ROTH Capital Partners

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Healthcare: BioPharmaceuticals

MacroGenics, Inc. | MGNX - $20.15 - NASDAQ | *Buy*

Company Update

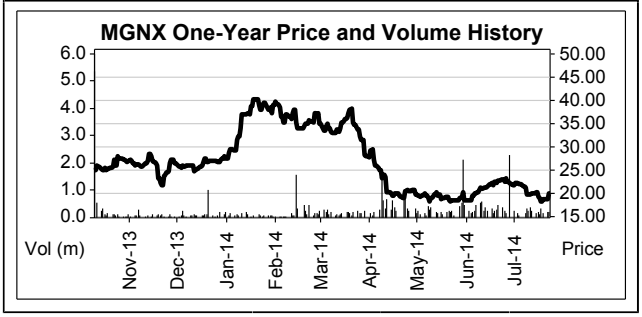
Stock Data	
52-Week Low - High	$17.96 - $41.00
Shares Out. (mil)	27.62
Mkt. Cap.(mil)	$556.5
3-Mo. Avg. Vol.	319,651
12-Mo.Price Target	$30.00
Cash (mil)	$198.0
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2013—	—2014E—	—2015E—
		Curr	Curr
1Q	-	(0.12)A	(0.20)E
2Q	-	(0.19)E	(0.39)E
3Q	-	(0.33)E	(0.31)E
4Q	-	(0.28)E	(0.45)E
YEAR	(0.04)A	(0.93)E	(1.34)E
P/E	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2013—	—2014E—	—2015E—
		Curr	Curr
1Q	-	14.7A	15.4E
2Q	-	13.3E	11.4E
3Q	-	10.3E	14.2E
4Q	-	12.3E	11.4E
YEAR	58.0A	50.6E	52.4E



MGNX: Neratinib Highlights Opportunities and Challenges for Margetuximab

Puma Biotechnology (PBYI-NC) stock performance today highlights opportunities in the biotechnology sector after announcing positive phase 3 data of neratinib in the adjuvant setting. Neratinib is an oral, irreversible, pan-HER, TKI, and much like the approved agents may have limited activity against lower HER2 expressing tumors, which represents ~70% or ~35,000 patients in the U.S. alone. Margetuximab is being developed for this large unmet need and phase 2 data during 2015 is eagerly anticipated.

Fc-optimization could be blue ocean strategy: Note MacroGenics lead product Margetuximab, maintains the antigen-binding properties of trastuzumab (Herceptin), while optimizing its interactions with human Fc# receptors (Fc#Rs). The Fc-optimization was designed to increase Antibody Dependent Cell-Mediated Cytotoxicity (ADCC)-mediated tumor cell kill, which is often the missing component in antibody-based therapies, hampered by genetic polymorphisms. Margetuximab is potentially superior to trastuzumab and other HER-2 directed therapies, because it combines the significant anti-proliferative activity against HER2 over-expressing tumors with an optimized Fc domain. This may facilitate enhanced activity against tumors with lower (1+ and 2+) HER2 expression. Based on phase 1 data, margetuximab's single agent response rate of 38% (three partial responses out of eight patients) appears to be comparable to prior data from neratinib in a similar patient population. Note that neratinib's response rates are derived from a larger pool of patients (N=63).

Phase 2 study underway: The first cohort of 21 patients should be enrolled during 2014, and preliminary data is expected during-or-before 1Q 2015. If two confirmed responses (>30% tumor shrinkage) are observed, the study will be expanded to include another 20 patients. Overall, five confirmed responses from the 41 patients will be deemed as a positive outcome. In our opinion, investors are likely to remain cautious ahead of the study readout because there is conflicting data that calls into question the impact of Fc-optimization on genetic polymorphisms. However, we note that a robust response rate from the study is likely to have implications beyond breast cancer and significantly broaden the market opportunity for margetuximab, validate the Fc-optimization strategy, open up the accelerated approval pathway, and significantly drive valuation.

Reiterate Buy and $30 price target: Risks include failure of margetuximab phase 2b study and other pipeline compounds.

Intraday Price: $21.63 at 10:57 AM ET

VALUATION

We arrive at our $30 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 till 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 $13/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.

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

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

ROTH makes a market in shares of MacroGenics, Inc. and as such, buys and sells from customers on a principal basis.

Within the last twelve months, ROTH has managed or co-managed a public offering for MacroGenics, Inc..

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.

Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 07/23/14	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**184**	**79.65**	**102**	**55.43**
Neutral [N]	**23**	**9.96**	**9**	**39.13**
Sell [S]	**1**	**0.43**	**0**	**0**
Under Review [UR]	**22**	**9.52**	**13**	**59.09**

Ratings System Definitions - ROTH employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH does not publish research or have an opinion about this security.

ROTH Capital Partners, LLC expects to receive or intends to seek compensation for investment banking or other business relationships with the covered companies mentioned in this report in the next three months. The material, information and