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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: Data on IL-4R as a Biomarker in Recurrent GBM Presented at ASCO; Phase 2b Data to be Presented This Month…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55 and MDNA109, MDNA.T is valued at $3.50/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 (06/04/19)	$0.95
Valuation	**$3.50**

INITIATION

On June 3, 2019, Medicenna Therapeutics Corp. (T.MDNA) announced data presented on the use of the interleukin (IL)-4 receptor as a biomarker in patients with recurrent glioblastoma (rGBM). The data was derived from the ongoing Phase 2b clinical trial of MDNA55 in which 18 of 21 subjects enrolled in the low dose cohort had IL-4R results. 75% (6/8) of subjects with moderate to high IL-4R showed disease control following one dose of MDNA55 compared to only 25% (2/8) of subjects with no or low IL-4R. IL-4R-positive patients at initial diagnosis had a shorter time to relapse (10.5 months) compared to subjects who were IL-4R-negative (18.1 months). Despite this, survival was significantly longer in the IL-4R-positive cohort (mOS = 15.2 months) compared to IL4R-negative patients (8.1 months) following one treatment of MDNA55.

We anticipate topline results from the Phase 2b trial of MDNA55 in patients with recurrent GBM to be presented at a scientific conference later this month.

SUMMARY DATA

52-Week High	**$2.30**
52-Week Low	**$0.64**
One-Year Return (%)	**-44.00**
Beta	**1.78**
Average Daily Volume (sh)	**22,570**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$27**
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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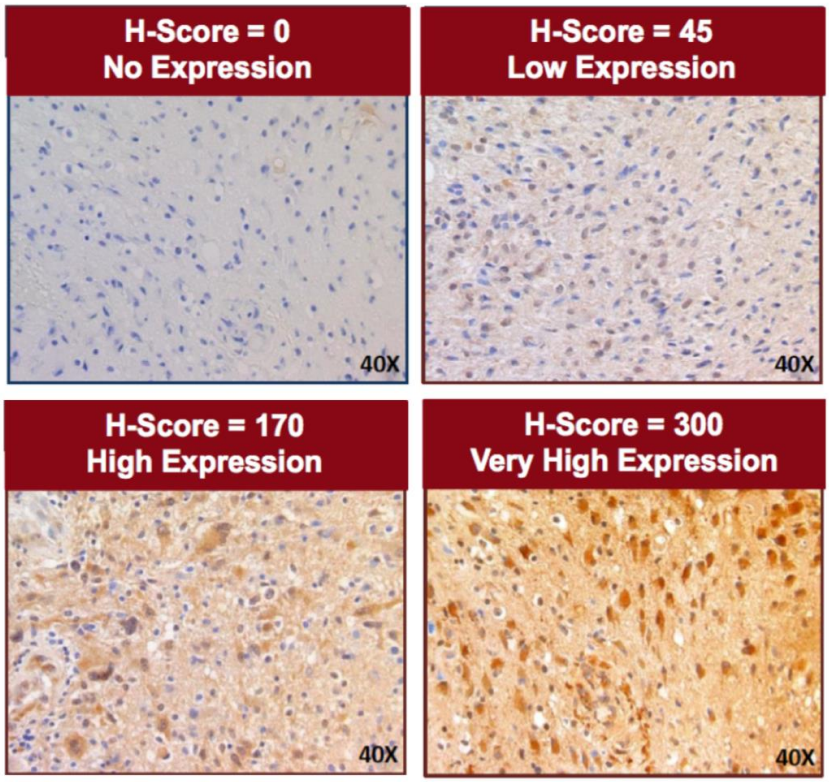
WHAT'S NEW

Business Update

Medicenna Therapeutics Corp. (MDNA.T) is a clinical stage immunotherapy company developing novel versions of the cytokines Interleukin (IL)-2, IL-4, and IL-13, which they term 'Superkines'. The Superkines can be utilized as monotherapies, used in combination with other immune modulating agents (e.g., checkpoint inhibitor antibodies), or fused with toxic agents to generate 'Empowered Cytokines' (EC) that precisely deliver cell-killing moieties to tumors. The company's lead EC is MDNA55, which has completed enrolment in a Phase 2b clinical trial for the treatment of recurrent glioblastoma (rGBM), the most common and deadly form of brain cancer. In addition, the company has a rich pipeline of pre-clinical assets, including its lead Superkine MDNA109, an enhanced version of IL-2.

