

XENCOR INC

FORM 8-K (Current report filing)

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| 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): **February 28, 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))
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Item 2.02 Results of Operations and Financial Condition.

On February 28, 2017, we announced our financial results for the fourth quarter and fiscal year ended December 31, 2016 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Item 2.02 and the attached Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of Xencor, Inc. dated February 28, 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: February 28, 2017

XENCOR, INC.

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

INDEX TO EXHIBITS

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Xencor Reports Fourth Quarter and Full Year 2016 Financial Results

— Reported promising preliminary data from Phase 2 study of XmAb®5871 in IgG4-Related Disease (IgG4-RD) —

— Announced strategic collaboration with Novartis for bispecific antibodies —

— Robust cash position supports operations beyond 2020 —

— Management to host conference call today at 4:30 p.m. ET —

MONROVIA, Calif., Feb. 28, 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 fourth quarter and full year ended December 31, 2016 and provided a review of 2016 and recent business and clinical highlights.

“During 2016, we made significant progress expanding our clinical development pipeline by starting five clinical trials across our XmAb portfolio. In addition, in February 2017 we dosed the first patient in the Phase 1 trial in non-Hodgkin lymphoma for XmAb @ 13676, which joins XmAb @ 14045 as our second bispecific oncology program in the clinic. We started a major collaboration with Novartis in 2016 that included ex-US commercial rights to these two lead bispecific programs and access to our platform. We also announced promising preliminary Phase 2 data for XmAb @ 5871 in IgG4-Related Disease (IgG4-RD) and broadened our pre-clinical pipeline with the addition of two new bispecific oncology programs, XmAb @ 18087 and XmAb @ 20717,” said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. “These achievements position us for a catalyst-rich 2017 and 2018. Looking ahead, we are focused on reporting top line results from our Phase 2 study of XmAb5871 in IgG4-RD and from our subcutaneous administration Phase 1 study of XmAb@7195, on understanding the clinical and regulatory pathways for XmAb5871 in IgG4-RD, and on continuing to expand our bispecific oncology pipeline. With \$403.5M in cash, cash equivalents and marketable securities, we are sufficiently funded to advance our novel antibody assets beyond 2020.”

2016 and Recent Business Highlights and Anticipated Upcoming Milestones

XmAb5871: XmAb5871 is a first-in-class monoclonal antibody that targets CD19 with its variable domain and that 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).

- Top line data from IgG4-RD Phase 2 trial expected in 2017
- Initial data from SLE Phase 2 trial expected in 2018

Xencor plans to report data from its subcutaneous administration Phase 1 study of XmAb5871 in the first half of 2017.

At the American College of Rheumatology 2016 Annual Meeting in November, Xencor presented preliminary data from its ongoing Phase 2 clinical study of XmAb5871 in IgG4-RD as of a data cut-off date of October 31, 2016, which showed that nine of 11 patients (82%) that had at least one post-treatment disease assessment achieved an initial response to therapy of at least a three-point reduction in the IgG4-RD Responder Index within two weeks of their first dose. Five patients attained disease remission (an IgG4-RD Responder Index of 0) during the study. XmAb5871 was well tolerated, with no serious adverse events reported. In January 2017, enrollment in the study was completed. The Company plans to engage with the U.S. Food and Drug Administration in 2017 to discuss future development plans for XmAb5871, including clinical trial design and potential registration requirements.

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.

- Top line data from the subcutaneous administration Phase 1b trial expected in 2017

At the American Thoracic Society 2016 International Conference in May, Xencor announced complete data results from its Phase 1a trial of XmAb7195, which showed rapid and extensive depletion of serum IgE at all doses tested, including from single intravenous doses in 75% of high IgE subjects. XmAb7195 was generally well tolerated, with transient, asymptomatic thrombocytopenia reported at doses ≥ 2.0 mg/kg. Moderate urticaria was reported in some treated patients with an apparent correlation of dose frequency with occurrence.

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 and other CD123-expressing hematologic malignancies.

- Initial data from XmAb14045 Phase 1 trial expected in 2017, pending alignment on timing with Novartis
- First patient dosed in Phase 1 trial for XmAb13676 in B-cell malignancies in February 2017 with initial data expected in 2018, pending alignment on timing with Novartis
- Investigational New Drug (IND) application filing for XmAb18087 for the treatment of neuroendocrine tumors expected in 2017

In June 2016, Xencor entered into a collaboration with Novartis Institutes for Biomedical Research, Inc. (Novartis) to develop and commercialize XmAb14045 and XmAb13676. Under the terms of the agreement with Novartis, Xencor and Novartis share worldwide development costs for the two compounds, with Xencor maintaining U.S. commercial rights and Novartis having commercial rights in the rest of the world. Novartis also received worldwide rights to Xencor's bispecific technology to develop and commercialize four additional targets selected by

Novartis, one of which Xencor may elect to co-detail in the U.S. The bispecific collaboration also includes molecular engineering by Xencor. Additionally, Novartis received a worldwide non-exclusive license to use Xencor's other XmAb Fc technologies in up to 10 molecules. Xencor received a \$150 million upfront payment and is eligible to receive up to \$2.41 billion in clinical, regulatory and sales milestone payments and royalties on sales.

