

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): **November 7, 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 November 7, 2017, we announced our financial results for the quarter ended September 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 November 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: November 7, 2017

XENCOR, INC.

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

Xencor Reports Third Quarter 2017 Financial Results and Provides Clinical Pipeline Update

— Announced Final Results from Phase 2 Trial of XmAb[®] 5871 in IgG4-Related Disease (IgG4-RD); Plan to Initiate Phase 3 Trial in 2H18 —
 — Phase 1b Data from Subcutaneous Administration Trial of XmAb[®] 7195 Show Potent IgE Reduction with Improved Tolerability —
 — Management to Host Conference Call Today at 4:30 p.m. ET —

MONROVIA, Calif., November 7, 2017 — Xencor, Inc. (NASDAQ:XNCR), 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 third quarter ended September 30, 2017 and provided a review of business and clinical highlights.

“Our third quarter results highlight the promise of our XmAb[®] technology to create a broad pipeline of engineered antibodies with improved performance across a range of unmet needs,” said Bassil Dahiyat, Ph.D., president and chief executive officer of Xencor. “We recently announced promising, final results from our Phase 2 trial of XmAb5871 in IgG4-RD, which suggest that XmAb5871 may offer patients the first approved therapy for this newly-defined autoimmune disease and support advancement of the program into a Phase 3 trial. Today, we are pleased to announce data from our Phase 1b trial of subcutaneously administered XmAb7195, which shows potent IgE reduction with improved tolerability compared to intravenous administration, and supports subcutaneous administration in future development. In addition, we continue to advance our bispecific oncology pipeline targeting the tumor microenvironment, have opened the IND for XmAb[®] 18087, our first solid tumor targeting bispecific, and expect to report the first clinical data from our oncology pipeline in 2018.”

Recent Business Highlights and Upcoming Clinical Plans

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 a Phase 2 clinical study for the treatment of systemic lupus erythematosus (SLE).

- Initiation of Phase 3 trial in IgG4-RD expected in 2H18.
- Initial data from SLE Phase 2 trial expected in late 2018.

In November 2017, Xencor announced the final results from its Phase 2 trial of XmAb5871 in IgG4-RD. 12 of 15 patients (80%) dosed completed the study, and all 12 achieved the primary endpoint of at least a two-point reduction in the IgG4-RD Responder Index (IgG4-RD RI) on Day 169. None of the 12 required corticosteroids (CS) after month two, and eight patients (53%) achieved disease remission (IgG4-RD of 0 and no CS after two months) and the other four achieved IgG4-RD RI scores of ≤ 4 at Day 169. Fourteen of 15 patients (93%) achieved a decrease of ≥ 5 in the IgG4-RD RI. XmAb5871 was well-tolerated, with all XmAb5871-related adverse events (AEs) graded as mild to moderate and no XmAb5871-related serious AEs reported. These results will be presented today at 8:15 pm ET during a late-breaking oral presentation at the American College of Rheumatology (ACR) 2017 Annual Meeting titled, “Final Results of an Open Label Phase 2 Study of a Reversible B Cell Inhibitor, Xmab[®] 5871 in IgG4-Related Disease.”

Xencor met with the Division of Pulmonary, Allergy and Respiratory Products (DPARP) of the Food and Drug Administration (FDA) in a Type B End of Phase 2 meeting in July 2017 to discuss the optimal pathway to advance XmAb5871 into Phase 3 development in IgG4-RD. The meeting resulted in guidance on endpoint definition and a path forward for Phase 3 development in IgG4-RD, which the FDA recognizes as a new disease entity with no regulatory precedence for an approval pathway. Based on the Phase 2 results and these preliminary discussions with DPARP, a randomized, placebo-controlled, double-blinded Phase 3 trial of approximately 250-350 patients evaluating the addition of XmAb5871 to standard of care is planned to be initiated in the second half of 2018. Xencor also intends to seek scientific advice from the European Medicines Agency in early 2018.

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.

Xencor recently completed its subcutaneous (SC) administration Phase 1b study of XmAb7195 evaluating four once-weekly doses of SC XmAb7195. The first part of this study was an open-label bioequivalence trial ranging from 0.1 to 1.0 mg/kg in cohorts of six healthy volunteers. The second part of the trial was a randomized, double-blinded, placebo-controlled multiple-ascending dose study in atopic patients at doses of 1.5 and 2.0 mg/kg. The half-life of SC XmAb7195 ranged from 3.6 - 4.9 days, comparable to the previously reported half-life of 3.9 days of intravenously administered XmAb7195. Bioavailability after the fourth dose exceeded 50%, which is typical for monoclonal antibodies, and drug concentration levels increased with successive doses.

