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Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: Updated MDNA55 P2b Data Continues to Exceed Currently Available rGBM Therapies…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55 and MDNA19, MDNA.T is valued at CAD$4.50/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 (12/02/19)	CAD$1.35
Valuation	**CAD$4.50**

OUTLOOK

On November 25, 2019, Medicenna Therapeutics Corp. (T.MDNA) announced additional survival data from the Phase 2b clinical trial of MDNA55 in patients with recurrent glioblastoma (rGBM). The data showed a median overall survival (mOS) of 15 months for patients with high levels of IL-4R. Of the 38 patients that were evaluable, 82% of them experienced tumor shrinkage or stabilization from nadir. The 12-month survival rate for the first 40 subjects treated with MDNA55 was 45%, irrespective of IL-4R expression, which compares quite favorably for agents used to treat rGBM (12-month OS of 18-34%). The company will be conducting an 'end-of-Phase 2' meeting with the FDA in the first quarter of 2020 to get guidance for the regulatory pathway for MDNA55, including if there is any opportunity for accelerated approval.

SUMMARY DATA

52-Week High	**$2.38**
52-Week Low	**$0.64**
One-Year Return (%)	**9.76**
Beta	**2.46**
Average Daily Volume (sh)	**68,050**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$46**
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 A	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	-$0.07 A	-$0.04 E	-$0.04 E	-$0.19 E
2021					-$0.15 E
2022					-$0.14 E

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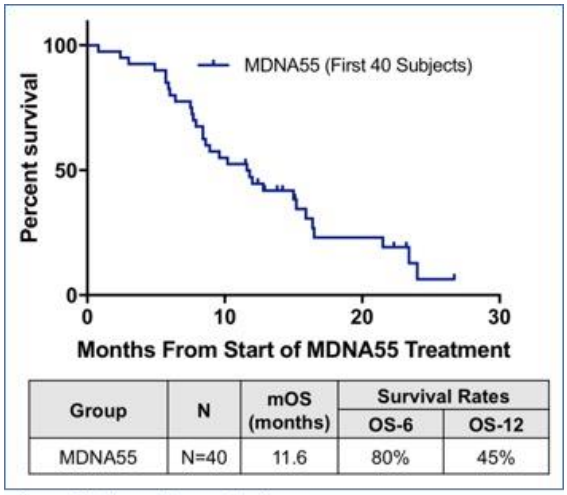
WHAT'S NEW

Business Update

Additional P2b Data for MDNA55 Presented

On November 25, 2019, Medicenna Therapeutics Corp. (MDNA) announced the presentation of additional clinical data from the ongoing Phase 2b clinical 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.

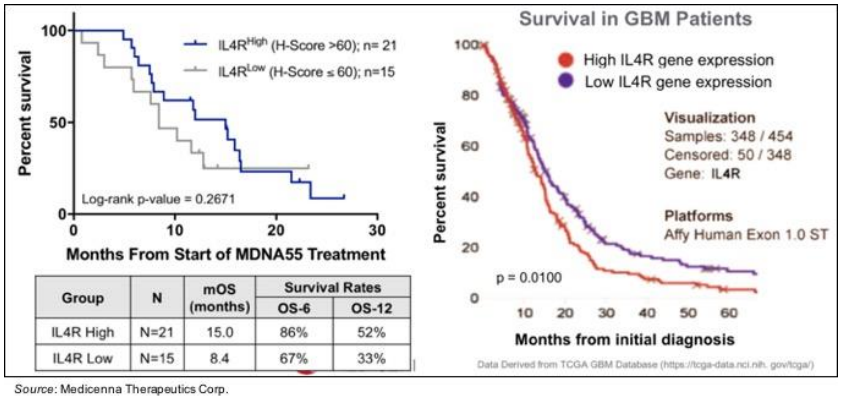
The company provided an update based on a data cutoff of Oct. 31, 2019 that included an additional seven patients since the prior update in September 2019. The following chart shows the survival curve for the first 40 subjects evaluated, which includes a mOS of 11.6 months and OS at 12 months of 45%. Those numbers are in-line with what the company reported in September 2019.



