

April 9, 2014

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Xencor (XNCR - OUTPERFORM): XNCR's Bispecifics Emerge: Preclinical Data with a CD38 Bispecific Demonstrate Anti-Tumor Activity in Multiple Myeloma - Reiterate OUTPERFORM

Price: \$10.25

12-Month Price Target: \$18

- **At the Annual Summit on Practical and Emerging Trends in Multiple Myeloma, last week, Xencor presented data for XmAb13694, a CD38xCD3 T-cell redirecting bispecific antibody showing anti-tumor activity against multiple myeloma cell's *in vitro* and *ex vivo* in patient-derived PBMC's (page 4-6).** XmAb13694 redirects T-cells through the CD3 receptor to CD38-expressing plasma cells. XmAb13694 depleted CD38+ cells in *ex vivo* multiple myeloma patient plasma at 1µg/ml and killed multiple myeloma cells *in vitro* with half-max redirected T-cell cytotoxicity (RTCC) of ~0.1 ng/ml. It has a half-life of 7.6 days in mice, significantly superior to BiTE's half-lives' on the order of hours. XmAb13694 induced serial lysis and was potent at low effector-to-target cell ratios. XmAb13694 inhibited anti-tetanus response and decreased IgG and IgM levels in mice, indicative of a plasma cell depletion effect.
- **CD38 represents a validated target for the treatment of multiple myeloma as several anti-CD38 antibodies are in late-stage clinical trials, including daratumumab in Phase III.** Notably, daratumumab demonstrated [statistically significant](#) increases in PFS in a Phase I/II trial in relapsed/refractory MM (page 6). CD38 is one of the few antigens expressed on the plasma cells deregulated in MM.
- **In cynomolgus monkey trials, Xencor's CD19xCD3 bispecific depleted B-cells more potently and for a longer duration than a BiTE-like format (page 8).** Despite greater *in vitro* potency, BiTE-like formats could not deplete B-cells as effectively or for as long as Xencor's bispecific, highlighting the multiple advantages of long half-life.
- **Xencor is also developing bispecific antibodies targeting HER2xCD3 and CD123xCD3.** The HER2xCD3 antibody had a half-life of 6.2 days and a half-max redirected T-cell cytotoxicity of 0.1ng/ml against a breast cancer cell line. CD123, also known as the interleukin-3 α receptor (IL3α), is a cytokine receptor broadly up-regulated in B-cell malignancies, especially hairy cell leukemia.
- **Fc-knock-out technology, utilized in the bispecific program, mitigates the risk of cytokine storm by inhibiting binding to immune effector cells.** Other Fc domains could potentially be combined with bispecifics, increasing half-life still further (Xtend).
- **Xencor's bispecific technology allows for the production of humanized bispecific antibodies with long half-lives differentiated from current BiTE's (blinatumomab) that require continuous infusion.** Their novel technique for generating high yields of bispecific antibodies facilitates significant flexibility in targeting domains. Structurally, the company's bispecific technology can produce novel antibodies where one or both heavy/light chain pairs is missing the C_H1 and C_L domains, generating an Fv fragment directly linked to the Fc domain.
- **We view XNCR as undervalued at current levels, ~\$320M MC – particularly relative to comps such as MacroGenics (MGNX: OUTPERFORM), ~\$950M MC and given Micromet's \$1.16 billion acquisition by Amgen in early 2012.**
- **XmAb7195, Xencor's lead compound, is a Xolair (omalizumab) bio-superior for the treatment of allergic asthma and other IgE mediated disease, set to enter the clinic in H1:14 with first in humans data by YE:14.** In '7195, XNCR's Fc-modifications impart two novel mechanisms of action to XmAb7195 resulting in superior clearance and reduction of IgE levels compared to Xolair and high-affinity anti-IgE candidates in the clinic.
- **Reiterating our OUTPERFORM rating and an \$18 price target.** Our \$18 price target is derived from the sum of multiples on sales and royalties from XNCR's proprietary and partnered products each discounted back to YE:14 (Pg 3).

