb5871 is currently in Phase 2 clinical studies for the treatment of IgG4-Related Disease (IgG4-RD) and systemic lupus erythematosus (SLE).

- Topline data from IgG4-RD Phase 2 trial expected in 2017
- Initial data from SLE Phase 2 trial expected in late 2018/early 2019

Xencor recently completed its subcutaneous (SC) administration Phase 1 study of XmAb5871. Multiple dose SC administration of XmAb5871 was safe and well tolerated at doses of 125 to 375 mg in all 40 subjects administered SC XmAb5871. Treatment emergent adverse events (TEAEs) occurring in subjects receiving any dose of SC XmAb5871 were mild in severity. The only drug-related TEAE occurring in more than two subjects who received any dose of SC XmAb5871 was injection site bruising (three subjects, 8%). No subject receiving SC XmAb5871 discontinued the study due to an adverse event and there were no serious adverse events during the study. Pharmacokinetic and bioavailability data from the study support an every other week dosing schedule. Based on these results, Xencor plans to implement SC administration in newly-initiated clinical trials.

At the 3rd International Symposium on IgG4-Related Disease and Fibrosis in February 2017, investigators from Xencor's ongoing Phase 2 study of XmAb5871 in IgG4-RD presented an update on IgG4-RD biomarker development, including flow cytometry methods for measuring circulating B cells, plasmablasts and CD4-positive cytotoxic T lymphocytes. The presentation also included preliminary flow cytometry data for patients enrolled in the ongoing Phase 2 study, which showed a partial reduction in B cells, consistent with previous clinical experience, and a rapid reduction of circulating plasmablasts following treatment with XmAb5871. No significant apoptosis of B cells or CD4 T cells was induced by XmAb5871 therapy.

XmAb@7195: XmAb7195 is a first-in-class monoclonal antibody that targets IgE with its variable domain and uses Xencor's XmAb Immune Inhibitor Fc domain to target FcγRIIb, resulting in three distinct mechanisms of action for reducing IgE levels. A subcutaneously administered formulation of XmAb7195 is currently in a Phase 1b study for the treatment of allergic disease.

- Topline data from subcutaneous administration Phase 1b trial expected in 2017

Bispecific Oncology Pipeline: Xencor's initial bispecific antibody programs are tumor-targeted antibodies that contain both a tumor antigen binding domain and a cytotoxic T-cell binding domain (CD3). These bispecific antibodies activate T cells for highly potent and targeted killing of malignant cells. Their XmAb Fc domains confer long circulating half-lives, stability and ease of manufacture. XmAb14045 is currently in a Phase 1 study for the treatment of acute myeloid leukemia (AML) and other CD123-expressing hematologic malignancies, and XmAb13676 is currently in a Phase 1 study for the treatment of B-cell malignancies.

- Initial data from XmAb14045 Phase 1 trial expected in 2017, pending alignment on timing with Novartis
- Initial data from XmAb13676 Phase 1 trial expected in 2018, pending alignment on timing with Novartis
- Investigational New Drug (IND) application filing for XmAb@18087, a somatostatin receptor 2 (SSTR2) x CD3 bispecific antibody for the treatment of neuroendocrine tumors, expected in 2017
- IND application filing for XmAb@20717, a PD-1 x CTLA-4 dual checkpoint inhibitor for the treatment of multiple oncology indications, expected in 2018

At the American Association for Cancer Research (AACR) 2017 Annual Meeting in April, Xencor presented preclinical data supporting the development of XmAb18087 for the treatment of SSTR2+ cancers, including neuroendocrine tumors and small cell lung cancer (SCLC). In *in vitro* and mouse models, XmAb18087 eliminated SSTR2+ tumor cells by stimulating redirected T cell-mediated cytotoxicity, and in cynomolgus monkeys, XmAb18087 stimulated SSTR2-dependent T cell activation, T cell margination and cytokine release. Xencor also presented preclinical data on additional bispecific antibodies deploying its XmAb bispecific and half-life extension technology, highlighting a bispecific antibody targeting PD-1 and an undisclosed co-stimulatory receptor (PD1 x costim) and IL15/IL15Rα heterodimeric Fc-fusions.