Group	N	mOS (months)	Survival Rates	
			OS-6	OS-12
MDNA55	N=40	11.6	80%	45%

Source: Medicenna Therapeutics Corp.

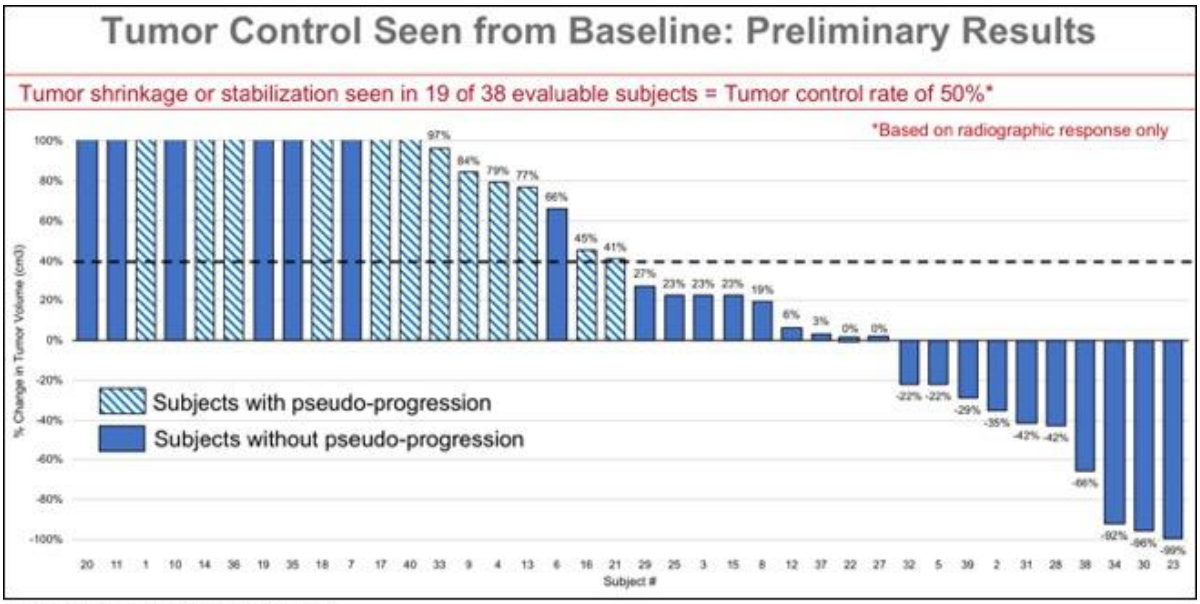
Similar to what was reported in Sep. 2019, there continues to be a survival advantage for patients who are high expressers of the IL-4 receptor (IL-4R). The figure on the lower left shows that patients who have high levels of IL-4R have a mOS of 15.0 months, while those that have low levels of IL-4R have a mOS of 8.4 months. What is most interesting about this is the fact that published data shows GBM patients that have high expression of IL-4R have a lower mOS than patients who are low expressers of IL-4R (lower right), thus the fact that these patients are living longer in the Phase 2b trial is highly encouraging.



Group	N	mOS (months)	Survival Rates	
			OS-6	OS-12
IL4R High	N=21	15.0	86%	52%
IL4R Low	N=15	8.4	67%	33%

