Xencor Inc
Form 8-K
November 30, 2016

# 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 13, 2016**

---

# XENCOR, INC.

(Exact name of registrant as specified in its charter)

---

| **Delaware** | **001-36182** | **20-1622502** |
|---|---|---|
| (State of incorporation) | (Commission File No.) | (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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01. Other Events.**

On November 13, 2016, Xencor, Inc. (the Company) announced preliminary data from XmAb5871-03, an ongoing, open-label, pilot Phase 2 study of XmAb5871 in patients with active IgG4-RD. Data show that 82% of patients achieved an initial response to therapy within two weeks of their first dose. The data was presented by John H. Stone, M.D., MPH, director of rheumatology at Massachusetts General Hospital, at the American College of Rheumatology 2016 Annual Meeting in the Miscellaneous Rheumatic and Inflammatory Disease session on November 13, 2016.

As of a data cutoff of October 31, 2016, 12 patients with active IgG4-RD have been enrolled and dosed with XmAb5871 (median number of infusions = 7, range 1-12). Patients had a median IgG4-RD responder index (RI) of 10 (range 2-30) with a median of four organs involved (range 1-10) at the time of study entry. Organ site involvement occurring at a frequency of greater than or equal to 50% included lymph nodes, submandibular glands, parotid glands and lacrimal glands.

Preliminary Safety Data:

Every other week intravenous administration of XmAb5871 has been well tolerated. As of October 31, 2016, no serious adverse events (AEs) have been reported. Treatment-related AEs have occurred in five patients (42%). Treatment-related AEs that occurred in more than one patient were abdominal pain/discomfort in three patients (25%), occurring as part of Grade 1 (mild) infusion-related gastrointestinal symptoms (nausea and/or vomiting and/or diarrhea) during the first infusion, and Grade 1 (mild) headaches in two patients (16.7%). One patient discontinued the study as the result of an AE. The patient developed a Grade 2 (moderate) hypersensitivity reaction with rash and arthritis, commonly referred to as serum sickness, following the fifth infusion. The event resolved quickly without the need for medical management. This patient was subsequently found to have developed anti-drug antibodies.

Preliminary Efficacy Data:

11 of the 12 patients dosed with XmAb5871 have had at least one IgG4-RD RI performed following dosing as of the data cutoff date. Nine of 11 patients (82%) have had an initial response to XmAb5871 therapy of at least a three-point reduction in the IgG4-RD RI within two weeks of the first dose. Five patients attained disease remission (an IgG4-RD RI of 0) during the study. Two patients entering the study on corticosteroids have been able to taper and discontinue steroid use during the study.

In addition to the patient with early study termination due to an AE, two other patients have discontinued treatment prior to receipt of all 12 planned infusions. One patient had a response to therapy (IgG4-RD RI reduction of six points), but lost response following the sixth infusion, at which point this patient discontinued treatment. One patient had no response to therapy as defined by a greater than or equal to two-point decrease in the IgG4-RD RI. This patient had an atypical presentation of larynx involvement as the only organ involved. The patient discontinued the study after six infusions. Neither of these two patients have responded to subsequent rituximab treatment.

On November 29, 2016, the Company updated the slide presentation to be used by the Company at investor meetings by adding a slide presenting data from XmAb5871-03. A copy of that revised slide is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company is filing certain information for the purpose of updating descriptions of the Company s risk factors contained in the Company s other filings with the Securities and Exchange Commission. A copy of this additional disclosure is attached as Exhibit 99.2 to this report and incorporated herein by reference.

Forward Looking Statements:

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are forward-looking statements within the meaning of applicable securities laws, including expectations relating to the Company s business, research and development programs, including ongoing clinical trials of XmAb5871, and the immune inhibitory Fc domain technology, partnering efforts or the Company s capital requirements. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements, including those of the complete clinical trial of XmAb5871, 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 the Company s public securities filings. All forward-looking statements are based on the Company s current information and belief as well as assumptions made by the Company. Readers are cautioned not to place undue reliance on such statements and the Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Slide presenting data from XmAb5871-03 from Xencor, Inc. Presentation, as updated on November 29, 2016 |
| 99.2 | Risk Factors |

**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 30, 2016

**XENCOR, INC.**

By: /s/ Lloyd A. Rowland
Lloyd A. Rowland
Senior Vice President and General Counsel

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Slide presenting data from XmAb5871-03 from Xencor, Inc. Presentation, as updated on November 29, 2016 |
| 99.2 | Risk Factors |