



#### Rating Price (09 Jul 14, US\$) Target price (US\$) 52-week price range Market cap. (US\$ m) Enterprise value (US\$ m)

OUTPERFORM\* [V] 10.33 14.00¹ 13.90 - 7.55 323.96 277.16

\*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

<sup>1</sup>Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

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# Xencor, Inc (XNCR)

**SMALL & MID CAP RESEARCH** 

## Update on the "Class of 2013": Part 2

Given the large number of new public companies over the past 24 months, we are revisiting the names in our coverage that came public last year and assessing their accomplishments and upcoming catalysts.

XNCR came public in December 2013 with plans to advance its proprietary antibody technology platform and its lead proprietary drug XmAb7195 for asthma and allergic diseases.

- Programs on track with original timelines: Since its IPO, XNCR has initiated Phase I testing of its asthma drug XmAb7195 (anti-IgE) on time, presented preclinical data on its bispecific program, and completed enrollment in its Phase IIa trial of XmAb5871 in RA with initial data expected by year-end 2014. Partner Merck paid a milestone for starting Phase I with an antibody using XNCR's technology. Partner Morphosys continues its broad development program for MOR208 (anti-CD19) including a new combination trial of MOR208 and Revlimid in CLL, an indication that Morphosys also recently gained Orphan Drug Status.
- Upcoming catalysts: We are expecting several early stage proof of concept readouts over the next nine months including (1) XmAb7195 Phase I data including IgE reduction in healthy volunteers and high IgE volunteers in H1:15, (2) early proof of concept data for XmAb5871 in RA by year-end 2014, and (3) updated Phase II data for MOR208 in ALL and NHL potentially at ASH in December 2014.

### Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-3.85	-0.72	-0.65	-0.62
Prev. EPS (US\$)	_	_	_	_
P/E (x)	-2.7	-14.4	-15.9	-16.8
P/E rel. (%)	-14.9	-87.0	-106.7	-125.1
Revenue (ÚS\$ m)	10.2	5.5	7.0	11.0
EBITDA (ÚS\$ m)	-9.8	-22.5	-22.7	-26.3
OCFPS (US\$)	-0.24	-0.69	-0.43	-0.74
P/OCF (x)	-37.6	-15.0	-23.8	-14.1
EV/EBITDA (current)	-26.0	-11.3	-11.2	-9.7
Net debt (US\$ m)	-69	-47	-124	-100
ROIC (%)	-234.14	-439.19	-434.59	-501.84
Number of shares (m)	31.36	IC (current, US\$	m)	4.49
BV/share (Next Qtr., US\$)	2.2	EV/IC (x)	,	49.5
Net debt (Next Qtr., US\$ m)	-64.8	Dividend (current	t, US\$)	_
Net debt/tot cap (Next Qtr., %)	-92.5	Dividend yield (%	(a)	_

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### Three important catalysts for internal programs

- First proof of concept for immune down regulation: The XmAb5871 Phase IIa trial in RA is fully enrolled and expected to read out in Q4:14. While the trial is relatively small, it should give some initial indication of how well B-cell down regulation compares to other biologic approaches, including B-cell depletion. A positive result could also have a halo effect on the XmAb7195 program, which also relies in part on immune down regulation.
- Initial IgE reduction data: The primary value driver for XNCR is its proprietary anti-IgE antibody XmAb7195. This drug works by three mechanisms (1) binding free IgE, (2) reducing total IgE by increasing clearance, and (3) down regulating the production of IgE. The ongoing two-part Phase I trial should provide initial proof of concept in H1:15 in subjects with elevated baseline IgE.
- Bispecific program could drive increased investor and partnering interest: XNCR has two preclinical bispecific programs in multiple myeloma (CD38xCD3) and acute myeloid leukemia (CD123xCD3). On its upcoming earnings call (Aug. 2014), XNCR hopes to identify which of the two are its lead bispecific candidate and plans to present preclinical data from both at ASH in December. While an IND is not expected until H2:15, the areas of bispecifics and immune-oncology a particularly "hot" at the moment, and greater appreciation of XNCR's technology in this space could drive near-term value.

## Positive thesis on broad antibody platform

We continue to believe that XNCR's engineered antibody platform is one of the most diverse in the industry, enabling higher potency antibodies (MOR208 and multiple partnered programs), immune down regulating antibodies (XmAb5871 and XmAb7195), enhanced target clearance (XmAb7195), and longer half-life (Merck program). In total, there are now seven drugs in the clinic using XNCR's antibody technology.

