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Medicenna Therapeutics Corp. (MDNA-NASDAQ)

MDNA: Preliminary Update from ABILITY Trial of MDNA11 in Late Calendar 2021…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55 and MDNA11, MDNA is valued at $12/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 (11/16/21)	$2.12
Valuation	**$12.00**

OUTLOOK

On November 12, 2021, Medicenna Therapeutics Corp. (MDNA) announced financial results for the second quarter of fiscal year 2021 that ended September 30, 2021 and provided a business update. The company recently began dosing patients in the Phase 1/2 ABILITY (A Beta-only IL-2 ImmunoTherapY Study) clinical trial of MDNA11. We anticipate initial safety, PK/PD, and biomarker data by the end of calendar 2021 and initial efficacy data in mid-calendar 2022. Once a Phase 2 dose is established, dose expansion cohorts consisting of metastatic melanoma, advanced renal cell carcinoma (RCC) and patients with other solid tumor types will be treated in both monotherapy and combination (with a checkpoint inhibitor) settings, with results expected during 2022. The company recently received IND clearance in the U.S., with expansion of the trial to the U.K. and Canada expected following submissions to those regulatory agencies, which should occur before the end of calendar 2021.

SUMMARY DATA

52-Week High	**$5.97**
52-Week Low	**$1.91**
One-Year Return (%)	**-43.01**
Beta	**0.91**
Average Daily Volume (sh)	**146,540**
Shares Outstanding (mil)	**54**
Market Capitalization (C$mil)	**$114**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**25**
Insider Ownership (%)	**33**
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	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 E	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share
(in $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	-$0.05 A	- $0.08 A	-$0.11 A	-$0.11 A	-$0.35 A
2022	-$0.12 A	-$0.15 A	-$0.12 E	-$0.13 E	-$0.52 E
2023					-$0.48 E
2024					-$0.49 E

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WHAT'S NEW

Business Update

Phase 1/2 ABILITY Trial Underway; Initial Safety and Biomarker Data by Year-End 2021

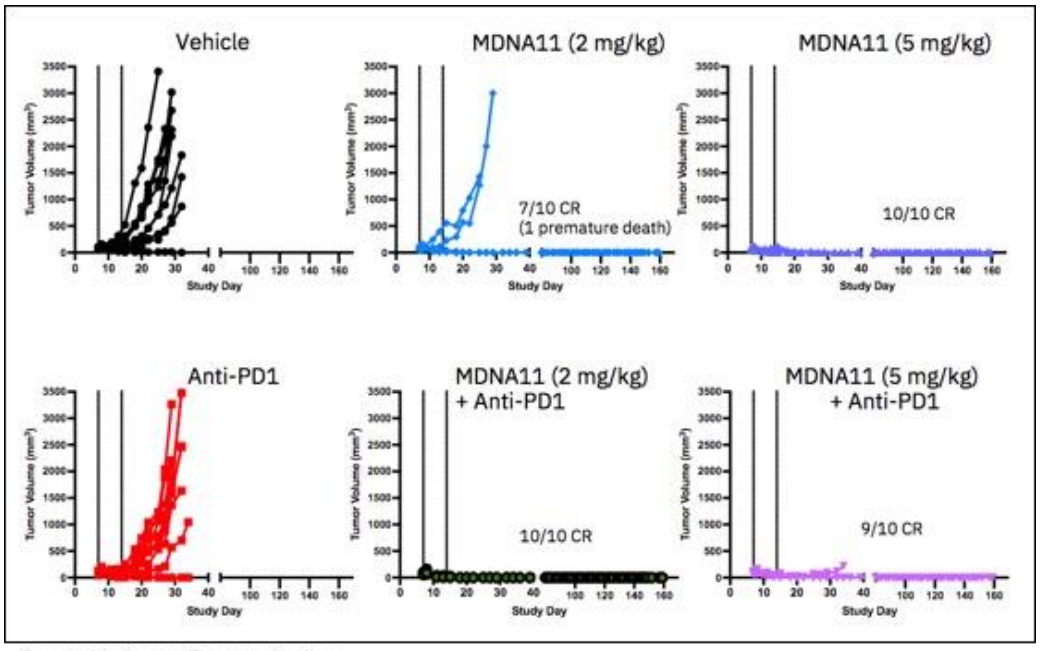
Medicenna Therapeutics Corp. (MDNA) recently initiated the Phase 1/2 ABILITY Study (A Beta-only IL-2 ImmunoTherapY Study) of MDNA11 in patients with advanced solid tumors. It is designed to assess the safety, pharmacokinetics (PK)/pharmacodynamics (PD), and effect on various biomarkers of MDNA11 as both a monotherapy as well as in combination with a checkpoint inhibitor. The trial is initiating in Australia with a plan to have 4-6 sites and the company recently received IND clearance with the U.S. FDA with a plan for 8-10 sites in the U.S. We anticipate the trial eventually expanding to clinical sites in the U.K. and Canada, with submissions to their regulatory agencies expected by the end of calendar 2021.

