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Medicenna Therapeutics Corp. (MDNA-NASDAQ)

MDNA: Multiple Catalysts Expected in 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 (02/17/21)	$4.15
Valuation	**$12.00**

OUTLOOK

On February 12, 2021, Medicenna Therapeutics Corp. announced financial results for the third quarter of fiscal year 2021 ending Dec. 31, 2020 and provided a business update. The company completed a number of milestones during the previous quarter and we anticipate multiple upcoming catalysts in calendar 2021. Following positive feedback from the UK's MHRA on the plans for a Phase 1/2a clinical trial of MDNA11, we anticipate an IMPD being filed such that the trial can initiate in mid-2021. The FDA has accepted the company's proposed Phase 3 trial design for MDNA55 that includes the use of matched external controls for 2/3rd of the control arm. Medicenna is actively pursuing partnership opportunities for MDNA55.

SUMMARY DATA

52-Week High	**$5.97**
52-Week Low	**$1.59**
One-Year Return (%)	**61.48**
Beta	**1.50**
Average Daily Volume (sh)	**279,142**
Shares Outstanding (mil)	**51**
Market Capitalization (C$mil)	**$210**
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	**High**
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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share
(in $CAD)

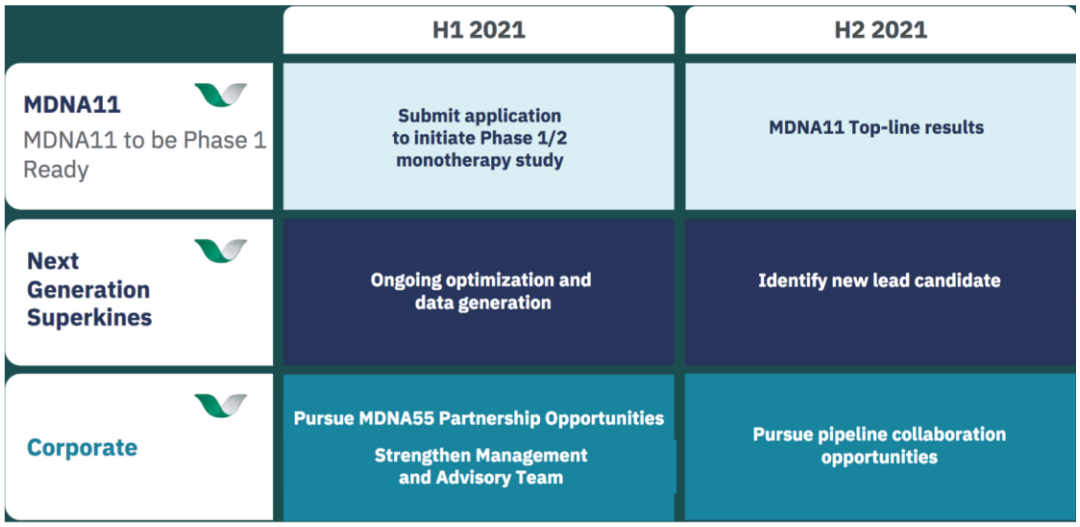
	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2020	-$0.05 A	- $0.07 A	-$0.07 A	-$0.07 A	-$0.26 A
2021	-$0.05 A	-$0.08 A	-$0.11 A	-$0.06 E	-$0.32 E
2022					-$0.42 E
2023					-$0.54 E

WHAT'S NEW

Business Update

Multiple Catalysts Ahead in 2021

Medicenna Therapeutics Corp. (MDNA) has two lead development programs: MDNA11, an enhanced version of IL-2 being developed as a cancer immunotherapy, and MDNA55, which is being developed for the treatment of recurrent glioblastoma. In addition, the company has a number of next-generation 'Superkines' (enhanced cytokines) under development. We anticipate the following milestones for those programs in the upcoming year:

