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Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: Additional MDNA55 Data to be Presented at Society for NeuroOncology Annual Meeting Nov 20-24, 2019…

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 (11/12/19)	CAD$1.31
Valuation	**CAD$4.50**

OUTLOOK

On November 5, 2019, Medicenna Therapeutics Corp. (T.MDNA) announced financial results for the second quarter of fiscal year 2020 that ended September 30, 2019 and provided a business update. The company has a couple of important inflection points upcoming in the next few months: 1) Additional survival data from the Phase 2b clinical trial of MDNA55 will be presented at the Society for NeuroOncology Annual Meeting, which is taking place Nov. 20-24, 2019; and 2) An 'End-of-Phase 2' meeting will take place with the FDA in the first quarter of 2020. Medicenna recently completed a CAD$6.9 million public offering, which will provide sufficient capital to fund operations through the end of 2020.

SUMMARY DATA

52-Week High	**$2.38**
52-Week Low	**$0.64**
One-Year Return (%)	**-7.80**
Beta	**N/A**
Average Daily Volume (sh)	**14,180**
Shares Outstanding (mil)	**34**
Market Capitalization ($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 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

MDNA55 Update

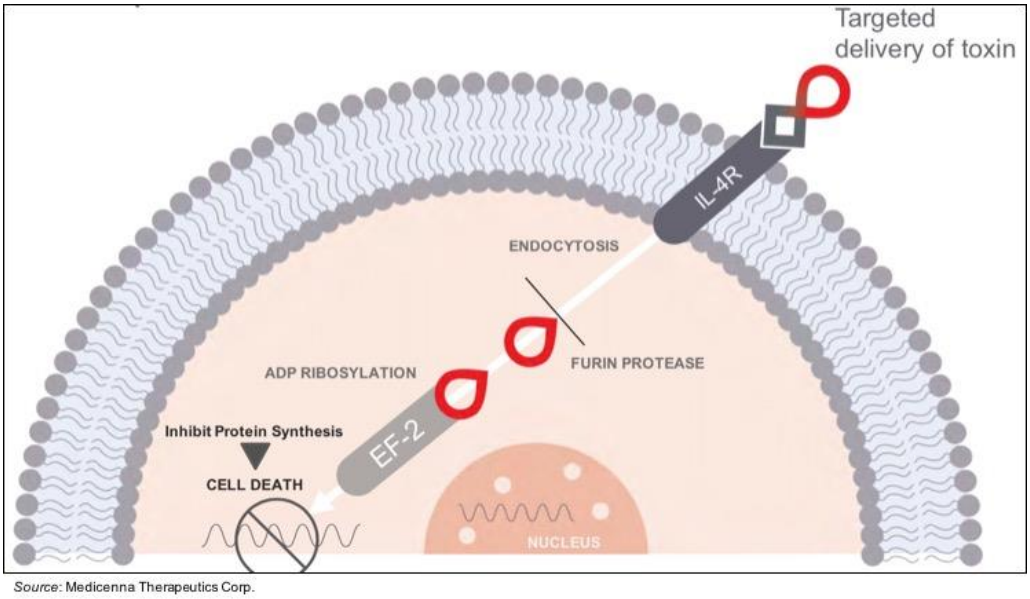
Medicenna Therapeutics, Inc. (MDNA) is developing MDNA55 for the treatment of recurrent glioblastoma (rGBM). The company is currently conducting a Phase 2b clinical trial in a total of 46 patients experiencing either first or second GBM relapse (NCT02858895). It is a multi-center, open label, single 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.

MDNA55 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.



