

# Zacks Small-Cap Research

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July 6, 2023  
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## Medicenna Therapeutics Corp.

(MDNA-NASDAQ)

### **MDNA: Full MDNA11 Clinical Update in Calendar 3Q23...**

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 (07/06/23) **US\$0.49**  
Valuation **US\$7.00**

### SUMMARY DATA

52-Week High	<b>\$1.78</b>
52-Week Low	<b>\$0.40</b>
One-Year Return (%)	<b>-57.46</b>
Beta	<b>1.13</b>
Average Daily Volume (sh)	<b>75,479</b>
Shares Outstanding (mil)	<b>70</b>
Market Capitalization (\$mil)	<b>\$34</b>
Short Interest Ratio (days)	<b>1</b>
Institutional Ownership (%)	<b>13</b>
Insider Ownership (%)	<b>33</b>
Annual Cash Dividend	<b>\$0.00</b>
Dividend Yield (%)	<b>0.00</b>
5-Yr. Historical Growth Rates	
Sales (%)	<b>N/A</b>
Earnings Per Share (%)	<b>N/A</b>
Dividend (%)	<b>N/A</b>
P/E using TTM EPS	<b>N/A</b>
P/E using 2018 Estimate	<b>N/A</b>
P/E using 2019 Estimate	<b>N/A</b>

### OUTLOOK

On June 27, 2023, Medicenna Therapeutics Corp. (MDNA) announced financial results for the fourth quarter and full fiscal year 2023 that ended March 31, 2023. We anticipate a comprehensive data update and next steps for MDNA11 in calendar 3Q23 as the company continues to collect results from the remaining patients in the high dose cohorts of the ABILITY trial. Thus far, the company has reported a fourth-line metastatic pancreatic cancer patient has achieved a partial response continuing for over 40 weeks and a third-line metastatic melanoma patient has achieved stable disease for over 70 weeks. The single agent dose expansion portion of the ABILITY trial is anticipated to begin in calendar 3Q23 and the company's current cash on hand is expected to last through calendar 3Q24 along with several key milestones of the ABILITY trial.

Risk Level	High
Type of Stock	Small-Value
Industry	Med-Biomed/Gene

### ZACKS ESTIMATES

Revenue (in millions of \$CAD)	Q1	Q2	Q3	Q4	Year
	(Jun)	(Sep)	(Dec)	(Mar)	(Mar)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 E	0 E	0 E	0 E	0 E
2025					0 E
2026					0 E
Earnings per Share (in \$CAD)	Q1	Q2	Q3	Q4	Year
	(Jun)	(Sep)	(Dec)	(Mar)	(Mar)
2023	-\$0.08 A	-\$0.01 A	-\$0.02 A	-\$0.05 A	-\$0.16 A
2024	-\$0.05 E	-\$0.05 E	-\$0.05 E	-\$0.06 E	-\$0.21 E
2025					-\$0.20 E
2026					-\$0.20 E