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Risks to the attainment of our price target include 1) failure to reach sales expectations for XmAb7195, XmAb5574, XmAb5871 2) failure in the clinic of either XmAb7195, XmAb5574, XmAb5871, 3) changes or discontinuation of Xencor's partnerships for XmAb5574, XmAb5871 or other partnered programs.

Upcoming Milestones

H1:14	Initiation of a Phase Ia trial of XmAb7195 (IgE, immune inhibitor Fc) in healthy subjects
Mid-2014	Initiation of IND-enabling studies for a bispecific candidate
H2:14	Top-line data from the Phase II trial of XmAb5574/MOR208 (CD19, enhanced ADCC Fc) in ALL
H2:14	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 in ALL at ASH
Dec 6-9, 2014	Potential interim data from a Phase II trial of MOR208 in NHL at ASH
YE:14	Top-line data from the Phase Ia trial of XmAb7195 in healthy subjects including IgE reduction
H2:15	Complete recruitment in Phase II trial of MOR208 in CLL
2015	IND filing for a bispecific candidate
2015	Complete recruitment in Phase II trial of MOR208 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
Q1:16	Potential top-line data from the Phase Ib trial of XmAb7195 in mild to moderate asthma
2016	Initiation of a Phase IIb proof-of-concept trial of XmAb7195 in poorly controlled asthma
2017	Potential top-line data from the Phase IIb POC trial of XmAb7195 in patients with poorly controlled asthma
2017	Potential top-line data from the Phase IIb trial of XmAb5871 in patients with rheumatoid arthritis
2017	Potential exercise of Amgen's option to license XmAb5871

Figure 1: Xencor's Development Pipeline

Name	Fv Target	Fc Target	Fc Modification	Indication	Status	Next Event	Partner
XmAb7195	IgE	FcγRIIb	Immune Inhibitor	Allergic Asthma	Phase I	Phase Ia trial initiation in H1:14	-
XmAb5871	CD19	FcγRIIb	Immune Inhibitor	Auto-immune	Phase II	Top-line Phase IIa trial data in RA in H1:14	Amgen
XmAb5574/ MOR208	CD19	FcγRIIIa, FcγRIIa	ADCC	CLL/ALL/NHL	Phase II	Top-line Phase II trial data in NHL and B-ALL potentially in 2016	MorphoSys
Xtend-TNF	TNF	FcRn	X-tend	Auto-immune	Pre-clinical	IND filing, potentially in 2014	-
CD3 x CD38	CD38	-	Bi-specific	Oncology	Pre-clinical	IND filing, potentially in 2014	-
CD3 x CD123	CD123	-	Bi-specific	Oncology	Pre-clinical	IND filing, potentially in 2014	-
Xtend-CTLA4	CTLA4	FcRn	Xtend	Auto-immune	Pre-clinical	IND filing, potentially in 2014	-
Anti-X/CD32b	-	FcγRIIb	Immune Inhibitor	TBD	Discovery	IND filing	-
Undisclosed	-	FcγRIIIa, FcγRIIa	ADCC	Oncology	Phase I	-	BI
Undisclosed	-	FcγRIIIa, FcγRIIa	ADCC	Oncology	Phase I	-	BI
Undisclosed	-	FcγRIIIa, FcγRIIa	ADCC	Oncology	Phase I	-	CSL
Undisclosed	-	FcRn	Xtend	Hematology	Pre-clinical	-	CSL
Undisclosed	-	FcRn	Xtend	Autoimmune	Pre-clinical	-	Janssen
Undisclosed	-	-	Stability	Autoimmune	Pre-clinical	-	Merck
Undisclosed	-	FcRn	Xtend	Undisclosed	Pre-clinical	-	Undisclosed

Source: Company data, Wedbush Securities, Inc.