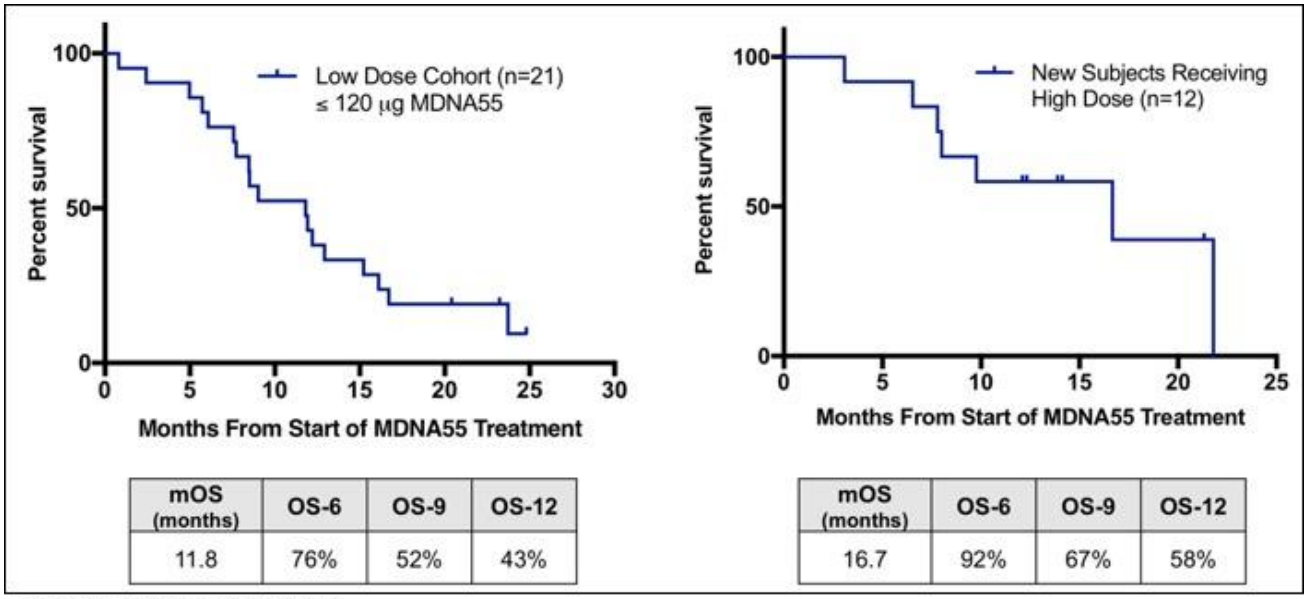
Source: Medicenna Therapeutics Corp.

Following binding of MDNA55 to the IL-4 receptor (IL-4R), the entire compound is endocytosed into the cell. 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. The mechanism of action is depicted in the following figure.



Source: Medicenna Therapeutics Corp.

The company previously announced preliminary topline results from the Phase 2b trial for 21 patients enrolled in the 'low-dose' cohort, in which they experienced a median overall survival (mOS) of 11.8 months, as well as for 12 patients from the 'high-dose' cohort, in which they experienced a mOS of 16.7 months. Those results are depicted in the following figures, along with survival data for six, nine, and 12 months.



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.

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. Each of the cohorts treated with MDNA55 have experienced higher mOS, particularly those patients who have high expression of the IL-4R.

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.

Additional mOS data from the Phase 2b trial will be presented at the upcoming Society for NeuroOncology Annual Meeting, which is taking place Nov. 20-24, 2019. During the presentation we anticipate updates on the remaining 13 'high dose' patients. We also anticipate an 'end-of-Phase 2' meeting taking place with the FDA in the first quarter of 2020, at which time the company expects to receive feedback on the regulatory pathway for MDNA55 and if there is any potential for accelerated approval.

Putting MDNA55 Data into Context

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 (not statistically significant from standard of care). While those 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.

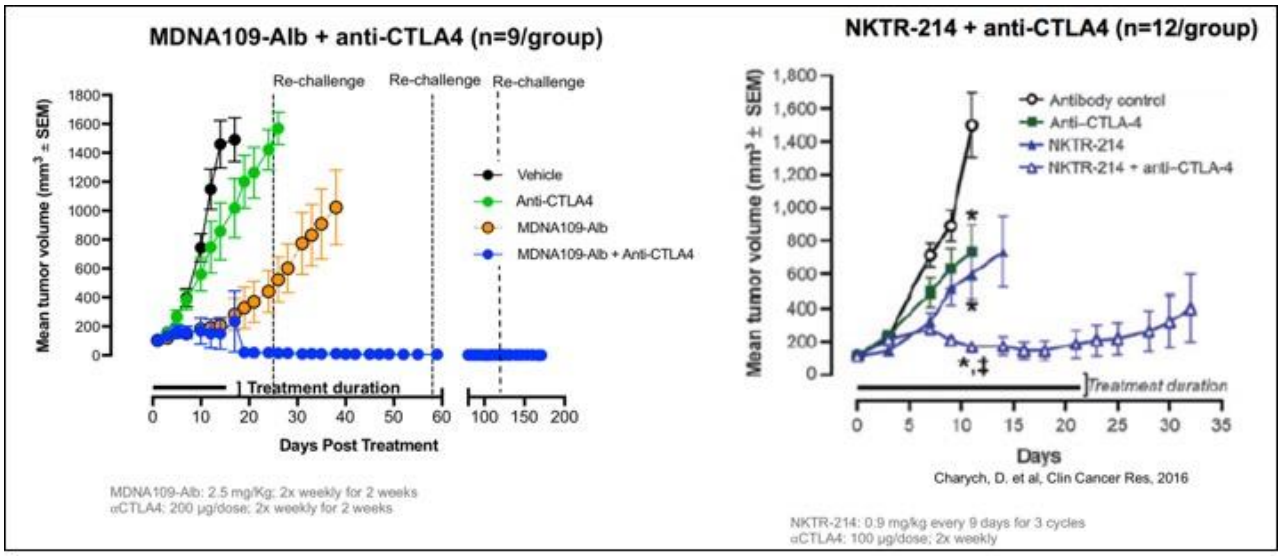
Publication in Nature Communications *on IL-2 Superkine Platform*