- The emerging bispecific platform provides extra upside beyond the disclosed programs, and could be a major source of future partnerships.
- The most exciting clinical-stage program in our view, is the proprietary anti-IgE antibody (XmAb7195), which could be a much better version of Xolair.
- Our \$14 target price is based on a probability-adjusted DCF, assigning a 40% probability of success to XmAb7195 and a 25% probability to XmAb5871. We use a 12% discount rate through the products' lifecycles. The bispecific program is all upside.

# XmAb5871 – Proof of concept data by year end

XmAb5871 is a CD19 targeted immune modulating antibody that is designed to down regulate activated B-cells (rather than killing them). The initial proof of concept trial is in patients with active RA who are on a stable dose of non-biologic DMARDs (e.g. methotrexate).

XNCR completed enrollment in this 30-patient Phase IIa trial in H1:14 and expects to have data released in Q4:14.

The trial includes 12 weeks of treatment (6 doses every other week), with standard RA endpoints at 12 and 24 weeks.



A positive result would lead to a larger Phase IIb trial and an additional \$12M in funding from AMGN. The Phase IIb trial would be the basis for AMGN to make a decision on its development option for this program.

### XmAb7195 - Initiated Phase I trial

### Preclinical data presented

In May 2014, XNCR presented preclinical data at the American Thoracic Society meeting (ATS) comparing XmAb7195 to Roche's Xolair. Results demonstrated more rapid and sustained reductions in both free and total IgE versus Xolair and highlighted the three complementary mechanisms of action of XmAb7195 (rapid clearance of IgE, sequestration of soluble IgE, and reduction in IgE production).

### Clinical program initiated - proof of concept likely in H1:15

In May 2014, XNCR announced the start of a Phase I trial of XmAb7195 in both healthy volunteers and healthy subjects with a history of allergic rhinitis, conjunctivitis, and/or atopic dermatitis.

The two part Phase I trial has the following features: It is a 64-patient, randomized, placebo-controlled, single ascending dose study.

- Part A is in healthy volunteers, and
- Part B is in patients with a history of allergic diseases.

Patients will receive a single IV infusion of XmAb7195 at escalating doses. Given IgE is present in both healthy volunteers and at elevated levels in volunteers with a history of allergic diseases, it may be possible to assess the mechanism of XmAb7195 in a Phase I setting. The trial has an estimated completion date of June 2015, but data from Part A will likely be released prior to completion of the full study.

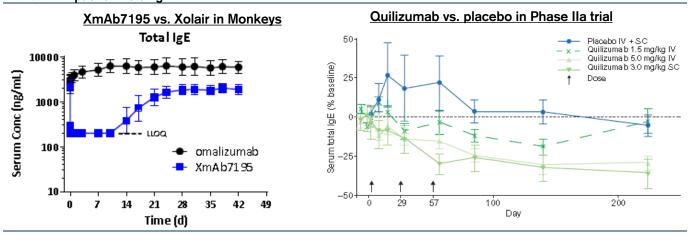
### Competitor data offers insight into potential benefit of targeting IgE production

Genentech recently published results of quilizumab (anti-M1 prime). This novel anti-IgE antibody binds to cell surface bound IgE and shuts down the production of IgE. The data from a Phase IIa trial shows a sustained reduction in total and serum IgE (as would be expected from reducing the production of IgE). Results also showed a clinical benefit and reduction in new IgE in allergic asthma patients who were subjected to an allergen challenge.

The reduction in total IgE is much more rapid and complete with XmAb7195 in experimental animal models because XmAb7195 blocks free IgE, clears bound IgE, and shuts down the production of new IgE. By contrast, the clinical data for quilizumab shows a sustained but less robust reduction in IgE and the full effect takes up to 2 months to achieve (Exhibit 1).



Exhibit 1: Impact on Total IgE



Source: Gauvreau et al. Sci Tranl Med 6, 2014 and Moore et al. ATS poster, 2014.

