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David Bautz, PhD
(312) 265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Medicenna Therapeutics Corp. (MDNA-NASDAQ)

MDNA: Phase 1 Trial of MDNA11 to Initiate in 3Q21…

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 (06/02/21)	$3.58
Valuation	**$12.00**

OUTLOOK

On May 28, 2021, Medicenna Therapeutics Corp. announced financial results for fiscal year 2021 that ended March 31, 2021 and provided a business update. The company will be submitting a regulatory package to Australian authorities which will happen before the end of June 2021, such that a Phase 1/2a trial of MDNA11 can initiate in the third calendar quarter of 2021. Medicenna is also planning to submit an Investigational Medical Product Dossier (IMPD) in the UK to open clinical trial sites for the Phase 1/2a trial. The company is also continuing to hold partnership discussions with potential collaborators to advance MDNA55 into a Phase 3 trial for the treatment of recurrent glioblastoma (rGBM).

SUMMARY DATA

52-Week High	**$5.97**
52-Week Low	**$3.24**
One-Year Return (%)	**-23.09**
Beta	**1.28**
Average Daily Volume (sh)	**138,689**
Shares Outstanding (mil)	**54**
Market Capitalization (C$mil)	**$192**
Short Interest Ratio (days)	**N/A**
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 E	0 E	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	-$0.06 E	-$0.08 E	-$0.10 E	-$0.12 E	-$0.37 E
2023					-$0.44 E
2024					-$0.46 E

WHAT'S NEW

Business Update

MDNA11 Phase 1/2a Trial to Initiate 3Q21

Medicenna Therapeutics Corp. (MDNA) is planning to initiate a Phase 1/2a clinical trial of MDNA11 in Australia and the U.K. We anticipate the company submitting a regulatory package to Australian authorities before the end of June 2021 and the trial initiating in the third calendar quarter of 2021, with trial sites opening in the U.K later in the year. The company is initiating the trial outside of the U.S. as this will allow the dose escalation study to begin at doses that are closer to therapeutically effective doses along with those countries having a higher population of checkpoint inhibitor-naïve patients. Medicenna will initially be studying MDNA11 as a monotherapy in a dose escalation phase, which will be followed by a dose expansion phase examining MDNA11 as a monotherapy as well as in combination with a checkpoint inhibitor. Biopsies will be collected both pre- and on-treatment that should give insight into the mechanistic activity of MDNA11. We anticipate initial safety, PK/PD, and biomarker data being available before the end of 2021 and the potential for monotherapy efficacy signals to be shared in the first half of 2022.

MDNA11 is a long-acting variant of interleukin (IL)-2 that is engineered to have enhanced binding to CD122 and no affinity for CD25. 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.

The following table shows that MDNA11 (and MDNA19, the company's other long-acting IL-2 variant) binds to CD122 with enhanced affinity compared to native IL-2 (as shown by the lower K_D value), and that neither compound binds to CD25, thus preferentially activating immune effector cells but not T regulatory cells.

	K_D [CD25 (IL-2Rα)]	K_D [CD122 (IL-2Rβ)]
IL-2[a]	24 nM	210 nM
MDNA109 (*1st Gen.*)[a]	26 nM	1.8 nM
MDNA109-Fc (*2nd Gen.*)[b]	14 nM	2.7 nM
MDNA109-Alb (*2nd Gen.*)[a]	56 nM	3.5 nM
MDNA19 (*3rd Gen.*)[b]	**No binding**	**2.1 nM**
MDNA11 (*3rd Gen.*)[a]	**No binding**	**6.6 nM**

Source: Medicenna Therapeutics Corp.

Publication of Phase 2b Data for MDNA55

On May 7, 2021, Medicenna announced the peer-reviewed publication of Phase 2b clinical data for MDNA55 in patients with recurrent glioblastoma (rGBM) in *Clinical Cancer Research* (Ellingson *et al*., 2021). The paper, entitled "Modified RANO, Immunotherapy RANO, and Standard RANO Response to Convection-enhanced Delivery of IL4R-targeted Immunotoxin MDNA55 in Recurrent Glioblastoma", described results that showed a strong correlation between progression free survival (PFS) and overall survival (OS) using modified RANO (mRANO) for both local and centrally determined reads. These data strongly suggest that using mRANO may be superior to the standard RANO and iRANO at predicting OS, particularly for immunotherapies.