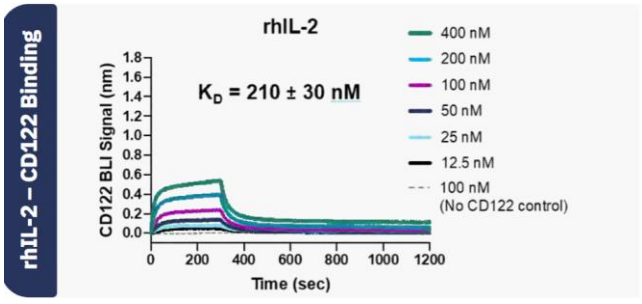


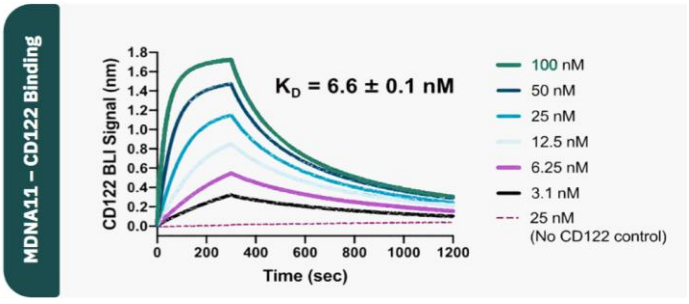
Source: Medicenna Therapeutics Corp.

MDNA11

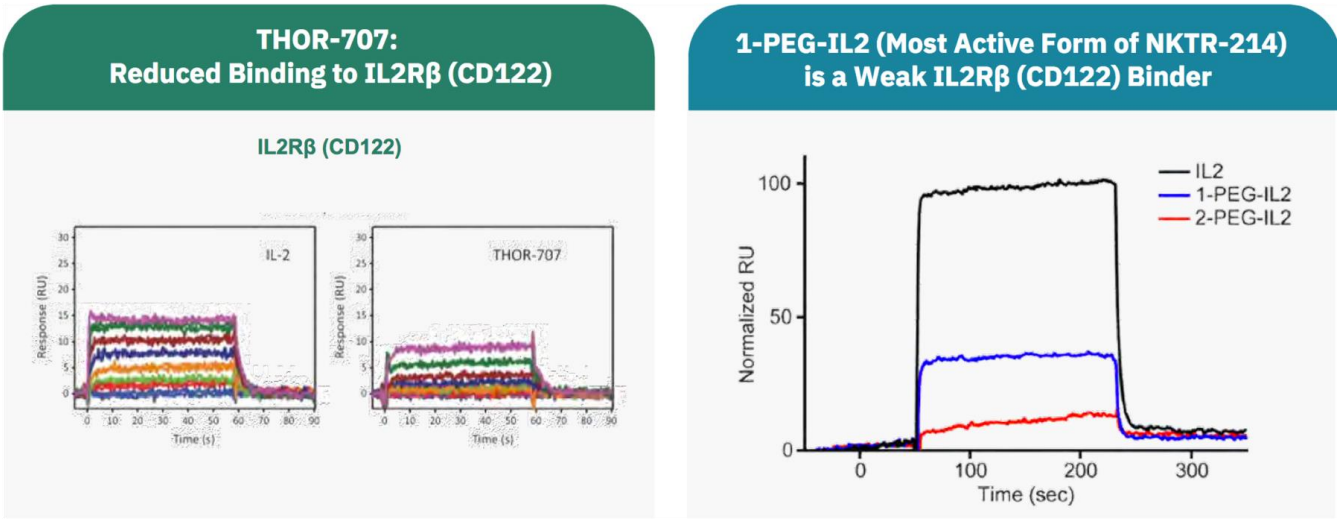
MDNA11 is a long-acting variant of IL-2 that is engineered to have enhanced binding to CD122 and no affinity for CD25. IL-2 is a 16 kDa protein that activates a wide range of leukocytes, including T cells and natural killer (NK) cells through binding IL-2 receptors (IL-2Rα [CD25], IL-2Rβ [CD122], and 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.