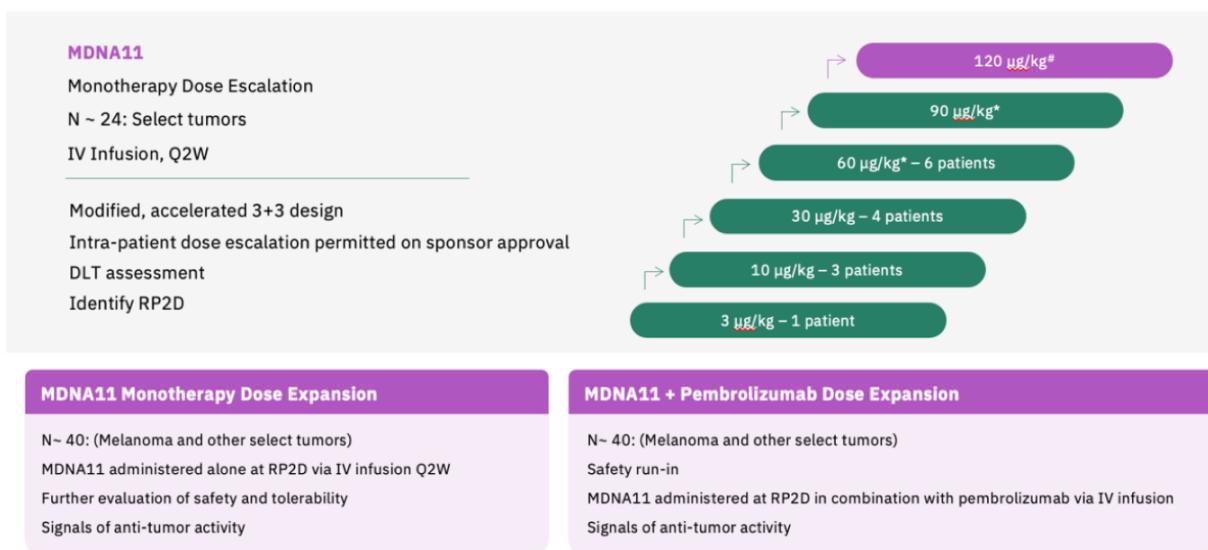
## WHAT'S NEW

### Business Update

#### *Update on ABILITY Trial Expected in Calendar 3Q23*

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](https://clinicaltrials.gov/ct2/show/NCT05086692)). In the ongoing dose escalation portion of the study, MDNA11 is administered intravenously once every two weeks to patients with advanced solid tumors. The first two cohorts evaluated MDNA11 at doses  $\leq$  10  $\mu\text{g}/\text{kg}$ . The third cohort was administered a dose of 30  $\mu\text{g}/\text{kg}$ . Patients in the fourth and fifth cohorts received two 30  $\mu\text{g}/\text{kg}$  “priming” doses of MDNA11 before stepping up to receive fixed doses of 60 and 90  $\mu\text{g}/\text{kg}$ , respectively. Cohort six will receive a target dose of 120  $\mu\text{g}/\text{kg}$  following three priming doses of 30, 60, and 90  $\mu\text{g}/\text{kg}$ . This is summarized in the following figure.

### Phase 1/2 ABILITY Study Schema: Enrolling Dose Level 6



Source: Medicenna Therapeutics Corp.

The company is currently enrolling patients in the sixth and final dose escalation cohort, which we expect will complete in mid-calendar year 2023. Following that, we anticipate a comprehensive update on PK, PD, safety, and efficacy from all six cohorts, which will include initial anti-tumor activity data from the fifth and sixth dose escalation cohorts in calendar 3Q23. We expect the Phase 2 monotherapy dose expansion portion of the trial to commence in calendar 3Q23 and the combination therapy (MDNA + Keytruda) to initiate in calendar 4Q23.

Key Data from the first four dosing cohorts includes:

#### **Safety:**

- There were no dose-limiting toxicities in Cohort 4
- There have been no significant increases in eosinophil count from baseline associated with MDNA11 treatment. This is important as high eosinophil count is associated with vascular leak syndrome, a serious side effect that is known to occur with high-dose recombinant human IL-2 (Proleukin®)

#### **PK/PD:**

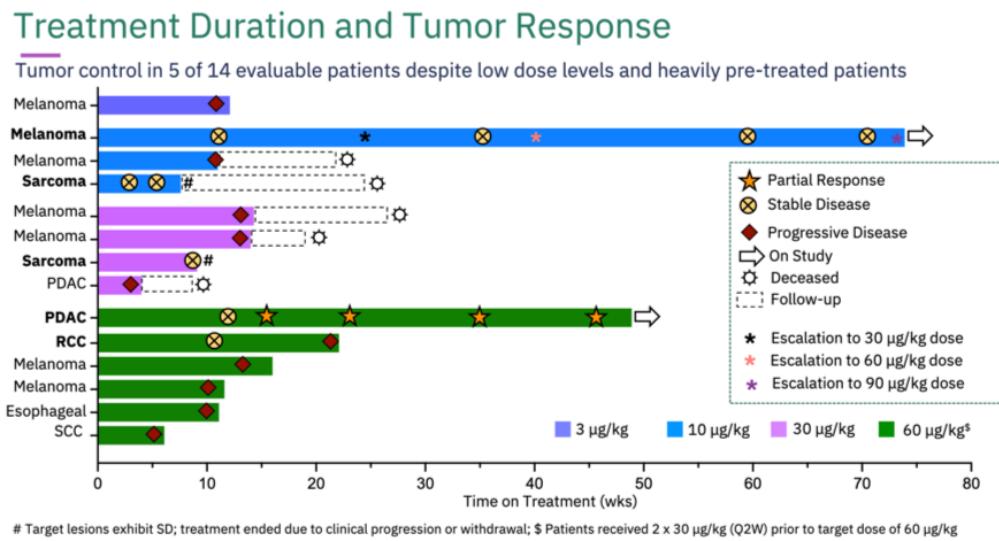
- Dose dependent increases in Cmax and Area Under the Curve were observed
- No sign of immunogenicity as exhibited by a lack of anti-drug antibodies
- MDNA11 preferentially expanded anti-cancer NK and CD8+ T cells without stimulating proliferation of pro-tumor Treg cells

