Medgenics, Inc. (MDGN)

First Program Emerges from CHOP Collaboration

MARKET OUTPERFORM | Price: $7.24 | Target Price: $15.00

MARKET DATA

Price	$7.24
52-Week Range:	$3.68 - $9.63
Shares Out. (M):	24.8
Market Cap ($M):	$179.6
Average Daily Vol. (000):	76.0
Cash (M):	$22
Cash/Share:	$1.01
Enterprise Value (M):	$224
Float (M):	20.5

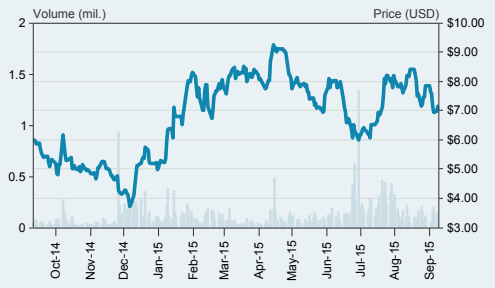
Source: Thomson Reuters and JMP Securities LLC

FY DEC		2014A	2015E	2016E
Revenue ($M)	1Q	$0.0	$0.0A	--
	2Q	$0.0	$0.0A	--
	3Q	$0.0	$0.0	--
	4Q	$0.0	$0.0	--
	FY	**$0.0**	**$0.0**	**$20.0**
EPS	1Q	($0.28)	($0.36)A	--
	2Q	($0.21)	($0.28)A	--
	3Q	($0.16)	($0.36)	--
	4Q	($0.30)	($0.32)	--
	FY	**($0.96)**	**($1.31)**	**($1.14)**
	P/E	NM	NM	NM

EPS: Diluted EPS

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



INVESTMENT HIGHLIGHTS

Medgenics announced that it will acquire neuroFix Therapeutics to integrate a Phase II ready asset (NFC-1) for a genetically defined subset of ADHD; reiterate our Market Outperform rating and $15 price target based on a DCF, sum-of-the-parts analysis, and comparable companies valuation methodology. neuroFix is a private company founded by Dr. Hakonarson, Director, Center for Applied Genomics (CAG) at The Children's Hospital of Philadelphia (CHOP). The acquisition was consummated with a $2M upfront payment, with the remainder being made up through milestone and royalty payments. This is the first program to emerge from MDGN's collaboration with CHOP and, in our opinion, it represents a real value add for MDGN. Work at CHOP led to the discovery that genetic alterations in the metabotropic glutamate receptor (mGluR) network could be linked to ADHD in approximately 20% of patients. Dr. Hakonarson then verified in a Phase I trial that treatment with an mGluR neuromodulator demonstrated signs of efficacy in this population. The acquisition of neuroFix gives MDGN access to both the mGluR agonist NFC-1 (which has been extensively clinically tested, but discontinued in another indication) and to the accompanying diagnostic assays that will be marketed with the therapeutic. The ADHD market commands over $10B in sales annually and with management's extensive experience at Shire, we think MDGN is well positioned to enter this space.

NFC-1 is a well validated clinical candidate. NFC-1 has been tested in over a thousand patients. According to management, it has strong pharmacokinetic and safety profiles, but was discontinued due to a lack of efficacy in vascular dementia, a condition unrelated to attention deficit hyperactivity disorder (ADHD). NFC-1 has been tested in a Phase I trial in pediatric patients with severe ADHD symptoms (Figure 2). NFC-1 demonstrated a strong efficacy signal by Clinical Global Impression of Improvement (CGI-I) and by Vanderbilt Parent Rating. While the study was not powered for statistical significance, a repeated measures analysis demonstrated statistically significant improvement in average CGI-I score ($p<0.001$) and Vanderbilt score ($p<0.001$) (Figure 2). When the patients were categorized in tiers based on how relevant their genetic mutations were to the mGluR network (Figure 3), those in the top two tiers appeared to respond more strongly (Figure 4), adding a measure of validation.

