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Medicenna Therapeutics Corp. (MDNA-NASDAQ)

MDNA: ABILITY Study Advancing to Sixth Dosing Cohort…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55, MDNA11, and the Superkine platform MDNA is valued at $7.00/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 (02/16/23)	US$0.70
Valuation	**US$7.00**

OUTLOOK

On February 7, 2023, Medicenna Therapeutics Corp. (MDNA) announced financial results for the third quarter of fiscal year 2023 that ended December 31, 2022. Enrollment has completed in the fifth dosing cohort of the Phase 1/2 ABILITY study. Thus far, there have been no dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues. We anticipate updated efficacy data from the first four dosing cohorts along with PK/PD data from the fifth dosing cohort during the first quarter of calendar 2023. Based on the safety data from the fifth dosing cohort, the trial has advanced to a sixth dosing cohort in which participants will receive 30, 60, and 90 μg/kg "priming" doses of MDNA11 followed by a step-up to a fixed 120 μg/kg dose. Initial efficacy data from the sixth dosing cohort could be available in the third quarter of calendar 2023.

SUMMARY DATA

52-Week High	**$1.78**
52-Week Low	**$0.40**
One-Year Return (%)	**-59.60**
Beta	**1.20**
Average Daily Volume (sh)	**176,527**
Shares Outstanding (mil)	**70**
Market Capitalization (C$mil)	**$49**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**20**
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	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	0 A	0 E	0 E
2024					0 E
2025					0 E

Earnings per Share
(in $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2022	-$0.12 A	- $0.15 A	-$0.09 A	-$0.06 A	-$0.42 A
2023	-$0.08 A	-$0.01 A	-$0.02 A	-$0.09 E	-$0.31 E
2024					-$0.41 E
2025					-$0.42 E

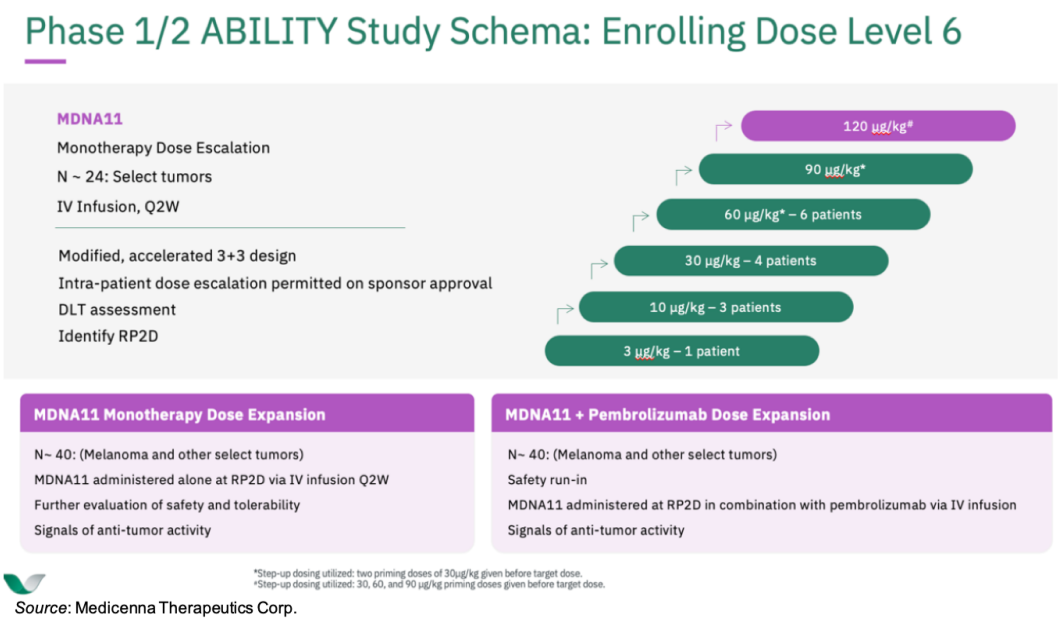
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WHAT'S NEW