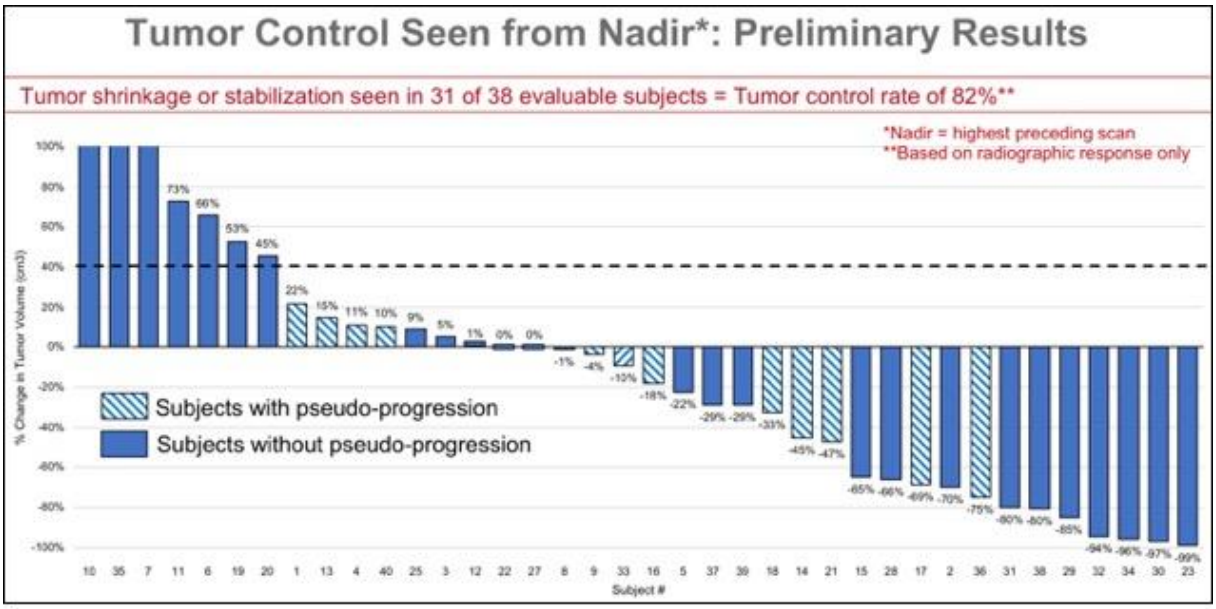
Source: Medicenna Therapeutics Corp.

Medicenna also reported updated tumor control data for the 38 evaluable patients. The following figure shows tumor control from baseline, in which 19 of 38 (50%) evaluable patients saw either stabilization of the tumor or a decrease in tumor size.



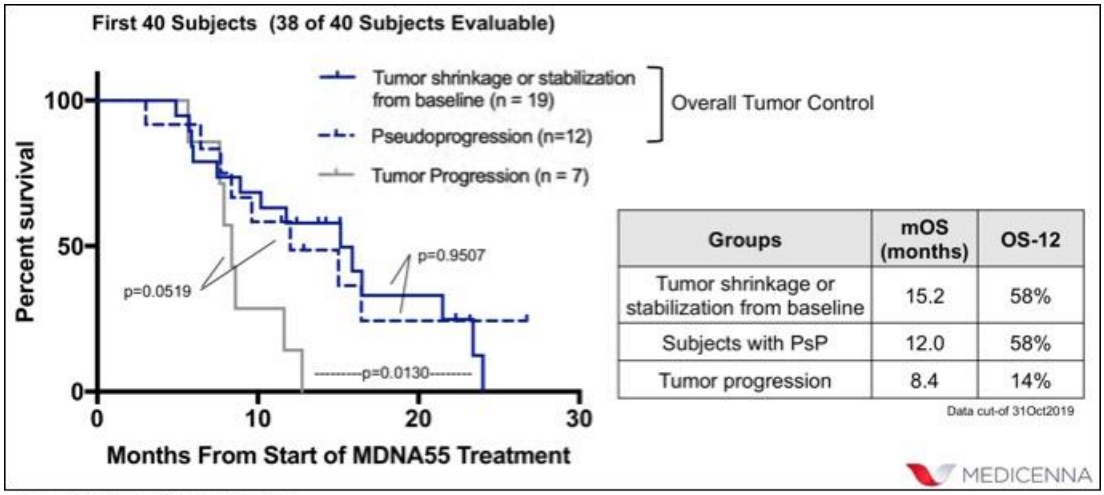
Source: Medicenna Therapeutics Corp.