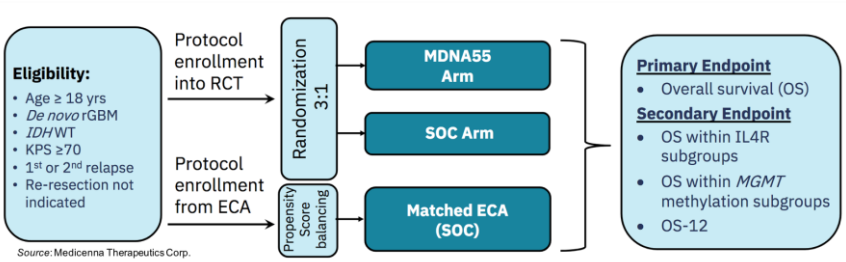
MDNA55 is Medicenna's targeted immunotherapy that consists of a fusion protein containing a circularly permuted version of IL-4 linked to a fragment of the potent bacterial toxin *Pseudomonas* Exotoxin A (PE). The entire complex is endocytosed following its binding to the IL-4 receptor (IL-4R). The PE 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 approved by the FDA for the treatment of adult patients with relapsed hairy cell leukemia.

Following an 'End-of-Phase 2' meeting with the U.S. FDA, the agency has guided for the company to proceed with a Phase 3 registration trial of MDNA55 in patients with rGBM that harbor no IDH1/IDH2 mutations. There are two noteworthy points regarding the proposed trial:

1) The trial will utilize a matched external control group for 2/3rd of the control arm.
2) Patients will be randomized 3:1 to receive MDNA55 or standard of care (SOC). SOC will consist of physician's choice (temozolomide, bevacizumab, lomustine, etc.)

This is the first instance we are aware of where a company has been encouraged to utilize a substantial external control arm for a cancer trial and could represent a paradigm shift in the way trials are conducted for diseases that have a significant unmet need for improved therapeutics. In addition, the use of a sizeable external control arm will decrease the number of patients required in the trial, which will help to defray costs and could expedite the time to complete the trial. With a 3:1 randomization it will also allow for more patients to receive MDNA55 than would be possible with a standard 1:1 randomization.

We estimate a total of approximately 150 patients will be enrolled in the treatment arm, with approximately 50 patients enrolled in the control arm. Another 100 patients will be enrolled into the external control arm, with records for those patients derived from previous clinical trials that have been conducted since January 2016. Patients included in the external control arm will have characteristics similar to those enrolled in the treatment and control arms and will be identified in a manner similar to that used for the company's analysis of the Phase 2 clinical trial that utilized a synthetic control arm. An outline of the trial is given below.



We anticipate partnership discussions to ramp up in 2021 now that the Phase 3 trial design is complete as the company has indicated the initiation of the Phase 3 program will not commence until a collaboration agreement with a larger pharmaceutical company is in place.

Additions to Management Team

In the past couple of months, Medicenna has strengthened its leadership team with the appointment of two industry veterans with extensive experience in immuno-oncology drug development.

- In April 2021, Medicenna announced the appointment of Kevin Moulder, PhD as the company's Chief Scientific Officer. Dr. Moulder has over 30 years of experience in drug discovery, protein design, antibody technology, immuno-oncology, inflammation, and autoimmune disease. He most recently held C-level positions at PolyProx Therapeutics Ltd. and Tusk Therapeutics. At Tusk, Dr. Moulder oversaw the development of an anti-CD25 antibody that exhibited anticancer activity by depleting Tregs without affecting IL-2 activity on effector T cells.

- In May 2021, Medicenna announced the appointment of Mann Muhsin, MD as the company's Chief Medical Officer. Dr. Muhsin has over 20 years of experience in medical practice and drug development. He began his clinical career at PICR phase I unit, where he conducted clinical trials for companies such as AstraZeneca, Hoffman La Roche, Merck, Novartis, Eli Lilly, Johnson & Johnson, and Bayer. In addition, Dr. Muhsin has designed and executed oncology trials for many companies and was most recently at Nektar Therapeutics where he led the Phase 3 PIVOT-12 trial and global product strategy for NKTY-262.

Financial Update

On May 28, 2021, Medicenna announced financial results for fiscal year 2021, which ended March 31, 2021. As expected, the company did not report any revenues for fiscal year 2021. Net loss was CAD$17.3 million, or $0.35 per share, compared to a net loss of CAD$8.2 million, or $0.26 per share, for the year ending March 31, 2020. R&D

expenses for fiscal year 2021 were approximately CAD$10.9 million, compared to approximately CAD$5.9 million for fiscal year 2020. The increase was primarily due to increased manufacturing costs for MDNA11, increased discovery and pre-clinical expenses for MDNA IND-enabling studies, and no reimbursement of expenses from the CPRIT grant. G&A expenses in fiscal year 2021 were CAD$6.5 million, compared to CAD$2.4 million for fiscal year 2020. The increase was primarily due to increased insurance premiums and higher fees associated with the NASDAQ listing.

As of March 31, 2021, Medicenna had approximately CAD$40.4 million in cash and cash equivalents. We estimate that the company is funded through the end of 2022. As of March 31, 2021, Medicenna had approximately 53.5 million shares of common stock outstanding and, when factoring in warrants and stock options, a fully diluted share count of 61.7 million.

