

October 31, 2014

HEALTHCARE/BIOTECHNOLOGY

Stock Rating:
OUTPERFORM

12-18 mo. Price Target	\$22.00
XNCR - NASDAQ	\$10.50

3-5 Yr. EPS Gr. Rate	NA
52-Wk Range	\$14.41-\$5.75
Shares Outstanding	31.4M
Float	24.2M
Market Capitalization	\$329.7M
Avg. Daily Trading Volume	46,195
Dividend/Div Yield	\$0.00/0.00%
Book Value	\$2.89
Fiscal Year Ends	Dec
2014 ROE	NA
LT Debt	\$0.0M
Preferred	NA
Common Equity	\$70M
Convertible Available	No

Xencor, Inc.

Renegotiated '5871 Rights a Positive; Development to Continue in IgG4 Disease

SUMMARY

Xencor recently announced renegotiation of its agreement with Amgen for XmAb5871, a CD19/FcγRIIb antibody for autoimmune disease. We anticipate data from the ongoing (still blinded) P1b/2a trial of XmAb5871 in patients with RA around year-end 2014. We believe regaining rights to '5871 will increase focus on this until now ignored but promising candidate. Although XNCR intends to bring '5871 forward in rare disease, its mechanism of action may lead to broader application, potentially not dissimilar from BTK-inhibition for autoinflammatory disease. XNCR will not incur additional cost as a result of renegotiating these rights and has not changed cash burn guidance, expecting to end the year with \$54M. **Xencor is our top pick in the group.**

KEY POINTS

- **We believe that XmAb5871, by inhibiting B-cell activation instead of depleting B-cells, may be similarly efficacious to current B-cell targeted therapies but better tolerated, with a potentially lower risk of serious infections.** XmAb5871: a CD19-targeted immune inhibitory antibody, to co-engage FcγRIIb, inhibiting BCR signaling. Details pp. 5-8 of this report.
- **Xencor plans to further develop XmAb5871 in rare IgG4-related diseases, starting with initial POC studies in 2015.** XmAb5871 is currently administered by IV; future studies may transition to SC dosing. We review clinical/pre-clinical results for the candidate on pp. 6-8.
- **IgG4-RD is a rare, multifocal, fibroinflammatory disorder associated with high serum IgG4 and dense lymphoplasmacytic infiltrates rich in IgG4+ plasma cells.** The disorder impacts estimated 10-20K patients in the US. No therapies are currently approved, leaving XNCR an opportunity to define a clinical path forward for this high unmet need. IgG4-related disease/SOC details pp. 3-4.
- **Fourth quarter to be catalyst-filled:** We anticipate key value inflection points in 4Q, with first in human results for XmAb7195 (an anti-IgE therapy, Xolair biobetter), P2 results for XmAb5574/MOR208 in ALL and NHL at ASH (Dec. 6-9), and top-line results from the P2a of XmAb5871 in RA.
- **We continue to estimate** XmAb5871 is worth \$3/share of our \$22 price target.

Stock Price Performance



Company Description

Xencor is a clinical-stage biopharmaceutical company focused on discovering and developing engineered monoclonal antibodies to treat severe and life-threatening diseases with unmet medical need.