Investment Thesis

Xencor is a biopharmaceutical protein-engineering company focused on developing and commercializing engineered monoclonal antibodies to treat severe and life-threatening diseases with unmet medical needs. The company has developed a substantial antibody toolkit based upon their proprietary Fc-engineering platform. Xencor has systematically and rationally engineered novel Fc-domains that augment the ability of antibodies in several ways including: immune inhibitor Fc domains that target inhibitory and clearance functionality (FcγRIIb target); cytotoxic Fc domains, that increase cytotoxicity/ADCC (targeting FcγRIIIa and FcγRIIIa receptors), Xtend Fc domains that extend half-life (targeting FcRn) and allow for the creation of novel bispecifics. We believe this best-in-class platform, which has produced two partnered products in Phase II studies, 6 internal early stage programs and a total of 7 collaborations is the core of Xencor's value.

Importantly Xencor has also created Fc variants that enable heterodimeric Fv domains for the creation of novel bispecific antibodies. We believe that Xencor's bispecific candidates could represent a significant value driver for the company as they enter the clinic potentially in 2015.

Xencor's lead candidate is XmAb7195, an anti-IgE antibody therapy for the treatment of allergic asthma employing Fc-modification to enhance FcγRIIb binding up to 400x. These modifications lead to enhanced liver clearance of IgE and suppressed production through co-engagement with B-cell bound IgE. These new functionalities, in our opinion, make XmAb7195 a best-in-class anti-IgE therapy and highlight potential broad utility of Xencor's technology. The Fc-domain in XmAb7195 is also utilized in their Phase II compound XmAb5871, supporting the safety and tolerability of these Fc-modifications. XmAb7195 is in IND-enabling studies and a Phase I trial is planned for early 2014. Importantly, Phase I data, expected around YE:14, will include IgE levels, a marker of activity and potential clinical benefit.

We believe that partnerships with Amgen, Alexion, MorphoSys, Janssen, Merck, Boehringer Ingelheim and CSL have validated Xencor's approach, with \$65M in revenues to date, potentially \$1.31 billion in additional milestones and single to double digit royalties. XmAb5871, optioned to Amgen, is Xencor's Phase II candidate for autoimmune disorders that represents a novel targeted strategy for selectively inhibiting B-cells without depletion. XmAb5871 targets both CD19 and FcγRIIb to uniquely inhibit B-cell activity without depletion, a potentially broadly applicable and valuable approach in autoimmune disorders and oncology. Top-line data from a Phase 2a study is anticipated late 2014. XmAb5574/MOR208, partnered with MorphoSys is Xencor's other CD19 therapy that employs Fc-engineered higher affinity for FcγRIIIa and FcγRIIIa receptors to potentially deplete CD19 expressing B-cells offering utility in B-cell malignancies where CD20 therapies are not effective.

Valuation Methodology

We arrive at our \$18 price target by a sum-of-the-parts analysis. We ascribe \$12/share to applying a 6x multiple of our estimated peak revenues of \$1.2 billion (2022) for XmAb7195 in severe asthma and IgE mediated diseases, discounted 45% annually. We ascribe \$6/share to Xencor's two partnered programs XmAb5871 and XmAb5574 based on royalties (mean 10%) from sales in 2022 of \$1 billion and \$600 million discounted 45% and 35% annually, respectively. Similarly we also arrive at our \$6/share value to Xencor's potential milestones based upon the NPV discounted 45% over an estimated 10-year realization period. We do not value Xencor's early stage pipeline novel bispecifics at this time.