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 that includes increased affinity to CD122 and no CD25 binding. The following graphs show that compared to native IL-2, MDNA11 shows enhanced CD122 binding as exhibited by its lower K_D value. In addition, this enhanced binding to CD122 is not seen in competitors IL-2 variants, with both THOR-707 and NKTR-214 showing decreased affinity for CD122 compared to native IL-2.



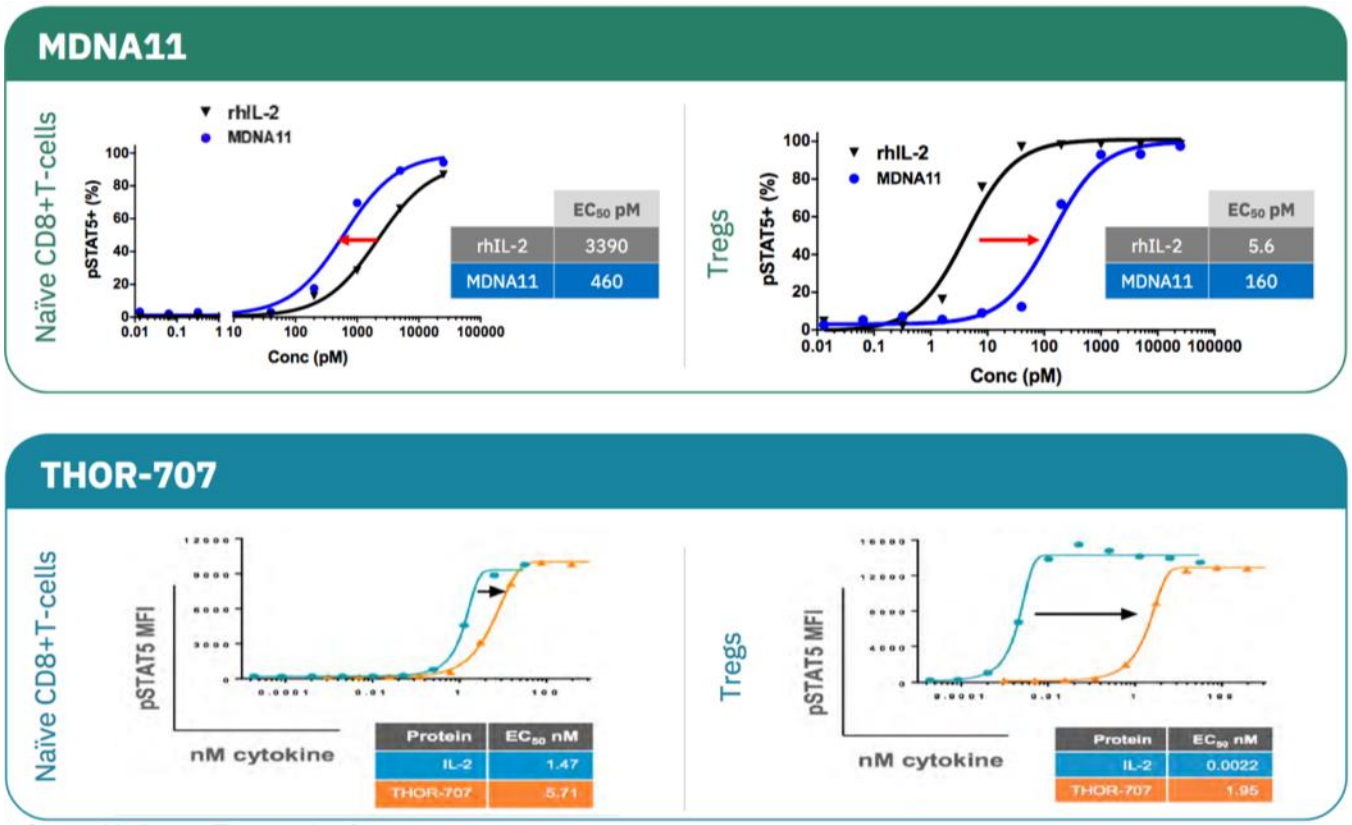


Source: Medicenna Therapeutics Corp.