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Upcoming Milestones

4Q14	Announcement of selection and Initiation of IND-enabling studies for a bispecific candidate (either CD38xCD3, CD123xCD3 or CD20xCD3)
4Q14	Top-line data from the Phase II trial of XmAb5574/MOR208 (CD19, enhanced ADCC Fc) in ALL
4Q14	Top-line data from the Phase IIa trial of XmAb5871 (CD19, immune inhibitor Fc) in rheumatoid arthritis
Dec 6-9, 2014	Potential full data from a Phase II trial of MOR208 (CD19, enhanced ADCC Fc) in ALL at ASH
Dec 6-9, 2014	Potential interim data from a Phase II trial of MOR208 (CD19, enhanced ADCC Fc) in NHL at ASH
YE:14	Top-line data from a Phase Ia trial of XmAb7195 (anti-IgE) in up to 30 healthy subjects with IgE reduction data
1Q15	Initiation of a Phase Ib trial of XmAb7195 (anti-IgE) in mild to moderate asthma with IgE reduction and clinical benefit data
2H15	Complete recruitment in Phase II trial of MOR208 (CD19, enhanced ADCC Fc) in CLL
2015	Complete recruitment in Phase II trial of MOR208 (CD19, enhanced ADCC Fc) in NHL
2015	Initiation of a Phase IIb proof-of-concept trial of XmAb5871 (CD19, immune inhibitor Fc) in rheumatoid arthritis
2015	IND filing and first-in-human clinical trials for Xencor's first clinical bispecific candidates (either CD38xCD3 or CD123xCD3)
1Q16	Potential top-line data from the Phase Ib trial of XmAb7195 (anti-IgE) in mild to moderate asthma
2016	Initiation of a Phase IIb proof-of-concept trial of XmAb7195 (anti-IgE) in poorly controlled asthma
2017	Potential top-line data from the Phase IIb POC trial of XmAb7195 (anti-IgE) in patients with poorly controlled asthma
2017	Potential top-line data from the Phase IIb trial of XmAb5871 (CD19, immune inhibitor Fc) in patients with rheumatoid arthritis
2017	Potential exercise of Amgen's option to license XmAb5871 (CD19, immune inhibitor Fc)

Source: company data; Oppenheimer & Co. Inc. estimates

XmAb5871 for Autoimmune Disease

XmAb5871 is a CD19 targeted immune inhibitory antibody that uniquely employs Xencor's technology to co-engage FcγRIIb to inhibit B-cell activation. Importantly, unlike XmAb5574/MOR208 and CD20 antibodies (such as rituximab), it does not kill B-cells, but instead cross-links the FcγRIIb receptor to the B-cell receptor (BCR), where FcγRIIb inhibits BCR signaling and B-cell activation.

XmAb5871 is in a Phase IIa trial in patients with rheumatoid arthritis under a prior agreement with Amgen. Xencor successfully renegotiated all rights to '5871.

Data from the ongoing Phase Ib/IIa trial in patients with RA is expected around year-end 2014.

In 2015 XNCR will bring XmAb5871 into the IgG4-RD setting.

IgG4-RD, a Newly Identified Autoimmune Disease

Immunoglobulin G4-related disease (IgG4-RD) is an immune-mediated condition resulting in several disorders that share specific pathologic, serologic and clinical features. The disease of unknown etiology often occurs in middle-aged to older men. Current treatment includes glucocorticoids (prednisone); though spontaneous improvements can occur, recurrence typically occurs without treatment and relapses follow discontinuation of treatment. Clinical trials are evaluating the use of rituximab in IgG4-RD.

A hallmark of IgG4-RD is commonly isolated submandibular gland enlargement.

Exhibit 1: IgG4 Related Sialadenitis (inflammation of salivary gland)



Source: CurrOpinion Rheum 2011; 23:72

IgG4-RD Features and Manifestations

Common features of IgG4-RD include:

- Tumor-like swelling of involved organs
- Lymphoplasmacytic infiltrate enriched with IgG4+ plasma cells
- Fibrosis with a “storiform” pattern
- 60-70% of patients elevated serum concentrations of IgG4 are present
- Good initial response to glucocorticoids

Manifestations of IgG4-RD include:

- Type 1 autoimmune pancreatitis (AIP) and IgG4-related sclerosing cholangitis
- Mikulicz’s disease and sclerosing sialadenitis (Küttner’s tumor), inflammatory orbital pseudotumor, and chronic sclerosing dacryoadenitis
- Idiopathic retroperitoneal fibrosis and related disorders
- Chronic sclerosing aortitis and periaortitis
- Riedel’s thyroiditis and a subset of Hashimoto’s thyroiditis
- IgG4-related interstitial pneumonitis and pulmonary inflammatory pseudotumors
- IgG4-related renal disease, particularly tubulointerstitial nephritis (TIN)

Previously recognized conditions that may comprise parts of the IgG4-RD spectrum include:

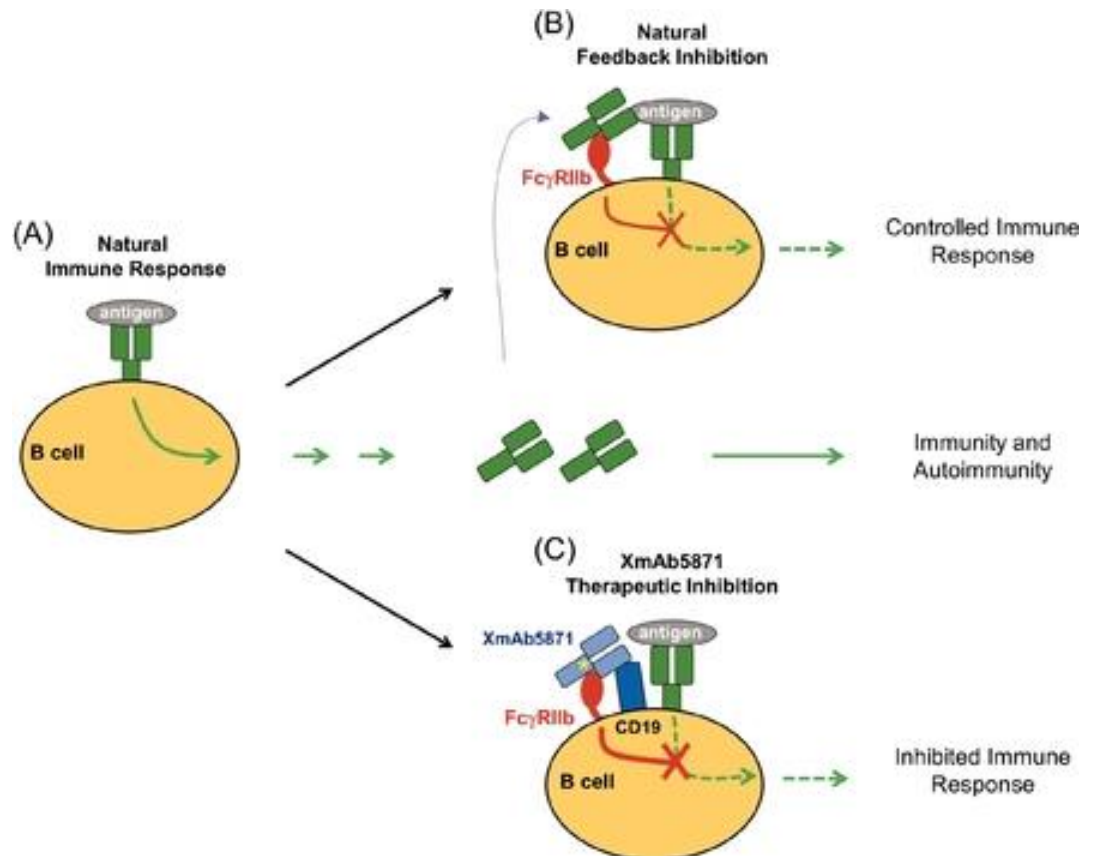
- Mikulicz’s disease
- Kuttner’s tumor
- Riedel’s thyroiditis
- Eosinophilic angiocentric fibrosis
- Multifocal fibrosclerosis
- Lymphoplasmacytic sclerosing pancreatitis/auto imm

XmAb5871 - FcγRIIb Inhibits BCR Signaling— Opportunities in Autoimmune Disorders and Oncology

FcγRIIb is an inhibitory receptor expressed on B-cells that normally binds the Fc domain of IgG antibodies with low affinity where it functions in a negative feedback loop to limit the normal antibody response. FcγRIIb only inhibits B-cell signaling when it is recruited to the BCR. Xencor's proprietary Fc modifications increase the affinity of their antibodies for this receptor.

Inhibiting B-cell activity represents a validated target in rheumatoid arthritis by Rituxan (rituximab), a B-cell depleting therapy. XmAb5871 inhibits B-cells, but does not kill them as Rituxan does. This may allow physicians to rapidly reverse B-cell inhibition in the event of an infection, improving the safety profile and broadening the potential patient population. Rituxan treatment, by contrast, depletes B-cells for months or years ([Leandro 2006](#)), inhibiting the immune response and causing an increased risk of severe infection and death in patients with auto-immune diseases ([Diaz-Lagares 2011](#)).