Genetically defined population opens a clear path to market. The ability to screen for the target population genetically provides a number of advantages. First, MDGN should be able to select the patients most likely to respond in its clinical trials. Second, payers are more willing to reimburse for expensive medications when the proper patient population can be identified. Third, for a disease like attention deficit hyperactivity disorder, for which there is a broad spectrum of symptoms and a great deal of popular misunderstanding, a genetic screen provides a clear and marketable target population.

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Fourth, 90% of patients with the 22q11.2 deletion syndrome are missing at least one member of the mGluR network. This deletion appears at a rate of approximately ¼,000 individuals, providing a clear orphan population to pursue for breakthrough designation. The Phase I trial with NFC-1 included two individuals with 22q11.2 syndrome and both families elected to continue in the safety extension trial. If the company receives orphan designation, it will also provide seven years of exclusivity to complement its diagnostics patent protection.

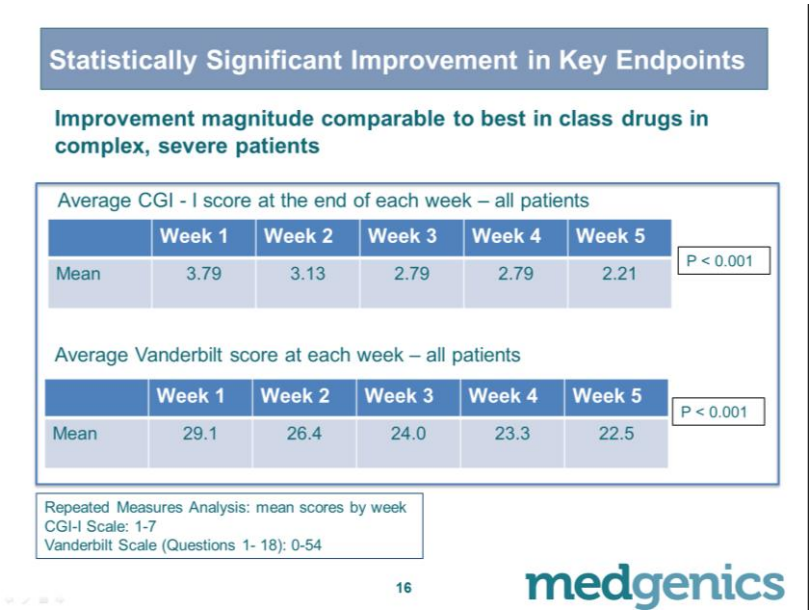
We remain buyers of MDGN shares at current levels. We retain a high level of conviction of the TARGT platform, supported by the initial results of the proof-of-concept trial with $TARGT_{EPO}$ and by the preclinical data from $TARGT_{GLP2}$. The acquisition of neuroFix Therapeutics represents a significant expansion of the clinical program and diversifies the risk for MDGN. As MDGN reports clinical meaningful data in 2015 and beyond, we see the potential for significant appreciation.

FIGURE 1. Upcoming Catalysts

Timing	Drug	Milestones
Oct 26-31	NFC-1	Phase I data in ADHD Patients
2Q15	$TARGT_{EPO}$ / MDGN-201	Initiate Phase II in MDS
1H15	$TARGT_{GLP2}$ / MDGN-205	Pre-IMPD meeting for GLP2
2H15	$TARGT_{EPO}$ / MDGN-201	Pre-IMPD meeting for beta-thalessemia intermedia
2H15	TARGT	Initiate preclinical studies: lead program from CHOP collaboration announcement
2015	$TARGT_{EPO}$ / MDGN-201	Data readouts from Phase I/II in ESRD anemia