Business Update

ABILITY Trial Moving to Sixth Dosing Cohort

Medicenna Therapeutics Corp. (MDNA) is currently conducting the Phase 1/2 ABILITY Study (A Beta-only IL-2 ImmunoTherapY Study) of MDNA11 in patients with advanced solid tumors (NCT05086692). Enrollment has completed in the fifth dosing cohort. Importantly, MDNA11 continues to demonstrate a favorable tolerability profile as a monotherapy. To date, there have been no reports of dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues. Based on the favorable safety data, enrollment is currently underway in the sixth dosing cohort. Patients will receive 30, 60, and 90 μg/kg "priming" doses of MDNA11 followed by fixed doses of 120 μg/kg. Once a recommended Phase 2 dose (RP2D) is determined, Medicenna will begin the monotherapy dose expansion portion of the trial with approximately 40 patients. The company will then begin a combination therapy arm of MDNA11 + pembrolizumab in an additional 40 patients. An outline of the company's plans is given below.

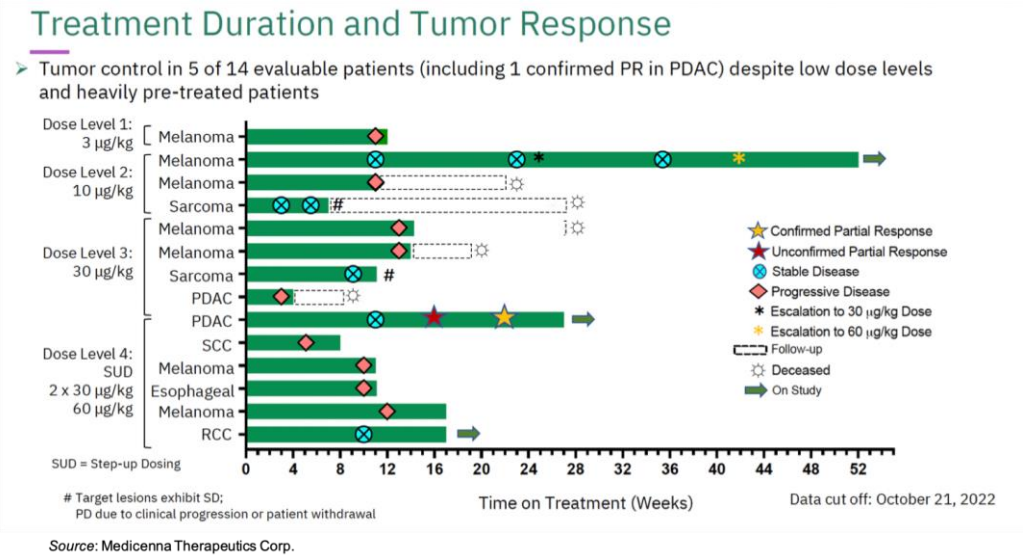


Source: Medicenna Therapeutics Corp.

In September 2022, the company provided updated anti-tumor activity data from the first four dosing cohorts. The data included a confirmed partial response (PR) in a patient with metastatic pancreatic ductal adenocarcinoma (PDAC) that had failed prior chemotherapy and checkpoint inhibitor therapies. The confirmatory scan for that patient showed that they continue to show tumor reduction when compared to prior scans. Overall, of the 14 evaluable patients, five have achieved tumor control (PR or stable disease [SD]) with MDNA11 monotherapy. The five patients that have achieved tumor control are listed below, with a summary of all patients treated thus far in the following chart:

1. Fourth-line (4L) PDAC Stage IV (Dose Level 4 @ 60 μg/kg following two divided doses of 30 μg/kg); confirmed PR
2. 3L non-clear cell renal cell carcinoma (Dose level 4 @ 60 μg/kg); SD
3. 4L sarcoma (Dose level 3 @ 30 μg/kg); SD
4. 3L melanoma (initial dose level 2 @ 10 μg/kg; escalated to dose level 3 @ 30 μg/kg and dose level 4 @ 60 μg/kg); SD
5. 3L sarcoma (initial dose level 2 @ 10 μg/kg); SD

A summary of the treatment duration and responses for each of the 14 evaluable patients is shown below:



Source: Medicenna Therapeutics Corp.

In November 2022, Medicenna presented new safety, pharmacokinetic (PK), and pharmacodynamic (PD) data at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting. Of note, the company reported that PK data remained consistent with repeat dosing, which suggests that there is no anti-drug antibody response. In addition, MDNA11 continues to show a selective and dose-dependent stimulating of anti-cancer immune cells in the low- and mid-dose cohorts, which suggests that there may be additional anti-tumor activity in the higher dose cohorts. PD data shows that MDNA11's effects on anti-cancer immune cells is sustained beyond serum exposure (>11 days), which indicates a prolonged PD effect. In regards to safety, 92% of treatment-related adverse events have been Grade 1-2 and transient, with the majority resolving within 1-2 days.

