

# XENCOR INC

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

Filed 08/07/17 for the Period Ending 08/07/17

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

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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 7, 2017**

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**XENCOR, INC.**

(Exact name of registrant as specified in its charter)

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**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**

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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 (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.

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

On August 7, 2017, we announced our financial results for the quarter ended June 30, 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 August 7, 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: August 7, 2017

**XENCOR, INC.**

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

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release dated August 7, 2017.

**Xencor Reports Second Quarter 2017 Financial Results**

— Management to Host Conference Call Today at 4:30 p.m. ET —

MONROVIA, Calif., August 7, 2017 — Xencor, Inc. (NASDAQ:XCOR), a clinical-stage biopharmaceutical company developing engineered monoclonal antibodies for the treatment of autoimmune disease, asthma and allergic diseases, and cancer, today reported financial results for the second quarter ended June 30, 2017 and provided a review of business and clinical highlights.

“In the second quarter, we continued to advance our pipeline of wholly-owned and partnered XmAb® antibody drug candidates,” said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. “In June, we announced encouraging interim data from our ongoing Phase 2 study of XmAb®5871 in IgG4-RD, and our partner, MorphoSys, announced the initiation of a pivotal Phase 3 trial with XmAb®5574/MOR208, the third XmAb asset to enter Phase 3 development. Still ahead in 2017, we expect topline results from our Phase 2 study of XmAb5871 in IgG4-RD and our Phase 1 subcutaneous administration study of XmAb®7195, and preclinical data from our bispecific oncology candidates targeting the tumor microenvironment. Looking at our internal portfolio more broadly, by the end of 2018 we expect to have proof-of-concept data from our four lead programs, including our first bispecific programs, XmAb®14045 and XmAb®13676, and to advance additional bispecific oncology antibodies into clinical testing.”

**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-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

At the Annual European Congress of Rheumatology (EULAR 2017) in June, Xencor presented interim data from its ongoing Phase 2 clinical study of XmAb5871 in IgG4-RD. As of the April 18, 2017 data cutoff, 14 of 15 treated patients (93%) achieved a response to therapy of greater than or equal to a three-point reduction in the IgG4-RD Responder Index (IgG4-RD RI), including 12 patients (80%) who achieved a response to therapy within two weeks of their first dose. Six patients achieved disease remission (an IgG4-RD RI of 0) during the study. XmAb5871 continues to be well-tolerated, with all XmAb5871-related adverse event (AEs) graded as mild or moderate and no XmAb5871-related serious AEs reported.

In May, XmAb5871 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the treatment of IgG4-RD. This designation qualifies Xencor for certain development incentives, including tax credits for qualified clinical testing, prescription drug user fee expansions and seven-year marketing exclusivity upon FDA approval. Xencor plans to engage with the FDA in 2017 to discuss future development plans for XmAb5871, including clinical trial design and potential registration requirements.

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**XmAb7195:** 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 2018, 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

**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, including three in Phase 3 studies.

- In June 2017, MorphoSys AG announced the initiation of the pivotal Phase 3 portion of its Phase 2/3 clinical trial of XmAb5574/MOR208 in combination with bendamustine for the treatment of relapsed or refractory large B-cell lymphoma (B-MIND trial). MOR208 uses Xencor's XmAb Cytotoxic Fc Domain. The trial initiation triggered a milestone payment to Xencor of \$12.5 million.

#### **Corporate:**

- In June 2017, Xencor announced the appointment of Raphael Clynes, M.D., Ph.D., as vice president of translational biology. In this newly-created role, Dr. Clynes will focus on understanding the biological mechanisms of XmAb antibody drug candidates, particularly in immuno-oncology.
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## **Second Quarter Ended June 30, 2017 Financial Results:**

Cash, cash equivalents and marketable securities totaled \$378.7 million as of June 30, 2017, compared to \$403.5 million on December 31, 2016. The decrease reflects net spending on operations in the six months ended June 30, 2017.

Revenues for the second quarter ended June 30, 2017 were \$13.3 million, compared to \$66.0 million for the same period in 2016. Revenues for the six months ended June 30, 2017 were \$17.7 million, compared to \$73.3 million for the same period in 2016. Revenues in the three and six-month period ended June 30, 2017 were primarily milestones received from the Company's CSL and MorphoSys collaborations, compared to revenues for the same period in 2016, which were earned primarily from the Company's Novartis and Amgen collaborations.

Research and development expenditures for the second quarter ended June 30, 2017 were \$16.9 million, compared to \$14.4 million for the same period in 2016. Total research and development expenses for the six-month period ended June 30, 2017 were \$32.0 million, compared to \$24.4 million for the same period in 2016. The increased research and development spending for the three and six months ended June 30, 2017 is primarily due to additional spending on Xencor's pipeline of bispecific oncology candidates.