Subcutaneous administration of XmAb7195 was well tolerated. No severe AEs or serious treatment-emergent AEs occurred during the study. The most frequently occurring treatment-emergent AEs were injection-site related and most were mild. No diffuse urticaria or other systemic hypersensitivity reactions were reported. No apparent effect of SC XmAb7195 on platelet count was seen when dosed at 0.1 - 1.0 mg/kg weekly for four weeks. At 1.5 - 2.0 mg/kg weekly for four weeks, mild platelet count reductions were observed. Four of 15 patients in the 2.0 mg/kg group had at least one platelet count of less than $150 \times 10^3 / \mu\text{L}$ at some time point. The lowest count observed was $126 \times 10^3 / \mu\text{L}$, and recovery to within normal range occurred within a few days.

In 23 of 27 (85%) subjects with detectable baseline free IgE (≥ 9.59 ng/mL limit of quantitation); (median 76.2 ng/mL, range: 17.4-846 ng/mL), treated with four weekly SC XmAb7195 doses of 0.3 to 2.0 mg/kg, free IgE was suppressed to below the limit of quantitation (BLQ) at some time point during the treatment period. In 20 (74%) subjects, BLQ values were maintained for the remainder of the treatment period and for at least seven days following the last dose. Similarly, in the subgroup of atopic subjects, 14 of 14 (100%) subjects with detectable baseline free IgE (median 150.0 ng/mL, range: 46.4-846 ng/mL) treated with four weekly SC XmAb7195 doses of 1.5 to 2.0 mg/kg, free IgE was suppressed to BLQ at some time point during the treatment period. In 12 (86%) atopic subjects, BLQ values were maintained for the remainder of the treatment period and for at least seven days following the last dose. Similarly, total IgE was profoundly suppressed in nearly all subjects for at least seven days following the last dose.

These results support subcutaneous delivery for future development, and analysis of the data is proceeding to determine the optimal dosing schedule. Xencor is seeking a development partner for XmAb7195.

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. XmAb[®] 14045 is currently in a Phase 1 study for the treatment of acute myeloid leukemia (AML) and other CD123-expressing hematologic malignancies, and XmAb[®] 13676 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.
- The Investigational New Drug (IND) application for XmAb18087, a somatostatin receptor 2 (SSTR2) x CD3 bispecific antibody for the treatment of neuroendocrine tumors and gastrointestinal stromal tumors, was approved in October 2017; clinical trial start expected in the first quarter of 2018.

Xencor is expanding its bispecific pipeline to build a suite of tumor microenvironment activators that engage multiple targets, such as T-cell checkpoints or agonists, with three IND's scheduled to be filed over the next 12 months:

- 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.
 - IND application filing for XmAb[®] 22841, a CTLA-4 x LAG-3 dual checkpoint inhibitor for the treatment of multiple oncology indications, expected in 2018.
 - IND application filing for XmAb[®] 23104, a PD-1 x ICOS bispecific antibody for the treatment of multiple oncology indications, expected in 2018.
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At the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting in November, Xencor will present preclinical data on XmAb20717 and XmAb23104.

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 two in Phase 3 studies.

Third Quarter Ended September 30, 2017 Financial Results:

Cash, cash equivalents and marketable securities totaled \$373.0 million as of September 30, 2017, compared to \$403.5 million on December 31, 2016. The decrease reflects net spending on operations in the nine months ended September 30, 2017.

Revenues for the third quarter ended September 30, 2017 were \$7.1 million, compared to \$7.8 million for the same period in 2016. Revenues for the nine months ended September 30, 2017 were \$24.8 million, compared to \$81.1 million for the same period in 2016. Revenues in the three and nine-month period ended September 30, 2017 were earned primarily from the Company's Amgen and MorphoSys collaborations, compared to revenues from the same period in 2016, which were earned primarily from the Company's Novartis and Amgen collaborations.

Research and development expenditures for the third quarter ended September 30, 2017 were \$19.4 million, compared to \$14.1 million for the same period in 2016. Total research and development expenses for the nine-month period ended September 30, 2017 were \$51.4 million, compared to \$38.5 million for the same period in 2016. The increased research and development spending for the three and nine months ended September 30, 2017 is primarily due to increased spending on the Company's bispecific pipeline and development candidates.

General and administrative expenses for the third quarter ended September 30, 2017 were \$4.2 million, compared to \$3.0 million in the same period in 2016. Total general and administrative expenses for the nine-month period ended September 30, 2017 were \$13.1 million, compared to \$10.0 million for the same period in 2016. Increased spending on general and administrative expenses for the three and nine months ended September 30, 2017 reflects increased staffing and stock-based compensation charges.

