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Medgenics, Inc. (MDGN)

Overweight

Acquires Phase II Ready CNS Drug to Broaden Orphan Pipeline; Reiterate OW

CONCLUSION

Today Medgenics acquired neuroFix for NFC-1, a non-stimulant small-molecule neuromodulator of the metabotopic glutamate receptor (mGluR). The acquisition is the first target to come out of the UPenn CHoP alliance and signals a broadening of the company's Precision Medicine focus. Medgenics plans to develop NFC-1 in the orphan indication 22q11.2 Deletion Syndrome, as well as mGluR+ ADHD. Medgenics will file an IND in 4Q:15 for a Phase I/II study in 22q11.2 patients with data in mid-2016, and intends to initiate a Phase II/III trial in mGluR+ ADHD patients with top-line data in 2H:16. Medgenics paid \$2 million cash upfront, bringing estimated cash to \$20 million. We reiterate our Overweight rating and \$15 price target.

- Acquires neuroFix. NFC-1 is the first candidate to be identified from Medgenics' CHoP genetics discovery alliance. NFC-1 is an oral, non-stimulating small molecule modulator of mGluR. Research at CHoP's Center for Applied Genomics (CAG) identified mutations in the mGluR network in ~20% of ADHD patients and 90% of 22q11.2 deletion patients, an orphan indication with more severe disease manifestation including neurocognition. Medgenics will pay only \$2 million upfront and owe milestones and single-digit royalties. Importantly, this acquisition represents a broadening of Medgenics' precision medicine focus and we expect additional discoveries to come out of the CHoP alliance.
- NFC-1 Development Path. NFC-1 previously failed in vascular dementia; however, the drug was dosed in >1,000 patients showing a clean safety profile and twice-daily (BID) dosing. neuroFix ran a Phase Ib trial in 30 ADHD children demonstrating dose and duration-dependent symptom improvement with data to be presented at the American Academy of Child and Adolescent Psychiatry (AACAP) meeting in October. The cohort included two 22.q11.2 patients (one deletion, one duplication) that saw marked symptom improvement. Medgenics will file an IND in 4Q:15 for a Phase I/II dose ranging study in 22q11.2 patients with data in mid-2016. The company will also initiate a Phase II/III trial in mGluR+ ADHD patients with top-line data in 2H:16. We expect Medgenics to develop a companion diagnostic to target ADHD patients.
- TARGT Platform Still Important. The NFC-1 opportunity is an add-on to Medgenics' TARGT ex vivo gene therapy platform. Medgenics is running Phase II trials of TARGT-EPO in peritoneal dialysis, the first of several orphan ESRD populations. MDGN has selected Glucagon-like peptide-2 (GLP-2) as a 2nd development candidate for short bowel syndrome, where Gattex is highly efficacious but creates unwanted toxicity due to short half-life. MDGN plans to enter the clinic in Israel this year.

RISKS TO ACHIEVEMENT OF PRICE TARGET

TARGT is novel technology. Products may fail in the clinic or to gain approval. Medgenics may not sign partnerships and are likely to require additional capital.

COMPANY DESCRIPTION

Medgenics is developing TARGT technology to treat orphan diseases.

REVENUE (US\$ m) **EARNINGS PER SHARE (US\$)** Mar Jun Sep FY RM Mar Jun FY P/E 2014A 81.ox (0.28)(0.21) (0.16)(0.96)NM 0.0 1.2 0.3 2.2 (0.30)2015E NM 0.3 2.5 71.3X (0.36)A(0.24)A(0.33)(0.36)(1.29)2016E 2.5 (0.38)0.3 71.3X (0.37)(0.34)(0.43)(1.51)

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PRICE: US\$7.10 TARGET: US\$15.00

Proj. EV of \$467M less mid'16E net debt + warrants

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Changes	Previous	Current
Rating	_	Overweight
Price Tgt	_	US\$15.00
FY15E Rev (mil)	_	US\$2.5
FY16E Rev (mil)	_	US\$2.5
FY15E EPS	_	US\$(1.29)
FY16E EPS	_	US\$(1.51)
52-Week High / Low	US\$9	.63 / US\$3.68
Shares Out (mil)		25.1
Diluted shares out	t as of 2Q:15	
Market Cap. (mil)		US\$178.2
Avg Daily Vol (000)		205

Avg Daily Vol (000) 205
Book Value/Share US\$0.84
Net Cash Per Share US\$0.80
2Q:15 cash less \$2M neuroFix upfront

Debt to Total Capital 0.0%
Div (ann) US\$0.00
Fiscal Year End Dec



Source: Bloomberg

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INVESTMENT RECOMMENDATION

We reiterate our Overweight rating and \$15 price target based on a projected enterprise value of \$467 million, up from \$382 million, as we roll forward our discount period to mid'16. Today we are adding \$100 million for NFC-1, which should begin Phase II studies in 22q11.2 Deletion Syndrome and ADHD patients soon.

