Zacks Small-Cap Research

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Medgenics Inc (MDGN-AMEX)

MDGN: Pipeline Update. Affirming Buy Recommendation

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/08/2014
Current Price (01/22/16)	$4.02
Target Price	**$11.00**

OUTLOOK

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.

Recent neuroFix acquisition brought high-potential NFC-1 candidate. Ph 1 data looks very encouraging. This could move rapidly through development and be the first commercialized product - could address both ADHD and orphan indications. Add'l positive data, expected in 2016, we think could be a needle-mover to the share price.

SUMMARY DATA

52-Week High	**$10.25**
52-Week Low	**$3.54**
One-Year Return (%)	**-43.73**
Beta	**0.20**
Average Daily Volume (sh)	**171,835**
Shares Outstanding (mil)	**33**
Market Capitalization ($mil)	**$132**
Short Interest Ratio (days)	**12.16**
Institutional Ownership (%)	**21**
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 2016 Estimate	**N/A**
P/E using 2017 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 A	0 A	0 A	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	-$0.24 A	-$0.66 A	-$0.25 E	-$1.48 E
2016					-$1.20 E
2017					-$1.11 E

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

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Pipeline Update: TARGT$_{EPO}$ Stable >18 mo's, Beta Thal Initiated, NFC-1 Data Expected Mid-2016…

MDGN continues to make substantive progress with moving its various pipeline programs along, including TARGT with their ongoing EPO dose-ranging study as well as a newly launched beta thalalassemia program. And earlier this month, through an agreement with Stanford University, they in-licensed rights to GeneRide technology for delivery of hematopoietic stem cells for sickle cell anemia and beta thalassemia.

And MDGN's NFC-1 programs, which could be fairly fast-moving, are now heading towards larger and later-stage trials. Data is expected in both ADHD and 22q11.2 Deletion Syndrome this year. ***We continue to believe that if data from the about-to-be initiated phase 2/3 ADHD study supports what was seen in phase I, that this could be a catalyst to MDGN's stock price.*** Top-line data is anticipated in the second half of this year.

- **TARGT$_{EPO}$:** latest reported data points were in late October. Low, mid dose and Peritoneal Dialysis cohorts are all fully enrolled. It was determined a high dose group was not needed. Safety has not been an issue with no treatment related serious adverse events reported. Results were presented at ASN in November
    - Nine of the thirteen patients maintained hgb in targeted range for at least five months
        - five of six patients in low dose
        - two of four in mid dose
        - two of three in PD cohort

MG-EP-RF-02 Low Dose HD 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	16	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	7	Returned to baseline; received rHuEPO.
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	5.6	Required rescue d/t pneumonia, exited study.

MG-EP-RF-02 Mid Dose HD 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	HTN, CHF, DM	16K	3	7	Ongoing; stable Hb
E401 (Patient 9)	66	M	4.6	HTN, DM, PVD	2K	5	5	Ongoing; phlebotomized 3 times d/t Hb above 13 and one TARGT excised
E104 (Patient 10)	35	F	0.5	HTN	5K	2	2	Ongoing; stable Hb

MG-EP-RF-03/04 Summary PD Patients Results Low Dose								
Subject #	Age	Gender	Dialysis (years)	Medical History	rHuEPO Run-in Dose (IU/wk)	# of TARGTs	Months Post Implant	Status
E102 (Patient 11)	62	F	0.8	HTN	6K	1	5	Returned to baseline; received rHuEPO.
E103 (Patient 12)	43	M	1.25	HTN	3K	2	5	Ongoing; Stable Hb
E801 (Patient 13)	48	M	1.75	DM, HTN	6K	2	2	Required rHuEPO rescue, exited study.
E802 (Patient 14)	44	M	3.25	DM, HTN	20K	N/A	N/A	Skin failure
E803 (Patient 15)	36	F	11	DM	6K	N/A	N/A	Screen failure

