ROTH Capital Partners

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Healthcare: BioPharmaceuticals

MacroGenics, Inc. | MGNX - $20.19 - NASDAQ | *Buy*

Analysis of Sales/Earnings

Estimates Changed

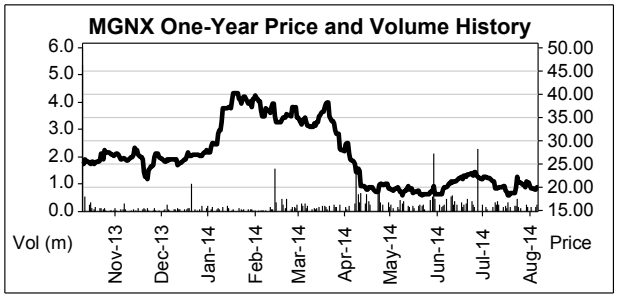
Stock Data	
52-Week Low - High	$17.96 - $41.00
Shares Out. (mil)	27.74
Mkt. Cap.(mil)	$560.0
3-Mo. Avg. Vol.	298,327
12-Mo.Price Target	$32.00
Cash (mil)	$194.0
Tot. Debt (mil)	$0.0

EPS $

Yr Dec	—2013—	—2014E—		—2015E—	
		Curr	Prev	Curr	Prev
1Q	-	(0.12)A	(0.12)A	(0.31)E	(0.20)E
2Q	-	(0.44)A	(0.19)E	(0.49)E	(0.39)E
3Q	-	(0.38)E	(0.33)E	(0.41)E	(0.31)E
4Q	-	(0.38)E	(0.28)E	(0.55)E	(0.45)E
YEAR	(0.04)A	(1.32)E	(0.93)E	(1.77)E	(1.34)E
P/E	NM	NM	NM	NM	NM

Revenue ($ millions)

Yr Dec	—2013—	—2014E—		—2015E—
		Curr	Prev	Curr
1Q	-	14.7A	14.7A	15.4E
2Q	-	9.2A	13.3E	11.4E
3Q	-	11.2E	10.3E	14.2E
4Q	-	12.3E	12.3E	11.4E
YEAR	58.0A	47.6E	50.6E	52.4E



MGNX: Pipeline Advances, But Limited Near-Term Catalysts

For 2Q14, MacroGenics reported EPS of ($0.44) *vs*. our estimate of ($0.19) principally driven by higher R&D and G&A. The $194M cash on the balance sheet should be sufficient to fund operations into 2017. In our opinion, MacroGenics will be valued based on incremental pipeline progress and not on quarterly EPS adjustments. We believe MacroGenics is well positioned at the cutting edge of immuno-oncology with four clinical stage compounds and we anticipate value-creating data should start rolling out during 2015.

Margetuximab: Phase 1 intermittent dosing regimen has now tested 18mg/kg/qw dose, without any DLT. Margetuximab continues to exhibit both a favorable safety profile and evidence of single-agent activity in refractory HER-2 positive cancer patients. Enrollment in the phase 2a breast cancer study in low HER-2 expressing patients has been slow, and MacroGenics intends to address this by increasing the number of centers as well as expand the eligibility to enroll patients with both 2+ and 1+ HER2+ tumors. Phase 3 study in gastroesophageal cancer (MAGENTA) planning underway and we anticipate patient enrollment will begin during 4Q14.

MGA271: MacroGenics expects to complete enrollment of the first three dose-expansion cohorts (melanoma, prostate, and other tumor types) of its phase 1 study during 4Q14. MacroGenics also plans to initiate further studies of MGA271 in combination with other therapies in 2015. We anticipate preliminary data during ASCO 2015.

MGD007 and MGD006: Phase 1 study with MGD006 for the treatment of AML is underway and the study will enroll up to 58 patients. MGD006 recognizes both CD123 and CD3. CD123, the interleukin-3 receptor alpha chain, is expressed on leukemia and leukemic stem cells. 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. MGD007 phase 1 to begin shortly. MGD007 recognizes both gpA33 and CD3. 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. MGD007 is designed to bind to the CD3 protein found on T cells and redirect them to kill gpA33-expressing cells.

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

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.

MacroGenics recently announced the initiation of a phase 1 study with MGD006 for the treatment of Acute Myeloid Leukemia (AML). The phase 1 dose-escalation study is designed to assess the safety and tolerability of MGD006 in patients with relapsed or refractory AML. The study will enroll up to 58 patients across multiple sites in the U.S. We note that MacroGenics has a portfolio of over 100 DART molecules and expects to advance multiple additional DART candidates into clinical development in 2014 and 2015 and beyond.