The first data reported from the trial will include preliminary safety, PK, PD, and biomarker data from the initial dose escalation cohorts, which are expected by end of this calendar year. In regards to PK, the company is hoping to see albumin-mediated half-life extension that would support dosing once every two to three weeks. In regards to PD and biomarker data, the company will be evaluating various biomarkers in peripheral blood as well as any available paired tumor biopsies to look for anti-cancer immune cell activation and a lack of regulatory T cell activation. Subsequent data including efficacy data readouts will continue throughout 2022 for both monotherapy and combination treatment.

Additional MDNA11 Preclinical Data Presented at AACR-NCI-EORTC

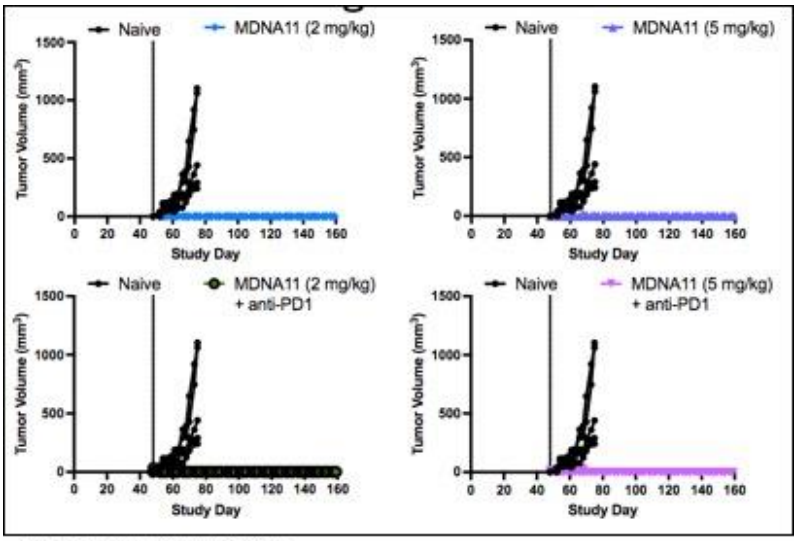
On October 7, 2021, Medicenna announced the presentation of new preclinical data from the MDNA11 program at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. A copy of the presentation can be found here. The data were from mouse and non-human primate (NHP) IND-enabling studies. Mouse studies evaluated MDNA11 as a monotherapy as well as in combination with an anti-PD1 checkpoint inhibitor. NHP studies evaluated the safety and PK/PD of three repeat doses of 0.15 mg/kg, 0.3 mg/kg, or 0.6 mg/kg MDNA11.

The following graphs show the anti-tumor effect of MDNA11 at two different doses as a monotherapy and in combination with an anti-PD1 antibody in the MC38 mouse model. MDNA11 monotherapy at 5 mg/kg and at 2 mg/kg in combination with an anti-PD1 antibody resulted in complete tumor elimination. The anti-PD1 antibody as a monotherapy was not effective in this model.



