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Medicenna Therapeutics Corp. (T.MDNA-TSX)

T.MDNA: End-of-Phase 2 Meeting with FDA for MDNA55 in 1Q20…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55 and MDNA19, MDNA.T is valued at CAD$13/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 (01/14/20)	CAD$3.17
Valuation	**CAD$13.00**

OUTLOOK

On January 13, 2020, Medicenna Therapeutics Corp. (MDNA.TO) announced results from the Phase 2b trial of MDNA55 in patients with recurrent glioblastoma (rGBM) compared to an eligibility-matched control arm. The control arm consisted of 81 rGBM patients that recently received approved therapies including Avastin, Lomustine, and temozolomide. Of the 21 IL-4 receptor high patients that received MDNA55, the median overall survival (mOS) was 15.8 months, compared to 6.2 months for the control arm (n=17), while the 12-month OS was 62% in the MDNA55 arm compared to 24% for the control arm. For the entire cohort, MDNA55-treated subjects had a mOS of 12.4 months versus 7.7 months for the control arm. Medicenna will be submitting an 'End-of-Phase 2' meeting package to the FDA in the first quarter of 2020. At this meeting the company will receive clarity on the registration path forward for MDNA55 and whether the potential exists for accelerated approval.

SUMMARY DATA

52-Week High	**$3.87**
52-Week Low	**$0.64**
One-Year Return (%)	**246**
Beta	**2.41**
Average Daily Volume (sh)	**124,410**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$108**
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

Highly Encouraging Results for MDNA55 When Comparing with Synthetic Control Arm

On January 13, 2020, Medicenna Therapeutics Corp. (MDNA) announced encouraging data for the company's Phase 2b clinical trial of MDNA55, an IL-4 targeted toxin, in patients with recurrent glioblastoma (rGBM) when compared to an eligibility-matched arm of control subjects (n=81) who were treated with approved therapies, including Avastin®, lomustine, and temozolomide. The control subjects had similar baseline features as patients treated with MDNA55 including *de novo* grade IV GBM at 1st or 2nd relapse following standard 1st-line treatments with surgery and radio-chemotherapy, tumors between 1 cm x 1 cm to 4 cm x 4 cm, Karnofsky Performance Status (KPS) of ≥ 70, not eligible for surgery/resection at relapse, and no known mutations of IDH1 and/or IDH2. In this study, survival results for both arms were computed from the date of relapse rather than from the date of treatment, which was how results were previously reported by the company.

The results showed that:

- Median overall survival (mOS) for patients with high expression of IL-4R was 15.8 months for the MDNA55-treated cohort (n=21) compared to 6.2 months for the control arm (n=17).
    - Note: Medicenna only had access to 40 archived tissue samples for the control arm, thus the percentage of patients in that arm who had high expression of IL-4R (43%) was similar to that seen in the Phase 2b trial (48%).
- For patients with high expression of IL-4R, 12-month OS for the MDNA55-treated cohort was 62% compared to 24% for the control arm.
- When considering all patients, mOS in the MDNA55-treated cohort was 12.4 months compared to 7.7 months in the control arm.
- When considering all patients, 12-month OS for the MDNA55-treated cohort was 53% compared to 25% for the control arm.

We believe this data is very compelling, particularly for those patients with high expression of IL-4R. The company will take this data to the FDA as part of the 'End-of-Phase 2' meeting that will be taking place in the second quarter of 2020. At this meeting we expect the agency to provide guidance on the regulatory path forward for MDNA55 as well as if the opportunity exists for accelerated approval.

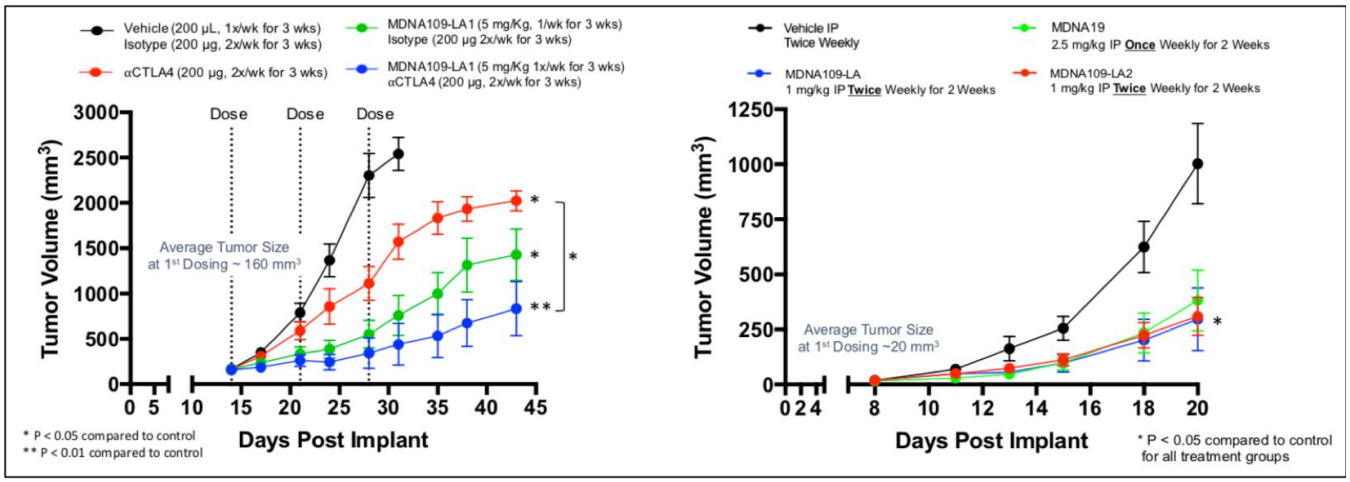
Synthorx Acquisition Puts Spotlight on Enhanced IL-2's

