Xencor Inc
Form 10-K
February 20, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10 K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2014

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 001 36182

Xencor, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	20 1622502
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
111 West Lemon Avenue, Monrovia, CA	91016
(Address of Principal Executive Offices)	(Zip Code)

(626) 305 5900

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.01 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10 K or any amendment to this Form 10 K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non accelerated filer or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b 2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b 2 of the Securities Exchange Act of 1934). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2014 was $151,512,499

The number of outstanding shares of the registrant's common stock, par value $0.01 per share, as of February 6, 2015 was 31,472,763.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2015 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10 K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2014.

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Xencor, Inc.

FORM 10 K

For the Fiscal Year Ended December 31, 2014

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PART I

Forward Looking Statements

This Annual Report on Form 10 K or this Annual Report, may contain "forward looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We have based these forward looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward looking statements. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth below under Part I, Item 1A, "Risk Factors" in this Annual Report. These statements, which represent our current expectations or beliefs concerning various future events, may contain words such as "may," "will," "expect," "anticipate," "intend," "plan," "believe," "estimate" or other words indicating future results. Such statements may include, but are not limited to, statements concerning the following:

- the initiation, cost, timing, progress and results of our research and development activities, preclinical studies and future clinical trials;
- our ability to obtain and maintain regulatory approval of our future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our plans to research, develop and commercialize our future product candidates;
- our strategic alliance partners' election to pursue development and commercialization;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our future product candidates;
- the size and growth potential of the markets for our future product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our future product candidates;
- the rate and degree of market acceptance of our future product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our use of the proceeds from our recently completed initial public offering and private placement; and
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and need for additional financing.

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Given these uncertainties, you should not place undue reliance on these forward looking statements. These forward looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10 K and, except as required by law, we undertake no obligation to update or revise publicly any forward looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10 K. We qualify all of our forward looking statements by these cautionary statements.

Item 1. Business.

Our Business

We are a clinical stage biopharmaceutical company focused on discovering and developing engineered monoclonal antibodies to treat severe and life threatening diseases with unmet medical needs. We use our proprietary XmAb technology platform to create next generation antibody product candidates designed to treat autoimmune and allergic diseases, cancer and other conditions. In contrast to conventional approaches to antibody design, which focus on the portion of antibodies that interact with target antigens, we focus on the portion of the antibody that interacts with multiple segments of the immune system. This portion, referred to as the Fc domain, is constant and interchangeable among antibodies. Our engineered Fc domains, the XmAb technology, can be readily substituted for natural Fc domains. We believe our Fc domains enhance antibody performance by, for example, increasing immune inhibitory activity, improving cytotoxicity, extending circulating half life or stabilizing novel antibody structures, while maintaining 99.5% identity in structure and sequence to natural antibodies. By improving over natural antibody function, we believe that our XmAb engineered antibodies offer innovative approaches to treating disease and potential clinical advantages over other treatments.

Our business strategy is based on the plug and play nature of the XmAb technology platform to modify features of natural antibodies and create numerous differentiated antibody product candidates. We have internally generated a pipeline that has allowed us to selectively partner certain development programs while maintaining full ownership of other programs. We also have a number of technology licenses under which we have licensed the XmAb technology platform to pharmaceutical and biotechnology companies for use in a limited number of programs, providing multiple revenue streams that require no further resources from Xencor. There are currently eight antibody product candidates in clinical trials that have been engineered with XmAb technology, including six candidates being advanced by licensees and development partners.

Our internally generated pipeline includes the following three lead XmAb engineered antibodies that are currently in development:

· XmAb5871, our most recently advanced wholly-owned program recently completed a Phase 1b/2a clinical trial in rheumatoid arthritis (RA) and we are planning to initiate an open-label pilot clinical trial in IgG4-related disease (IgG4-RD) to assess disease control activity measured by the IgG4-RD Responder Index (Carruthers, et al., 2012, Int J Rheum) in 2015. XmAb5871 uses our XmAb Immune Inhibitor Fc Domain and targets B cells, an important component of the immune system. In January 2015, we announced that in the Phase 2a part of the trial 15 XmAb5871-ttreated patients and eight placebo-treated patients were evaluable for RA disease activity at the protocol specified disease activity assessment time point of two weeks following the sixth biweekly infusion. 33% of patients (5 of 15) that received all six biweekly doses of XmAb5871 achieved DAS28-CRP remission or low disease activity compared to zero patients that were treated with the placebo achieving DAS28-CRP remission or low disease activity. Three ACR70 responses (20%) and six ACR50 responses (40%) occurred in the XmAb5871 group compared to zero and one (13%) respectively in the placebo group. ACR70 and ACR50 responses refer, respectively to 70% and 50% reductions in the American College of Rheumatology rheumatoid arthritis symptom scale, a common measure of RA disease activity. Across the entire Phase 1b/2a clinical trial, biweekly administration of XmAb5871 for 12 weeks was generally well tolerated. The most common XmAb5871 treatment

related adverse related events (AEs) observed were predominantly mild to moderate gastrointestinal toxicities (nausea, vomiting, diarrhea) occurring during the first infusion of XmAb5871. These gastrointestinal AEs did not typically recur on subsequent infusions and no infusions were discontinued due to these AEs. Other treatment related AEs experienced in more than two XmAb5871 treated patients were pyrexia (fever) and headache. Treatment related serious adverse events (SAEs) occurred in two patients that received

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XmAb5871: infusion related reaction and venous thrombosis (blood clot). Two patients in the placebo treated group also reported SAEs.

We believe XmAb5871 has the potential to address a key unmet need in autoimmune therapies due to its combination of potent B-cell inhibition without B-cell depletion and will be exploring other indications in 2015. In October 2014, we announced that we sought and regained all rights to XmAb5871from our partner, Amgen Inc. (Amgen), who had an option to acquire an exclusive worldwide license. In return, we granted Amgen a first right to negotiate a proposed license for XmAb5871 prior to seeking future partners. This right expires upon the earlier of the initiation of Phase 3 clinical testing of XmAb5871, a change of control of Xencor, or October 2019.

- XmAb7195 is our wholly-owned program being developed for the treatment of severe asthma and allergic diseases. It uses our XmAb Immune Inhibitor Fc Domain and is designed to reduce blood serum levels of IgE, which mediates allergic responses and allergic disease. Its three specific mechanisms of action give it potential advantages over current therapies: (i) increased IgE binding, (ii) inhibition of IgE production and (iii) rapid clearance of IgE from circulation. In 2014 we filed an IND for XmAb7195 for allergic asthma with the FDA and in May initiated a Phase 1a single ascending dose clinical trial in healthy volunteers and in allergen-sensitive subjects with high IgE levels. In January 2015, we reported that interim data from the trial show rapid reduction of circulating free IgE levels to below the limit of detection at the end of the XmAb7195 infusion in 90% of XmAb7195 treated subjects that had detectable free IgE pre-dose, including those at the lowest dose evaluated of 0.3 mg/kg. Total IgE levels were also reduced in a parallel fashion. Two subjects with high pre-dose IgE levels (above 400 IU/mL) were treated with XmAb7195, one each at 0.75 mg/kg and 3.0 mg/kg doses, and both had reduction of free IgE levels to below the limit of detection lasting for at least one week. A dose limiting toxicity of transient, asymptomatic thrombocytopenia (low blood platelet count) was observed at the 3.0 mg/kg dose. The decrease in platelet count was transient with a minimum by 24 hours post-dose, recovery starting by 48 hours post-dose and near full platelet count recovery by study Day 8 in all cases, at which time serum drug concentrations still exceeded levels that eliminate detectable IgE. No evidence of thrombocytopenia has been observed in any of the clinical trials of XmAb5871, an anti-CD19 antibody with the identical XmAb Immune Inhibitor Fc domain as that of XmAb7195. Moderate urticaria (hives) was reported in a total of seven XmAb7195 treated subjects with an apparent correlation of dose with frequency of occurrence. In all cases regardless of dose, the signs/symptoms of urticaria were mild, non-diffuse and easily treated with oral antihistamine, and the study drug infusions were continued to completion without worsening of symptoms. Otherwise, there were no other adverse events that occurred in more than two XmAb7195 treated subjects. There were no serious adverse events reported and no subject discontinued Part 1 of trial early.
- XmAb5574/MOR208 is being developed by our partner MorphoSys AG (MorphoSys) for the treatment of blood based cancers and uses our XmAb Cytotoxic Fc Domain. In a Phase 1 clinical trial of XmAb5574/MOR208 completed by Xencor in patients with high-risk, heavily-pretreated chronic lymphocytic leukemia (CLL), in which the antibody showed encouraging signs of preliminary anti-tumor activity and an acceptable safety profile and was well tolerated. The trial protocol was amended to include a period of extended dosing for a total of eight patients at the 12 mg/kg dose to study the effect of longer duration of exposure on safety and response rate. Overall response rate by IWCLL 2008 criteria was 29.6% (eight partial responses in 27 evaluable patients). Using NCI-WG CLL 1996, response criteria resulted in a response rate of 66.7% (18 partial responses). At the highest dose studied, 12 mg/kg, 12 of 16 patients (75%) had a partial response by NCI-WG CLL 1996 and six patients (37.5%) had a partial response using additional CT criteria (IWCLL 2008). Median progression free survival for all patients was 199 days and for the extended treatment arm (at 12 mg/kg) was 420 days. Blood disease cleared in most patients, with median reduction in absolute lymphocyte count from baseline of 90.8%.

