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September 30, 2019
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Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: Increased Overall Survival in rGBM Patients Seen with High Dose MDNA55…

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 (09/30/19)	CAD$1.51
Valuation	**CAD$5.00**

OUTLOOK

On September 25, 2019, Medicenna Therapeutics Corp. (T.MDNA) presented updated clinical results from the ongoing Phase 2b trial of MDNA55, an IL4-guided toxin, in patients with recurrent glioblastoma (rGBM). The company had previously presented overall survival (OS) data for the 21 patients in the low-dose cohort, and there are now 12 patients from the high-dose cohort with mature survival data. The low-dose cohort had a median OS of 11.8 months while the first 12 patients from the high-dose cohort had a median OS of 16.7 months. Both of those results compare quite favorably to OS results seen from currently available treatments such as Avastin®, lomustine, or temozolomide, which have median OS of 8-9 months. We anticipate additional OS data from the majority of the rest of the patients in the high-dose cohort before the end of 2019, after which the company will hold an 'end-of-Phase 2' meeting with the FDA.

SUMMARY DATA

52-Week High	**$2.38**
52-Week Low	**$0.64**
One-Year Return (%)	**24.22**
Beta	**2.86**
Average Daily Volume (sh)	**31,910**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$44**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2019	-$0.04 A	- $0.04 A	-$0.07 A	-$0.04 A	-$0.18 A
2020	-$0.05 A	-$0.04 E	-$0.04 E	-$0.04 E	-$0.17 E
2021					-$0.15 E
2022					-$0.14 E