On Dec. 9, 2019, SynthoRx, Inc. announced it was being acquired by Sanofi for $68 per share, which represents a fully diluted value for SynthoRx of approximately $2.5 billion. SynthoRx's lead development candidate, THOR-707, is an interleukin (IL)-2 variant that is pegylated at a specific site to block binding to the IL-2 receptor α chain and extend the half-life. It is currently being studied in a Phase 1 clinical trial as a single agent and will be tested in combination with immune checkpoint inhibitors in future trials. SynthoRx also has additional preclinical cytokine variant programs, including an IL-15 and an IL-10 program.

IL-2 is a 16 kDa protein that activates a wide range of leukocytes, including T cells and natural killer (NK) cells through binding IL-2 receptors (IL-2Rα [CD25], IL-2Rβ [CD122], and IL-2Rγ [CD132]), with the arrangement of these receptors dictating the response seen. Binding of IL-2 to a heterodimer consisting of CD122 and CD132 is of "intermediate affinity', whereas a heterotrimer consisting of all three IL-2Rs is a 'high affinity' complex. The heterotrimer is typically found on activated T cells (including regulatory T cells) while naïve T cells and NK cells only express the heterodimer. Thus, modifying IL-2 signaling to enhance binding to the CD122/CD132 complex could enhance T cell activation while diminishing the effect of regulatory T cells. An enhanced version of IL-2 that exhibited increased affinity to CD122 was first described in 2012 (Levin *et al*., 2012) and additional work has yielded a family of long-acting 'IL-2 Superkines' with enhanced features compared to IL-2.

Medicenna previously presented preclinical data for MDNA19, the company's lead IL-2 Superkine, that showed the compound has no affinity for CD25, enhanced affinity for CD122, and is active as both a monotherapy and in combination with checkpoint inhibitors. The following figure on the left shows decreased tumor growth in mice treated with MDNA19 (green line) and enhanced anti-tumor activity when MDNA19 is administered along with an α-

CTLA4 antibody (blue line). The figure on the right shows that MDNA19 achieves similar efficacy to other MDNA109 family members with less frequent dosing in an aggressive B16F10 melanoma mouse model.



Source: Rafei *et al*., 2019

Medicenna will be advancing MDNA19 into clinical development as the lead IL-2 Superkine based on the lack of affinity for CD25 and enhanced affinity for CD122. We believe this is the only enhanced long-acting IL-2 in development that combines both of those characteristics, and it likely has potential in a number of therapeutic applications, including in combination with checkpoint inhibitor therapy, as part of an 'armed' oncolytic virus, or as a fusion protein with antibodies or other cytokines. Pre-IND work is continuing on MDNA19 such that it can be advanced into the clinic in 2021.

Valuation and Conclusion

The comparison Medicenna performed with a synthetic control arm highlights the effectiveness of MDNA55 treatment in rGBM patients and shows that it could offer a much better option than currently available therapies for this patient population. We are eager to hear the outcome of the 'end-of-Phase 2' meeting with the FDA and while we continue to believe the agency will require a Phase 3 trial prior to approval, we will be very interested to learn about the potential for accelerated approval.

The acquisition of SynthoRx is an intriguing development for Medicenna, particularly the price that Sanofi was willing to pay for a lead compound that just began Phase 1 testing. We estimate that Medicenna is approximately one year behind SynthoRx in the development of MDNA19, however we believe MDNA19 offers a number of attributes that could lead it to becoming a best-in-class molecule. Based on the valuation assigned to SynthoRx we have increased our estimated valuation for MDNA19 and the Superkine platform to CAD$500 million, which has increased our valuation to CAD$13 per share. Following the SynthoRx acquisition the stock has advanced >100%, however we believe there is significant upside potential based on the advancement of both MDNA55 and MDNA19.

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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