Zacks Small-Cap Research

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Medgenics Inc (MDGN-AMEX)

MDGN: Add'l Data Supports Efficacy in EPO and GLP-2 Applications. Reiterating Buy Recommendation

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/08/2014
Current Price (06/15/15)	$7.76
Target Price	**$12.00**

OUTLOOK

New management team brought on in late 2013 with goal of accelerating development of flagship Biopump technology for orphan and rare diseases. Biopump, a novel ex-vivo gene therapy which uses the patient's own skin to produce and deliver proteins/peptides, has significant advantages over traditional gene therapies. Initial clinical studies demonstrated efficacy and excellent safety. With proof-of-concept accomplished, Biopump is being further validated in a recently initiated phase I/II study - preliminary data from which has been very promising. Rare/orphan disease markets are particularly attractive due to certain incentives and inherent economics. Clinical development may also be accomplished faster, cheaper and with lower risk.

SUMMARY DATA

52-Week High	**$9.63**
52-Week Low	**$3.68**
One-Year Return (%)	**3.85**
Beta	**0.17**
Average Daily Volume (sh)	**100,560**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$202**
Short Interest Ratio (days)	**10.28**
Institutional Ownership (%)	**23**
Insider Ownership (%)	**27**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in '000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 E	0 E	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.28 A	-$0.21 A	-$0.16 A	-$0.30 A	-$0.96 A
2015	-$0.36 A	-$0.34 E	-$0.24 E	-$0.26 E	-$1.22 E
2016					-$0.92 E
2017					-$0.81 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT's NEW…

TARGT$_{EPO}$ Trial Update: Continued Positive Response w/ One Patient Now Through 11 Weeks. Initial Mid-Dose Data…

Medgenics presented the latest data from the ongoing MDGN-201 study at the 20th Congress of the European Hematology Association (EHA) in Austria on June 13th. Results continue to be promising with all three low-dose cohort patients that had stable EPO secretion and hemoglobin (in predefined target range of 9 - 12 g/dl) as of the last update on April 17th, remaining so as of this EHA presentation. This includes one patient in the low-dose cohort that has now been stable through 11 months post-implantation. The other two patients have been stable for 5 and 7 months.

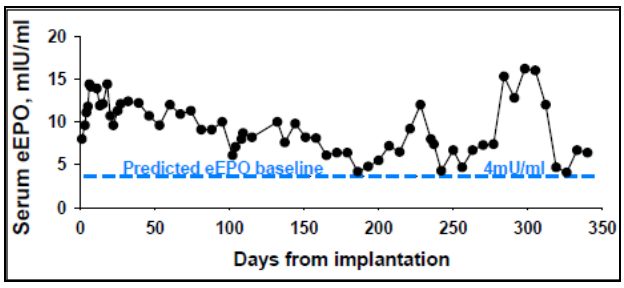
Patient 5 who as of the mid-April update was still in the study through 5 months was under evaluation at that time as he had refused 3 of 4 depo-medrol injections which was a violation of the trial protocol. He has since been removed from the study.

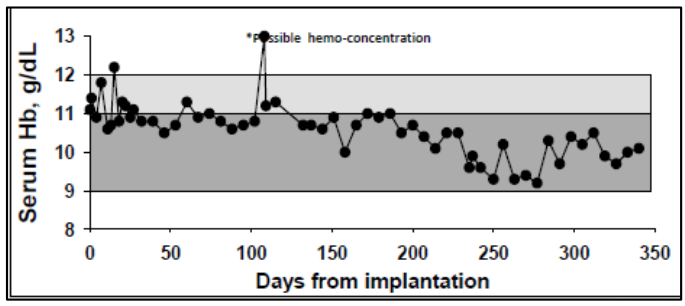
Of the six patients enrolled in the low-dose cohort, five have now shown a stable response for at least five months.

Low Dose Patients Summary

Subject #	Age	Gender	Dialysis (years)	Medical History	rHuEPO Run-in Dose (IU/wk)	# of TARGTs	Months Post Implant	Status
E101 (Patient 1)	70	M	4	hypertension, diabetes	12K	3	11	Ongoing; stable Hb
E102 (Patient 2)	26	M	0.8	hypertension, IgA nephropathy	12K	2	5	Returned to baseline; received rHuEPO. Exited study.
E201 (Patient 3)	74	F	1.4	hypertension, diabetes, stroke	20K	1	2	Required rHuEPO following surgery unrelated to therapy. Exited study.
E202 (Patient 4)	76	M	9	hypertension, stroke, MI	20K	2	8	Ongoing; stable Hb
E203 (Patient 5)	67	M	1	diabetes	20K	3	6	Returned to baseline; received rHuEPO.
E204 (Patient 6)	64	F	0.75	hypertension	8K	3	5	Ongoing; stable Hb