Sum-of-the-Parts Valuation Components

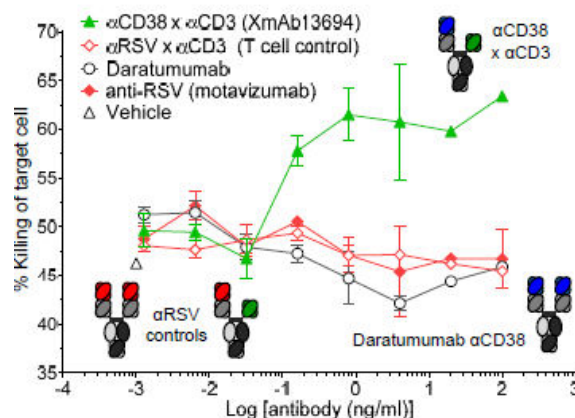
Product	Indication	Est. Addressable Market	Penetration	Annual Cost	Sales	Multiple	Royalty rate	Year	Discount rate	Value per share
XmAb7195	Severe asthma	350,000*	15%	\$22K	\$1.2B	6x	NA	2022	45%	\$12
XmAb5574	ALL	16,000	38%	\$100K	\$600M	15x	~10%	2022	35%	\$3
XmAb5871	RA	460,000	10%	\$25K	\$1.2B	15x	~10%	2022	45%	\$3
Total										\$18

*US market only

Xencor's CD38xCD3 bispecific antibody utilizes an Fc knock out domain with no immunologic effector functions, mitigating the risk of T-cell cross-linking and cytokine storm. This compound is highly potent with half-max redirected T cell cytotoxicity of ~0.1 ng/ml.

Peripheral blood mononucleated cell's (PBMC's) are extracts of whole blood that contain T cells, B cells and NK cells. PBMC extracts are widely used to test immune-mediated cytotoxicity. XmAb13694 enhanced PBMC-mediated killing of a multiple myeloma line (Figure 2)

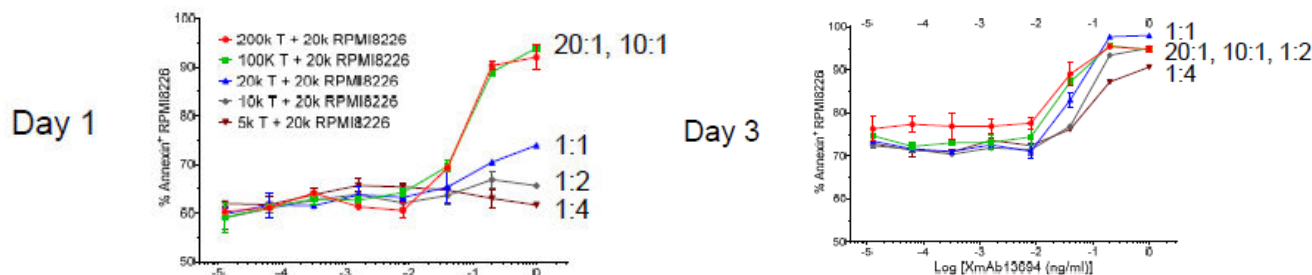
Figure 2: XmAb13694 Enhanced PBMC-mediated Killing of a Human Myeloma Cell Line



Source: Company data, Wedbush Securities, Inc.

Xencor showed this drug was effective even at low effector: target (E:T) cell ratios (1:4) (Figure 3). Although initially high E:T ratios led to rapid lysis, after 3 days even the 1:4 E:T ratio experiment reached 90% lysis.

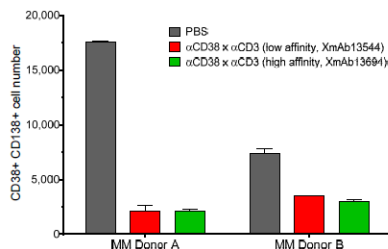
Figure 3: XmAb13694 Induces Serial Lysis



Source: Company data, Wedbush Securities, Inc.

Ex vivo experiments demonstrate that XmAb13694 significantly reduces plasma cell (CD38+, CD138+) count in PBMC's derived from multiple myeloma patients (Figure 4).