Source: Medicenna Therapeutics Corp.

When examining the effect on immune cells, only MDNA11 shows both enhanced potency toward anti-tumor CD8+ T cells and reduced potency toward pro-tumor regulatory T cells (Tregs). While THOR-707 does exhibit reduced potency toward Tregs, it also shows reduced potency toward anti-tumor CD8+ T cells when compared to native IL-2.

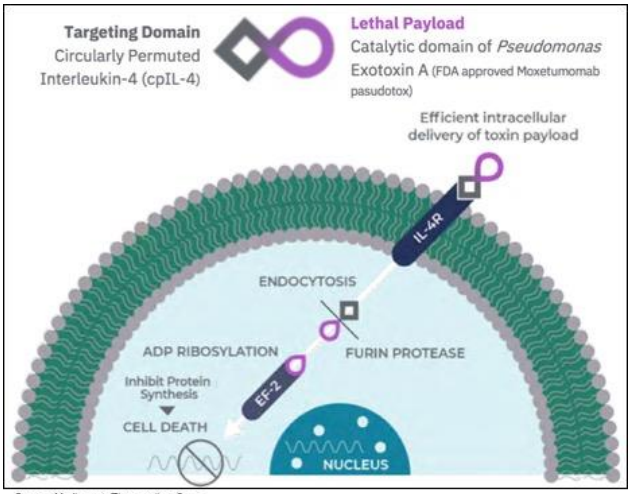


Source: Medicenna Therapeutics Corp.

In November 2020, Medicenna held a Scientific Advice Meeting (similar to a pre-IND meeting) for MDNA11 with the U.K. Medicines and Health products Regulatory Agency (MHRA). The company confirmed with the MHRA that its CMC, preclinical, and Phase 1/2a clinical plans were appropriate for submitting an Investigational Medical Product Dossier (IMPD) in order initiate a clinical trial in mid-2021. Medicenna chose to conduct the dose escalation portion of the Phase 1/2a trial in the U.K. since that population has a higher percentage of patients that are checkpoint inhibitor naïve. The company plans to open clinical trial sites in the U.S. following completion of the dose escalation portion of the study.

MDNA55

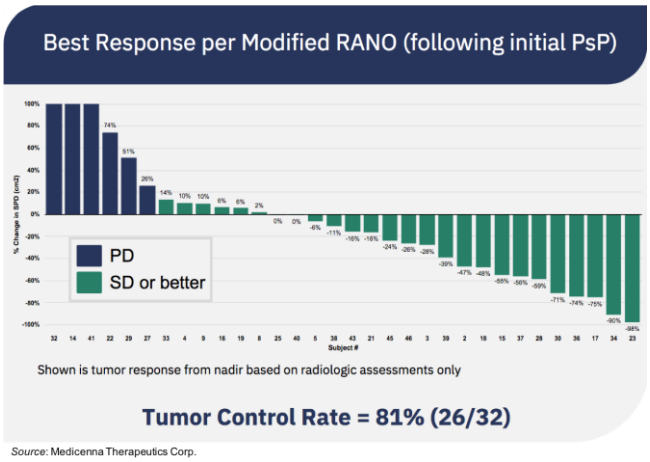
MDNA55 is Medicenna's targeted immunotherapy that has completed a Phase 2b clinical trial for the treatment of recurrent glioblastoma (rGBM). The compound consists of a fusion protein containing a circularly permuted version of IL-4 linked to a fragment of the potent bacterial toxin *Pseudomonas* Exotoxin 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. A cartoon representation of MDNA55 and its mechanism of action are depicted in the following figure.



Source: Medicenna Therapeutics Corp.