Patient #1: *11 months of TARGT$_{EPO}$ therapy with stable EPO and Hb in target range of 9g/dl - 12g/dl*





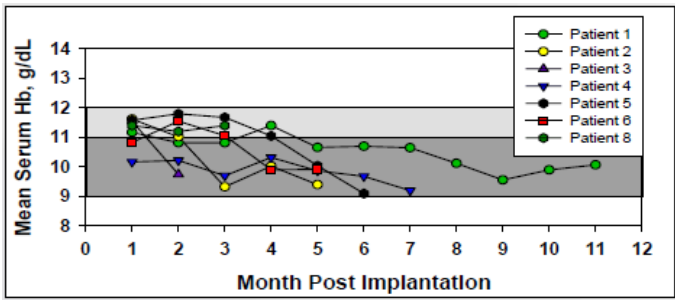
The EHA presentation included the first data from the mid-dose cohort, which has now enrolled three patients. Patient 7 is the only study participant so far to demonstrate no response to $TARGT_{EPO}$ therapy. However, after being removed from the study he also showed poor response to recombinant EPO. Of the other two mid-dose cohort patients, one is stable through two months following implantation and the other, which was implanted with $TARGT_{EPO}$ on May 28th, does not yet have data available.

Mid Dose Patients Summary

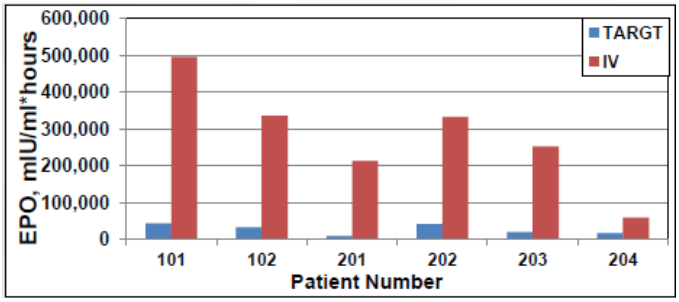
Subject #	Age	Gender	Dialysis (years)	Medical History	rHuEPO Run-in Dose (IU/wk)	# of TARGTs	Months Post Implant	Status
E206 (Patient 7)	62	M	0.7	Pseudo gout, FSGS, Thalassemia minor	20K	3	<1	Received rHuEPO. Exited study.
E205 (Patient 8)	50	M	2	hypertension, congestive heart failure, diabetes	16K	3	2	Ongoing; stable Hb
E401 (Patient 9)	66	M	4.6	hypertension, peripheral vascular disease, diabetes	2K	5	N/A	Implanted May 28, 2015; data not yet acquired.

So of the eight patients with available data that have been enrolled across the low and mid-dose cohorts, seven have shown positive response to $TARGT_{EPO}$ therapy. In addition, safety has not been an issue with no reported treatment-related serious adverse events. And exposure to EPO with $TARGT_{EPO}$ therapy is about 100x less than if the patients were being treated with recombinant EPO, which has been associated with serious safety risks, including cardiovascular complications.

Hemoglobin Response to $TARGT_{EPO}$ Therapy

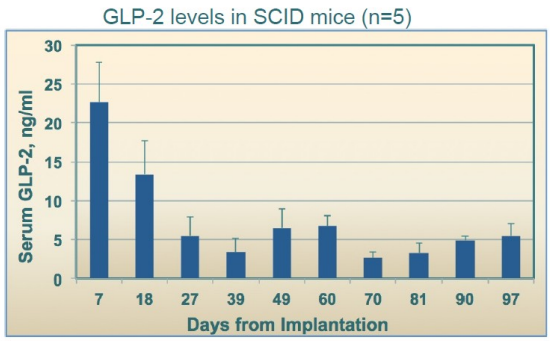


Much lower EPO Exposure w/ $TARGT_{EPO}$ Therapy

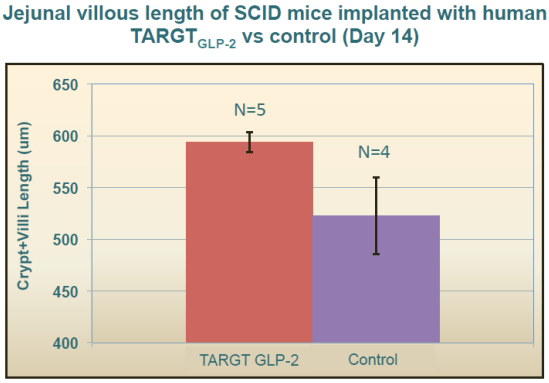


GLP Update: Additional Data Presented at ASGCT Further Indicates Utility of $TARGT_{GLP-2}$ in Short Bowel Syndrome

As a reminder, at the January 2015 Biotech Showcase presentation MDGN announced SCID mouse data of GLP-2 following 100 days after implantation which indicated the micro-organ has been able to produce GLP-2 through, the secreted GLP-2 reaches the mouse blood stream and shows only a slight peak through about the first two weeks. Also presented was SCID mouse data versus sham control which demonstrated a biological effect of the GLP-2 micro organ (data was through two weeks).