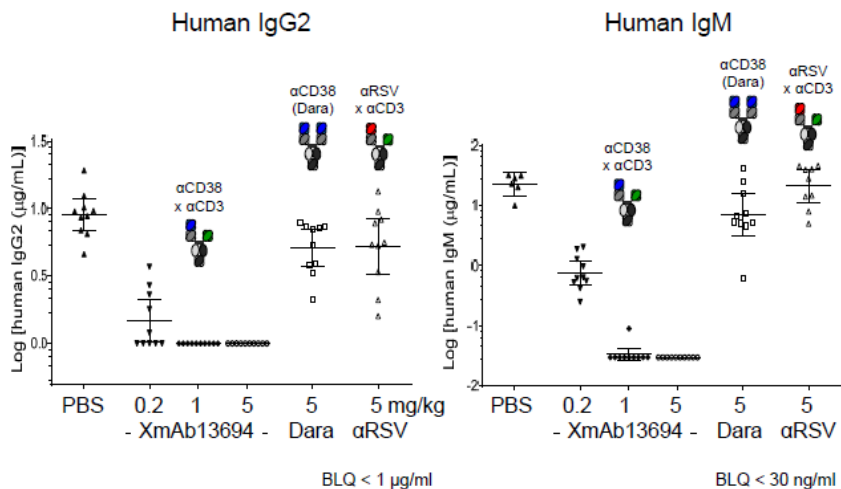
Figure 4: XmAb13694 Kills Multiple Myeloma Cells in Multiple Myeloma Derived PBMC



Source: Weers et al. *J Immunol.* 2011 Feb 1;186(3):1840-8, XmAb13694 1 µg/ml for 24 hours + multiple myeloma PBMC

Xencor used a tetanus-response model to investigate the effect of this bispecific antibody on plasma cells. They found that XmAb13694 inhibited the generation of anti-tetanus antibodies, as would be expected if XmAb13694 effectively depleted plasma cells.

Figure 5: XmAb13694 Eliminated IgG Production in SCID Mice Injected with huPBMC's after Tetanus Challenge



Source: Company data, Wedbush Securities, Inc.

CD38 Is Validated as a Target by Daratumumab in Phase III Trials

CD38 is a small Type II transmembrane glycoprotein widely represented on lymphoid and myeloid lineages, but absent from most mature resting lymphocytes. In many lymphoid tumors, including most cases of myeloma it is present on the cell surface at levels which render it an attractive target for therapeutic antibody.

There are currently three CD38 targeting antibodies in clinical trials, daratumumab (Phase III, Genmab), SAR650984 (Phase I, ImmunoGen/Sanofi) and MOR03087 (Phase I, Morphosys/Celgene). Janssen initiated a Phase III trial of daratumumab in March 2013 on the basis of interim, unreleased, data from ongoing Phase II trials.

Figure 6: CD38 Antibodies in Clinical Development for Multiple Myeloma

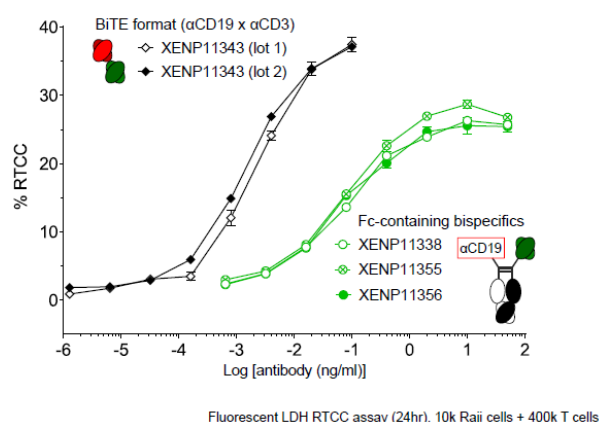
Drug	Daratumumab	SAR650984	MOR03087
N	32 (Dose escalation) + 16 (dose expansion)	24	82
Phase	I/II	I	I/II
Indication	MM R/R/ to 2+ lines	CD38+ MM or other	MM R/R to 2+ lines
Dose schedule	0.005 -> 24 mg/kg weekly iv infusion	up to 20 mg/kg	nd
Prior lines of therapy	5.5 (3-12)	nd	nd
Response	In 12 pts \geq 4 mg/kg, 5 PRs (42%), 3 MRs (25%)	Among 22 evaluable pts, 2 CR (10%), 4 PR, 2 MR, 9 SD and 5 PD for ORR of 28% Among 11 pts treated \geq 10 mg/kg 2 CR (20%), 2 PRs, 1 MR, 4SDs and 2 PDs for ORR of 40%	Ongoing
Duration of response	At doses from 4-24 mg/kg (n=12) Median PFS not reached at median follow up of 18.4 weeks (~ 4 months) vs. at 0.005-2 mg/kg (n=20) PFS is ~1 month (p=0.007)	Of 8 pts with objective response, 4 were on treatment for > 26 weeks, 1 > 52 weeks	Ongoing
Drug-related SAE's	Bronchospasm (2 pt), anemia (1 pt), thrombocytopenia (1 pt), ASAT > 5.2x ULN (1 pt), cytokine release syndrome (1 pt)	MTD not yet found at 20 mg/kg TEAE's fatigue, nausea, pyrexia, cough, anemia, headache	Ongoing
NCT	NCT00574288	NCT01084252	NCT01421186