XmAb5574/MOR208 was generally well tolerated with no maximum-tolerated dose identified. Clinically-significant, treatment-related adverse events (AEs) classified as Grade 3 or higher occurred in 5 out of twenty-seven patients. The most frequent treatment-related AEs were infusion-related reactions, which were reported for 66.7% of patients, all of which were grade 1 or 2, and no reactions were seen following the first infusion. Treatment-related AEs each reported for 18.5% of patients were ALT increased, AST

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increased, neutropenia and thrombocytopenia; all other treatment-related AEs were reported for ≤ 15% of patients. These events resolved, generally without requiring treatment, and did not lead to discontinuation.

MorphoSys is currently conducting two Phase 2 clinical trials of MOR208 in patients with B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphomas (NHL).

In 2014 our development efforts for XmAb bispecific antibodies expanded. Bispecific antibodies are designed with two different variable domains to elicit biological effects that require simultaneous binding to two targets. Previously, industry efforts at bispecific antibody design have generally been frustrated by poor molecular stability, difficulties in production and short in vivo half-life. Xencor's XmAb® bispecific Fc domain technology is designed to maintain full-length antibody properties in a bispecific antibody, potentially enabling stable molecules with favorable in vivo half-life and allowing for the use of standard antibody production methods. These bispecific Fc domains are used to generate a broad array of novel drug candidates. In November 2014, we announced preclinical data from three programs using our XmAb bispecific Fc technology showing that bispecific antibodies targeting CD123, CD20 and CD38 antigens each activated T-cells to rapidly kill target cells from a single dose IV bolus in cynomolgus monkeys and demonstrated prolonged half-life of approximately one week in mice. We also announced that we had selected our lead anti-CD123xCD3 bispecific antibody, XmAb14045, for IND-enabling studies and cGMP process development and manufacturing.

In addition, we have licensed our XmAb technology to pharmaceutical and biotechnology companies for use in a limited number of their programs. These licensees include Boehringer Ingelheim International GmbH (Boehringer Ingelheim), CSL Limited (CSL), Janssen R&D, LLC (Janssen), Merck, Sharp and Dohme, a subsidiary of Merck & Co., Inc. (Merck), Alexion Pharmaceuticals, Inc. (Alexion), and collectively these licensees have five Phase 1 clinical development-stage programs and two pre-clinical development-stage programs. In December 2014, we announced a discovery-collaboration with Novo Nordisk A/S (Novo Nordisk) to jointly discover novel biologic drug candidates for an undisclosed target by combining multiple Xencor XmAb technologies, including our bispecific and immune inhibitor technologies.

A summary of all our licensed programs is shown below:

Licensee	Year	Xencor Technology	Indication	Milestones	Royalties	Current Development Stage
Boehringer Ingelheim	2007	Cytotoxic	Oncology	Yes	Yes	Phase 1 trials (two candidates)
Janssen						