

## Healthcare: BioPharmaceuticals

# MacroGenics, Inc. | MGNX - \$20.01 - NASDAQ | Buy

### Company Update

#### Stock Data

|                    |                   |
|--------------------|-------------------|
| 52-Week Low - High | \$17.96 - \$41.00 |
| Shares Out. (mil)  | 27.74             |
| Mkt. Cap.(mil)     | \$555.1           |
| 3-Mo. Avg. Vol.    | 224,924           |
| 12-Mo.Price Target | \$32.00           |
| Cash (mil)         | \$194.0           |
| Tot. Debt (mil)    | \$0.0             |

#### EPS \$

| Yr Dec | —2013—  | —2014E—     | —2015E—     |
|--------|---------|-------------|-------------|
|        |         | <b>Curr</b> | <b>Curr</b> |
| 1Q     | -       | (0.12)A     | (0.31)E     |
| 2Q     | -       | (0.44)A     | (0.49)E     |
| 3Q     | -       | (0.38)E     | (0.41)E     |
| 4Q     | -       | (0.38)E     | (0.55)E     |
| YEAR   | (0.04)A | (1.32)E     | (1.77)E     |
| P/E    | NM      | NM          | NM          |

#### Revenue (\$ millions)

| Yr Dec | —2013— | —2014E—     | —2015E—     |
|--------|--------|-------------|-------------|
|        |        | <b>Curr</b> | <b>Curr</b> |
| 1Q     | -      | 14.7A       | 15.4E       |
| 2Q     | -      | 9.2A        | 11.4E       |
| 3Q     | -      | 11.2E       | 14.2E       |
| 4Q     | -      | 12.3E       | 11.4E       |
| YEAR   | 58.0A  | 47.6E       | 52.4E       |

MGNX One-Year Price and Volume History



## MGNX: Takeda Expands Deal with Potential \$1.6B in Additional Commitments

Takeda (TYO-NC) and MGNX have expanded their existing collaboration to develop and commercialize up to four new compounds based on MGNX's proprietary Dual-Affinity Re-Targeting (DART) platform. Although, there is no upfront payment, TYO will be responsible for all costs incurred during the development, which significantly expands MGNX's balance sheet flexibility. DART is MGNX's core asset in our opinion, and two oncology focused DART molecules are already in the clinic.

**New agreement covers developmental costs as well as commits \$1.6B for four new compounds:** TYO has an option to obtain worldwide licenses for up to four DART's. Importantly, TYO will fund all R&D including reimbursement of MGNX's expenses. MGNX could receive up to an additional \$400M in milestone payments for each of the four DART's. MGNX is also eligible to receive double-digit royalties on global net sales and has the option to co-promote each product in the U.S. MGNX may choose to fund a portion of phase 3 in exchange for a North American profit share.

**Original agreement focused on MGD010, targeting autoimmune diseases:** On May 22, 2014, MGNX entered into a license and option agreement with Takeda for MGD010. MGD010 simultaneously engages CD32B and CD79B, which are two B-cell surface proteins for the treatment of autoimmune diseases. Recall that as part of the agreement, MGNX received \$15M in upfront. MGNX is eligible for \$17M if TYO licenses MGD010 and could receive up to an additional \$468.5M in milestone payments, double-digit royalties on global net sales, along with the option to co-promote MGD010 in the U.S.

**Two DART's, MGD007 and MGD006 in the clinic:** Phase 1 (N=58) with MGD006 (binds to both CD123 and CD3) for the treatment of AML is underway. The primary mechanism of action of MGD006 is its ability to redirect T cells, via their CD3 component, to kill CD123-expressing cells. By simultaneously targeting CD123 (on leukemia cells) and the CD3 antigen expressed on T lymphocytes, MGD006 could simultaneously kill the leukemia cells as well as redirect T cells to kill CD123-expressing cells. In contrast MGD007 binds to both gpA33 and CD3. MGD007 is designed to bind to the CD3 protein found on T cells and redirect them to kill gpA33-expressing cells. The gpA33 antigen is found on over 95% of primary and metastatic human colorectal cancers, including cancer stem cells, which are thought to be responsible for tumor recurrence and metastasis.

