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Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: Highly Encouraging Preliminary Results from Phase 2b Trial in rGBM…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55 and MDNA109, MDNA.T is valued at CAD$5.00/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (06/19/19)	CAD$1.70
Valuation	**CAD$5.00**

INITIATION

On June 18, 2019, Medicenna Therapeutics Corp. (T.MDNA) announced the presentation of preliminary topline results from the company's ongoing Phase 2b clinical trial of MDNA55 in patients with recurrent glioblastoma (GBM). The preliminary results showed that treatment with MDNA55 resulted in an 83% disease control rate for all patients, including those treated with low-dose and high-dose MDNA55. In the low-dose cohort, 9/10 patients who were positive for IL-4 expression had their tumors either not increase in size or decrease from the nadir, while in the high-dose cohort 18/23 patients experienced a decrease in tumor volume from the nadir regardless of IL-4 expression. We anticipate survival data for the full cohort of patients to be available toward the end of 2019. Based on the encouraging data we have increased our valuation to CAD$5.00 per share.

SUMMARY DATA

52-Week High	**$2.38**
52-Week Low	**$0.64**
One-Year Return (%)	**37.84**
Beta	**1.54**
Average Daily Volume (sh)	**38,410**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

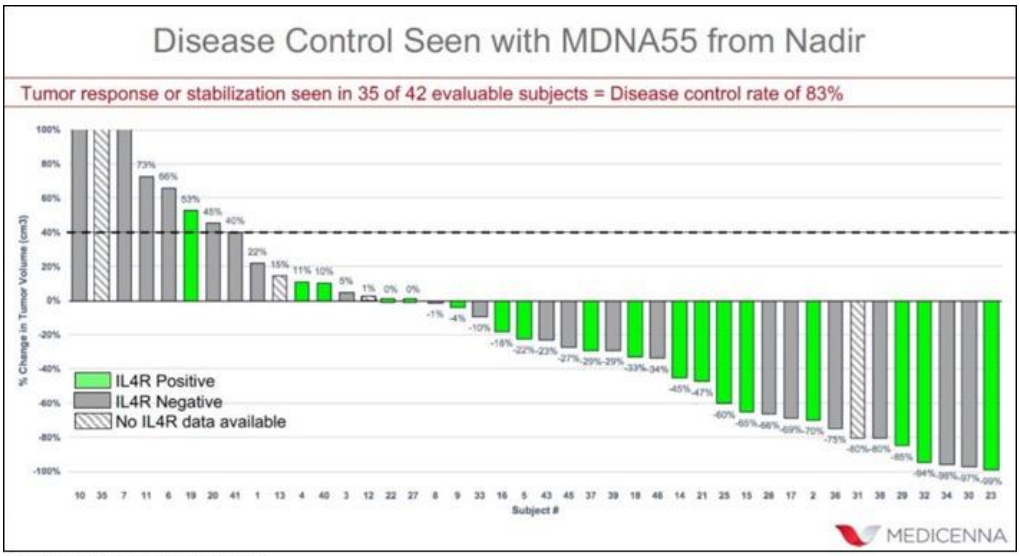
	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2018	-$0.09 A	- $0.07 A	-$0.09 A	-$0.05 A	-$0.30 A
2019	-$0.04 A	-$0.04 A	-$0.07 A	-$0.08 E	-$0.22 E
2020					-$0.21 E
2021					-$0.20 E