While a 50% tumor control rate is certainly encouraging, we don't believe the preceding chart gives a wholly accurate picture of MDNA55's treatment effect due to pseudoprogression, in which a tumor appears to be growing on radiographic imaging (due to an inflammatory response to treatment and not due to an increase in tumor mass) before decreasing in size. To account for this phenomenon, assessment of tumor response from nadir was utilized using the criteria for immunotherapy Response Assessment in Neuro-Oncology (iRANO) (Okada *et al*., 2015). The following figure shows that 21 of 38 (83%) patients saw either stabilization of the tumor or a decrease in tumor size when compared to nadir.



Source: Medicenna Therapeutics Corp.

There was also an association seen between tumor control and mOS, with those experiencing either tumor shrinkage or stabilization having a mOS of 15.2 months, those with pseudoprogression having a mOS of 12.0 months, and those with tumor progression only having a mOS of 8.4 months.



Source: Medicenna Therapeutics Corp.

While a bit disappointing that the mOS data did not improve from the data reported in September 2019 following the addition of data for seven 'high dose' patients, treatment with MDNA55 continues to exceed previously reported mOS data for other rGBM treatments such as Avastin®, lomustine, and temozolomide.

Approved Therapies	rGBM Population (n)	mOS (mos)	OS-12
Avastin[1]	n=85	9.2	22%*
Avastin[2]	n=50	8.0	26%
Lomustine[2]	n=46	8.0	30%
Lomustine[3]	n=149	8.6	34%
Temozolomide[4]	n=31	5.6	30%*
Temozolomide[5]	n=138	5.4	18%*
Gliadel[6]	n=72	6.5	12%*

*Approximations based on Kaplan-Meier curve.

MDNA55 Patient Groups	rGBM Population (n)	mOS (mos)	OS-12
First 40 subjects	n=40	11.6	45%
➢ IL4R High	n=21 (of 36 evaluable)	15.0	52%
➢ Tumor control	n=31 (of 38 evaluable)	15.0	58%

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.
6 Gliadel FDA Label 2018

Source: Medicenna Therapeutics Corp.

Medicenna will continue to present updated data on the remaining patients from the Phase 2b trial at upcoming scientific conferences. We anticipate the company conducting an 'end-of-Phase 2' meeting with the FDA in the first quarter of 2020 to determine the regulatory path forward for MDNA55 and whether the opportunity exists for accelerated approval.

Conclusion

The additional data presented by Medicenna continues to compare quite favorably to currently available rGBM treatments and we look forward to additional updates on the remaining patients in the study, which is likely to occur at future scientific conferences. The upcoming 'end-of-Phase 2' meeting with the FDA is a potential inflection point as the company will learn what the agency will require in terms of a Phase 3 clinical trial and whether there is any potential for accelerated approval. Our current valuation is CAD$4.50 and we continue to view the shares as significantly undervalued heading into a very important next couple of months for the company.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2019 A	Q1 FY20 A	Q2 FY20 A	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	$1.2	$1.0	$1.1	$4.2	$4.0	$4.1
General & Administrative	$1.7	$0.5	$0.6	$0.4	$0.4	$1.9	$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)	($1.9)	($1.4)	($1.5)	($6.1)	($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)	($1.9)	($1.4)	($1.5)	($6.1)	($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)**	**($1.9)**	**($1.4)**	**($1.5)**	**($6.1)**	**($6.0)**	**($6.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.18)**	**($0.05)**	**($0.07)**	**($0.04)**	**($0.04)**	**($0.19)**	**($0.15)**	**($0.14)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	25.7	28.6	28.8	33.3	35.0	31.4	40.0	45.0

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

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