IL-4R as a Biomarker in Recurrent GBM

On June 3, 2019, Medicenna announced the presentation of a poster at the American Society of Clinical Oncology (ASCO) 2019 meeting that reported on the use of the IL-4 receptor (IL-4R) as a biomarker in patients with rGBM. The analysis was performed using data from the low dose cohort in the ongoing Phase 2b clinical trial of MDNA55 in patients with rGBM. IL-4R levels were assessed quantitatively at the first diagnosis of GBM using an IL-4R immunohistochemistry (IHC)-based assay on archived tissue samples. Examples of no expression, low expression, high expression, and very high expression of IL-4R are shown below.



Source: Randazzo *et al.*, 2019

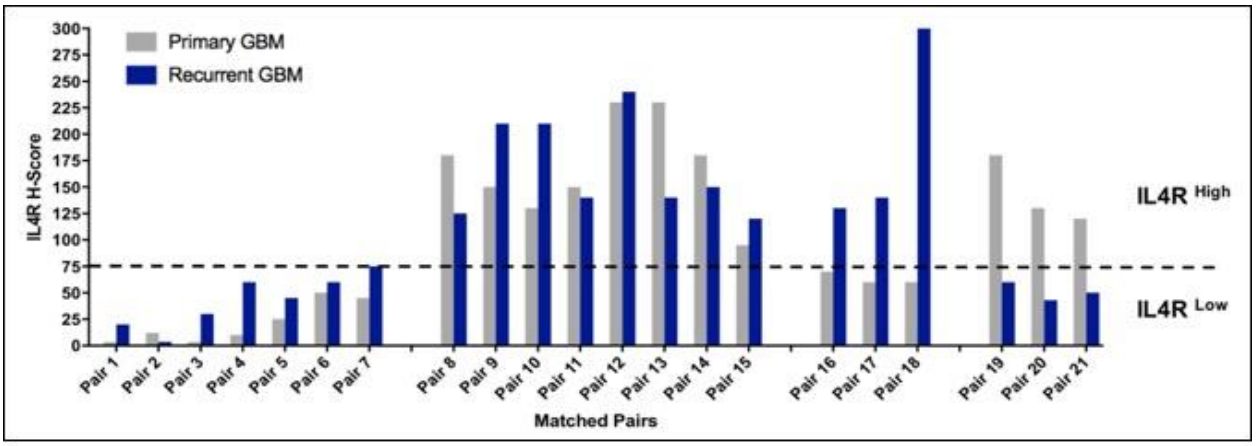
A score was then established based on the level of IL-4R expression by summing the percentage of tumor cells with intensity of expression multiplied by their corresponding intensity on a four-point semi-quantitative scale. This resulted in an 'H-Score' that ranged from 0-300, with IL-4R expression > 75 classified as 'High' and an H-Score ≤ 75 classified as 'Low'.

H-Score (range 0 – 300)	
0 - 75	No to low expression
76 - 150	Moderate expression
151 - 225	High expression
226 - 300	Very high expression