We anticipate updated anti-tumor activity data from the first four dosing cohorts along with PK/PD data from the fifth dosing cohort of the ABILITY trial in the first quarter of calendar 2023; early anti-tumor activity data from the sixth dosing cohort in the third quarter of calendar 2023; and early anti-tumor activity data from the combination arm of the trial in the fourth quarter of calendar 2023.

Phase 2b Results for Bizaxofusp (Formerly MDNA55) Published in Neuro-Oncology

In January 2023, the full results from the Phase 2b clinical trial of bizaxofusp (formerly MDNA55) were published in the journal *Neuro-Oncology* (Sampson *et al*., 2023). This was an open label, single arm trial in recurrent glioblastoma (GBM) patients on their 1st or 2nd recurrence (NCT02858895). Bizaxofusp was administered intratumorally as a single dose using convection enhanced delivery (CED). Results showed that bizaxofusp had an acceptable safety profile. Of the 44 evaluable patients, mOS was 11.6 months and OS-12 was 46%. The subgroup of IL4R high and low patients treated with a high dose of bizaxofusp (> 180 µg) showed the best benefit with mOS of 15 months and OS-12 of 55%. Following an 'End-of-Phase 2' meeting with the FDA in 2020, the agency guided for the company to proceed with a Phase 3 registration trial of MDNA55 in rGBM patients that harbor no IDH1/IDH2 mutations that includes an innovative design, including:

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.)

Medicenna is pursuing strategic partnerships to assist with the continued clinical development of bizaxofusp along with the commercialization and subsequent launch should it go on to be approved.

Financial Update

On February 7, 2023, Medicenna announced financial results for the third quarter of fiscal year 2023 that ended December 31, 2022. The company reported a net loss for the third quarter of fiscal year 2023 of CAD$1.1 million, or CAD$0.02 per share, compared to a net loss of CAD$4.8 million, or CAD$0.09 per share, for the three months ending December 31, 2021. R&D expenses for the third quarter of fiscal year 2023 were CAD$2.9 million compared to CAD$2.9 million for the third quarter of fiscal year 2022. G&A expenses for the third quarter of fiscal year 2023 were CAD$2.0 million compared to CAD$2.0 million for the third quarter of fiscal year 2022.

As of December 31, 2022, Medicenna had approximately CAD$36.2 million in cash, cash equivalents, and marketable securities. We estimate the company has sufficient capital to fund operations into the second quarter of calendar 2024, and importantly is sufficiently financed to complete both the monotherapy and combination therapy trials of MDNA11. As of February 7, 2023, Medicenna had approximately 69.6 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 91.6 million.

Conclusion

The advancement of the ABILITY trial to a sixth dosing cohort is encouraging as there continues to be no reports of dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues. We look forward to updated anti-tumor activity data for the first four dosing cohorts along with PK/PD data from the fifth dosing cohort later this quarter. We have made no adjustments to our model and our valuation remains at $7.00 per share.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2022 A	Q1 FY23 A	Q2 FY23 A	Q3 FY23 A	Q4 FY23 E	FY 2023 E	FY 2024 E	FY 2025 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	$14.7	$2.4	$2.4	$2.9	$4.5	$12.2	$17.0	$20.0
General & Administrative	$7.8	$1.9	$2.4	$2.0	$2.2	$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	($22.5)	($4.3)	($4.7)	($4.9)	($6.7)	($20.7)	($26.0)	($30.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.2)	($3.8)	($3.8)	($0.1)	($0.4)	($0.4)	($0.4)
Pre-Tax Income	($22.6)	($4.2)	($0.9)	($1.1)	($6.6)	($20.3)	($25.6)	($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	-$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($22.6)**	**($4.2)**	**($0.9)**	**($1.2)**	**($6.6)**	**($20.3)**	**($25.6)**	**($29.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.08)**	**($0.01)**	**($0.02)**	**($0.09)**	**($0.31)**	**($0.41)**	**($0.42)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	54.3	56.1	63.6	69.6	70.0	64.8	63.0	70.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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