We now value MDGN-201 in various ESRD populations including hyporesponsive ESRD patients, peritoneal dialysis, CKD transplant candidates, MDS and Beta thalassemia at \$367 million, down slightly from \$383 million, with the same 60% discount rate now through mid-'16E.

From this we now subtract out mid'16E net debt of \$16 million including today's \$2 million upfront for neuroFix. Previously we added YE:15E cash of \$1 million. Today we also add \$28 million in cash from the exercise of 4.96 million warrants at an average exercise price of \$5.62. (Source: Form 10Q as of June 30, 2015) Including these warrants, we now divide our projected market cap of \$479 million by 30.96 million diluted shares to support our \$15 price target.

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Medgenics Quarterly Earnings Estimates

(\$ in thousands except per share)

8/10/2015			(\$ Ir	n thousands ex	(cept per snare)										
G 15/2010	<u>1QA</u>	2QA	3QA	4QA	2014A	<u>1QA</u>	2QA	3QE	4QE	2015E	1QE	2QE	3QE	4QE	2016E
Revenues:															
Participation by Office of Chief Scientist	\$0	\$1,182	\$716	\$339	\$2,237	\$0	\$1,430	\$750	\$300	\$2,480	\$0	\$1,500	\$750	\$250	\$2,500
Product Sales	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total Revenues	\$0	\$1,182	\$716	\$339	\$2,237	\$0	\$1,430	\$750	\$300	\$2,480	\$0	\$1,500	\$750	\$250	\$2,500
Operating Expenses:															
Research and Development	2,142	1,955	2,281	4,112	10,490	3,901	4,458	5,000	5,500	18,859	5,500	6,000	6,500	7,000	25,000
General and Administrative	3,093	2,864	2,305	2,424	10,686	3,947	3,889	4,000	4,000	<u>15,836</u>	4,000	4,250	4,250	4,500	<u>17,000</u>
Total Operating Expenses	\$5,235	\$4,819	\$4,586	\$6,536	\$21,176	\$7,848	\$8,347	\$9,000	\$9,500	\$34,695	\$9,500	\$10,250	\$10,750	\$11,500	\$42,000
Operating Income/(Loss)	(\$5,235)	(\$3,637)	(\$3,870)	(\$6,197)	(\$18,939)	(\$7,848)	(\$6,917)	(\$8,250)	(\$9,200)	(\$32,215)	(\$9,500)	(\$8,750)	(\$10,000)	(\$11,250)	(\$39,500)
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Financials Expenses	(120)	(217)	(64)	333	(68)	(1,078)	(8)	0	0	(1,086)	0	0	0	0	0
Finanacial Incomes	3	15	896	(328)	586	5	843	10	5	863	0	(5)	(10)	(15)	(30)
Foreign currency exchange (loss) gain	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PreTax Income/(Loss)	(\$5,352)	(\$3,839)	(\$3,038)	(\$6,192)	(\$18,421)	(\$8,921)	(\$6,082)	(\$8,240)	(\$9,195)	(\$32,438)	(\$9,500)	(\$8,755)	(\$10,010)	(\$11,265)	(\$39,530)
Pretex Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Income Tax Benefit (Expense)	(5)	(1)	(2)	(4)	(12)	(1)	(4)	0	0	(5)	0	0	0	0	0
Tax Rate	NM	NM	NM	0.0%	-0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income/(Loss)	(\$5,357)	(\$3,840)	(\$3,040)	(\$6,196)	(\$18,433)	(\$8,922)	(\$6,086)	(\$8,240)	(\$9,195)	(\$32,443)	(\$9,500)	(\$8,755)	(\$10,010)	(\$11,265)	(\$39,530)
Net Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net Income/(Loss) per Share (Basic)	(\$0.28)	(\$0.21)	(\$0.16)	(\$0.30)	(\$0.96)	(\$0.36)	(\$0.24)	(\$0.33)	(\$0.36)	(\$1.29)	(\$0.37)	(\$0.34)	(\$0.38)	(\$0.43)	(\$1.51)
Basic Shares Outstanding	18,872	18,716	18,818	20,821	19,247	24,844	24,907	25,250	25,500	25,125	25,750	26,000	26,250	26,500	26,125
Source: Company reports and Piper Jaffray e	estimates														

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I: Initiating Coverage

R: Resuming Coverage

T: Transferring Coverage

D: Discontinuing Coverage

S: Suspending Coverage

OW: Overweight

N: Neutral

UW: Underweight NA: Not Available UR: Under Review

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			IB Serv.	/Past 12 Mos.				
Rating	Count	Percent	Count	Percent				
BUY [OW]	433	60.81	106	24.48				
HOLD [N]	262	36.80	11	4.20				
SELL [UW]	17	2.39	0	0.00				

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