Source: Randazzo *et al.*, 2019

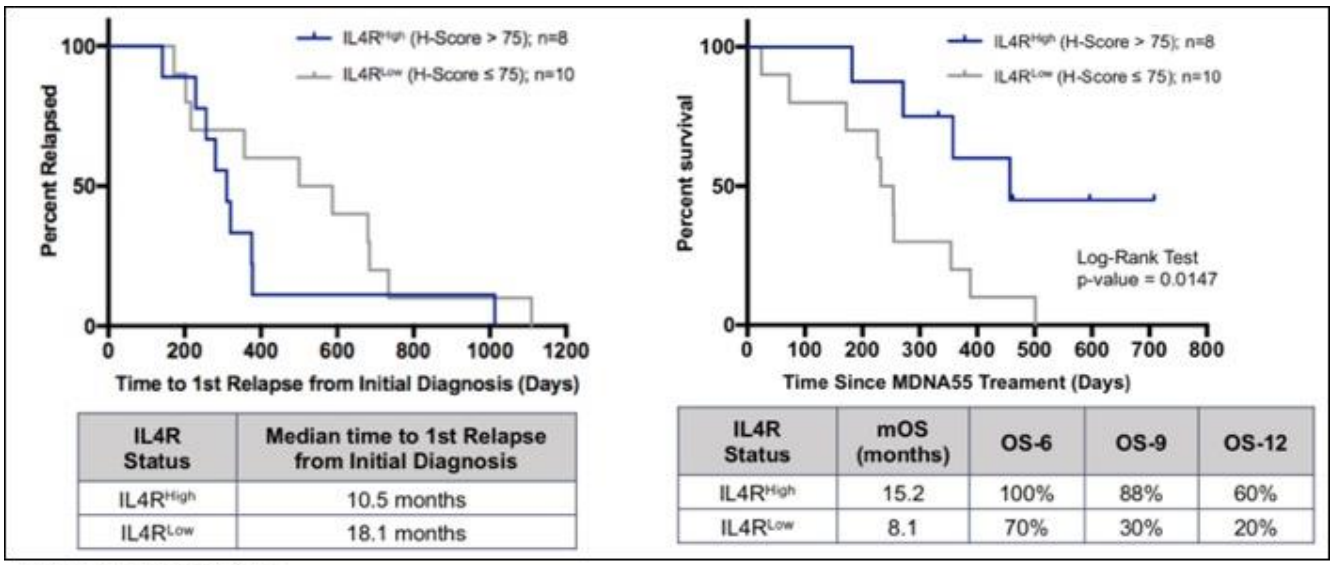
IL4R Status	
IL4R High	H-Score > 75
IL4R Low	H-Score ≤ 75

The company had 21 matched paired GBM biopsy samples taken from the initial diagnosis and at recurrence from the same patient. The following graph shows that 18/21 (86%) patients had similar or increased IL-4R expression at recurrence.



Source: Randazzo *et al.*, 2019

To examine the relevance of IL-4R as a biomarker, analyses were performed to determine any relationship between IL-4R expression and study outcomes. 18/21 patients enrolled in the first part of the MDNA55 Phase 2b trial were analyzed, with eight patients being classified as IL-4R^{High} and 10 patients classified as IL-4R^{Low}. The following graphs show that IL-4R^{High} expression is associated with a faster time to relapse (lower left), thus supporting the notion that IL-4R may represent a key biomarker in identifying aggressive forms of GBM. In addition, IL-4R^{High} expression is associated with a longer survival following one treatment with MDNA55 (lower right), with a median overall survival (mOS) of 15.2 months in IL-4R^{High} patients compared to 8.1 months in IL-4R^{Low} patients. Survival rates for IL-4R^{High} and IL-4R^{Low} were 100%, 88%, and 60% compared to 70%, 30%, and 20%, respectively.



IL4R Status	Median time to 1st Relapse from Initial Diagnosis
IL4R^{High}	10.5 months
IL4R^{Low}	18.1 months

IL4R Status	mOS (months)	OS-6	OS-9	OS-12
IL4R^{High}	15.2	100%	88%	60%
IL4R^{Low}	8.1	70%	30%	20%

Source: Randazzo *et al.*, 2019

Lastly, an analysis of best responses from nadir based on volumetric tumor measurements for patients in the IL-4R^{High} and IL-4R^{Low} groups showed that 8/8 (100%) IL-4R^{High} patients experienced stable disease or better compared to only 3/8 (38%) IL-4R^{Low} patients (2 patients in the IL-4R^{Low} cohort were not evaluable for best response). In addition, when examining best responses from baseline the IL-4R^{High} cohort also showed a higher rate of tumor control, with 6/8 (75%) IL-4R^{High} patients exhibiting stable disease or better compared to only 2/8 (25%) IL-4R^{Low} patients.