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WHAT'S NEW

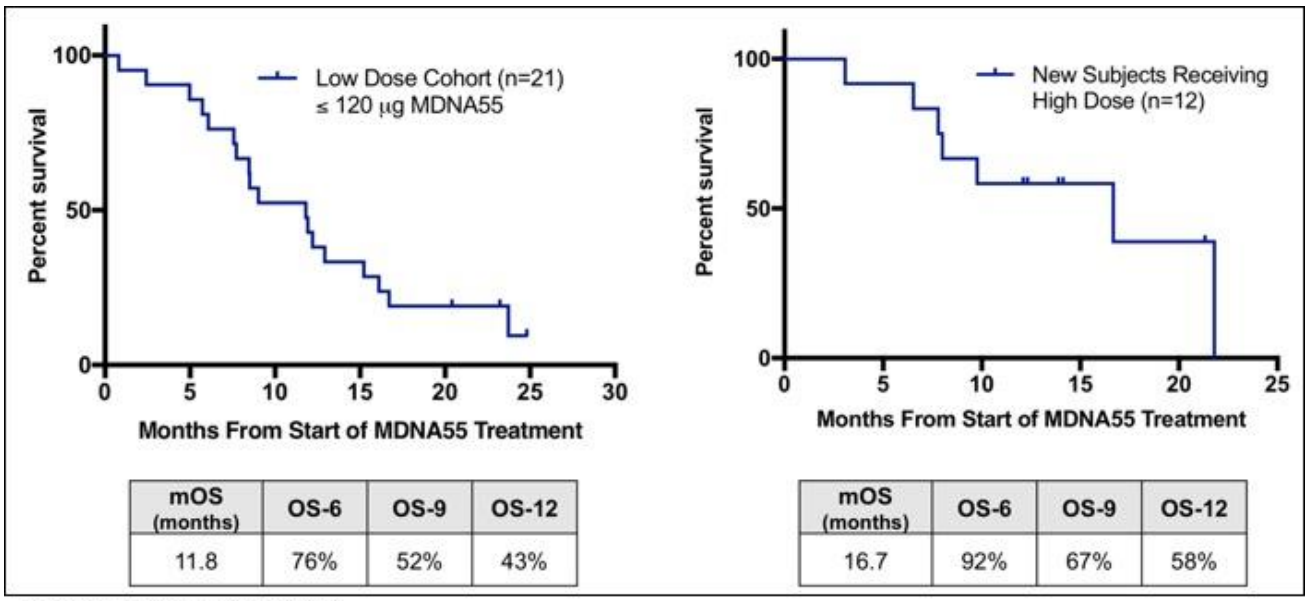
Business Update

Updated Data from Phase 2b Trial Presented at Targeting Innate Immunity Congress

On September 25, 2019, Medicenna Therapeutics Corp. (MDNA) announced the presentation of updated clinical data from the ongoing Phase 2b trial of MDNA55, an IL-4 targeted toxin, in patients with recurrent glioblastoma (rGBM). The Phase 2b clinical trial enrolled a total of 46 rGBM patients experiencing their first or second GBM 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 company had previously announced preliminary topline results for the 21 patients enrolled in the 'low-dose' cohort, in which patients received a median of 63 μg of MDNA55, with a mOS of 11.8 months. In addition, patients in the low-dose cohort experienced a disease control rate of 74%, with 14/19 patients having their tumors stabilize or decrease in size when compared to nadir (the largest tumor volume measured). Assessment of tumor response from nadir was utilized using the criteria for immunotherapy Response Assessment in Neuro-Oncology (iRANO) (Okada *et al*., 2015) 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).

The updated results show that the 12 evaluable patients in the 'high-dose' group had a mOS of 16.7 months. In addition, the percentage of patients alive at six, nine, and 12 months was increased compared to the low-dose cohort, as shown in the following figure.

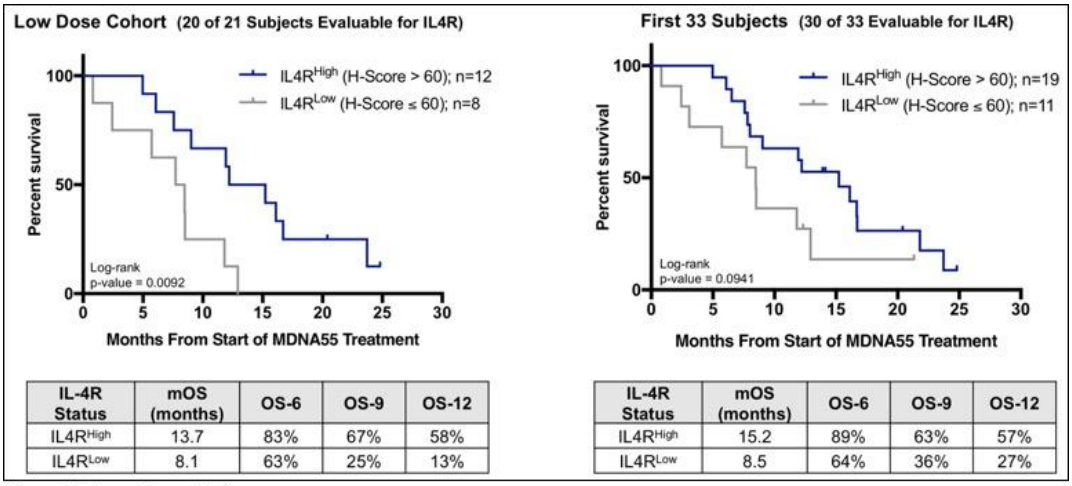


mOS (months)	OS-6	OS-9	OS-12
11.8	76%	52%	43%

mOS (months)	OS-6	OS-9	OS-12
16.7	92%	67%	58%

Source: Medicenna Therapeutics Corp.

A difference in mOS is also seen when examining survival as a function of IL-4R status. For both the low-dose cohort and the combined low-dose and high-dose evaluable patients, IL-4R^{High} patients (defined as an 'H-Score' > 60 based on immunohistochemistry analysis of IL-4R expression) showed both increased mOS as well as increased survival at six, nine, and 12 months. One other note about the data is that approximately 60% of the rGBM patients seen in this study were classified as 'IL-4R^{High}', which while lower than what the literature would suggest is still a significant potential market opportunity.