Source: Medicenna Therapeutics Corp.

When mice that showed complete tumor regression were re-challenged with tumors, there was no tumor growth seen, as shown in the following figure. This effect was exhibited in mice that had been treated with both MDNA11 monotherapy and in combination with an anti-PD1 antibody and was mediated through the induction of long-term, antigen-specific CD8+ T cells.



Source: Medicenna Therapeutics Corp.

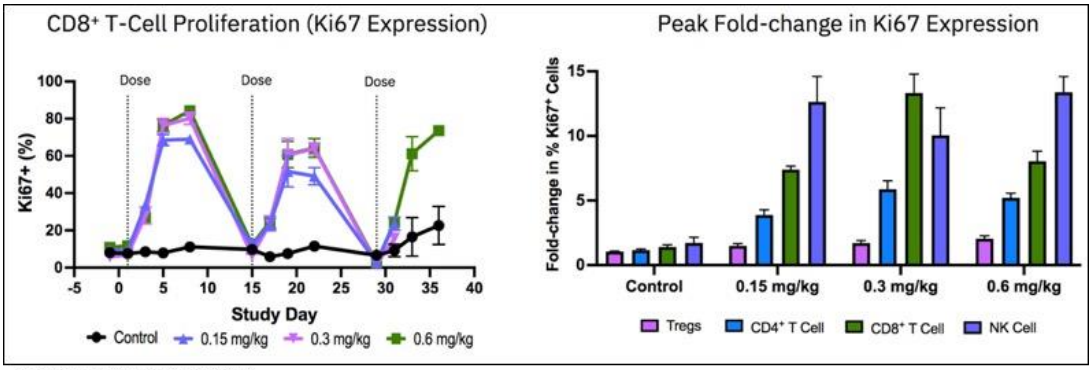
In regards to the NHP study, the following is a summary of key findings, which importantly included no evidence for cytokine release syndrome, no anti-drug antibodies (ADA), no evidence for edema or vascular leak syndrome (VLS), which was been an issue with other IL-2 therapies:

Key Findings:

- Main observations in cynomolgus monkeys were transient loss of appetite, reduced activity and diarrhea
  - More common in the high dose group (0.6 mg/kg); all animals recovered
  - Mostly observed after the 1st dose; lower incidence rate or not observed after 2nd and 3rd dose
- No cytokine release syndrome in cynomolgus monkeys
- No ADA in cynomolgus monkeys
- No histological evidence of pulmonary edema or VLS in cynomolgus monkeys

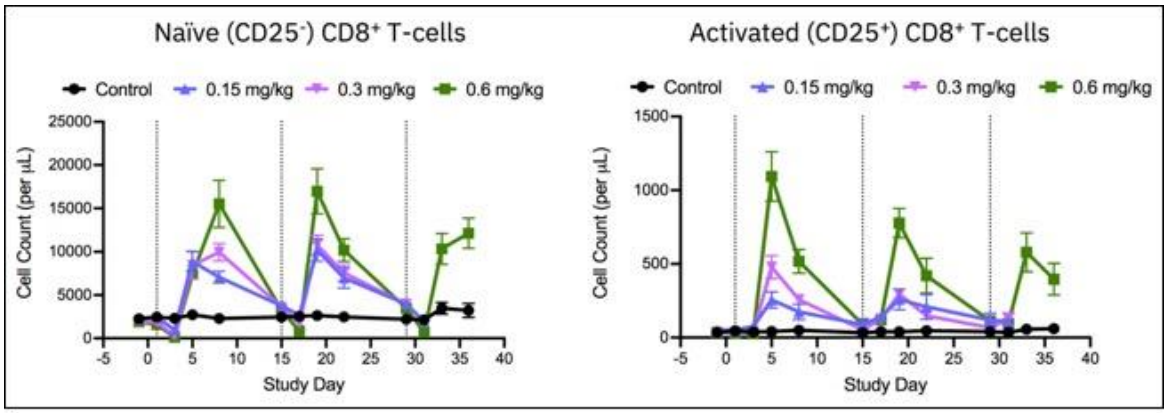
Source: Medicenna Therapeutics Corp.