Exhibit 2: XmAb5871 Recruits FcγRIIb to the BCR and inhibits B-cell Activation



Source: Xencor, Inc

XmAb5871 Clinical Program: Phase Ib/Ia Trial Design

In January 2013, Xencor initiated a Phase Ib/Ia placebo-controlled, double-blind, multiple ascending dose Phase IIa trial to assess the safety, tolerability and PK/PD of XmAb5871 in patients with active rheumatoid arthritis on stable non-biologic DMARD therapy. In the first part of the study Xencor dosed 29 RA patients at 0.3, 1, 3, and 10 mg/kg biweekly for six weeks by IV administration. In October 2013, Xencor initiated the second part of the study that will enroll 30 patients with active disease randomized 2:1 XmAb5871 vs. placebo at the highest 10 mg/kg dose every 14 days for a total of six cycles. Inclusion criteria include patients with active RA at screening defined as ≥ 4 swollen joints and ≥ 4 tender/painful joints (out of 28 joints examined) and at least 1 of erythrocyte sedimentation rate (ESR) ≥ 28 mm/hr, hsCRP ≥ 10 mg/L, or morning stiffness ≥ 45 minutes. The primary outcome measures of the study include determination of safety, tolerability and immunogenicity of XmAb5871. Secondary endpoints will assess clinical outcomes measured as Disease Activity Score 28 using C-reactive protein (DAS28-CRP) after 13 weeks.

XmAb5871 has been found to be well-tolerated in trials reported to date. A serious adverse event, infusion-related reaction with hypotension, was noted in one patient, resulting in discontinuation. No other patients discontinued therapy, and other adverse events reported in more than one patient (that may be related to therapy) include nausea, vomiting, fever-increased temperature, headache and bronchitis. Preliminary immunogenicity testing data for the first two cohorts through the treatment phase of the study have been negative.

Data from the Phase Ib/Ia trial is expected in late 2014. A potential IV to subcutaneous formulation bridging study for XmAb5871 is also planned.

Exhibit 3: XmAb5871 Phase Ib/Ia Trials

	XmAb5871 Phase IIa	XmAb5871 Phase Ib
Indication	Patients with active rheumatoid arthritis on stable non-biologic disease modifying anti-rheumatic drug therapy (DMARD)	Patients with active rheumatoid arthritis on stable non-biologic disease modifying anti-rheumatic drug therapy (DMARD)
N	30	29
Design	Double-blind, placebo-controlled, randomized 2:1	Double-blind, placebo-controlled, randomized
Dose	10 mg/kg XmAb7195 in biweekly infusions for 6 cycles	0.3, 1, 3 and 10 mg/kg in biweekly infusions for 6 cycles
Primary endpoint / results	Primary endpoint is disease activity score 28 (DAS28) using C-reactive protein at 13 weeks	Safe and well tolerated, reduced B-cells in a dose-dependent manner
Eudra-CT #	2012-003057-29	2012-003057-29

Source: Oppenheimer & Co. Inc.

XmAb5871 Demonstrated Safety and Activity in First-in-Human Phase Ia Trials

In December 2012, Xencor reported results from its Phase 1a clinical trial of XmAb5871. The randomized, blinded, placebo-controlled study assessed a single ascending dose of XmAb5871 in 48 healthy male volunteers. Subjects were randomized 3:1 to receive IV infusions of XmAb5871 or placebo in one of seven dose cohorts (0.03-10.0 mg/kg). The study assessed the PK and immunogenicity of single-dose XmAb5871 and also measured several biomarkers of efficacy.

XmAb5871 was well tolerated, and no dose-limiting toxicities or serious adverse events were observed. The most common adverse events observed included (mild-moderate) GI symptoms including nausea (one severe), vomiting, abdominal pain, epigastric discomfort and diarrhea. Anti-drug antibodies, that did not impact drug activity, were observed in 44% patients, 22% of which were greater than two-fold above baseline.

Biomarkers of efficacy showed target saturation and B-cell suppression at low-bi-weekly doses (0.03 mg/kg). XmAb5871 reduced B cells by 50% from baseline at all doses, and B-cell counts recovered proportionally to drug serum clearance (Exhibit 3). Challenge-based tests of XmAb5871 were conducted by immunizing healthy subjects with tetanus and KHL to elicit antibody responses. XmAb5871 effectively suppressed immune responses in at all but the lowest dose level with placebo-treated patients exhibiting a 12-fold increase in anti-tetanus antibody levels vs. a 4-fold increase in XmAb5871 treated subjects.