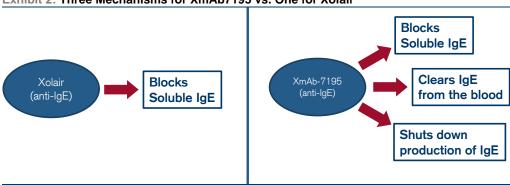
### A Better Xolair—XmAb7195 Blocks IgE by Three Mechanisms

XmAb7195 is designed to have the same IgE binding region as Xolair, but its Fc domain has been modified for enhanced activity. While Xolair simply binds soluble IgE, XmAb7195 also shuts down the production of IgE and facilitates the clearance of IgE from the blood (See Exhibit 2). This triple mechanism of action is expected to have a greater impact on IgE levels and therefore asthma symptoms. It is also likely to overcome the dosing problems of Xolair.

The attributes of XmAb7195 have been demonstrated in monkeys who naturally produce high levels of IgE.

- Xolair Rapidly Reduces Free IgE (Exhibit 2 left panel): Xolair can effectively bind free IgE. The reduction in free IgE is associated with reduced asthma symptoms. XmAb7195 also binds free IgE and effects even greater reduction in free IgE compared to Xolair.
- Xolair Has No Impact on Total IgE (Exhibit 2 right panel): Total IgE includes both antibody-bound and free IgE. Because Xolair does not induce the clearance of IgE, the bound IgE circulates and the free IgE levels return at the rate of antibody clearance. XmAb7195 lowers total IgE because the bound IgE is cleared from the blood. Total IgE levels recover but at a slower rate because of the immune down-regulation.

Exhibit 2: Three Mechanisms for XmAb7195 vs. One for Xolair



Source: Company data, Credit Suisse Research.

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# **Emerging bispecific program**

XNCR is developing a bispecific format that uses a full length Fc, which differentiates it from many of the other bispecifics including AMGN's BiTEs and MGNX's DARTs. REGN is also working on full-length bispecifics.

XNCR has two preclinical candidates.

- XmAb13694 (CD38xCD3) targets CD38, a clinically validated antibody target in multiple myeloma. Several "naked" antibodies are advancing in development including daratumumab (Genmab/JNJ), SAR650984 (Sanofi/IMGN), and MOR03087 (Morphosys/CELG).
- CD123xCD3 targets CD123, a validated target in AML. CD123 is found on AML cells and on tumor stem cells. Toxin fusions targeting CD123 have shown some evidence of anti-tumor activity.

We expect the following key developments in the bispecific program:

- (1) XNCR will announce its lead candidate, most likely on its Q2 earnings call in early August. Our best guess is that it will be the CD38 program, given the high level of interest in the target among investors and potential partners.
- (2) XNCR will present a large set of preclinical data for its bispecific program at ASH in December including data on its CD38 and CD123 programs.
- (3) XNCR plans to file an IND to start Phase I testing in late 2015.
- (4) XNCR will likely enter into a partnership for the technology or one of its preclinical candidates (potentially in 2015 no guidance on this topic).

Monospecific Bispecific scaffolds Bispecific antibodies antibodies w/o Fc domain w/Fc domain Anti-CD38 Anti-CD38 Anti-Anti-CD3 CD38 \ BiTEs, DARTs Tandabs, etc Daratumumab SAR650984 XmAb13694 MOR03087

Exhibit 3: XNCR's bispecific format for its anti-CD38

Source: Company data, Credit Suisse

# MOR208 - Three ongoing Phase II trials

There are currently three ongoing Phase II trials of MOR208 (Fc engineered anti-CD19 antibody) for a variety of B-cell malignancies. Of the three, the CLL trial was announced and initiated after XNCR's IPO. The next likely data is from the ALL trial, potentially at ASH in December.

- Acute lymphoblastic leukemia (ALL): This Phase II trial is expected to recruit up to 30 relapsed/refractory patients. The study is still recruiting patients.
- Non-Hodgkin lymphoma (NHL): This trial is expected to recruit up to 30 relapsed/refractory patients in each of several disease specific cohorts, including

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- follicular lymphoma (FL), mantle cell lymphoma (MCL), diffuse large B-cell lymphoma (DLBCL), and other indolent lymphomas (iNHL).
- Chronic lymphocytic leukemia (CLL): This investigator sponsored trial combines MOR208 with Revlimid in both relapsed/refractory and treatment naïve CLL. This trial is being conducted at Ohio State University. This trial was announced and initiated after XNCR's IPO.