The following graphs show that MDNA11 is able to induce CD8+ T cell proliferation (as shown by Ki67 expression) that peaked approximately 7 days following dosing and returned to base line by Day 15 (lower left) and the peak fold-change in Ki67 expression was much higher in CD8+ T cells and natural killer (NK) cells compared to regulatory T cells (Treg) and CD4+ T cells (lower right). PK data showed that MDNA11 was below the lower limit of quantitation by Day 4-5 following the first dose, however increased Ki67 expression was seen past that, indicating an extended PD effect for MDNA11.



Source: Medicenna Therapeutics Corp.

Lastly, as shown in the following graphs, MDNA11 is able to induce the proliferation of both naïve (CD25-) and activated (CD25+) CD8+ T cells, thus allowing for the use of the entire repertoire of CD8+ T cells and potentially leading to a more robust immune response.



Source: Medicenna Therapeutics Corp.

Financial Update

On November 12, 2021, Medicenna announced financial results for the second quarter of fiscal year 2022 that ended September 30, 2021. The company reported a net loss for the second quarter of fiscal year 2022 of CAD$8.2 million, or CAD$0.15 per share, compared to a net loss of CAD$3.8 million, or CAD$0.08 per share, for the three months ending September 30, 2020. R&D expenses for the second quarter of fiscal year 2022 were CAD$6.3 million compared to CAD$2.2 million for the second quarter of fiscal year 2021. The increase in expenses was primarily due to increased higher CMC costs, increased preclinical costs due to IND-enabling studies, discovery work on the BiSKITs platform, and higher salary and benefits costs. G&A expenses for the second quarter of fiscal year 2022 were CAD$2.0 million compared to CAD$1.7 million for the three months ending Septemberd 30, 2020. The increase was primarily due to increased directors and officer's liability insurance premiums, increased stock-based compensation, and increased salaries and benefits.

As of September 30, 2021, Medicenna had approximately CAD$26.7 million in cash, cash equivalents, and marketable securities. We estimate Medicenna has sufficient capital to fund operations through the end of calendar 2022. As of November 12, 2021, Medicenna had approximately 54.0 million shares outstanding and, when factoring in options and warrants, a fully diluted share count of approximately 62.4 million.

Conclusion

We are glad to see the ABILITY trial is underway and the first patients have been dosed at clinical sites in Australia. Now that the IND has cleared in the U.S. we anticipate sites opening up there in the first quarter of calendar 2022. We are really looking forward to seeing 'first-in-human' data for MDNA11 before the end of calendar 2021 that should include information on safety, PK/PD, and biomarker analysis. Our valuation remains at $12 per share, and with the stock continuing to underperform despite multiple upcoming catalysts investors have a nice opportunity to initiate or add to a position prior to the first data readouts from the ABILITY trial.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2021 A	Q1 FY22 A	Q2 FY22 A	Q3 FY22 E	Q4 FY22 E	FY 2022 E	FY 2023 E	FY 2024 E
MDNA55	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
MDNA11	$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	$10.9	$4.3	$6.3	$4.5	$4.7	$19.8	$20.0	$22.0
General & Administrative	$6.5	$1.9	$2.0	$2.2	$2.5	$8.5	$9.0	$10.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($17.4)	($6.2)	($8.2)	($6.7)	($7.2)	($28.3)	($29.0)	($32.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.1)	$0.2	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.4)
Pre-Tax Income	($17.3)	($6.4)	($8.2)	($6.6)	($7.1)	($28.3)	($28.6)	($31.6)
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	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($17.3)**	**($6.4)**	**($8.2)**	**($6.6)**	**($7.1)**	**($28.3)**	**($28.6)**	**($31.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.35)**	**($0.12)**	**($0.15)**	**($0.12)**	**($0.13)**	**($0.52)**	**($0.48)**	**($0.49)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	49.7	53.6	53.7	54.2	54.5	54.0	60.0	65.0