Exhibit 4: XmAb5871 Transiently Reduced B-cells in a Phase I Trial

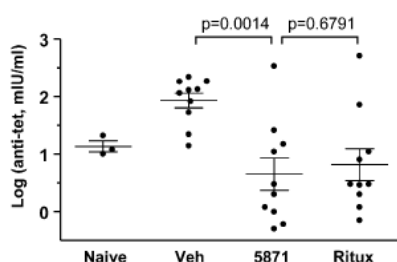
Cohort	Dose (mg/kg)	Days									
		1	2	4	8	15	22	29	43	71	
Placebo	0	100	112	101	92	99	84	87	94	108	> 70%
C1	0.03	100	59	52	73	107	77	92	99	97	30 - 70%
C2	0.1	100	48	44	39	83	77	73	84	76	< 30%
C3	0.2	100	59	59	44	62	68	86	89	92	
C4	0.6	100	56	48	44	53	76	85	92	137	
C5	2	100	60	59	41	49	54	72	105	99	
C6	5	100	79	68	47	53	49	57	71	92	
C7	10	100	71	62	49	50	52	44	69	87	

Source: Xencor, Inc

Preclinical Data Highlight Reversibility and Efficacy vs. Rituximab

Preclinical data demonstrate that XmAb5871 inhibits immune response to tetanus challenge in SCID mice engrafted with SLE PBMC (Exhibit 5). XmAb5871 was shown, both *in vitro* and *in vivo*, to suppress activity of B-cells donated from patients with lupus and rheumatoid arthritis. Importantly, we note that XmAb5871 is able to inhibit the immune response as effectively as rituximab without killing B cells. Additionally, Xencor demonstrated that XmAb5871 was well tolerated in 12- and 24-week multiple dose preclinical studies in monkeys. No adverse events were noted in doses up to 200 mg/kg.

Exhibit 5: XmAb5871 Inhibits Immune Response in SCID Mice Engrafted with SLE PBMC



Source: Horton et al. J Immunol. 2011 Apr 1;186(7):4223-33

XmAb5871 an Alternative to B-cell Depletion for Autoimmune Disease

We believe that XmAb5871, by inhibiting B-cell activation instead of depleting B-cells, may be similarly efficacious to current B-cell targeted therapies but better tolerated, with a potentially lower risk of serious infections. Current therapies for autoimmune disease leave much to be desired; if found to be safe and effective, XmAb5871 may find broad utility in autoimmune disease and B-cell associated disorders. Rituximab (Rituxan/MabThera), an increasingly adopted B-cell depletion therapy for autoimmune disease, improves symptoms but also depresses the immune system and increases infection risk. Additionally, TNF-alpha inhibitors (such as adalimumab, Humira) are also associated with infection risk and other serious side effects, and also frequently stop working in patients after as little as one year on therapy.

Significant unmet need and large markets for drugs that treat inflammatory disorders suggest to us that despite competition, there is likely a place for novel therapies like Xencor's '5871. However, recent small molecules that function on the BCR-signaling pathway may play a role in future treatments for inflammatory disease. We highlight that Imbruvica (ibrutinib) and next-generation BTK inhibitors may offer a similar approach to XmAb5871 by working to quiet B-cells to elicit disease response without B-cell depletion.

Investment Thesis

Xencor is a biopharmaceutical company focused on developing and commercializing engineered antibody therapies to treat severe diseases with unmet medical need. Xencor's engineered Fc domains enable high-yield production of IgG-like bispecific antibodies that may enable cost-effective immunotherapy for the treatment of cancer. This potentially best-in-class platform, which has two partnered products in Phase II studies, a wholly owned candidate in a Phase I trial, five further internal early-stage programs and a total of seven collaborations is, in our opinion, the core of Xencor's current value. Merck, Boehringer Ingelheim and CSL are validating of Xencor's approach. These partnerships also provide non-dilutive capital in upfront payments and up to \$1.31 billion in milestone payments as well as additional royalties (single to double-digit percentages).