**Reiterate Buy:** Our \$32 price target is based on probability adjusted NPV analysis of the company's pipeline.

Intraday: \$20.89, 12.50pm ET, 9/30/2014

## VALUATION

We arrive at our \$32 price target using a probability adjusted NPV analysis of the company's pipeline. Since we do not anticipate MacroGenics transforming into a revenue stage company until 2019, we believe a probability and risk adjusted NPV analysis is the best method for valuing the company. Based on the competitive environment, development stage of key pipeline assets, anticipated timelines pivotal trial data, we associate:

- A 19% probability for margetuximab in low expression HER2+ metastatic breast cancer. Our NPV for margetuximab in this indication is \$8/share
- A 25% probability for margetuximab in HER2+ overexpressing metastatic gastric and gastroesophageal cancers. Our NPV for margetuximab in this indication is \$5/share
- A 19% probability of success for MGA271 in prostate cancer and melanoma. Our NPV for MGA271 in these two indications is \$4/share
- We value the rest of the pipeline including the DART platform at \$15/share

Impediments to our price target include failure of margetuximab phase 2b study, which could call into question the clinical utility of the Fc-optimization strategy. Additionally, we believe that data from MGA271 will be closely watched and likely to be compared with the tumor response data from the PD-1 and PD-L1, programs. If the comparison is not favorable either from an efficacy or toxicity standpoint, MacroGenics stock could be negatively impacted.

## RISKS

**Competitive risks:** Immuno-oncology is an extremely competitive environment and MacroGenics faces direct competition from multiple big pharmaceutical competitors who are better financed and equipped. Additionally, the company's DART platform is still in pre-clinical evaluation and has some similarities with Amgen's BiTE program, which is already in phase 3 testing. Many of the company's competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than MacroGenics. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than MacroGenics and may also have products that have been approved or are in late stages of development, and collaborative arrangements in MacroGenics' target market with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that MacroGenics develops obsolete.

**Legal Risks:** In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. These lawsuits could be costly and could affect the company's results of operations and divert the attention of its management and scientific personnel. There is a risk that a court would decide that MacroGenics or its collaborators are infringing the third party's patents and would order the company and its collaborators to stop the activities covered by the patents. In that event, MacroGenics may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product.

**Regulatory Risks:** The final approval of all of MacroGenics' products rests with the FDA and the EMEA. Even if MacroGenics were to successfully complete the mandated clinical studies, there are no guarantees that these products will be approved by the regulatory agencies. A negative regulatory decision or significant delays in getting approval will have a negative impact to our price target.

**Manufacturing risks:** MacroGenics is pioneering multiple, complex, molecular engineering-based biologics. All of these products are likely to involve complex manufacturing, which may or may not be reproducible from batch-to-batch. Additionally, MacroGenics may not be able to scale up manufacturing to meet the anticipated commercial demand should its products be approved by the regulators. Inability to scale manufacturing prior to commercialization, could significantly delay regulatory approval and negatively impact the stock.

**Reimbursement/Funding Risks:** If approved, MacroGenics' products are likely to be priced in line with competitor biologics, at about \$100K/year. If the payors decide that the benefit of treating patients with Fc-optimized antibodies or DART-based biologics are marginal and does not justify the high cost, they may choose not to reimburse these products or reimbursement may not be commercially attractive for MacroGenics or

its commercial partners to continue manufacturing. Such a scenario could severely impact MacroGenics' valuation and negatively impact our outlook for the company.

**Financing and Market risks:** Because of a complex manufacturing process and clinical studies which are long drawn and expensive, MacroGenics will need to raise additional capital before operating cash flows can sustain the business. Hence, MacroGenics shareholders could face significant additional dilution depending upon market conditions. While the company has been very successful at attracting capital over the past few years, clinical trial failure or a major setback with manufacturing could dramatically alter the company's ability to meet its future capital requirements

## COMPANY DESCRIPTION

MacroGenics, Inc. is a clinical-stage biopharmaceutical company. MacroGenics focuses on discovering and developing monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. The Company's product candidates leverage its fully-integrated capabilities around the discovery, development, and production of antibodies and incorporate three technology platforms: its Dual-Affinity Re-Targeting (DART) platform enables MacroGenics to design candidate therapeutics that target multiple disease-causing cells or redundant disease-associated pathways with a single molecule; its Fc Optimization platform enhances the natural immune system's ability to mediate killing of cancer cells; and its Cancer Stem Cell platform provides new approaches to target cancers unresponsive to current therapy. As of 1Q 2014, MacroGenics had two oncology product candidates in clinical development.

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Within the last twelve months, ROTH has received compensation for investment banking services from MacroGenics, Inc..

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**On September 28, 2010, ROTH changed its rating system in order to replace the Hold rating with Neutral.**

**On May 26, 2011, ROTH changed its rating system in order to incorporate coverage that is Under Review.**



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| Rating            | Count | Percent | IB Serv./Past 12 Mos.<br>as of 09/30/14 |         |
|-------------------|-------|---------|---|---------|
|                   |       |         | Count                                   | Percent |
| Buy [B]           | 194   | 80.83   | 112                                     | 57.73   |
| Neutral [N]       | 25    | 10.42   | 10                                      | 40.00   |
| Sell [S]          | 1     | 0.42    | 0                                       | 0       |
| Under Review [UR] | 19    | 7.92    | 11                                      | 57.89   |

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