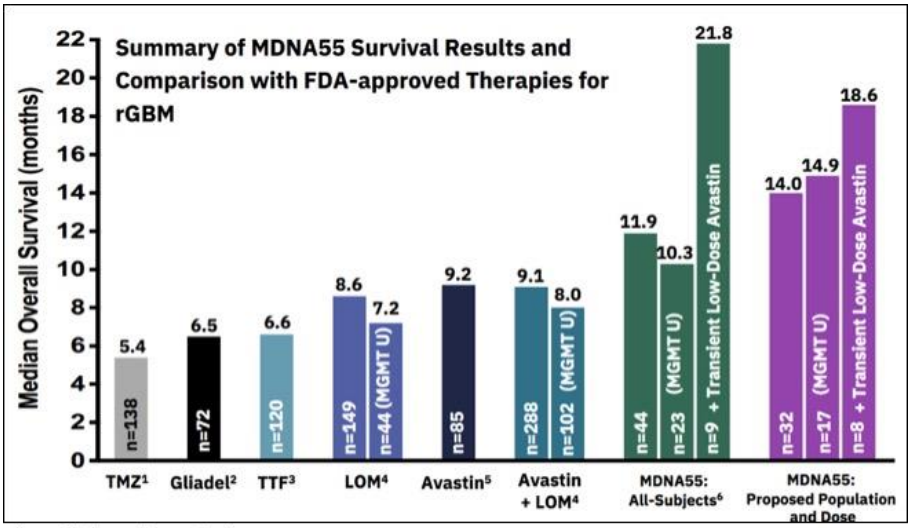
The Phase 2b clinical trial of MDNA55 was a multi-center, open label, single arm study with the primary endpoint of median overall survival (mOS) and a secondary endpoint of objective response rate (ORR) following a single intra-tumoral infusion of MDNA55 in adult rGBM subjects experiencing either a first or second GBM relapse (NCT02858895).

When patients were stratified by IL4R status, the results showed that almost all of those who exhibited tumor control in the IL4R low group received a high dose of MDNA55. Conversely, there was no association with the amount of MDNA55 received and response in those with high IL4R expression. What this signifies is that in the IL4R low group a sufficient amount of MDNA55 is required in order to see a response as there are a limited number of receptors available for the drug to bind. In contrast, in the IL4R high group, the amount of MDNA55 given is of less importance because there are more receptors available for the drug to interact with. The following chart shows the best response for all IL4R-high patients as well as the IL4R-low patients that received a high dose of MDNA55 ('Proposed Populaton'). The tumor control rate of 81% (when measured from nadir following pseudoprogression, PsP) is very encouraging for a patient population with no effective treatments available.



Source: Medicenna Therapeutics Corp.

The following graph gives a comparison of the results seen in the Phase 2b trial of MDNA55 to the results seen in other clinical trials for agents that are approved for treating rGBM. This is not a head-to-head comparison as each of those agents were evaluated in separate clinical trials, but is rather a representation for the type of results that were seen for other rGBM therapies. MDNA55 treatment compares quite favorably to other rGBM therapies, particularly in the 'Proposed Population' that saw median overall survival of 14.0 months.



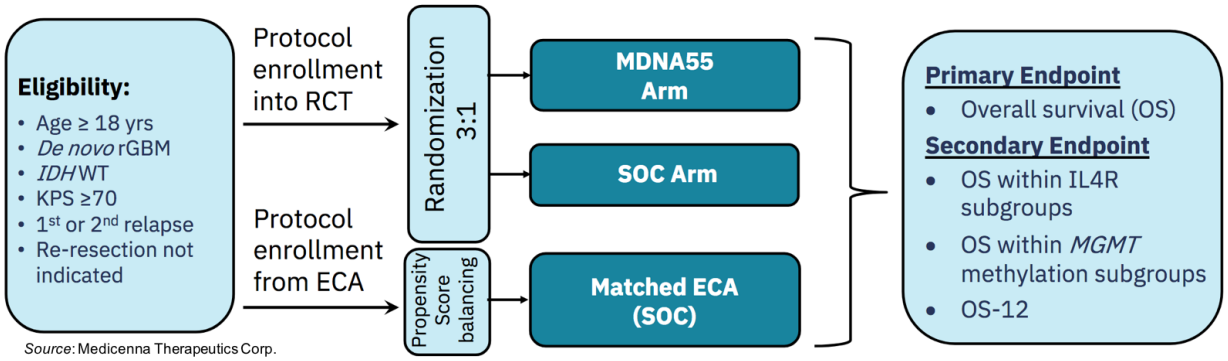
Source: Medicenna Therapeutics Corp.