Price Target Calculation

We arrive at our \$22 price target by a sum-of-the-parts analysis. We ascribe \$12/share by applying a typical oncology multiple of 6x to our estimated 2022 revenues of \$1.2 billion for XmAb7195 in moderate to severe asthma, discounted 45% annually. We ascribe \$3/share to each of Xencor's two partnered programs XmAb5871 and XmAb5574 based on a typical multiple of 15x royalties (estimated 10%) from US and EU sales in 2022 of \$900M and \$600M discounted 40% and 30% annually, respectively. We ascribe \$3/share to XmAbCD123 as a surrogate for the bispecific candidate Xencor expects to advance into the clinic in 2015.

Key Risks to Price Target

These risks include: 1) failure to reach sales expectations for Xmab7195, XmAb5574/MOR208, or XmAb5871; 2) failure in the clinic of Xmab7195, XmAb5574/MOR208, or XmAb5871; 3) changes to or discontinuation of Xencor's partnerships for XmAb5574/MOR208 or XmAb5871; 4) intellectual property risk; 5) manufacturing risk; 6) competitive risk from biotech companies with more resources; 6) strategic risk; 7) the risk of a dilutive financing; and 8) insider ownership risk as approximately 35% of the shares are closely held.

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Merck (MRK-NYSE, \$57.31, Not Covered)
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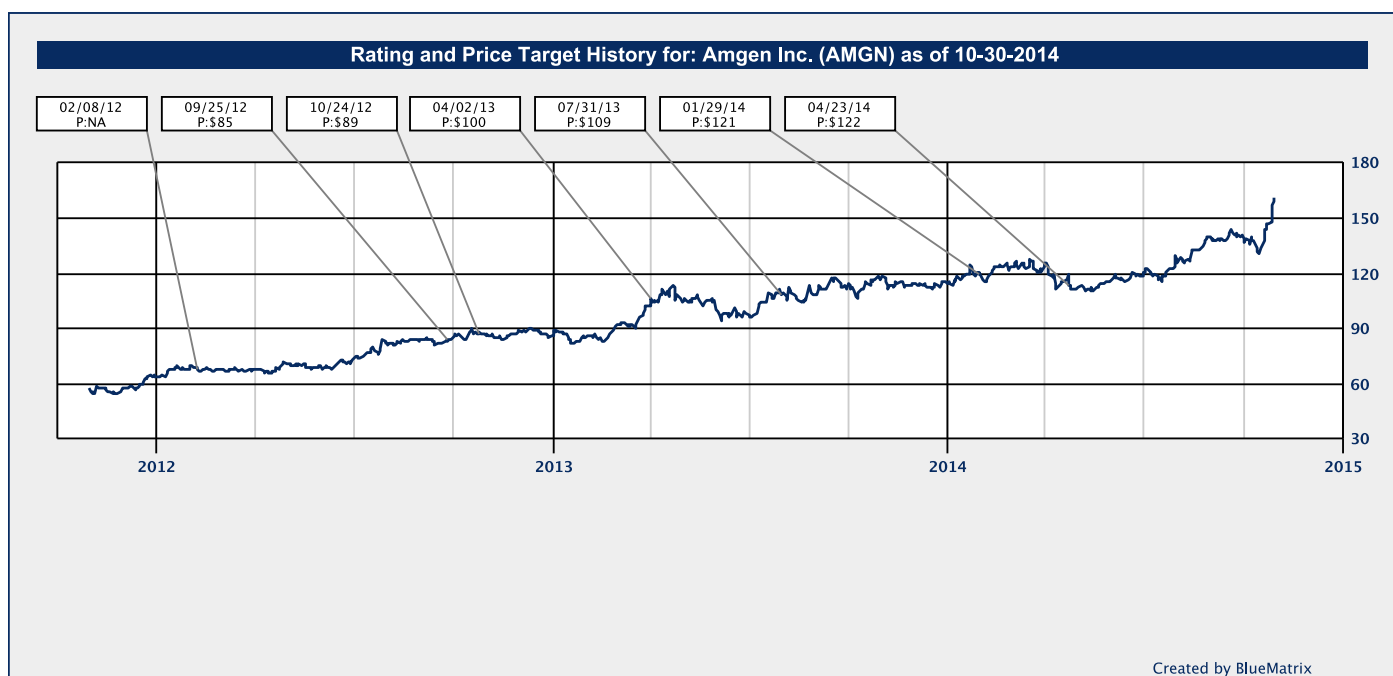
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Rating	Count	Percent	IB Serv/Past 12 Mos.	
			Count	Percent
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