Partnered XmAb Programs: Nine pharmaceutical companies and the National Institutes of Health are advancing novel drug candidates either discovered at Xencor or that rely on Xencor's proprietary XmAb® technology. Seven such programs are currently undergoing clinical testing.

- In March 2017, Xencor was notified by its partner, CSL Limited, that CSL licensee Janssen Biotech Inc. advanced CSL362 (now called talacotuzumab) to the Phase 3 portion of its ongoing Phase 2/3 study for the potential treatment of patients with AML. Talacotuzumab uses Xencor's XmAb Cytotoxic Fc Domain. The trial initiation triggered a milestone payment to Xencor from CSL Limited of \$3.5 million.

Corporate:

- In April 2017, Xencor announced the appointment of Kevin Gorman, Ph.D., to its Board of Directors. In March and April 2017, respectively, Xencor also announced that Bruce Carter, Ph.D., and Robert Baltera will not stand for re-election to the Board of Directors at the 2017 Annual Meeting of Stockholders.

First Quarter Ended March 31, 2017 Financial Results

Cash, cash equivalents, and marketable securities totaled \$392.7 million as of March 31, 2017, compared to \$403.5 million on December 31, 2016. The decrease reflects net spending on operations in the first quarter of 2017.

Revenues for the first quarter ended March 31, 2017 were \$4.3 million, compared to \$7.3 million in the same period of 2016. Decreased revenue for the first quarter of 2017 over revenue for the same period in 2016 is primarily the result of revenue earned from our Amgen collaboration in the first quarter of 2016 compared to milestone revenue received from CSL in the first quarter of 2017.

Research and development expenditures for the first quarter ended March 31, 2017 were \$15.0 million, compared to \$10.0 million for the same period in 2016. Increased research and development spending in the first quarter of 2017 over the same period in 2016 reflects increased spending on our bispecific pipeline of candidates including our first two clinical candidates, XmAb14045 and XmAb13676 and development spending on the next two candidates, XmAb18087 and XmAb20717.

General and administrative expenses in the first quarter ended March 31, 2017 were \$4.8 million, compared to \$4.0 million for the same period in 2016. Increased spending on general and administration in the first quarter of 2017 over the comparable period in 2016 reflects increases in stock based compensation charges in 2017.

Non-cash, share based compensation expense for the first quarter ended March 31, 2017 was \$3.2 million, compared to \$2.0 million for the same period in 2016.

Net loss for the first quarter ended March 31, 2017 was \$14.6 million, or \$(0.31) on a fully diluted per share basis, compared to a net loss of \$6.4 million, or \$(0.16) on a fully diluted per share basis, for the same period in 2016. The increased loss for the first quarter ended March 31, 2017 compared to 2016 is primarily due to lower revenue of \$2.9 million and increased spending of \$5.9 million in the first quarter of 2017 compared to the first quarter of 2016.

The weighted-average shares outstanding used to compute net loss per share was 46,598,797 for the quarter ended March 31, 2017, compared to 40,626,729 for the quarter ended March 31, 2016.

Financial Guidance

Based on current operating plans, Xencor expects to have cash to fund research and development programs and operations beyond the end of 2020. Xencor expects to end 2017 with approximately \$340 million in cash, cash equivalents, and marketable securities.

Conference Call and Webcast

Xencor will host a conference call today at 4:30 p.m. ET (1:30 p.m. PT) to discuss these first quarter 2017 financial results and provide a corporate update.

The live call may be accessed by dialing (877) 359-9508 for domestic callers or (224) 357-2393 for international callers, and referencing conference ID number: 10271460. A live webcast of the conference call will be available online from the investor relations section of the company website at www.xencor.com. The webcast will be archived on the company website for 30 days.

About Xencor, Inc.