### Anti-Tumor Activity:

Of the 14 evaluable patients, five achieved tumor control (stable disease, partial response, or complete response as per RECIST 1.1):

1. Metastatic Leiomyosarcoma Stage IV (Dose Level 2 @ 10  $\mu\text{g}/\text{kg}$ ); stable disease.
2. Metastatic Melanoma Grade 4C (initially enrolled at Dose Level 2 @ 10  $\mu\text{g}/\text{kg}$  Q2W with subsequent intra-patient dose escalations to Dose Level 3 @ 30  $\mu\text{g}/\text{kg}$  and Dose Level 4 @ 60  $\mu\text{g}/\text{kg}$ ), stable disease.
3. Metastatic Sarcoma Stage IV (Dose Level 3 @ 30  $\mu\text{g}/\text{kg}$ ), stable disease
4. Pancreatic Ductal Adenocarcinoma (PDAC) Stage IV (Dose Level 4 @ 60  $\mu\text{g}/\text{kg}$  following 2 priming doses of 30  $\mu\text{g}/\text{kg}$ ), confirmed partial response.
5. Non-clear cell 3L renal cell carcinoma patient (Dose Level 4 @ 60  $\mu\text{g}/\text{kg}$  following 2 priming doses of 30  $\mu\text{g}/\text{kg}$ ), stable disease.

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



Source: Medicenna Therapeutics Corp.

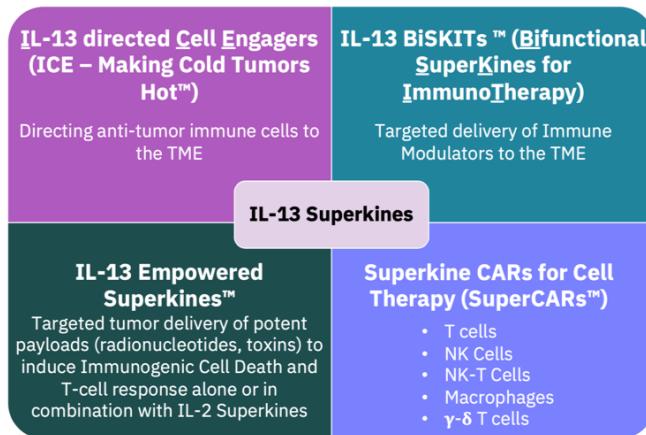
### New Preclinical Data on IL-13 Superkines Presented at AACR

In April 2023, Medicenna [announced](#) that new preclinical data characterizing the Interleukin-13 (IL-13) Superkines MDNA132 and MDNA213, along with a series of next-generation IL-13 Superkines, was presented at the 2023 Annual Meeting of the American Association for Cancer Research (AACR) ([Sharma et al., 2023](#)). IL-13 signals through two different receptors; The Type II receptor, which is composed of IL-4R $\alpha$ /IL-13R $\alpha$ 1, and the IL-13R $\alpha$ 2 decoy receptor, whose exact function is unclear. IL-13 binding to the Type II receptor activates the Stat6 signaling pathway that ultimately promotes M2 tumor associated macrophages (TAMs) and myeloid derived suppressor cells (MDSCs). Both of these cell types limit immune effector cells and promote an 'immunologically cold' tumor microenvironment ([Bhattacharjee et al., 2013](#)).