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.



Source: Medicenna Therapeutics Corp.

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.

Financial Update

On February 12, 2021, Medicenna announced financial results for the third quarter of fiscal year 2021 that ended December 31, 2020. The company reported a net loss for the third quarter of fiscal year 2021 of CAD$5.3 million, or CAD$0.11 per share, compared to a net loss of CAD$2.4 million, or CAD$0.07 per share, for the three months ending December 31, 2019. R&D expenses for the third quarter of fiscal year 2021 were CAD$3.2 million compared to CAD$1.7 million for the third quarter of fiscal year 2020. The increase in expenses was primarily due to no reimbursement under the CPRIT grant in the current quarter, increased manufacturing and development expenditures for the MDNA11 program, increased regulatory costs, and increased licensing and patent legal fees. G&A expenses for the third quarter of fiscal year 2021 were CAD$2.1 million compared to CAD$0.7 million for the three months ending December 31, 2019. The increase was primarily due to public company expenses associated with the Nasdaq listing and related directors and officer's liability insurance premiums.

As of December 31, 2020, Medicenna had approximately CAD$33.2 million in cash, cash equivalents, and marketable securities. Subsequent to the end of the quarter, the company raised approximately CAD$7.8 million from the at-the-market (ATM) facility and warrant exercises. We estimate Medicenna has sufficient capital to fund operations into late calendar 2022. As of February 12, 2021, Medicenna had approximately 52.9 million shares outstanding and, when factoring in options and warrants, a fully diluted share count of approximately 61.0 million.

Conclusion

Medicenna is laying the groundwork for a potentially transformative 2021, as we anticipate the company filing to initiate a Phase 1/2a clinical trial of MDNA11 in the U.K. such that the trial could begin around mid-year. If it does begin around that time, it is possible we could see initial data before the end of 2021. In addition, we are interested to learn more regarding the lead next-generation Superkine candidates in the year ahead. Lastly, now that the company has a clear plan in place for a Phase 3 trial for MDNA55 we are hopeful that a partnership can be entered into in the near term. We have moved our DCF model ahead one year, which has resulted in a slight increase to our valuation to $12 per share.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp.
Income Statement

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2020 E	Q1 FY21 A	Q2 FY21 A	Q3 FY21 A	Q4 FY21 E	FY 2021 E	FY 2022 E	FY 2023 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	$5.9	$1.8	$2.2	$3.2	$3.0	$10.2	$15.0	$20.0
General & Administrative	$2.4	$0.7	$1.7	$2.1	$0.8	$5.3	$6.0	$7.0
Other (Income) Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($8.2)	($2.5)	($3.9)	($5.3)	($3.8)	($15.5)	($21.0)	($27.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($0.0)	($0.2)	($0.1)	($0.1)	$0.0	($0.3)	$0.1	$0.1
Pre-Tax Income	($8.3)	($2.4)	($3.8)	($5.3)	($3.8)	($15.8)	($20.9)	($26.9)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Cumulative translation adjustment	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($8.2)**	**($2.4)**	**($3.8)**	**($5.3)**	**($3.8)**	**($15.8)**	**($20.9)**	**($26.9)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.26)**	**($0.05)**	**($0.08)**	**($0.11)**	**($0.08)**	**($0.32)**	**($0.42)**	**($0.54)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	31.9	48.3	48.8	49.2	49.0	48.9	50.0	50.0

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

HISTORICAL STOCK PRICE

Source: Zacks Small Cap Research

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