Xencor is a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune diseases, asthma and allergic diseases and cancer. Currently, 11 candidates engineered with Xencor's XmAb® technology are in clinical development internally and with partners. Xencor's internal programs include: XmAb®5871 in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb®7195 in Phase 1 development for the treatment of asthma and allergic diseases; XmAb®14045 in Phase 1 development for acute myeloid leukemia; XmAb®13676 in Phase 1 development for B-cell malignancies; XmAb®18087 in pre-clinical development for the treatment of neuroendocrine tumors; and XmAb®20717 in pre-clinical development for the treatment of multiple cancers. Xencor's XmAb antibody engineering technology enables small changes to the structure of monoclonal antibodies resulting in new mechanisms of therapeutic action. Xencor partners include Novartis, Amgen, MorphoSys, Merck, CSL/Janssen, Alexion and Boehringer Ingelheim. For more information, please visit www.xencor.com.

Forward Looking Statements:

Statements contained in this press release regarding matters that are not historical facts are forward-looking statements within the meaning of applicable securities laws, including the quotation from Xencor's President and CEO and any expectations relating to its financial expectations and business, its research and development programs, including XmAb®5871, XmAb®7195, and bispecific programs, including XmAb®14045, XmAb®13676, XmAb®20717 and XmAb®18087, its partnering efforts or its capital requirements. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements and the timing of events to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. Such risks include, without limitation, the risks associated with the process of discovering, developing, manufacturing and commercializing drugs that are safe and effective for use as human therapeutics and other risks described in Xencor's public securities filings. All forward-looking statements are based on Xencor's current information and belief as well as assumptions made by Xencor. Readers are cautioned not to place undue reliance on such statements and Xencor disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:

John Kuch, Vice President Finance, Xencor
Tel: 626-737-8013
jkuch@xencor.com

Corporate Communications Contact:

Jason I. Spark
Canale Communications for Xencor
Tel: 619-849-6005
jason@canalecomm.com

Xencor, Inc.
Condensed Balance Sheets
(in thousands)

	March 31, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$ 13,561	\$ 14,528
Short-term marketable securities	141,225	115,608
Accounts receivable	6,938	8,616
Prepaid expenses and other current assets	4,365	2,901
Total current assets	166,089	141,653
Property and equipment, net	3,360	3,105
Long-term marketable securities	237,865	273,340
Intangible assets, net	10,886	10,362
Other assets	103	103
Total assets	\$ 418,303	\$ 428,563
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 10,912	\$ 10,700
Current portion of deferred revenue	95,788	95,521
Income taxes	175	65
Total current liabilities	106,875	106,286
Deferred rent, less current portion	361	397
Deferred revenue, less current portion	7,319	7,926
Total liabilities	114,555	114,609
Stockholders' equity	303,748	313,954
Total liabilities and stockholders' equity	\$ 418,303	\$ 428,563

The 2016 balance sheet was derived from the 2016 annual financial statements included in the form 10-K that was filed on March 1, 2017.

Xencor, Inc.
Condensed Statements of Comprehensive Income (Loss)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2017 (Unaudited)	2016 (Unaudited)
Revenues	\$ 4,340	\$ 7,252
Operating expenses:		
Research and development	15,048	10,035
General and administrative	4,811	3,950
Total operating expenses	<u>19,859</u>	<u>13,985</u>
Loss from operations	(15,519)	(6,733)
Other income, net	<u>1,054</u>	<u>335</u>
Loss before income tax expense	(14,465)	(6,398)
Income tax expense	<u>170</u>	<u>—</u>
Net loss	<u>(14,635)</u>	<u>(6,398)</u>
Other comprehensive income		
Net unrealized gain on marketable securities	245	619
Comprehensive loss	<u>\$ (14,390)</u>	<u>\$ (5,779)</u>
Basic and diluted net loss per common share	\$ (0.31)	\$ (0.16)
Basic and diluted weighted average number of common shares	46,598,797	40,626,729