MDNA132 and MDNA213 target the IL-13R $\alpha$ 2 decoy receptor, which is overexpressed in a number of different cancer types (pancreatic, prostate, colorectal, etc.) but has little to no expression in normal tissues. In addition, increased expression of IL-13R $\alpha$ 2 correlates with cancer invasion, metastasis, and poor survival. Thus, IL-13R $\alpha$ 2 has become an attractive cancer target given its tumor specificity and high expression in immune suppressed "cold tumors".

Both MDNA132 and MDNA213 were designed to have increased affinity to IL-13R $\alpha$ 2 and no binding to IL-13R $\alpha$ 1. Directed evolution of IL-13 resulted in the selection of MDNA132, which exhibits no binding to IL-13R $\alpha$ 1 but also slightly decreased binding to IL-13R $\alpha$ 2. Additional mutations designed through in-silico modeling resulted in MDNA213, which also exhibits no binding to IL-13R $\alpha$ 1 but has increased affinity to IL-13R $\alpha$ 2 even when compared to native IL-13.

Medicenna is designing a family of next-generation IL-13 Superkines that combine the IL-13 binders with other molecules for enhanced anti-tumor activity or targeted delivery of potent toxins or immune modulators. The different IL-13 Superkines the company is developing is shown in the following figure.



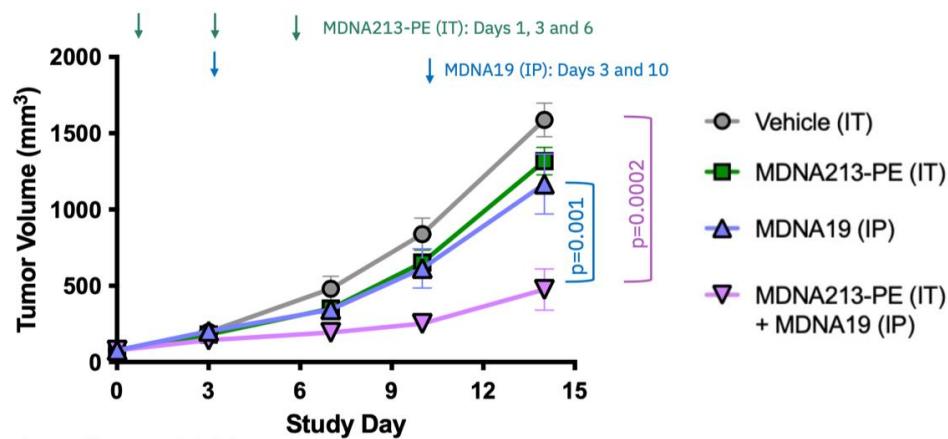
The presentation at AACR included data for a series of next-generation IL-13 Superkines:

**Anti-mCD3-MDNA132:** This is a first-in-class IL-13 directed Cell Engager (ICE-Making Cold Tumors Hot™) that is comprised of MDNA132 fused to an anti-CD3 antibody. The *in vitro* data showed that the molecule retains high affinity to IL-13Ra2, which is expressed on tumor cells, and CD3, which is expressed on immune cells. The theory behind this molecule is that it will recruit the patient's own immune cells to the tumor microenvironment to directly target immunologically “cold” tumors.

**MDNA19-MDNA213:** This is a first-in-class BiSKIT™ (Bifunctional SuperKines for ImmunoTherapy) that is comprised of MDNA213 fused to MDNA19, the Fc version of MDNA11. The *in vitro* data show that this BiSKIT retains strong binding to both IL-13Ra2 and CD122 (IL-2R $\beta$ ) while stimulating effector T cells and NK cells without stimulating Tregs.

**Anti-mPD1-MDNA213:** This is a first-in-class BiSKIT that is comprised of MDNA213 fused to an anti-PD-1 antibody. The *in vitro* data show that the molecule retains strong binding to both IL-13Ra2 and PD1 while effectively blocking the PD1/PD-L1 interaction with a similar potency as the native anti-PD1 antibody.

**MDNA213-PE:** This is an Empowered Superkine that is comprised of MDNA213 fused to the PE cytotoxin (same cytotoxin utilized in bixaxofusp, formerly MDNA55). The *in vitro* data show that the molecule exhibits potent cytotoxicity against human and murine cancer cells that express IL-13Ra2. In addition, as the following image shows, in a murine triple-negative breast cancer model, MDNA213-PE inhibited tumor growth as both a single agent and in combination with MDNA19.