- next steps in EPO program will be initiating studies in orphan indications
  - beta thalalassemia program officially launched in December. Dr. Stefano Rivella, professor of pediatrics at CHOP, will the lead program. Dr. Stefano's background includes leading a team of researchers at Cornell University in development of a novel gene therapy targeted at beta thalalassemia and sickle cell anemia
  - beta thal program will investigate TARGT$_{EPO}$ alone or in combination with iron restriction to improve anemia, via improvement in erythropoiesis, and reduction in iron overload. Preclinical work has begun at CHOP which will begin to measure improvement in anemia, reduction in the need for blood transfusions and reduction or prevention of iron overload
  - Myelodysplatic syndrome (MDS) program is expected to be initiated in Israel. MGDN has been working towards securing regulatory approval in order to commence clinicals

- **NFC-1**
  - In September MDGN acquired neuroFix Therapeutics, LLC and its lead candidate NFC-1, a compound targeting CNS disorders associated with mutations of the metabotropic glutamate receptors (mGluRs). Initial investigated indications are ADHD and 22q11.2 Deletion Syndrome. See our Sept 11, 2015 report for more background on the acquisition and NFC-1 trial data to-date
  - ADHD:
    - Positive phase I data (NFC1-GREAT) in ADHD presented at AACAP meeting in October
    - Due to efficacy observed in phase I study, 20 of 30 patients chose to remain in long-term
    - Will conduct non-interventional study in order to;
      - Identify individuals with tier 1 and 2 mutations (i.e. – those most likely to respond to NFC-1 therapy). Will genotype 1k subjects. Results will be used to facilitate enrollment of phase 2/3 study
      - Confirm that 20%-30% of child ADHD is influenced by mGluR signaling
      - Initiate study sites that will be used in phase 2/3 study
    - Phase 2/3 ADHD study
      - Expected to initiate this year, with initial data in 2H
      - Primary efficacy endpoints will be ADHD RS (parent assessment) and CGI-I
      - We think the phase 2/3 data, assuming it supports what was seen in ph 1, could be catalyst for the stock price as this should provide much more insight into the potential of NFC-1 in both ADHD and 22q11.2.
  - 22q11.2 Deletion Syndrome:
    - Given the rarity of incidence and lack of any effective treatment, it's possible (assuming demonstrated NFC-1 effectiveness) this could be a quick-moving regulatory orphan candidate
    - Filed IND in Q4 2015 to initiate a phase 1/2 indication and dose finding study
    - This initial study is expected to parse out the first (of potentially other follow-on) indication - which MDGN noted could be related to ADHD, anxiety or mood disorders
    - Still shooting for initial read-out around mid-2016
    - If the phase 1/2 study results are positive, MDGN may be able to go straight to a pivotal, regulatory approval-supporting study

FINANCIAL MODEL

Medgenics, Inc.

	2014 A	Q1A	Q2A	Q3A	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	$3,889.0	$2,996.0	$3,857.0	$14,689.0	$14,981.0	$15,444.0	$15,925.0
% SG&A	-	-	-	-	-	-	-	-	-
R&D, net of grants	$8,253.0	$3,901.0	$3,028.0	$12,371.0	$3,989.0	$23,289.0	$25,242.0	$26,687.0	$24,661.0
% R&D	-	-	-	-	-	-	-	-	-
Operating Income	($18,939.0)	($7,848.0)	($6,917.0)	($15,367.0)	($7,846.0)	($37,978.0)	($40,223.0)	($42,131.0)	($40,586.0)
Operating Margin	-	-	-	-	-	-	-	-	
Financial expense, net	$518.0	($1,073.0)	$835.0	($1,148.0)	$25.0	($1,361.0)	$47.0	$0.0	$0.0
Total Other Income (Expense)	$518.0	($1,073.0)	$835.0	($1,148.0)	$25.0	($1,361.0)	$47.0	$0.0	$0.0
Pre-Tax Income	($18,421.0)	($8,921.0)	($6,082.0)	($16,515.0)	($7,821.0)	($39,339.0)	($40,176.0)	($42,131.0)	($40,586.0)
Tax expense (benefit)	$12.0	$1.0	$0.0	$6.0	$0.0	$7.0	$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)	($6,082.0)	($16,521.0)	($7,821.0)	($39,346.0)	($40,176.0)	($42,131.0)	($40,586.0)
YOY Growth	*24.4%*	*-47.9%*	*13.6%*	*330.2%*	*157.4%*	*113.5%*	*2.1%*	*4.9%*	*-3.7%*
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($0.96)	($0.36)	($0.24)	($0.66)	($0.25)	($1.48)	($1.20)	($1.11)	($0.97)
YOY Growth	*-4.9%*	*36.8%*	*24.2%*	*165.9%*	*-5.6%*	*54.6%*	*-19.0%*	*-7.6%*	*-12.4%*
Diluted Shares O/S	19,247	24,844	24,907	24,983	31,540	26,568	33,512	38,016	41,800