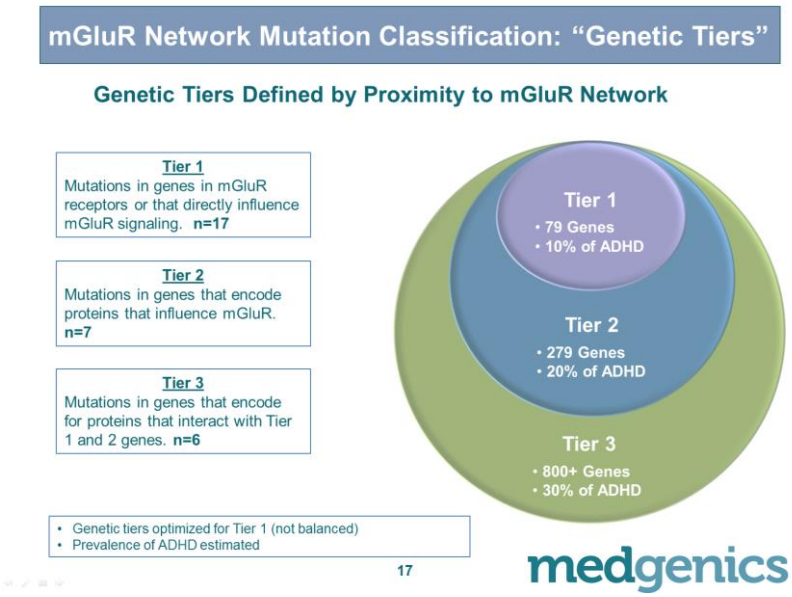
Source: JMP Securities LLC and Company Reports

FIGURE 2. NFC-1 Demonstrates Statistically Significant Improvement in Key Endpoints for Patients with ADHD and Genetically Defined Alterations in Members of the mGluR Network