Source: Sharma *et al.*, 2023

## **Financial Update**

On June 27, 2023, Medicenna announced financial results for fiscal year 2023, which ended March 31, 2023. As expected, the company did not report any revenues for fiscal year 2023. Net loss was CAD\$10.0 million, or \$0.16 per share, compared to a net loss of CAD\$22.6 million, or \$0.42 per share, for the fiscal year ending March 31, 2022. R&D expenses for fiscal year 2023 were approximately CAD\$9.3 million, compared to approximately CAD\$14.7 million for fiscal year 2022. The decrease was primarily due to costs associated with the development of MDNA11 incurred in fiscal year 2022, which included GMP manufacturing and IND enabling studies. G&A expenses in fiscal year 2023 were CAD\$7.0 million, compared to CAD\$7.8 million for fiscal year 2022. The decrease was primarily due to reduction in directors and officers liability insurance premiums.

As of March 31, 2023, Medicenna had approximately CAD\$33.6 million in cash and cash equivalents. We estimate that the company is funded through key milestones in the ABILITY trial and through calendar 3Q24. As of June 27, 2023, Medicenna had approximately 69.6 million shares of common stock outstanding and, when factoring in warrants and stock options, a fully diluted share count of approximately 91.4 million.

## **Conclusion**

The data reported thus far for the ABILITY trial has been very encouraging and we are looking forward to the comprehensive update in the third calendar quarter of 2023, which we expect will include preliminary anti-tumor activity for Cohorts five and six. While preliminary, the data presented at AACR shows the potential for the IL-13 Superkine platform and we look forward to additional updates on this and other preclinical programs the company has ongoing. With no changes to our model our valuation remains at \$7.00 per share.

## PROJECTED FINANCIALS

### Medicenna Therapeutics Corp.

#### Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2023 A	Q1 FY24 E	Q2 FY24 E	Q3 FY24 E	Q4 FY23 E	FY 2024 E	FY 2025 E	FY 2026 E
MDNA55 <i>YOY Growth</i>	\$0 -							
MDNA11 <i>YOY Growth</i>	\$0 -							
Other Income <i>YOY Growth</i>	\$0 -							
<b>Total Revenues</b>	<b>\$0</b>							
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Sales <i>Product Gross Margin</i>	\$0 -							
Research & Development	\$9.3	\$2.0	\$2.2	\$2.5	\$2.9	\$9.6	\$10.5	\$11.0
General & Administrative	\$7.0	\$1.5	\$1.7	\$2.0	\$2.2	\$7.4	\$8.0	\$8.5
Other (Income) Expense	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Operating Income	(\$16.3)	(\$3.5)	(\$3.9)	(\$4.5)	(\$5.1)	(\$17.0)	(\$18.5)	(\$19.5)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	(\$6.3)	(\$0.2)	(\$0.2)	(\$0.2)	(\$0.2)	(\$0.8)	(\$0.4)	(\$0.4)
Pre-Tax Income	(\$10.0)	(\$3.3)	(\$3.7)	(\$4.3)	(\$4.9)	(\$16.2)	(\$18.1)	(\$19.1)
Income Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Cumulative translation adjustment	(\$0.1)	(\$0.1)	(\$0.1)	(\$0.0)	(\$0.0)	(\$0.2)	(\$0.2)	(\$0.2)
<b>Net Income</b>	<b>(\$10.1)</b>	<b>(\$3.4)</b>	<b>(\$3.8)</b>	<b>(\$4.3)</b>	<b>(\$4.9)</b>	<b>(\$16.4)</b>	<b>(\$18.3)</b>	<b>(\$19.3)</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>(\$0.16)</b>	<b>(\$0.05)</b>	<b>(\$0.05)</b>	<b>(\$0.05)</b>	<b>(\$0.06)</b>	<b>(\$0.21)</b>	<b>(\$0.20)</b>	<b>(\$0.20)</b>
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	64.7	70.0	70.0	80.0	85.0	76.3	90.0	95.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

## HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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