Best Response from Nadir per mRANO*	**IL4R^{High}**	**IL4R^{Low}**
Stable disease or better	8 of 8 (100%)	3 of 8 (38%)
Progressive disease	0 of 0 (0%)	5 of 8 (62%)
Best Response from Baseline per mRANO*	**IL4R^{High}**	**IL4R^{Low}**
Stable disease or better	6 of 8 (75%)	2 of 8 (25%)**
Progressive disease	2 of 8 (25%)	6 of 8 (75%)**

*Preliminary response assessments based on volumetric tumor measurements.
**Only 8 of 10 subjects in the IL4R^{Low} group is evaluable for best response.

Source: Randazzo *et al*., 2019

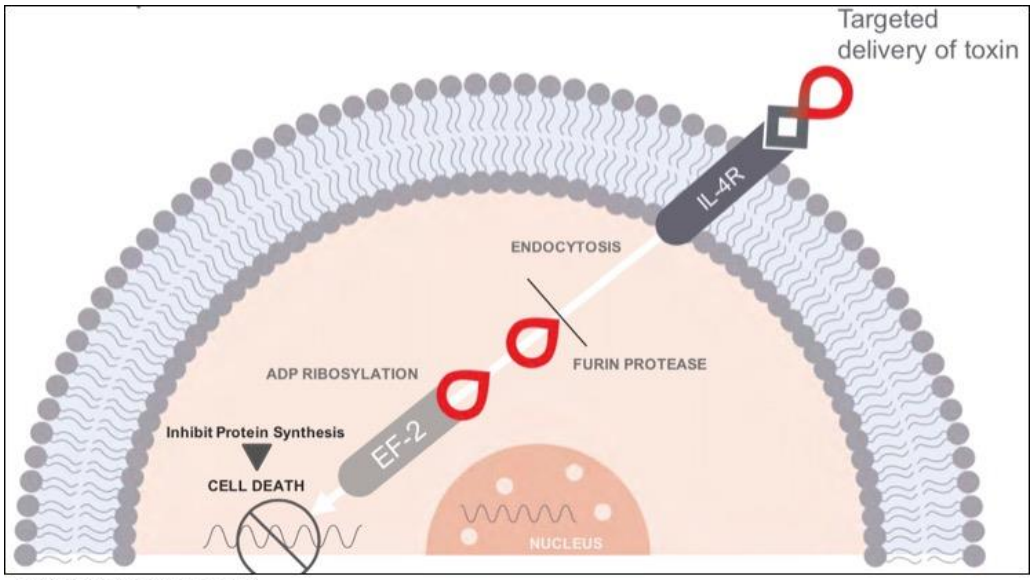
MDNA55

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

Medicenna has completed enrollment in the MDNA55-05 Phase 2b clinical trial in 46 rGBM patients experiencing their first or second relapse (NCT02858895). In this multi-center, open label, single arm study the primary endpoint is median overall survival (mOS) and objective response rate (ORR) is the secondary endpoint following a single intra-tumoral infusion of MDNA55 in adult rGBM subjects. In February 2019, the company reported positive interim data in a podium presentation at the 5th Annual Immuno-Oncology 360 Conference.

The following table gives a comparison between the data seen thus far for MDNA55 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 Cohorts*	rGBM (n=27)	11.8	89%	59%	46%
Avastin[1]	rGBM (n=50)	8.0	62%	38%	26%
Lomustine[1]	rGBM (n=46)	8.0	65%	43%	30%
Temozolomide[2]	rGBM (n=31)	5.6	NA	NA	NA
Temozolomide[3]	rGBM (n= 792)	NA	65%	NA	36.4%
MDNA55-05 High Dose Cohorts	*Currently enrolling*				

Source: Sampson *et al.*, 2019

We anticipate topline data for all 46 patients in the Phase 2b trial to be presented at a scientific conference in June 2019.

Conclusion

The data presented by Medicenna at ASCO 2019 are very encouraging, and support the use of IL-4R as a predictive biomarker for determining aggressive forms of GBM along with those patients that are more likely to respond to IL-4R targeted treatments such as MDNA55. We look forward to the topline data from the Phase 2b clinical trial of MDNA55 being presented at a scientific conference later this month. Heading into the data release our valuation stands at $3.50.

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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