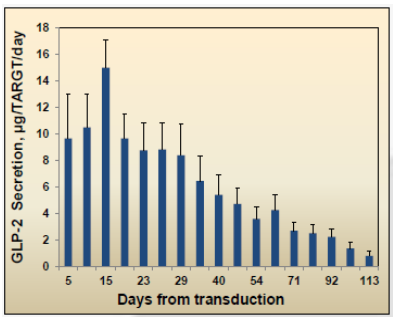


TARGT system has demonstrated the unique ability to produce peptides *in vivo*

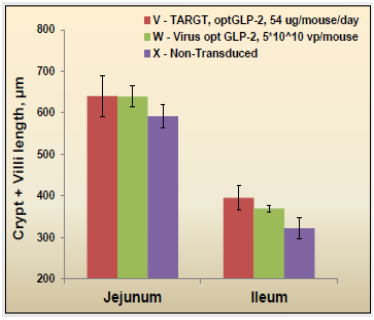


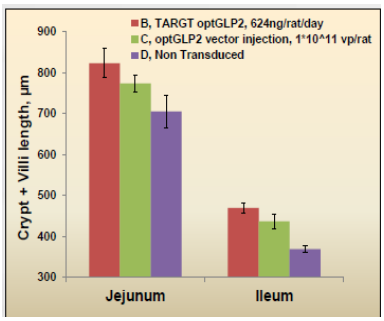
Additional data was presented at the American Society of Gene & Cell Therapy annual meeting in mid-May. This included in-vitro data showing $TARGT_{GLP-2}$ secretion of tens of micrograms per day. In addition, in-vivo mouse and rat data was presented demonstrating GLP-2 secreted by $TARGT_{GLP-2}$ has the effect of increasing intestinal length and cell proliferation. We view the data as continuing to show promise of $TARGT_{GLP-2}$ for the treatment of short-bowel syndrome.

$TARGT_{GLP-2}$ secretion



$TARGT_{GLP-2}$ intestinal activity in mice and rats





Opportunity in Short-Bowel Syndrome…

Short bowel syndrome (SBS) is typically the result of surgical removal of part of the small intestine as a result of a variety of disorders. SBS patients often suffer from malabsorption and may require intravenous nutrition. It is estimated that there are approximately 3k - 5k SBS patients in the U.S.

Gattex (teduglutide), marketed by NPS Pharma, is a GLP-2 analog that has orphan designation for SBS and was approved by FDA in late 2012. Gattex promotes intestinal absorption and is dosed once per day via subcutaneous injection. NPS has priced the therapy at approximately $295k per person per year. It is estimated that there are approximately 3k - 5k SBS patients in the U.S. As such the calculated potential market for Gattex is $1B+.

Gattex suffers from certain drawbacks however, such as being associated with nausea/vomiting, which may be a result of the rapid peak from the bolus injection which is characteristic of injected peptides. $TARGT_{GLP-2}$ could potentially eliminate or reduce peaks and troughs and potential related health risks associated with bolus injections.

FINANCIAL MODEL

Medgenics, Inc.

	2014 A	Q1A	Q2E	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Margin	-	-	-	-	-	-	-	-	-
SG&A	$10,686.0	$3,947.0	$3,103.0	$2,787.0	$2,901.0	$12,738.0	$12,801.0	$13,366.0	$13,080.0
% SG&A	-	-	-	-	-	-	-	-	-
R&D, net of grants	$8,253.0	$3,901.0	$5,414.0	$3,620.0	$3,724.0	$16,659.0	$12,077.0	$11,240.0	$10,805.0
% R&D	-	-	-	-	-	-	-	-	-
Operating Income	($18,939.0)	($7,848.0)	($8,517.0)	($6,407.0)	($6,625.0)	($29,397.0)	($24,878.0)	($24,606.0)	($23,885.0)
Operating Margin	-	-	-	-	-	-	-	-	
Financial expense, net	$518.0	($1,073.0)	$50.0	$40.0	$25.0	($958.0)	$47.0	$0.0	$0.0
Total Other Income (Expense)	$518.0	($1,073.0)	$50.0	$40.0	$25.0	($958.0)	$47.0	$0.0	$0.0
Pre-Tax Income	($18,421.0)	($8,921.0)	($8,467.0)	($6,367.0)	($6,600.0)	($30,355.0)	($24,831.0)	($24,606.0)	($23,885.0)
Tax expense (benefit)	$12.0	$1.0	$0.0	$0.0	$0.0	$1.0	$0.0	$0.0	$0.0
Tax Rate	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($18,433.0)	($8,922.0)	($8,467.0)	($6,367.0)	($6,600.0)	($30,356.0)	($24,831.0)	($24,606.0)	($23,885.0)
YOY Growth	*24.4%*	*-47.9%*	*58.2%*	*65.8%*	*117.2%*	*64.7%*	*-18.2%*	*-0.9%*	*-2.9%*
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($0.96)	($0.36)	($0.34)	($0.25)	($0.26)	($1.22)	($0.92)	($0.81)	($0.77)
YOY Growth	*-4.9%*	*36.8%*	*83.5%*	*30.9%*	*-4.0%*	*27.0%*	*-24.7%*	*-11.6%*	*-4.8%*
Diluted Shares O/S	19,247	24,844	24,910	25,000	25,080	24,958	27,110	30,400	31,000