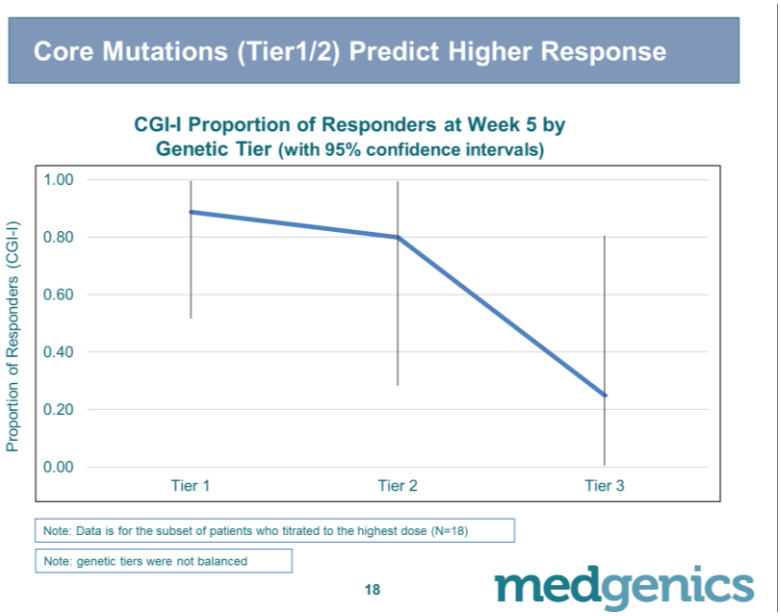
Source: Company Reports

FIGURE 3. Phase I Patients mGluR Tiers



Source: Company Report

FIGURE 4. Phase I Patient Response by Tier



Source: Company Report

FIGURE 5. Income Statement

Income Statement ($MM)	1Q15A	2Q15A	3Q15E	4Q15A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Product Sales and Royalties:															
MDGN-201 -US Sales					-	-	-	27.8	86.7	175.9	320.4	474.1	638.4	905.9	1,482.0
MDGN-201 - Ex-US Royalties					-	-	-	-	-	3.9	19.2	39.9	72.1	94.3	121.4
Total Product Sales and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	27.8	86.7	179.8	339.6	513.9	710.5	1,000.2	1,603.5
Collaborative Revenue					-	20.0	65.0	37.5	-	50.0	50.0	50.0	-	-	-
Total Revenue	0.0	0.0	0.0	0.0	0.0	20.0	65.0	65.3	86.7	229.8	389.6	563.9	710.5	1,000.2	1,603.5
Cost of Goods Sold								2.8	8.7	17.6	32.0	47.4	63.8	90.6	148.2
Gross Profit	0.0	0.0	0.0	0.0	0.0	20.0	65.0	62.5	78.1	212.2	357.5	516.5	646.7	909.6	1,455.3
Operating Expenses:															
Research and Development	3.9	4.458	4.7	4.9	18.0	35.9	52.1	63.8	75.3	86.6	98.7	111.5	124.9	137.4	144.2
General and Administrative	3.9	3.889	4.3	4.7	16.8	20.2	36.3	54.5	68.1	81.7	94.0	108.1	118.9	124.9	131.1
Total Operating Expenses	7.8	6.917	9.0	9.6	34.8	56.09	88.4	118.3	143.4	168.3	192.7	219.6	243.8	262.2	275.3
Operating income (loss)	(7.8)	(6.917)	(9.0)	(9.6)	(34.8)	(36.1)	(23.4)	(55.8)	(65.3)	43.9	164.8	296.9	402.9	647.4	1,179.9
Other income (expense):															
Financial expenses	(1.1)	(0.008)	(0.0)	(0.0)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Financial income	0.0	0.843	0.0	0.0	0.9										
Total other income, net	(1.1)	0.835	0.0	0.0	0.5	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Pretax income (loss)	(8.9)	(6.082)	(9.0)	(9.6)	(34.3)	(36.5)	(23.8)	(56.2)	(65.7)	43.5	164.4	296.5	402.5	647.0	1,179.5
Taxes on income		(0.004)													
Income tax benefit (Provision)	0.0		(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(8.2)	(74.1)	(140.9)	(226.4)	(412.8)
Comprehensive income (loss)	(8.9)	(6.086)	(9.0)	(9.6)	(34.3)	(36.5)	(23.8)	(56.2)	(65.7)	43.5	156.2	222.4	261.6	420.5	766.7
Basic EPS to common shareholders	$ (0.36)	$ (0.24)	$ (0.36)	$ (0.32)	$ (1.31)	$ (1.14)	$ (0.74)	$ (1.45)	$ (1.68)	$ 1.10	$ 3.91	$ 5.51	$ 6.41	$ 10.21	$ 18.43
Diluted EPS to common shareholders	$ (0.36)	$ (0.28)	$ (0.36)	$ (0.32)	$ (1.31)	$ (1.14)	$ (0.74)	$ (1.45)	$ (1.68)	$ 1.10	$ 3.90	$ 5.50	$ 6.41	$ 10.20	$ 18.42
Basic shares outstanding	24.8	24.9	25.2	29.9	26.2	32.0	32.3	38.8	39.2	39.6	40.0	40.4	40.8	41.2	41.6
Diluted shares outstanding	24.8	25.1	25.2	29.9	26.3	32.0	32.3	38.8	39.2	39.6	40.0	40.4	40.8	41.2	41.6

Source: JMP Securities LLC and Company Reports

Company Description

Medgenics, Inc. is a biotechnology company focused on the research and development of ex vivo gene therapies for orphan and rare disease therapeutic markets. The company's technology platform, TARGT, is designed to provide sustained protein and peptide therapy to treat a range of chronic diseases and conditions. The company's lead candidate, $TARGT_{EPO}$ (MDGN-201), is in a Phase I/II trial in end-stage renal disease (ESRD) patients with renal anemia, with the low-dose cohorts completed in 1Q15. The middle- and higher-dose enrollment and data are expected throughout 2015. Medgenics anticipates entering multiple small-sized trials with the same product candidate in several orphan indications within 2015, which include: anemic CKD transplant candidates, patients undergoing peritoneal dialysis with anemia, hypo-responders to recombinant EPO, MDS patients, and patients with beta-thalassemia intermedia. Medgenics plans to launch $TARGT_{EPO}$ in 2018.

Investment Risks

Like any biotechnology company, MDGN is subject to a range of risks related to the challenges associated with drug discovery and development.

