ROTH Capital Partners

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Healthcare: BioPharmaceuticals

MacroGenics, Inc. | MGNX - $22.31 - NASDAQ | *Buy*

Company Update

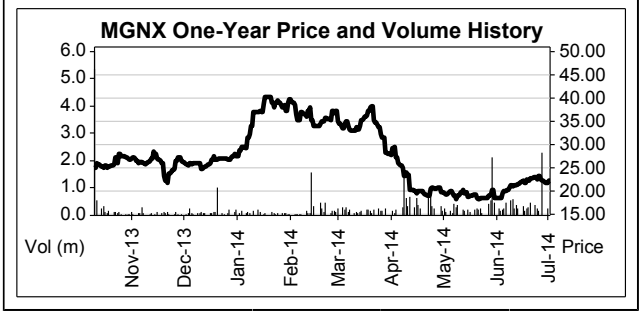
Stock Data	
52-Week Low - High	$17.96 - $41.00
Shares Out. (mil)	27.62
Mkt. Cap.(mil)	$616.2
3-Mo. Avg. Vol.	362,039
12-Mo.Price Target	$30.00
Cash (mil)	$198.0
Tot. Debt (mil)	$0.0

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: Competitor's Breakthrough Therapy Designation Bodes Well for The DART's

MacroGenics is pioneering immune-modulation-based therapies through its ability to engineer antibodies at the molecular level. With the recent addition of a DART-based compound to its clinical-stage pipeline, MacroGenics has formally entered the multi-target engagement race. We anticipate up to six (currently three) new compounds in the clinic by the end of 2015, spanning both solid and liquid tumors providing multiple shots on goal.

Event: Amgen (AMGN-NC) received FDA Breakthrough Therapy Designation (BTD) for its investigational BiTE antibody blinatumomab, for the treatment of for adults with Philadelphia-negative (Ph-) relapsed/refractory B-precursor Acute Lymphoblastic Leukemia. Note that BiTE antibodies are a type of immunotherapy designed to engage two different targets simultaneously, thereby juxtaposing T cells to cancer cells (helping to engage the body's immune system to detect and target malignant cells). We believe that AMGN is likely to pursue the accelerated approval pathway and file the NDA based on the robust phase 2 data on hand. Remember MacroGenics recently announced the initiation of a phase 1 study with MGD006 for the treatment of Acute Myeloid Leukemia (AML) with its DART platform, which has some similarities to the BiTE molecules but represents a significant advancement over the BiTEs. In our opinion, MacroGenics' DART platform has overcome many of the existing challenges of dual targeting by covalent di-sulfide linkages and unique amino acid sequences that efficiently pair the chains of the DART molecule. These changes have allowed for improved manufacturability, long-term structural stability, and the ability to tailor the half-lives of the DARTs to their clinical needs. Additionally, MacroGenics can tailor the DART molecule's valency (number of binding sites) and the binding affinity. MacroGenics has developed over a 100 such DART compounds and we expect multiple DART's in the clinic over the next 12-to-18 months.

Impact: Given the unique advantages of the DART-platform we believe that MacroGenics remains well positioned to file for BTD as clinical data become available, which could significantly shorten the time to market for the early DART compounds. Note that AMGN acquired the BiTE technology for ~$1.2B during 2012 and MacroGenic's current EV is about ~$400M.

Action: We reiterate our Buy rating and $30 price target. Key risks include: clinical failure of the Fc-optimization and DART platforms.

SUMMARY

MacroGenics is a biotechnology company pioneering multiple molecular engineering platforms against a range of immunology targets with a primary focus on immuno-oncology. We anticipate up to least six (currently two) new compounds in the clinic by the end of 2015, spanning both solid/liquid tumors and other chronic conditions, which provides multiple shots on goal. In our opinion, MacroGenics's expertise in the areas of Fc-optimization and Dual Affinity Receptor Targeting (DART) will continue to generate partnering interest once new clinical data validates the core observations in relapsed/refractory cancers.

While a phase 3 study in gastric and gastro-esophageal cancer has been initiated, topline data is about four years out. Hence, over the near term, there is a lot riding on the outcome of the margetuximab phase 2a trial in metastatic breast cancer in patients who have low levels (1+ and 2+) of HER2-expression. In our opinion, the 12% response rate needed to justify further investment is a high hurdle in this patient population, especially given that conventional HER2-directed therapies are not very active in this setting. We are cautious ahead of the trial readout because there is conflicting data that calls into question the impact of Fc-optimization on genetic polymorphisms. Additionally, neratinib an oral, irreversible, pan-HER, tyrosine kinase inhibitor, which is being developed by PUMA Biotechnology (PBYI-NC), has captured the imagination of investors with robust single agent and combination therapy data. Based on phase 1 data, we believe margetuximab as a single agent has a response rate of 38% (N=8), which is comparable to neratinib. However, we note that neratinib's response rates are derived from a larger pool of 63 patients.