In September 2019, Medicenna announced the publication of a paper in *Nature Communications* titled "A next-generation tumor-targeting IL-2 preferentially promotes tumor infiltrating CD8+ T-cell response and effective tumor control" (Sun *et al*., 2019). The paper describes how MDNA109 (referred to as sumIL-2-Fc in the paper):

- has reduced CD25 binding and enhanced CD122 binding
- a longer half-life, efficient tumor targeting, less toxicity, and preferential binding to cytotoxic T cells (but not T regulatory cells) when compared to native IL-2
- when given prior to surgical resection it significantly extended the survival of mice
- can help overcome resistance to checkpoint inhibitor therapy with PD-L1 antibodies
- works synergistically with tyrosine kinase inhibitors, a class of compounds utilized to treat a wide variety of tumors

The potential for MDNA19 (the company's lead IL-2 clinical candidate derived from MDNA109) is exemplified in the following graphs, which depict results from an *in vivo* study in which mice were injected with CT26 colon cancer cells and then treated with an anti-CTLA4 antibody, MDNA109, NKTR-214, or a combination of either anti-CTLA4 + MDNA109 or anti-CTLA4 + NKTR-214. NKTR-214 is a long-acting IL-2 variant being developed by Nektar Therapeutics, which signed a collaboration agreement with Bristol-Myers Squibb for the development of NKTR-214 that included an upfront payment of $1.0 billion.

The results show that the combination of MDNA109 and anti-CTLA4 results in complete elimination of the tumor that persists out to >150 days, while treatment with NKTR-214 and anti-CTLA4 results in decreased tumor size until treatment stops, at which point the tumor begins growing again.



Source: Medicenna Therapeutics, Inc.

The company is continuing IND-enabling work with MDNA19, which includes the completion of the non-GLP pharmacodynamic studies by the second quarter of 2020 such that a pre-IND meeting can occur with the FDA shortly thereafter. We believe IND-enabling studies will complete by the end of 2020 such that an IND can be filed and a Phase 1 clinical trial can initiate in the first quarter of 2021.

Financial Update

On November 5, 2019, Medicenna announced financial results for the second quarter of fiscal year 2020 that ended Sep. 30, 2019. The company reported a net loss for the second quarter of fiscal year 2020 of CAD$1.9 million, or CAD$0.07 per share, compared to a net loss of CAD$0.9 million, or CAD$0.04 per share, for the three months ending Sep. 30, 2018. R&D expenses for the second quarter of fiscal year 2020 were CAD$1.2 million compared to CAD$0.4 million for the second quarter of fiscal year 2019. However, when accounting for expenses reimbursed by CPRIT, R&D expenses totaled CAD$1.3 million and CAD$2.0 million for the three months ending Sep. 30, 2019 and Sep. 30, 2018, respectively. The decrease in expenses when excluding amounts received from CPRIT were mainly due to lower clinical trial costs due to the completion of enrollment of the P2b rGBM trial and lower licensing fees, patent fees, and royalty costs. G&A expenses for the second quarter of fiscal year 2020 were CAD$0.6 million compared to CAD$0.4 million for the three months ending Sep. 30, 2018. The increase was due to lower amounts of expenses eligible for reimbursement from CPRIT along with higher facilities and operations expenses.

As of Sep. 30, 2019, Medicenna had approximately CAD$2.0 million in cash and cash equivalents. In October 2019, the company announced the closing of a public offering in which the company issued a total of 5,307,695 units, with each unit comprising one common share of stock and one-half of one common share purchase warrant, which resulted in gross proceeds of approximately CAD$6.9 million. The warrants have an exercise price of CAD$1.75 and expire in Oct. 2022. Based on decreased spending over the next year due to the end of the Phase 2b trial, we estimate that the company is now funded through the end of 2020 and importantly through important upcoming inflection points, including the presentation of additional overall survival data from the Phase 2b trial of MDNA55 in November 2019 and an 'end-of-Phase 2' meeting with the FDA in the first quarter of 2020.

Medicenna had approximately 28.8 million shares outstanding on Sep. 30, 2018 and following the public offering in October we estimate the company now has approximately 34.1 million shares outstanding. When factoring in options and warrants we estimate a fully diluted share count of 45.1 million.

Conclusion

Medicenna now has funding in place through 2020 and most importantly, through the near-term inflection points that include the announcement of additional mOS data from the MDNA55 Phase 2b trial at the Society for NeuroOncology Annual Meeting and the 'end-of-Phase 2' meeting with the FDA in the first quarter of 2020 regarding the regulatory path forward for MDNA55. 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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