## Other partnered programs

### Boehringer Ingelheim has two drugs in the clinic using XNCR's technology

- BI 836826 is an anti-CD37 antibody with enhanced ADCC activity. It is in two Phase I trials for CLL and relapsed/refractory NHL. The NHL trial is expected to complete in November 2014 and the CLL trial is expected to complete in March 2015. It is possible we could see some data at ASH in December 2014.
  - A competitor program from IMGN (IMGN529) also targets CD37. This drug has shown anti-tumor activity, though with substantial toxicity.
- BI 836858 is an anti-CD33 antibody with enhanced ADCC activity. It is in Phase I testing for relapsed/refractory AML. CD33 is a validated target in AML. Previously, Pfizer marketed Mylotarg, and antibody-drug conjugate targeting CD33.
  - SGEN has a competitive program in Phase I. SGN-CD33A is an antibody-drug conjugate targeting CD33. IMGN also has a drug conjugate targeting CD33 in preclinical development.

### CSL Limited licensed its anti-CD123 antibody to Janssen

- CSL362 is an anti-CD123 antibody with enhanced ADCC activity. It is in Phase I testing for relapsed/refractory AML. The ongoing Phase I trial has a projected completion date of October 2014, and it is possible that initial data could be presented at ASH in December.
  - CD123 is also known as the IL3 receptor. It is found on AML cells and on cancer stem cells. Several drugs are in development for CD123 (including a preclinical bispecific program at XNCR).



Exhibit 4: XNCR pipeline

Drug	Target	Technology	Indication	Stage	Partner
XmAb5574/MOR208	CD19	High ADCC	CLL, NHL, ALL	Phase II	Morphosys
XmAb5871	CD19	Immune inhibitory	Autoimmune	Phase I/II	AMGN has option
XmAb7195	lgE	Immune inhibitory	Asthma/Allergy	Phase I	Proprietary
BI 836826	CD37	High ADCC	CLL, NHL	Phase I	Boehringer Ingelheim
BI 836858	CD33	High ADCC	AML	Phase I	Boehringer Ingelheim
CSL362	CD123 (IL3R)	High ADCC	AML	Phase I	CSL/Janssen
ND	ND	Stability	Autoimmune	Phase I	Merck
Xtend-TNF	TNF	Long half-life	Autoimmune	Preclinical	Proprietary
CD3 X CD38	CD38	Bispecific	Oncology	Preclinical	Proprietary
CD3 X CD123	CD123	Bispecific	Oncology	Preclinical	Proprietary
Xtend-CTLA4	CTLA4	Long half-life	Autoimmune	Preclinical	Proprietary
Anti-X/ CD32b	ND	Immune inhibitory	TBD	Discovery Lead	Proprietary
ND	ND	Long half-life	Hematology	Preclinical	CSL
ND	ND	Long half-life	Autoimmune	Preclinical	Janssen
ND	ND	Long half-life	Undisclosed	Discovery Lead	Alexion

Source: Company data, Credit Suisse

**Exhibit 5: XNCR newsflow** 

Product/Event	Indication	Catalyst	Expected Date
Bispecific	N/A	Announce lead program	Mid-2014
XmAb5871	RA	Phase Ila results	Q4:14
MOR208	ALL, NHL, and CLL	Potential Phase II data at ASH	Dec. 2014
Bispecific	N/A	Presentation of preclinical data at ASH	Dec. 2014
XmAb5871	RA	Start Phase Ilb (150-250 pts)	Q1:15
XmAb7195	Asthma	Phase la data in patients with asthma and allergic disease (includes high IgE cohort)	H1:15
Bispecific	N/A	IND for proprietary program	H2:15
XmAb7195	Asthma	Phase lb start	Q1:15
XmAb7195	Asthma	Start Phase II in poorly controlled	late 15/ early 16
MOR208	ALL, NHL, and CLL	IST to complete enrollment of CLL study	H2:15
XmAb5871	RA	Phase IIb data/ AMGN option	late 16/ early 17