Source: Company data, Wedbush Securities, Inc.

CD19xCD3 Bispecific Antibodies Compare Favorably to Blinatumomab

Xencor has generated CD19xCD3 bispecific antibodies that have long half-life (6 days) and high potency *in vivo*. We note that although they are not as potent on an ng/ml basis, the Fc-containing bispecific is roughly twice as heavy, shifting the curves slightly closer together on a molar basis.

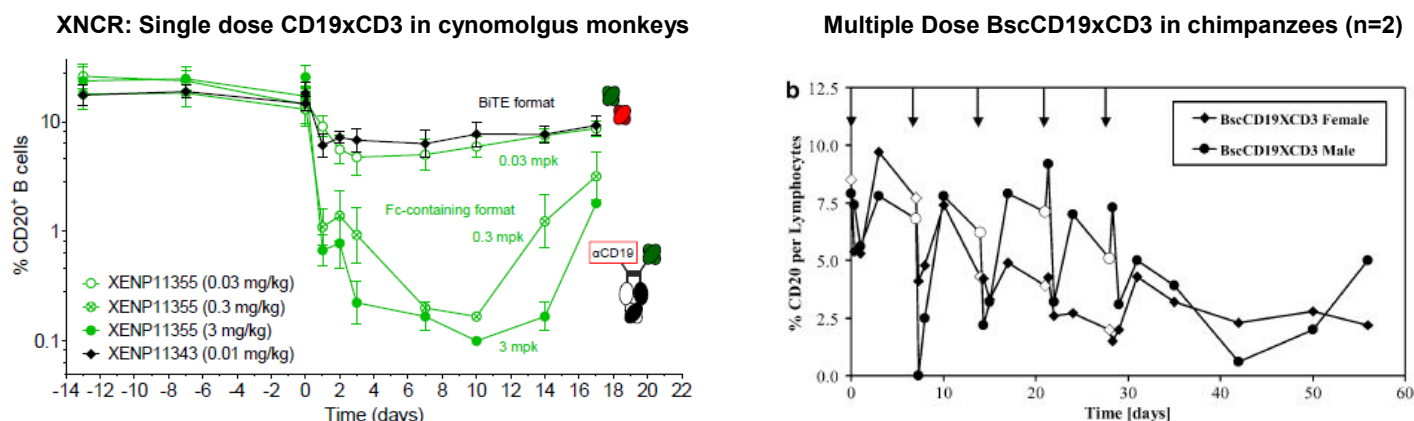
Figure 7: Xencor's Bispecific CD19xCD3 Antibodies Are Highly Potent



Source: Company data, Wedbush Securities, Inc.