Also in June 2016, Xencor announced that it has initiated development of XmAb20717, its first bispecific antibody that simultaneously engages two T-cell checkpoint targets to activate T cells against multiple tumor types. These dual checkpoint bispecific antibodies have the potential to improve the selectivity of combination checkpoint inhibitor therapy and eliminate the need for multiple checkpoint antibodies.

- IND application filing for XmAb20717, a PD-1 x CTLA-4 bispecific antibody for potential use in multiple oncology indications, expected in 2018

At the Society for Immunotherapy of Cancer 2016 Annual Meeting in November, Xencor presented preclinical data supporting the development of XmAb20717 for the treatment of human malignancies. In preclinical studies, the dual blockade of PD-1 and CTLA-4 with a bispecific antibody resulted in T cell activation comparable to a combination of bivalent antibodies targeting PD-1 and CTLA-4. Specific targeting of human lymphocytes positive for both PD-1 and CTLA-4 with a bispecific antibody may promote similar efficacy to a combination of bivalent antibodies, with fewer adverse events. Xencor also presented pre-clinical data on multiple additional dual checkpoint bispecific antibodies, highlighting lead candidates against CTLA-4 x LAG-3 and PD-1 x LAG-3.

Partnered XmAb Programs: Eight pharmaceutical companies and the National Institutes of Health (NIH) 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 December 2016, Alexion Pharmaceuticals, Inc. initiated a Phase 3 clinical trial for an undisclosed program under a license agreement for Xtend technology, and Xencor subsequently received a milestone payment of \$5 million.
- In September 2016, MorphoSys AG announced it began dosing in the safety evaluation portion of a Phase 2/3 combination trial of XmAb@5574/MOR208 with bendamustine for relapsed or refractory diffuse large B-cell lymphoma (B-MIND trial). Following Phase 2 safety evaluation, study expected to transition into a pivotal Phase 3 trial in 2017.
- In January 2016, the National Institutes of Health (NIH) initiated a Phase 1 clinical trial of VRC01LS, a therapeutic antibody for HIV that uses Xencor's Xtend antibody half-life extension technology.

Corporate: In December 2016, Xencor sold 5,272,750 shares of its common stock at a price of \$24.00 per share. The Company received net proceeds from the offering of \$119.3 million.

Fourth Quarter and Full Year Ended December 31, 2016 Financial Results

Cash, cash equivalents, and marketable securities totaled \$403.5 million as of December 31, 2016, compared to \$193.3 million on December 31, 2015. The 2016 year-end cash balance reflects upfront proceeds of \$150 million received in connection with our Novartis Collaboration and net proceeds of \$119.3 million from a financing in excess of spending on our operations for 2016. The 2015 cash balance reflects the upfront payment of \$45 million received from our Amgen Collaboration and net proceeds of \$115 million received from a financing in excess of spending on operations in 2015.

Revenues for the fourth quarter ended December 31, 2016 were \$6.4 million, compared to \$21.8 million in the same period of 2015. Revenues for full year 2016 were \$87.5 million, compared to \$27.8 million in 2015. Revenues are earned from technology licensing fees and milestone payments from Xencor's partners for the license of its drug candidates and use of its proprietary XmAb antibody engineering technologies. Revenue for the fourth quarter of 2016 related primarily to a milestone received from Alexion while revenue for the same period in 2015 included milestone and option payments from Alexion in addition to revenue earned from our Amgen collaboration. Total revenues earned in 2016 were higher than 2015 due to revenue earned from our Novartis Collaboration.

Research and development expenditures for the fourth quarter ended December 31, 2016 were \$13.4 million, compared to \$10.9 million for the same period in 2015. Research and development expenditures were \$51.9 million for the full year ended December 31, 2016, compared to \$34.1 million in 2015. Research and development spending in the fourth quarter and for the full year ended December 31, 2016 was greater than expenditures incurred over comparable periods in 2015 due to increased spending on our clinical programs including our Xmab5871 and XmAb7195 programs and also development of our pipeline of bispecific clinical candidates.

General and administrative expenses in the fourth quarter ended December 31, 2016 were \$3.1 million, compared to \$3.4 million for the same period in 2015. General and administrative expenses were \$13.1 million in the full year 2016, compared to \$12.0 million in 2015. Additional spending on general and administration for the full year ended December 31, 2016 over the comparable period in 2015 reflects increased staffing costs and compliance costs related to SEC filing obligations.

Non-cash, share based compensation expense for the year ended December 31, 2016 was \$7.8 million, compared to \$4.9 million for the year ended December 31, 2015.