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WHAT'S NEW

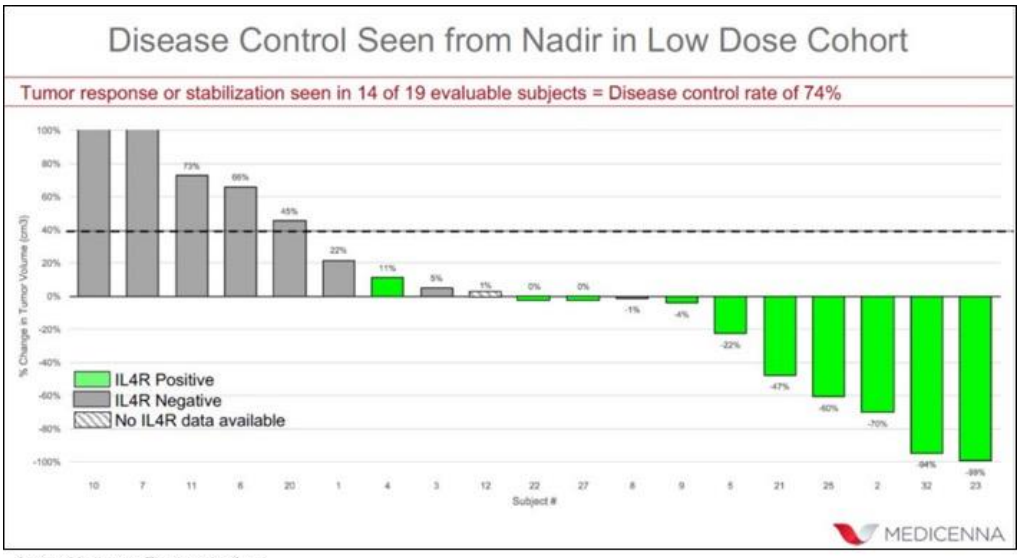
Business Update

On June 18, 2019, Medicenna Therapeutics Corp. (MDNA) announced the presentation of preliminary topline results from the company's ongoing Phase 2b trial of MDNA55, an IL-4R targeted toxin, in patients with recurrent glioblastoma (rGBM). The trial is not far enough along to report data on the primary outcome of the trial, which is overall survival, however Medicenna did present data on the percent change in tumor volume for each patient in the study. To account for the phenomenon of pseudoprogression, in which a treated tumor appears to be growing on subsequent scans following treatment (Van Mieghem *et al*., 2013), assessment as a response from nadir (the largest tumor volume measured) was presented using the criteria for immunotherapy Response Assessment in Neuro-Oncology (iRANO) (Okada *et al*., 2015). The following plot shows that 35/42 evaluable patients experienced either stabilization or a decrease in tumor size from nadir for a disease control rate (DCR) of 83%.



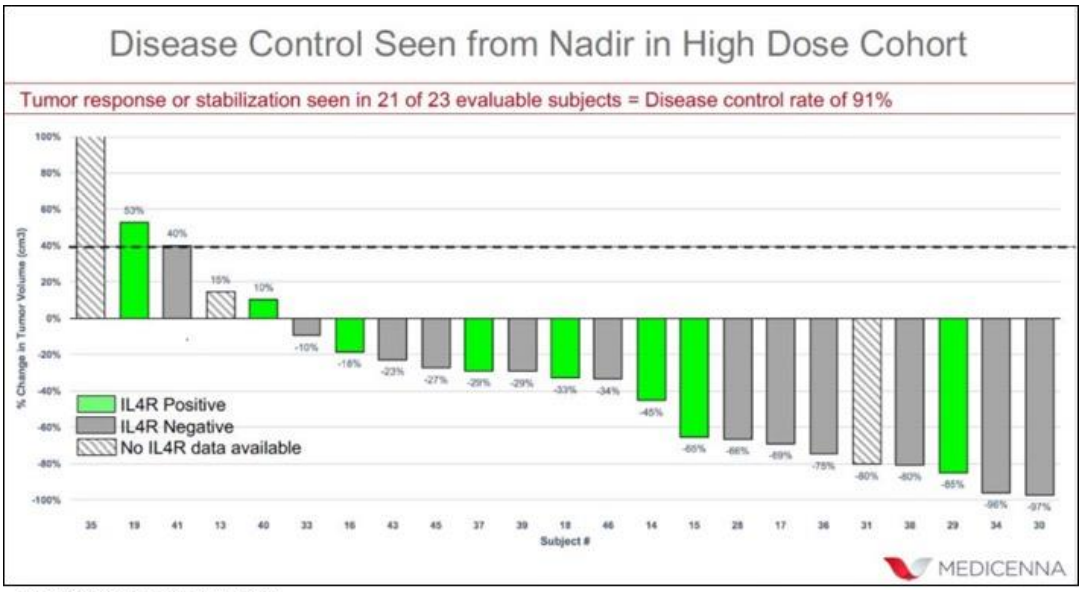
Source: Medicenna Therapeutics Corp.

When the patient population is subdivided into the low-dose and high-dose cohorts an interesting dose response is evident. The following chart shows disease control for patients in the low-dose cohort (median dose of 63 μg), in which a decrease in tumor size is essentially limited to only those with high IL-4R expression.



Source: Medicenna Therapeutics Corp.

This is in contrast to the high-dose group, where a decrease in tumor volume is seen equally in those with both high and low IL-4R expression.