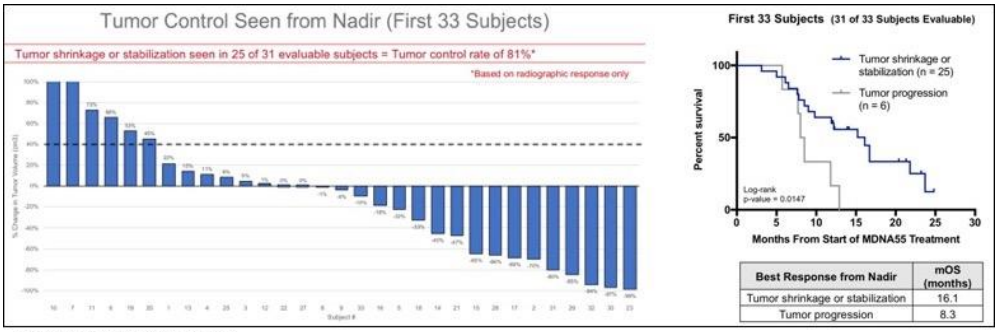


IL-4R Status	mOS (months)	OS-6	OS-9	OS-12
IL4R^{High}	13.7	83%	67%	58%
IL4R^{Low}	8.1	63%	25%	13%

IL-4R Status	mOS (months)	OS-6	OS-9	OS-12
IL4R^{High}	15.2	89%	63%	57%
IL4R^{Low}	8.5	64%	36%	27%

Source: Medicenna Therapeutics Corp.

Medicenna also reported on tumor control data for the 31 evaluable patients for which there was also OS data. The following figure shows that 25 of 31 (81%) patients saw either stabilization of the tumor or a decrease in tumor size when compared to nadir. There was also an association seen between tumor control and mOS, with those experiencing either tumor shrinkage or stabilization having a mOS of 16.1 months compared to those who saw tumor progression having a mOS of 8.3 months.



Best Response from Nadir	mOS (months)
Tumor shrinkage or stabilization	16.1
Tumor progression	8.3

Source: Medicenna Therapeutics Corp.

The mOS data seen thus far is highly encouraging, particularly in comparison to mOS data seen in trials of other rGBM treatments including Avastin®, lomustine, and temozolomide. The following charts show the mOS results seen from previous clinical trials with those agents, which averaged approximately 8-9 months. This compares to the mOS of 11.9 months seen for the first 33 subjects evaluated in the Phase 2b trial of MDNA55, including a mOS of 16.7 months for the first 12 patients evaluated in the high-dose cohort.

Approved Therapies	rGBM Population (n)	mOS (months)
Avastin[1]	n=85	9.2
Avastin[2]	n=50	8.0
Lomustine[2]	n=46	8.0
Lomustine[3]	n=149	8.6
Temozolomide[4]	n=31	5.6
Temozolomide[5]	n=138	5.4

1 Friedman et al., J Clin Oncol. 2009 Oct 1;27(28):4733-40.
2 Taal et al., Lancet Oncol 2014 Aug;15(9):943-53.
3 Wick et al., N Engl J Med. 2017 Nov 16;377(20):1954-1963.
4 Kim et al., J Clin Neuroscience 22 (2015) 468–473, 2015.
5 Brada et al., Ann Oncol. 2001;12(2):259–266.

MDNA55 Patient Groups	rGBM Population (n)	mOS (months)
Low Dose Cohort	n=21	11.8
High Dose Cohort	n=12 (of 25 at high dose)	16.7
First 33 subjects	n=33	11.9
IL4R^{High} - Low Dose Cohort	n=12 (of 20 evaluable)	13.7
IL4R^{High} - First 33 subjects	n=19 (of 30 evaluable)	15.2
Tumor control* - Low Dose Cohort	n=14 (of 19 evaluable)	13.7
Tumor control* - First 33 subjects	n=25 (of 31 evaluable)	16.1

Source: Medicenna Therapeutics Corp.