Non-cash, share based compensation expense for the nine months ended September 30, 2017 was \$10.2 million, compared to \$5.9 million for the same period in 2016.

Net loss for the third quarter ended September 30, 2017 was \$15.6 million, or \$(0.33) on a fully diluted per share basis, compared to a net loss of \$8.1 million, or \$(0.20) on a fully diluted per share basis, for the same period in 2016. For the nine months ended September 30, 2017, net loss was \$37.1 million, or \$(0.79) on a fully diluted per share basis, compared to a net income of \$32.7 million, or \$0.78 on a fully diluted per share basis, for the same period in 2016. The higher loss for the three months ended September 30, 2017 over the loss reported for the same period in 2016 is primarily due to additional research and development expenses on the Company's bispecific pipeline and development candidates, while the loss reported for the nine months ended September 30, 2017 compared to the income earned over the same period in 2016 is primarily due to revenue reported from the Company's Novartis collaboration in 2016 and additional research and development expenses in 2017.

The total shares outstanding was 46,955,365 as of September 30, 2017, compared to 41,138,851 as of September 30, 2016. The increase in total shares at September 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.

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 third 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: 99272433. 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. 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.

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 chief executive officer, 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, XmAb[®] 18087, XmAb[®] 22841 and XmAb[®] 23104, the timing of regulatory filings associated with such programs, 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)

| | September 30, 2017 (Unaudited) | December 31, 2016 |
|---|--------------------------------------|----------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 13,634 | \$ 14,528 |
| Short-term marketable securities | 196,318 | 115,608 |
| Accounts receivable | 831 | 8,616 |
| Prepaid expenses and other current assets | 7,027 | 2,901 |
| Total current assets | 217,810 | 141,653 |
| Property and equipment, net | 6,085 | 3,105 |
| Long-term marketable securities | 163,052 | 273,340 |
| Intangible assets, net | 11,043 | 10,362 |
| Other assets | 265 | 103 |
| Total assets | \$ 398,255 | \$ 428,563 |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 11,238 | \$ 10,700 |
| Current portion of deferred revenue | 89,088 | 95,521 |
| Income taxes | — | 65 |
| Total current liabilities | 100,326 | 106,286 |
| Deferred rent, less current portion | 1,202 | 397 |
| Deferred revenue, less current portion | 6,188 | 7,926 |
| Total liabilities | 107,716 | 114,609 |
| Stockholders' equity | 290,539 | 313,954 |
| Total liabilities and stockholders' equity | \$ 398,255 | \$ 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 September 30, | | Nine months ended September 30, | |
|---|----------------------------------|---------------------|---------------------------------|---------------------|
| | 2017 (Unaudited) | 2016 (Unaudited) | 2017 (Unaudited) | 2016 (Unaudited) |
| Revenues | \$ 7,090 | \$ 7,821 | \$ 24,771 | \$ 81,080 |
| Operating expenses: | | | | |
| Research and development | 19,408 | 14,069 | 51,376 | 38,512 |
| General and administrative | 4,172 | 3,007 | 13,074 | 10,000 |
| Total operating expenses | <u>23,580</u> | <u>17,076</u> | <u>64,450</u> | <u>48,512</u> |
| Income (loss) from operations | (16,490) | (9,255) | (39,679) | 32,568 |
| Other income, net | <u>1,101</u> | <u>580</u> | <u>3,220</u> | <u>1,272</u> |
| Income (loss) before income tax expense | (15,389) | (8,675) | (36,459) | 33,840 |
| Income tax expense | <u>173</u> | <u>(598)</u> | <u>623</u> | <u>1,150</u> |
| Net income (loss) | (15,562) | (8,077) | (37,082) | 32,690 |
| Other comprehensive income (loss) | | | | |
| Net unrealized gain (loss) on marketable securities | 143 | (466) | 344 | 266 |
| Comprehensive income (loss) | <u>\$ (15,419)</u> | <u>\$ (8,543)</u> | <u>\$ (36,738)</u> | <u>\$ 32,956</u> |
| Basic net income (loss) per common share | \$ (0.33) | \$ (0.20) | \$ (0.79) | \$ 0.80 |
| Diluted net income (loss) per common share | \$ (0.33) | \$ (0.20) | \$ (0.79) | \$ 0.78 |
| Basic weighted average number of common shares | 46,929,498 | 41,033,973 | 46,766,562 | 40,814,587 |
| Diluted weighted average number of common shares | 46,929,498 | 41,033,973 | 46,766,562 | 41,861,361 |