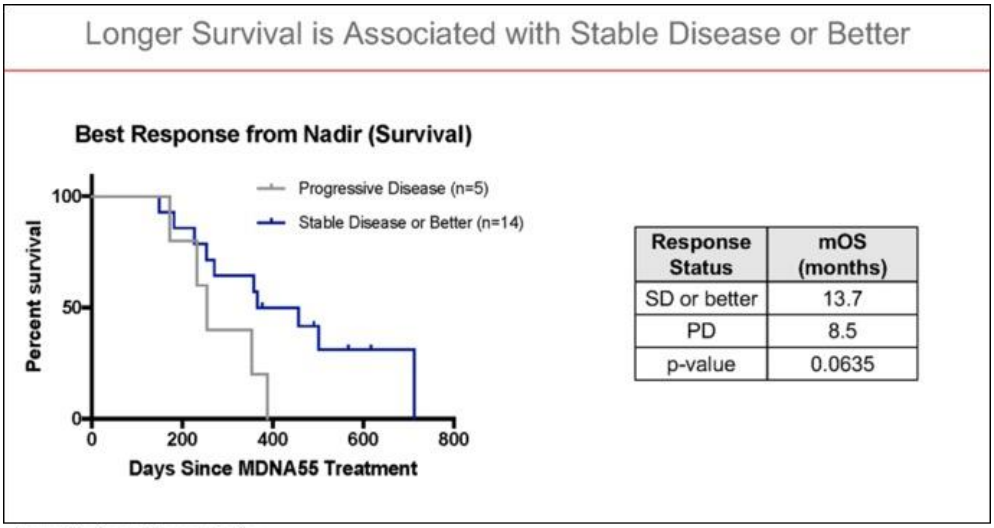


Source: Medicenna Therapeutics Corp.

While we are uncertain about what exactly is driving the phenomenon of tumor response in patients with low IL-4R expression, we believe there are at least two possibilities (which may not be mutually exclusive):

1) The amount of MDNA55 in the low-dose cohort may only be enough to trigger a response in patients who express a high level of IL-4R, while the high-dose cohort may be receiving enough drug that even tumors with low level expression of IL-4R respond.
2) IL-4R is expressed on myeloid derived suppressor cells (MDSCs), which dampen the immune system's response to tumors. Thus, MDNA55 may be depleting the MDSC population and allowing an immunological response to the tumor.

Regardless of the mechanism, we believe the data shown thus far by Medicenna is clearly indicative of a dose response in patients treated with MDNA55 and the tumor regressions seen are highly encouraging in this patient population. We anticipate survival data for the entire cohort of patients to be available toward the end of 2019, however the following chart does show that for the low-dose cohort, experiencing stable disease or better is a good prognosticator for an improvement in overall survival. Thus, with a disease control rate of 91% for the high-dose cohort, we are looking forward to seeing if that will translate to an improvement in overall survival beyond the six to nine months that is expected for patients with rGBM.



Source: Medicenna Therapeutics Corp.

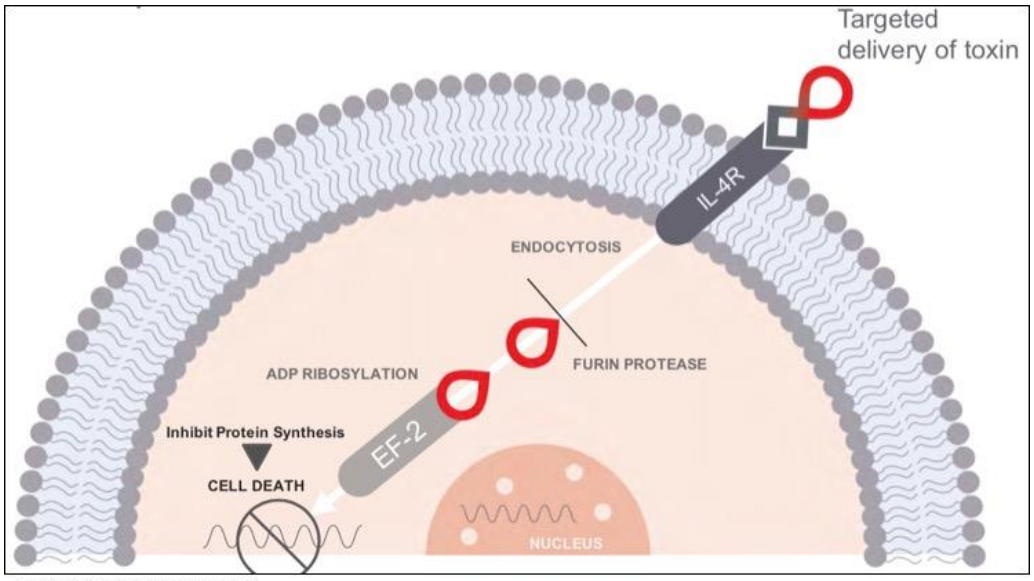
MDNA55

MDNA55 is Medicenna's lead development candidate currently in a Phase 2b clinical trial for the treatment of rGBM. The compound consists of a fusion protein containing a circularly permuted version of IL-4 linked to a fragment of the potent bacterial toxin *Pseudomonas* Exotoxin A (PE). A cartoon representation of the compound is shown in the following figure.



Source: Medicenna Therapeutics Corp.