Conclusion

We look forward to the initiation of the Phase 1/2a clinical trial of MDNA11 and anticipate initial safety, PK/PD, and biomarker data before the end of 2021 and initial efficacy data in the first half of 2022. We also anticipate an update on partnership talks for MDNA55 and the selection of a lead development product from the company's BiSKIT platform before the end of 2021. With no changes to our model our valuation remains at $12 per share.

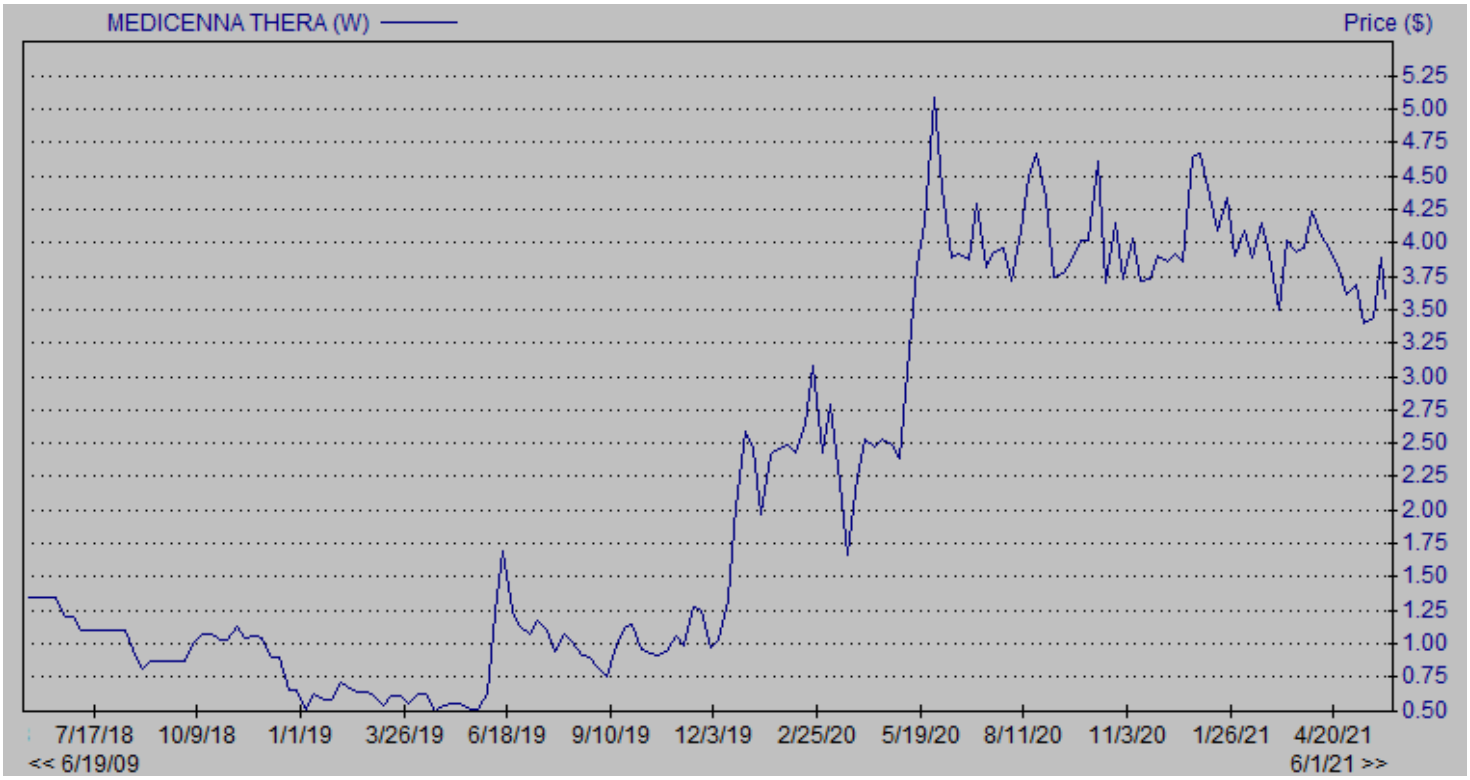
PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2021 A	Q1 FY22 E	Q2 FY22 E	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	$2.0	$2.8	$3.5	$4.0	$12.3	$18.0	$20.0
General & Administrative	$6.5	$1.5	$1.8	$2.2	$2.5	$8.0	$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)	($3.5)	($4.6)	($5.7)	($6.5)	($20.3)	($27.0)	($30.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.1)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.4)	($0.4)
Pre-Tax Income	($17.3)	($3.4)	($4.5)	($5.6)	($6.4)	($19.9)	($26.6)	($29.6)
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)**	**($3.4)**	**($4.5)**	**($5.6)**	**($6.4)**	**($19.9)**	**($26.6)**	**($29.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.35)**	**($0.06)**	**($0.08)**	**($0.10)**	**($0.12)**	**($0.37)**	**($0.44)**	**($0.46)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	49.7	53.5	54.0	54.2	54.5	54.1	60.0	65.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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