General and administrative expenses for the second quarter ended June 30, 2017 were \$4.1 million, compared to \$3.0 million in the same period in 2016. Total general and administrative expenses for the six-month period ended June 30, 2017 were \$8.9 million, compared to \$7.0 million for the same period in 2016. Increased spending on general and administrative for the three and six months ended June 30, 2017 reflects increased charges for stock based compensation.

Non-cash, share based compensation expense for the six months ended June 30, 2017 was \$6.6 million, compared to \$4.0 million for the same period in 2016.

Net loss for the second quarter ended June 30, 2016 was \$6.9 million, or \$(0.15) on a fully diluted per share basis, compared to a net income of \$47.2 million, or \$1.13 on a fully diluted per share basis, for the same period in 2016. For the six months ended June 30, 2017, net loss was \$21.5 million, or \$(0.46) on a fully diluted per share basis, compared to a net income of \$40.8 million, or \$0.98 on a fully diluted per share basis, for the same period in 2016. The loss reported for the three and six months ended June 30, 2017 compared to income for the same periods in 2016 is primarily due to milestone revenue received from CSL and MorphoSys in 2017 compared to revenue recognized under Xencor's Novartis and Amgen collaborations in 2016.

The total shares outstanding was 46,854,762 as of June 30, 2017, compared to 40,944,080 as of June 30, 2016. The increase in total shares at June 30, 2017 reflects the sale of shares in the December 2016 financing.

### **Financial Guidance:**

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

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**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 second 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: 55777665. A live webcast of the conference call will be available online from the investor relations section of the company's website at [www.xencor.com](http://www.xencor.com). The webcast will be archived on the company's 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](http://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 statements related to expectations relating to Xencor's financial expectations and business, the timing and future results of Xencor's research and development programs, including XmAb®5871, XmAb®7195 and bispecific programs, including XmAb®14045, XmAb®13676, XmAb®20717 and XmAb®18087, Xencor's potential partnering efforts or Xencor's 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, including without limitation Xencor's Annual Report on Form 10-K for the year ended December 31, 2016. 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.

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**Xencor, Inc.**  
**Condensed Balance Sheets**  
(in thousands)

	June 30, 2017 (Unaudited)	December 31, 2016
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 11,220	\$ 14,528
Short-term marketable securities	177,269	115,608
Accounts receivable	14,876	8,616
Prepaid expenses and other current assets	7,617	2,901
<b>Total current assets</b>	<b>210,982</b>	<b>141,653</b>
Property and equipment, net	3,861	3,105
Long-term marketable securities	190,242	273,340
Intangible assets, net	10,865	10,362
Other assets	214	103
<b>Total assets</b>	<b>\$ 416,164</b>	<b>\$ 428,563</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	\$ 11,363	\$ 10,700
Current portion of deferred revenue	95,613	95,521
Income taxes	455	65
<b>Total current liabilities</b>	<b>107,431</b>	<b>106,286</b>
Deferred rent, less current portion	614	397
Deferred revenue, less current portion	6,754	7,926
<b>Total liabilities</b>	<b>114,799</b>	<b>114,609</b>
<b>Stockholders' equity</b>	<b>301,365</b>	<b>313,954</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 416,164</b>	<b>\$ 428,563</b>

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)

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
<b>Revenues</b>	\$ 13,340	\$ 66,007	\$ 17,681	\$ 73,259
<b>Operating expenses:</b>				
Research and development	16,919	14,408	31,967	24,443
General and administrative	4,091	3,043	8,903	6,993
<b>Total operating expenses</b>	<u>21,010</u>	<u>17,451</u>	<u>40,870</u>	<u>31,436</u>
<b>Income (loss) from operations</b>	<u>(7,670)</u>	<u>48,556</u>	<u>(23,189)</u>	<u>41,823</u>
Other income, net	<u>1,065</u>	<u>358</u>	<u>2,120</u>	<u>693</u>
<b>Income (loss) before income tax expense</b>	(6,605)	48,914	(21,069)	42,516
Income tax expense	<u>280</u>	<u>1,749</u>	<u>450</u>	<u>1,749</u>
<b>Net income (loss)</b>	<u>(6,885)</u>	<u>47,165</u>	<u>(21,519)</u>	<u>40,767</u>
<b>Other comprehensive income (loss)</b>				
Net unrealized gain (loss) on marketable securities	(44)	113	201	732
<b>Comprehensive income (loss)</b>	<u>\$ (6,929)</u>	<u>\$ 47,278</u>	<u>\$ (21,318)</u>	<u>\$ 41,499</u>
<b>Basic net income (loss) per common share</b>	\$ (0.15)	\$ 1.16	\$ (0.46)	\$ 1.00
<b>Diluted net income (loss) per common share</b>	\$ (0.15)	\$ 1.13	\$ (0.46)	\$ 0.98
<b>Basic weighted average number of common shares</b>	46,767,759	40,800,586	46,683,744	40,703,688
<b>Diluted weighted average number of common shares</b>	46,767,759	41,738,460	46,683,744	41,701,262