The mechanism of action for MDNA55 is depicted in the following figure. The entire complex is endocytosed following its binding to the IL-4R. The PE domain is then cleaved from the IL-4 domain through proteolytic cleavage by furin-like proteases. Once liberated in the cytoplasm, PE ADP-ribosylates the eukaryotic elongation factor-2 (eEF-2) on ribosomes (Iglewski *et al*., 1977). This inactivates eEF-2 and effectively shuts down protein biosynthesis in the cell, which leads to apoptosis and cell death. The PE domain in MDNA55 is identical to the PE domain of Lumoxiti™ (Astra Zeneca), which was recently approved by the FDA for the treatment of adult patients with relapsed hairy cell leukemia.



Source: Medicenna Therapeutics Corp.

Phase 2b Clinical Trial

The MDNA55-05 Phase 2b clinical trial enrolled a total of 46 rGBM patients experiencing their first or second relapse (NCT02858895). It is a multi-center, open label, single arm study with the primary endpoint of median overall survival (mOS) and a secondary endpoint of objective response rate (ORR) following a single intra-tumoral infusion of MDNA55 in adult rGBM subjects.

The following table gives a comparison between the overall survival data seen thus far for MDNA55 for the low-dose cohort and prior clinical trials of approved rGBM therapies. MDNA55 treatment, irrespective of IL-4R expression, results in superior median overall survival (mOS = 11.8 months) as well as OS at six, nine, and 12 months when compared to Avastin®, lomustine, and TMZ.

Monotherapy	Population (n)	Survival			
		mOS (mos.)	OS-6	OS-9	OS-12
MDNA55-05 Low Dose (median 63 µg)	rGBM (n=21)	11.8	81%	60%	45%
Avastin[1]	rGBM (n=85)	9.2	NA	NA	NA
Avastin[2]	rGBM (n=50)	8.0	62%	38%	26%
Lomustine[2]	rGBM (n=46)	8.0	65%	43%	30%
Temozolomide[3]	rGBM (n=31)	5.6	NA	NA	NA
Temozolomide[4]	rGBM (n= 792)	NA	65%	NA	36.4%
MDNA55-05 High Dose Cohort (median 180 µg)	*Enrolment completed; currently collecting survival data*				

1 Friedman et al., Bevacizumab Alone and in Combination With Irinotecan in Recurrent Glioblastoma. J Clin Oncol. 2009 Oct 1;27(28):4733-40.
2 Taal et al, Single-agent bevacizumab or lomustine versus a combination of bevacizumab plus lomustine in patients with recurrent glioblastoma (BELOB trial): a randomised controlled phase 2 trial. Lancet Oncol 2014 Aug;15(9):943-53
3 Kim et al., Outcome of salvage treatment for recurrent glioblastoma. J Clin Neuroscience 22 (2015) 468–473, 2015.
4 Chen et al., The efficacy of temozolomide for recurrent glioblastoma multiforme (Meta-analysis). Eur J Neurol. 2013 Feb; 20(2):223-30.

MEDICENNA

Source: Medicenna Therapeutics Corp.

Conclusion

We are very encouraged by the preliminary data shown thus far for the Phase 2b trial of MDNA55 in rGBM patients. We believe there is a clear dose response and the very high DCR is also highly encouraging, particularly in a patient population that is not expected to live for more than 9 months on average. If the DCR reported thus far translates into a positive effect on survival in the high-dose cohort as well, we believe MDNA55 could go onto become a superior treatment option for patients with rGBM.

We anticipate the company meeting with the FDA in the second half of 2019 in order to determine if there is a path forward for accelerated approval, however at this point we continue to assume that a Phase 3 trial will be required. Based on the positive preliminary data of the Phase 2b trial we have increased the probability of approval for MDNA55 along with increasing the potential market share. Our new valuation is CAD$5.00 per share.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2018 A	Q1 FY19 A	Q2 FY19 A	Q3 FY19 A	Q4 FY19 E	FY 2019 E	FY 2020 E	FY 2021 E
MDNA55	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MDNA109	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Other Income	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$5.1	$0.6	$0.4	$1.3	$0.3	$2.7	$3.3	$3.8
General & Administrative	$2.3	$0.4	$0.4	$0.4	$1.6	$2.9	$3.0	$3.1
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($7.4)	($1.0)	($0.9)	($1.7)	($1.9)	($5.6)	($6.3)	($6.9)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.0)	($0.0)	$0.0	($0.0)	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($7.47)	($1.0)	($0.9)	($1.7)	($1.9)	($5.6)	($6.3)	($6.9)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Cumulative translation adjustment	-$0.1	$0.0	$0.0	$0.1	$0.0	$0.1	$0.0	$0.0
Net Income	**($7.5)**	**($1.0)**	**($0.9)**	**($1.7)**	**($1.9)**	**($5.5)**	**($6.3)**	**($6.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.31)**	**($0.04)**	**($0.04)**	**($0.07)**	**($0.08)**	**($0.22)**	**($0.21)**	**($0.20)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	24.6	24.6	24.6	25.0	25.0	24.8	30.0	35.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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