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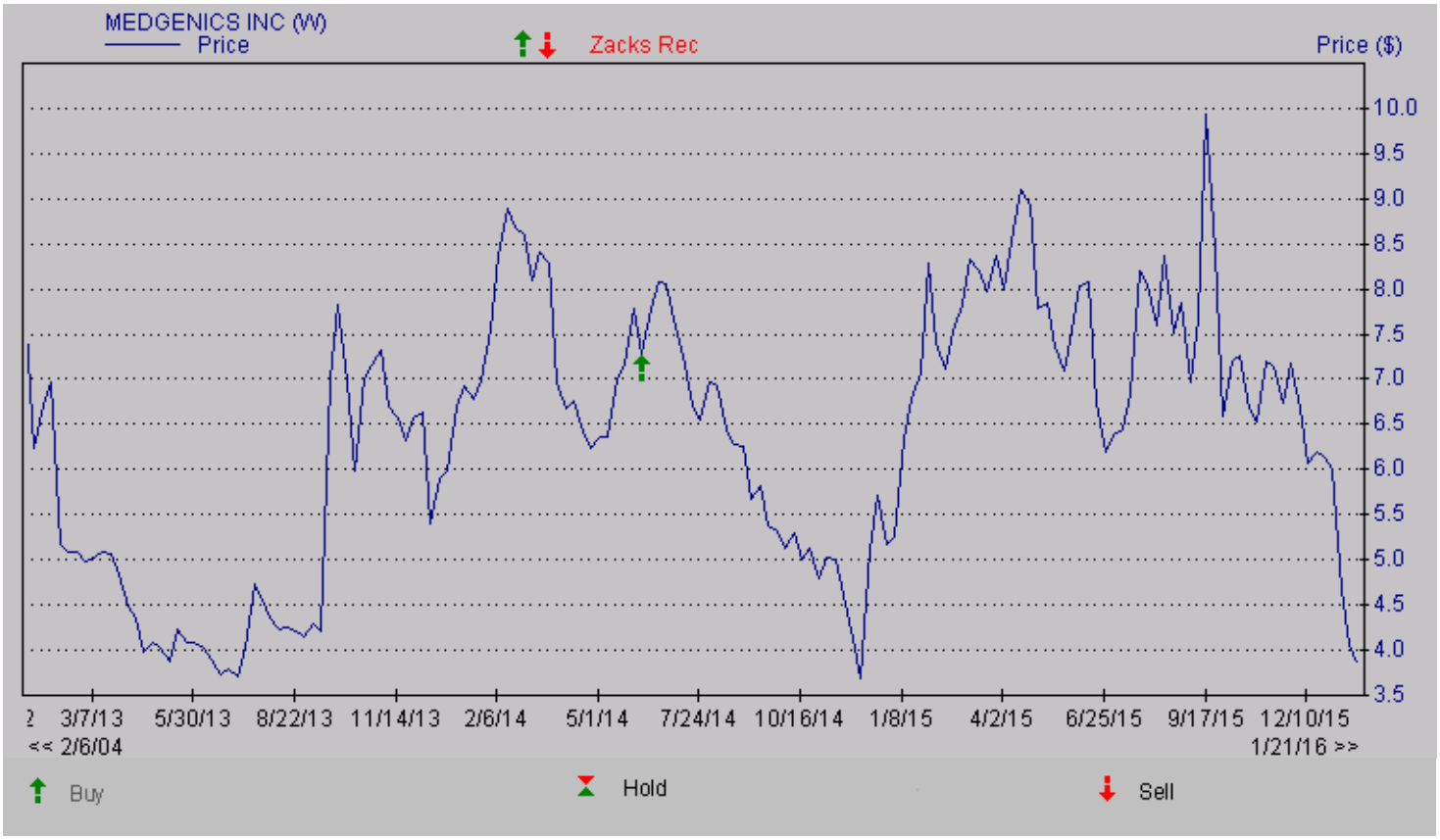

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