Net loss for the fourth quarter ended December 31, 2016 was \$9.1 million compared to a net income of \$7.8 million for the same period in 2015. The net loss incurred in the fourth quarter of 2016 reflects spending on operations in excess of the Alexion milestone for the period. Net income for the full year ended December 31, 2016 was \$23.6 million or \$0.56 on a fully diluted per share basis, compared to net loss of \$17.6 million, or \$(0.45) on a fully diluted per share basis, for the same period in 2015. The income earned for the year ended December 31, 2016 over the loss sustained in 2015 is primarily due to the revenue earned from our Novartis collaboration.

The weighted-average shares outstanding used to compute diluted earnings per share was 42,388,867 for the year ended December 31, 2016, compared to 39,015,131 for the year ended December 31, 2015. The increase in weighted-average shares outstanding reflects the additional shares issued in our December 2016 follow-on financing.

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 and cash equivalents.

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 fourth quarter and full year 2016 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: 66045775. 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: XmAb5871 in Phase 2 development for the treatment of IgG4-Related Disease, and also for the treatment of Systemic Lupus Erythematosus; XmAb7195 in Phase 1 development for the treatment of asthma and allergic diseases; XmAb14045 in Phase 1 development for acute myeloid leukemia; XmAb13676 in Phase 1 development for B-cell malignancies; and XmAb18087 for the treatment of neuroendocrine tumors, in pre-clinical development. 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 XmAb5871, XmAb7195, and bispecific programs, including XmAb14045, XmAb13676, 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.

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Xencor, Inc.
Condensed Balance Sheets
(in thousands)

| | December 31, | |
|---|-------------------|-------------------|
| | 2016 | 2015 |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 14,528 | \$ 12,590 |
| Short-term marketable securities | 115,608 | 83,840 |
| Accounts receivable | 8,616 | — |
| Other current assets | 2,901 | 1,245 |
| Total current assets | 141,653 | 97,675 |
| Property and equipment, net | 3,105 | 2,310 |
| Long-term marketable securities | 273,340 | 96,891 |
| Intangible assets, net | 10,362 | 9,971 |
| Other assets | 103 | 63 |
| Total assets | \$ 428,563 | \$ 206,910 |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 10,572 | \$ 10,034 |
| Current portion of deferred revenue | 95,521 | 33,287 |
| Other current liabilities | 193 | 108 |
| Total current liabilities | 106,286 | 43,429 |
| Deferred rent, less current portion | 397 | 507 |
| Deferred revenue, less current portion | 7,926 | 542 |
| Total liabilities | 114,609 | 44,478 |
| Stockholders' equity | 313,954 | 162,432 |
| Total liabilities and stockholders' equity | \$ 428,563 | \$ 206,910 |

The 2015 balance sheet was derived from the 2015 annual financial statements included in the form 10-K that was filed on March 8, 2016.

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

| | Three months ended December 31, | | Year ended | |
|---|---------------------------------|-----------------|------------------|--------------------|
| | 2016 | 2015 | 2016 | 2015 |
| | (unaudited) | | | |
| Revenues | \$ 6,440 | \$ 21,754 | \$ 87,520 | \$ 27,762 |
| Operating expenses: | | | | |
| Research and development | 13,360 | 10,877 | 51,872 | 34,140 |
| General and administrative | 3,108 | 3,439 | 13,108 | 11,960 |
| Total operating expenses | <u>16,468</u> | <u>14,316</u> | <u>64,980</u> | <u>46,100</u> |
| Income (loss) from operations | (10,028) | 7,438 | 22,540 | (18,338) |
| Other income, net | 803 | 319 | 2,076 | 746 |
| Income (loss) before income taxes | <u>(9,225)</u> | <u>7,757</u> | <u>24,616</u> | <u>(17,592)</u> |
| Income tax (benefit) provision | <u>(160)</u> | <u>—</u> | <u>991</u> | <u>—</u> |
| Net income (loss) | (9,065) | 7,757 | 23,625 | (17,592) |
| Other comprehensive loss | | | | |
| Net unrealized loss on marketable securities | (1,192) | (510) | (925) | (516) |
| Comprehensive income (loss) | <u>\$ (10,257)</u> | <u>\$ 7,247</u> | <u>\$ 22,700</u> | <u>\$ (18,108)</u> |
| Net income (loss) per share: | | | | |
| Basic net income (loss) per share | \$ (0.21) | \$ 0.19 | \$ 0.57 | \$ (0.45) |
| Fully diluted net income (loss) per share | \$ (0.21) | \$ 0.19 | \$ 0.56 | \$ (0.45) |
| Weighted average number of shares used in computing net income (loss), basic | 42,615,813 | 40,501,653 | 41,267,329 | 39,015,131 |
| Weighted average number of shares used in computing net income (loss), fully diluted | 42,615,813 | 41,668,852 | 42,388,867 | 39,015,131 |