Lastly, we believe the results seen thus far with MDNA55 are all the more impressive when considering the patient population included in the trial, particularly when compared to results seen recently from other clinical trials involving rGBM patients conducted by Ziopharm Oncology (ZIOP) and Tocagen Inc. (TOCA). Ziopharm reported mOS of 12.7 months in a study of a transcriptionally regulated human interleukin-12 gene (Chiocca *et al*., 2019) while Tocagen reported mOS of 11.1 months for a virally delivered cytosine deaminase gene with 5-fluorocytosine (those results were not statistically significant from standard of care). While the mOS numbers look similar to those reported by Medicenna, important differences in inclusion criteria for the Ziopharm and Tocagen studies show that those trials used a more heterogeneous patient population with characteristics known to associate with increased survival.

Medicenna employed strict inclusion criteria for the Phase 2b trial of MDNA55 that included:

1) patients could not be eligible for resection at the time of recurrence
2) patients had to have GBM at recurrence
3) patients needed to have GBM at the initial diagnosis (those with lower grade gliomas were not eligible)
4) patients could not have IDH1 or IDH2 mutations.

Those inclusion criteria are in contrast to the inclusion criteria for the studies conducted by Ziopharm and Tocagen, which included:

1) patients eligible for resection
2) patients with high-grade glioma at recurrence (including GBM and Grade 3 anaplastic astrocytoma)
3) patients originally diagnosed with lower grade glioma but had recurrence with higher grade glioma
4) patients could have IDH1 and/or IDH2 mutations

Surgical resection (Bloch *et al*., 2012), Grade 3 gliomas (Dong *et al*., 2015) and IDH1/IDH2 mutations (Zou *et al*., 2013) are all known to be associated with increased survival in GBM patients compared to those with no surgical resection, Grade 4 gliomas, and no IDH1/IDH2 mutations. Thus, the patient population in the Phase 2b trial of MDNA55 was comprised of patients with worse prognoses than the overall patient populations in the Ziopharm and Tocagen trials. We believe these factors are important to understand and help to differentiate MDNA55 from other GBM therapies currently under development while highlighting what we believe to be impressive results in a very difficult to treat patient population.

We anticipate additional mOS data from the majority of the remaining patients from the high-dose cohort before the end of 2019. The company then anticipates conducting an 'end-of-Phase 2' meeting with the FDA to determine the regulatory path forward for MDNA55 and whether the opportunity exists for accelerated approval.

Conclusion

The updated clinical results from the MDNA55 Phase 2b trial further strengthen our belief that the drug could have a significant impact on the treatment of rGBM patients. The mOS of 16.7 months for the first 12 evaluable patients from the high-dose cohort is approximately two times the current standard of care, and we are eager to see if those results are confirmed for the remainder of the patients in that cohort. We are maintaining our valuation of CAD$5.00 per share.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2019 A	Q1 FY20 A	Q2 FY20 E	Q3 FY20 E	Q4 FY20 E	FY 2020 E	FY 2021 E	FY 2022 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	$3.0	$0.8	$0.9	$1.0	$1.1	$3.8	$4.0	$4.1
General & Administrative	$1.7	$0.5	$0.4	$0.4	$0.4	$1.7	$2.0	$2.2
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($4.7)	($1.3)	($1.3)	($1.4)	($1.5)	($5.6)	($6.0)	($6.3)
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	($4.7)	($1.3)	($1.3)	($1.4)	($1.5)	($5.6)	($6.0)	($6.3)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Cumulative translation adjustment	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0
Net Income	**($4.7)**	**($1.3)**	**($1.4)**	**($1.4)**	**($1.5)**	**($5.6)**	**($6.0)**	**($6.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.18)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.17)**	**($0.15)**	**($0.14)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	25.7	28.6	33.0	33.3	35.0	32.5	40.0	45.0

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

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HISTORICAL STOCK PRICE



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