The five-year survival rate of patients under 60 years of age with AML is less than 30%, with progressively worse prognosis for more elderly patients. Recent progress at understanding the cellular and molecular basis of this aggressive disease points to the involvement of Leukemia Stem Cells (LSCs) at the heart of post-treatment relapse and emergence of chemo-resistance. Over-expression of CD123 on AML cells confers a range of growth advantages over normal hematopoietic stem cells (HSCs) and is correlated with multiple negative prognostic factors including:

- Spontaneous signal transducer and activator of transcription 5 (STAT5) activation
- Resistance to apoptosis
- Higher blast counts at diagnosis and a lower complete remission rate that results in reduced survival

Collectively, these point to the significance of CD123 expression in leukemia cell stimulation and AML patient outcome. In our opinion, the increased expression of CD123 on LSCs compared with HSCs presents an opportunity for selectively targeting AML-LSCs with MacroGenics' DART platform. By simultaneously targeting CD123 (on leukemia cells) and the CD3 antigen expressed on T lymphocytes, the DART molecule (MGD006) could simultaneously kill the leukemia cells as well as redirect T cells to kill CD123-expressing cells, and could represent an ideal therapeutic candidate for clinical testing, in our opinion.

MacroGenics announced the initiation of a phase 1 study with MGD007 for the treatment of Colorectal Cancer (CRC). The phase 1 dose-escalation study is designed to assess the safety and tolerability of MGD007 in patients with metastatic CRC. Company should receive a $5M milestone payment from partner Servier. Servier may exercise its option for MGD007 upon the completion of the phase 1 study in all territories outside North America, Japan, Korea and India. We note that MacroGenics has a portfolio of over 100 DART molecules and expects to advance multiple additional DART candidates into clinical development in 2014 and 2015 and beyond.

MGD007 is a humanized DART molecule that recognizes both gpA33 and CD3. 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. Note that humanized, radiolabeled, antibodies against the gpA33 antigen have been investigated by multiple academic centers. These radiolabeled anti-A33 antibodies were safe and exhibited selective and rapid localization to CRC tumors, with penetration into tumor cell clusters within the center of necrotic tumors. The ability to localize in the tumor core despite extensive necrosis is an important observation, as interstitial pressure, and vascular supply often hinder antibodies efficacy. While the radiolabeled antibodies depend on the isotope payload to increase tumor kill, MGD007 is designed to bind to the CD3 protein found on T cells and redirect them to kill gpA33-expressing cells, and could represent an ideal therapeutic candidate for clinical testing, in our opinion.

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.

MACROGENICS INC
INCOME STATEMENT, in thousands

	FY 2013A	1Q 2014A	2Q 2014A	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	$ 9,202	$ 11,241	$ 12,141	$ 46,985	$ 15,200	$ 11,250	$ 14,100	$ 11,200	$ 51,750
Grant revenue	1,282	318	18	110	175	$ 621	210	120	110	175	$ 615
Total revenues	58,035	14,719	9,220	11,351	12,316	47,606	15,410	11,370	14,210	11,375	52,365
Costs and expenses:											
Research and development	46,582	14,569	17,335	17,855	18,569	68,328	19,498	20,473	21,087	21,930	82,987
General and administrative	11,087	3,259	4,145	4,269	4,397	16,070	4,617	4,710	4,851	4,996	19,174
Total costs and expenses	57,669	17,827	21,480	22,124	22,967	84,398	24,115	25,182	25,938	26,927	102,162
Income (loss) from operations	366	(3,109)	(12,260)	(10,773)	(10,651)	(36,793)	(8,705)	(13,812)	(11,728)	(15,552)	(49,797)
Other income (expense)	(627)	0	1	187	176	364	180	165	187	176	708
Net comprehensive income (loss)	(261)	(3,108)	(12,259)	(10,586)	(10,475)	(36,428)	(8,525)	(13,647)	(11,541)	(15,376)	(49,089)
Basic and diluted net income (loss) per common share	$ (0.04)	$ (0.12)	$ (0.44)	$ (0.38)	$ (0.38)	$ (1.32)	$ (0.31)	$ (0.49)	$ (0.41)	$ (0.55)	$ (1.77)
Weighted average common shares outstanding, basic and diluted	6,848	26,262	27,651	27,679	27,706	27,325	27,762	27,790	27,817	27,845	27,803
Balance sheet and cash flows estimates											
Cash		**198**	**194**	**188**	**183**	**172**	**165**	**163**	**157**	**148**	**125**
Debt		0	0	0	0	0	0	0	0	0	0
Cash from operations		**5**	**(3)**	**(5)**	**(5)**	**(9)**	**(7)**	**(1)**	**(5)**	**(8)**	**(21)**
Net income		(3.11)	(12.26)	(10.59)	(10.47)	(36.43)	(8.53)	(13.65)	(11.54)	(15.38)	(49.09)
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	8	4	4	23	0	10	4	4	18
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**									

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 08/06/14	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**188**	**80.34**	**103**	**54.79**
Neutral [N]	**22**	**9.40**	**9**	**40.91**
Sell [S]	**1**	**0.43**	**0**	**0**
Under Review [UR]	**22**	**9.40**	**13**	**59.09**

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.