The implications of a robust phase 2b readout include:

- Significant de-risking of the Fc-optimization platform that could drive partnering interest surrounding the strategy for currently approved antibody-based therapies
- Potential expansion of margetuximab's clinical program to other indications with low HER2 expression, which may include colon, lung, and prostate
- Potential for accelerated approval in the metastatic breast cancer indication with response rates and progression free survival dependent endpoints from a follow on study
- Substantial value accretion to the MGA271 program, which also depends upon Fc-optimization, in our opinion

MacroGenics' second clinical stage candidate, MGA271, is a first-in-class, Fc-optimized, monoclonal antibody that targets B7-H3, a tumor-specific antigen and a member of the B7 family of immune regulators. Although its specific receptor has yet to be discovered, B7-H3 is widely expressed in many solid tumors and is associated with poor prognosis. B7-H3 is in the same axis as the other immune-checkpoint inhibitors like PD-1 and PD-L1, which has captured investor enthusiasm in the sector. A phase 1 program, with over 90 patients (nine dose cohorts, 15 different tumor types) is currently underway and comprehensive data could be available during mid-2015. We note that Servier has an option to license the European rights for this program and based on the progress thus far it is likely that Servier will exercise the option during 2014, which could trigger a $30M milestone payment.

MacroGenics has a third key asset (the DART-platform), which has attracted multiple high value partnerships and in its current form could generate ~$5B in royalty and milestone payments. While the DART-platform has some similarities to Amgen's, BiTE, it is substantially differentiated and side-by-side comparison has shown that the CD19xCD3 DART construct is superior to a similar BiTE molecule. We note that DART format has consistently outperformed the BiTE format with respect to key immunologic parameters, which bodes well for the treatment of relapsed/refractory patients. MacroGenics has over a 100 optimized DART-based targets. Two of these are on track to enter the clinic in 2014.

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. Key risks to our price target include failure of margetuximab phase 2a 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.

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.

MACROGENICS INC
INCOME STATEMENT, in thousands

	FY 2013A	1Q 2014A	2Q 2014E	3Q 2014E	4Q 2014E	FY 2014E	1Q 2015E	2Q 2015E	3Q 2015E	4Q 2015E	FY 2015E
Revenues:											
Revenue from collaborative research	$ 56,753	$ 14,401	$ 13,211	$ 10,141	$ 12,141	$ 49,894	$ 15,200	$ 11,250	$ 14,100	$ 11,200	$ 51,750
Grant revenue	1,282	318	120	110	175	$ 723	210	120	110	175	$ 615
Total revenues	58,035	14,719	13,331	10,251	12,316	50,617	15,410	11,370	14,210	11,375	52,365
Costs and expenses:											
Research and development	46,582	14,569	15,297	15,756	16,386	62,008	17,206	18,066	18,608	19,352	73,232
General and administrative	11,087	3,259	3,324	3,423	3,526	13,532	3,702	3,777	3,890	4,007	15,375
Total costs and expenses	57,669	17,827	18,621	19,180	19,913	75,540	20,908	21,842	22,498	23,359	88,607
Income (loss) from operations	366	(3,109)	(5,290)	(8,929)	(7,597)	(24,924)	(5,498)	(10,472)	(8,288)	(11,984)	(36,242)
Other income (expense)	(627)	0	200	187	176	563	180	165	187	176	708
Net comprehensive income (loss)	(261)	(3,108)	(5,090)	(8,742)	(7,421)	(24,360)	(5,318)	(10,307)	(8,101)	(11,808)	(35,534)
Basic and diluted net income (loss) per common share	$ (0.04)	$ (0.12)	$ (0.19)	$ (0.33)	$ (0.28)	$ (0.93)	$ (0.20)	$ (0.39)	$ (0.31)	$ (0.45)	$ (1.34)
Weighted average common shares outstanding, basic and diluted	6,848	26,262	26,289	26,315	26,341	26,302	26,394	26,420	26,447	26,473	26,434
Balance sheet and cash flows estimates											
Cash		**198**	**183**	**165**	**149**	**104**	**90**	**171**	**155**	**136**	**68**
Debt		0	0	0	0	0	0	0	0	0	0
Cash from operations		**5**	**(14)**	**(18)**	**(16)**	**(43)**	**(13)**	**(18)**	**(16)**	**(19)**	**(66)**
Net income		(3.11)	(5.09)	(8.74)	(7.42)	(24.36)	(5.32)	(10.31)	(8.10)	(11.81)	(35.53)
Share based compensation		0.6	0.5	0.7	1	2.81	1.5	1.8	1.9	2.4	7.6
Depreciation and Amortization		0.4	0.4	0.4	0.4	1.59	0.5	0.5	0.5	0.5	2
Change in working capital		7	-10	-10	-10	-23	-10	-10	-10	-10	-40
Cash from investing		**-0.5**	**-0.5**	**-0.5**	**-0.5**	**-2**	**-0.5**	**-0.5**	**-0.5**	**-0.5**	**-2**
Cash from financing		**76**						**100**			

Source: MacroGenics SEC filings and ROTH Capital Partners estimates.

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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 07/02/14	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**180**	**78.60**	**100**	**55.56**
Neutral [N]	**24**	**10.48**	**9**	**37.50**
Sell [S]	**1**	**0.44**	**0**	**0**
Under Review [UR]	**23**	**10.04**	**14**	**60.87**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

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.