Brian Marckx, CFA

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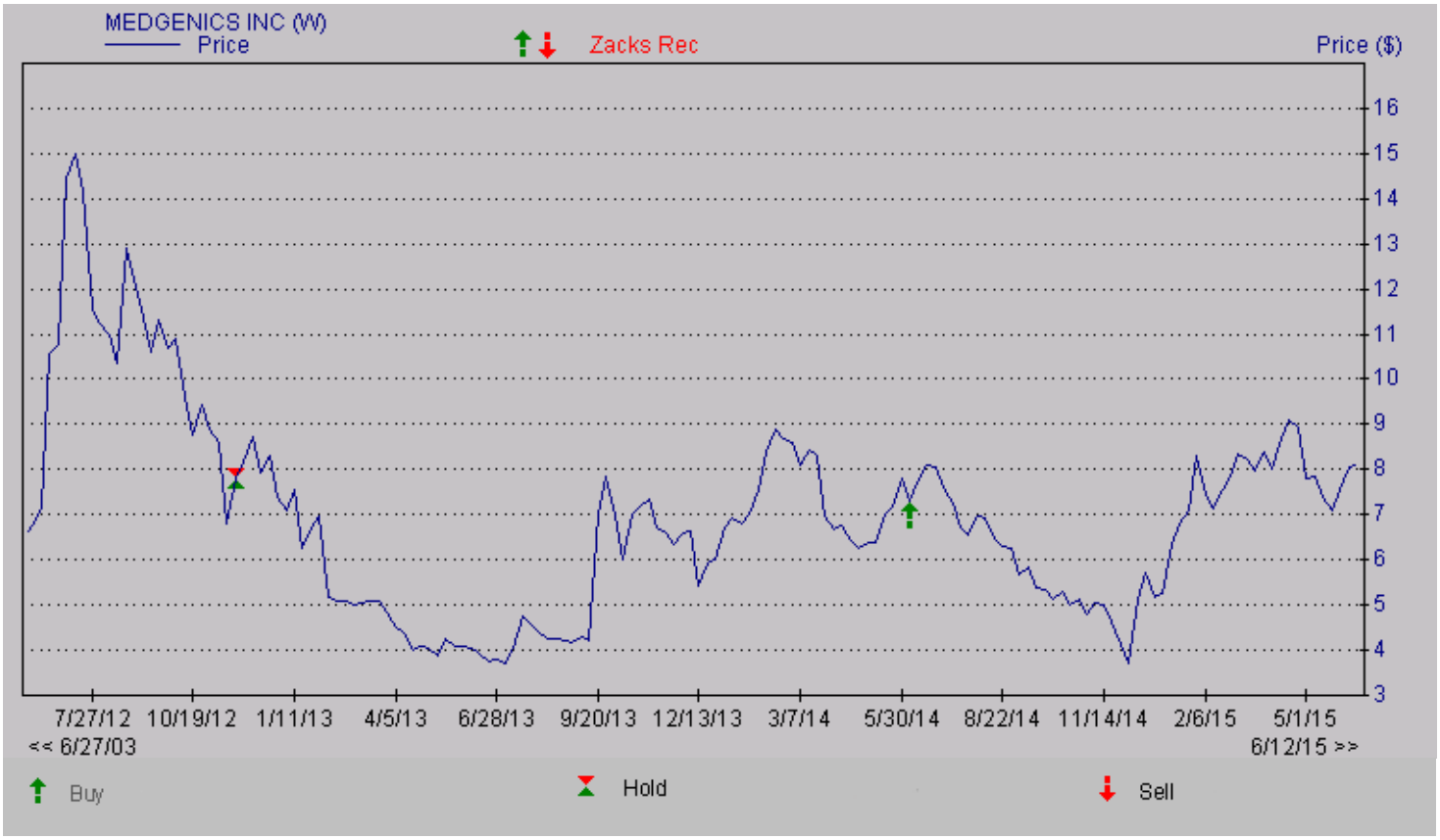
HISTORICAL ZACKS RECOMMENDATIONS



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