Clinical. Drug development is an inherently risky enterprise, and MDGN could experience clinical trial failures for one or more of its programs. MDGN's TARGT platform (and all future drug candidates derived from it) may fail to demonstrate meaningful enough levels of efficacy in current or future clinical trials, or may show adverse safety issues following long-term exposure or with broader use. Given the novel nature of the therapy, MDGN may fail to recruit adequate patient numbers for clinical trials. A clinical setback could have a larger than normal effect on MDGN shares, as investors may lose faith in the underlying technology, in addition to the specific program at issue.

Regulatory and commercial. The ability of MDGN or its future partners to market its treatments depends upon the approval of the therapies from the FDA and foreign regulatory agencies. Failure to achieve approval or delays within the expected timelines could negatively impact the company's share price. MDGN may fail to scale up the TARGT-derived therapeutics. The TARGT system is a novel platform that may not be commercially viable, or may not achieve adequate patient adoption and market acceptance.

Competitive. Erythropoietin (EPO) products represent a very competitive field and with $TARGT_{EPO}$ therapy (the company's first and most advanced product), MDGN faces heavy competition from companies with development-stage drug candidates addressing the same biologic mechanisms, and from companies attempting to broaden the applicable indications for products already approved for use. Some of these companies may possess substantially greater R&D and commercial resources than MDGN or its future partners. As such, there is no assurance that MDGN will be competitive.

Intellectual property and licensing risk. The ability of MDGN to compete depends on the company's ability to maintain and enforce the intellectual property (IP) rights directed to the TARGT platform. MDGN currently has 55 issued patents and 43 allowed and pending patent applications. In addition to MDGN's core technology, the larger gene therapy space is still relatively immature. Thus far, no gene therapy treatments have reached clinical approval in the U.S. and only one (UniQure's Glybera) has reached approval in the EU. While we view MDGN's IP position as enabling the company to have freedom to operate, the IP landscape in the gene therapy space carries risk and uncertainty that could have a negative impact on investor enthusiasm for MDGN shares.

Financial. Following a public offering in 2014, Medgenics ended 4Q14 with $33.29MM in cash and cash equivalents – adequate resources to fund operations into 3Q16, according to company guidance. In the event that a partner cannot be secured (to bring in cash in exchange for licenses to MDGN IP or for rights to product candidates), we anticipate the company may need to seek additional equity financing via the capital markets, creating dilutive risk for existing shareholders.

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JMP Securities expects to receive OR intends to seek compensation for investment banking services from Medgenics, Inc. in the next 3 months.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.
Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.
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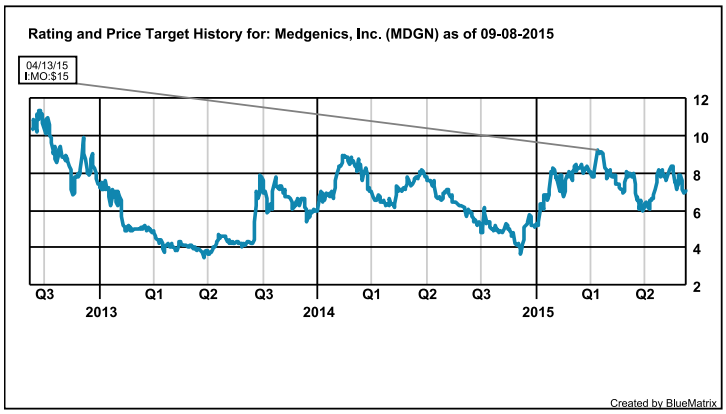
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	295	*62.90%*	Buy	295	*62.90%*	86	*29.15%*
MARKET PERFORM	Hold	147	*31.34%*	Hold	147	*31.34%*	16	*10.88%*
MARKET UNDERPERFORM	Sell	6	*1.28%*	Sell	6	*1.28%*	0	*0%*
COVERAGE IN TRANSITION		21	*4.48%*		21	*4.48%*	4	*19.05%*
TOTAL:		469	*100%*		469	*100%*	106	*22.60%*

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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