Source: Company data, Credit Suisse estimates



**Exhibit 6: XNCR Model** 

	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E
Revenues											
US sales of XmAb7195											
Ex-US royalies on XmAb7195											
Royalties on XmAb5871											
Partnering, grants, milestones	9.5	10.2	2.2	0.8	0.8	1.6	5.5	7.0	11.0	26.1	15.0
Total Revenues	9.5	10.2	2.2	0.8	0.8	1.6	5.5	7.0	11.0	26.1	15.0
Expenses											
Cost of goods											
Research and development	12.7	17.0	4.2	5.0	5.6	6.3	21.2	21.7	28.5	31.4	39.3
Sales, general, administrative	3.1	3.7	1.7	1.8	1.8	1.9	7.1	7.9	8.7	9.9	14.3
Total Operating Expenses	15.8	20.7	6.0	6.8	7.4	8.2	28.3	29.6	37.2	41.3	53.6
Operating income (loss)	(6.2)	(10.5)	(3.8)	(5.9)	(6.6)	(6.6)	(22.8)	(22.7)	(26.3)	(15.2)	(38.6)
Total Other Income (Expense)	(2.4)	(49.7)	0.0				0.0				
Pre Tax Income	(8.6)	(60.3)	(3.8)	(5.9)	(6.6)	(6.6)	(22.8)	(22.7)	(26.3)	(15.2)	(38.6)
Income tax											
Net Income	(8.6)	(60.3)	(3.8)	(5.9)	(6.6)	(6.6)	(22.8)	(22.7)	(26.3)	(15.2)	(38.6)
EPS - diluted (proforma)	(\$38.31)	(\$3.85)	(\$0.12)	(\$0.19)	(\$0.21)	(\$0.20)	(\$0.72)	(\$0.65)	(\$0.62)	(\$0.33)	(\$0.77)
Shares outstanding - basic (proforma)	0.22	15.65	31.36	31.67	31.99	32.31	31.83	34.88	42.70	46.21	49.98
Shares outstanding - diluted (proforma)	0.22	15.65	31.36	32.91	33.25	33.60	33.08	36.23	44.16	47.80	51.69

Source: Company data, Credit Suisse estimates



### Companies Mentioned (Price as of 09-Jul-2014)

Alexion Pharmaceuticals Inc. (ALXN.OQ, \$164.52)

Amgen Inc. (AMGN.OQ, \$119.57) Celgene Corp. (CELG.OQ, \$87.52) GENMAB (GEN.CO, Dkr214.3) ImmunoGen, Inc. (IMGN.OQ, \$11.23) Johnson & Johnson (JNJ.N, \$106.04) Merck & Co., Inc. (MRK.N, \$58.55)

Regeneron Pharmaceutical (REGN.OQ, \$310.93)

Sanofi (SASY.PA, €76.38)

Xencor, Inc (XNCR.OQ, \$10.33, OUTPERFORM[V], TP \$14.0)

### **Disclosure Appendix**

#### Important Global Disclosures

Jason Kantor, PhD, Ravi Mehrotra PhD and Lee Kalowski each certify, with respect to the companies or securities that the individual analyzes, that (1) the views expressed in this report accurately reflect his or her personal views about all of the subject companies and securities and (2) no part of his or her compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

### 3-Year Price and Rating History for Xencor, Inc (XNCR.OQ)

XNCR.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
03-Dec-13	8.34		R
03-Jan-14	9.15	14.00	0 *

<sup>\*</sup> Asterisk signifies initiation or assumption of coverage.



The analyst(s) responsible for preparing this research report received Compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities

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Neutral/Hold*	39%	(49% banking clients)
Underperform/Sell*	13%	(48% banking clients)
Restricted	3%	

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Price Target: (12 months) for Xencor, Inc (XNCR.OQ)

Method: Our \$14 target for XNCR is derived using a probability-adjusted DCF (discounted cash flow), including \$9 for XmAb7195 (40% POS), \$3 for XmAb5871 (25% POS), and \$1 each for MOR208 and the technology licensees. We us a 12% discount rate and model through the products' entire lifecycle.

Risk:

Risks to our \$14 target price for Xencor, Inc include: 1) unexpected negative result for proprietary or partnered clinical programs, 2) financing risk from expected future equity raises, 3) competition in the CD19 and asthma programs, and 4) significant delay in one or more clinical programs that pushes potential approval timeline(s) out.

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See the Companies Mentioned section for full company names

The subject company (XNCR.OQ, IMGN.OQ, CELG.OQ, REGN.OQ, MRK.N, AMGN.OQ, JNJ.N) currently is, or was during the 12-month period preceding the date of distribution of this report, a client of Credit Suisse.

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