CD19 targeted therapies aim to deplete B-cells, allowing for rapid verification of mechanistic activity. Xencor found that Cd19xCD3 bispecific antibodies induced long-lasting and potent B-cell depletion of greater duration and depth than a Cd19xCD3 BiTE molecule produced by Xencor. We are given confidence that XCNr's BiTE is similar to other CD19xCD3 BiTE's as it demonstrated qualitatively similar reductions in CD-20+ lymphocytes to those found in Schlereth's (2006) work in chimpanzees (XNCR BiTE: ~5-10-fold reduction vs. Schlereth ~4 fold reduction from baseline 10 days after last dose). We note that Schlereth's MT103-like bispecific single-chain (Bsc) construct did not bind to B and T-cell populations in cynomolgus monkey PBMC's.

Figure 8: XNCR's Bispecific Depletes B-Cells in Cynomolgus Monkeys



Source: Schlereth et al. Cancer Immunol Immunother. 2006 May;55(5):503-14, Company data

Covered Companies Mentioned Table

COMPANY	TICKER	RATING	PRICE TARGET	PRICE
MacroGenics, Inc.	MGNX	O	\$70	\$23.24

RATING SCALE / DEFINITION

O = Outperform

N = Neutral

U = Underperform

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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Company	Disclosure
Xencor	1,3,5,7
MacroGenics	1,3,4,5,7

Research Disclosure Legend

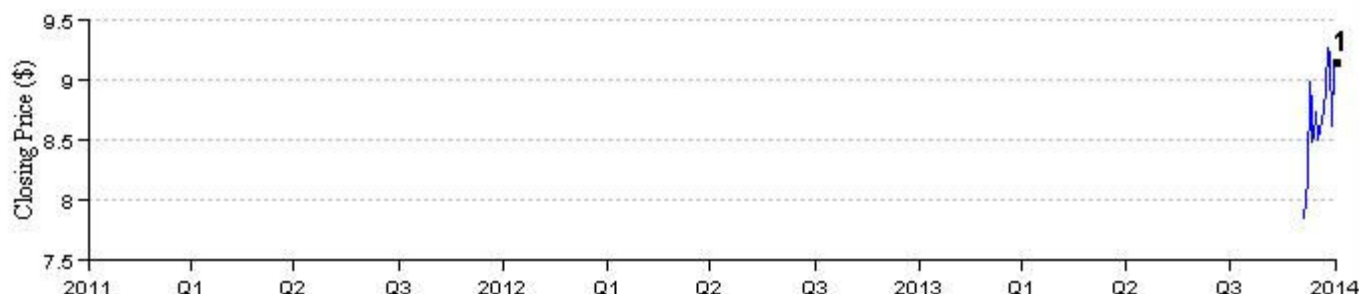
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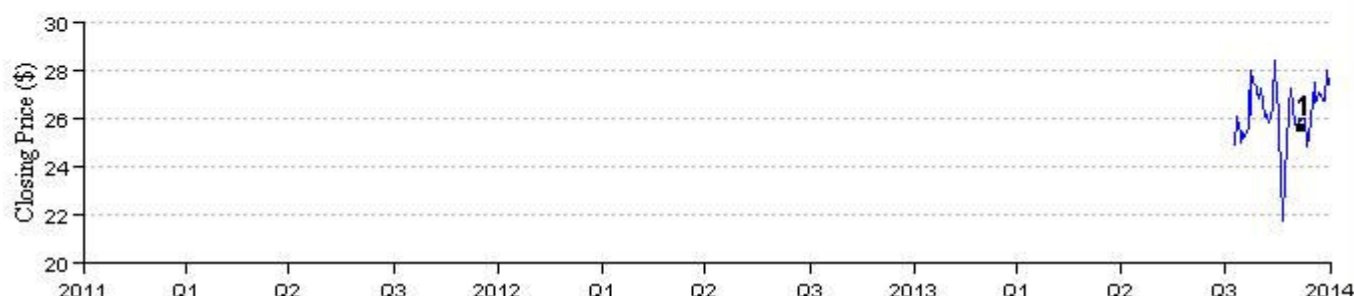
XNCR

1) 12/31/13
OUTPERFORM \$18



MGNX

1) 12/03/13
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