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

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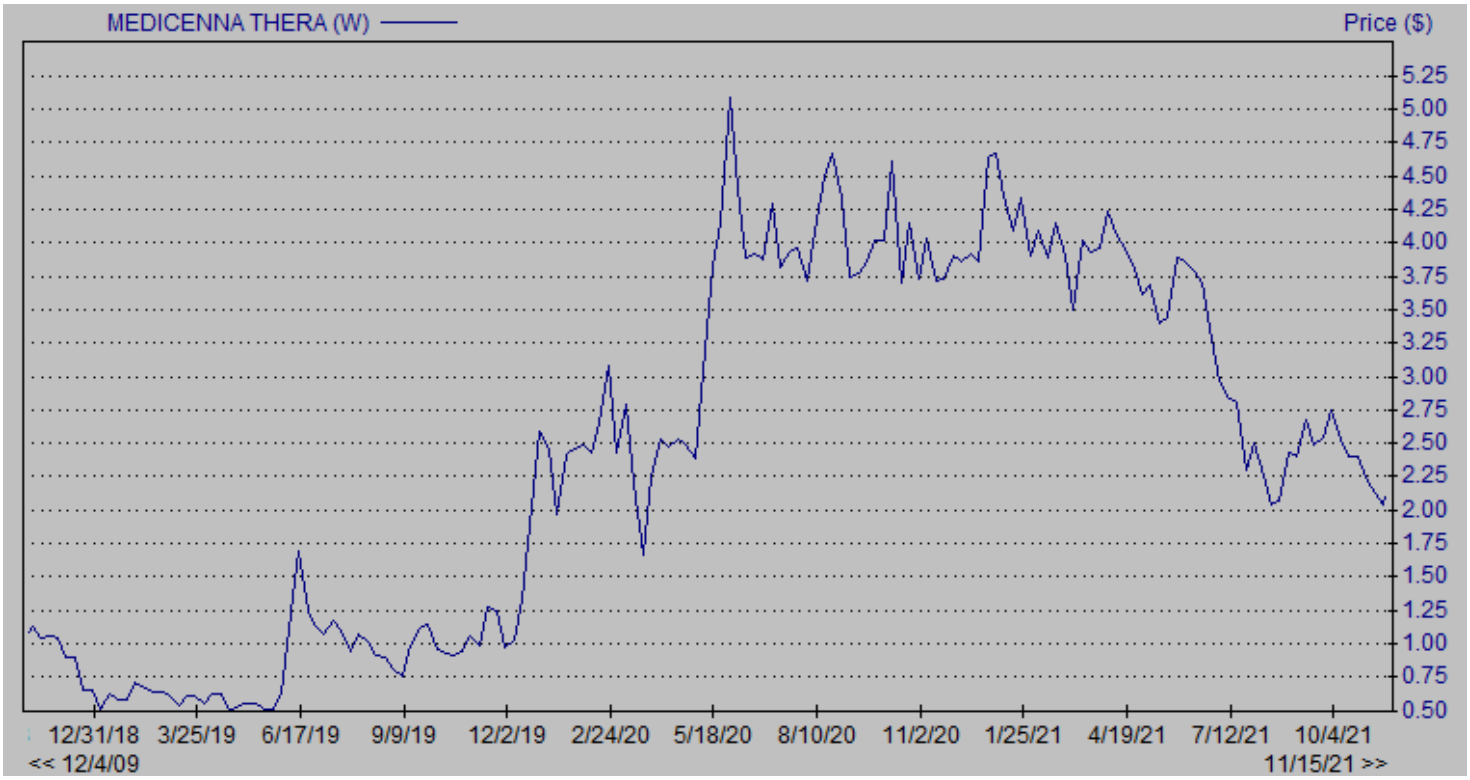
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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