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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. (T.MDNA-TSX)

T.MDNA: Overall Survival Data from Phase 2b Trial of Bizaxofusp Presented at SNO 2023…

Based on our probability adjusted DCF model that takes into account potential future revenues of MDNA55, MDNA11, and the Superkine platform MDNA.T is valued at $9.00/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 (11/20/23)	$0.44
Valuation	**$9.00**

OUTLOOK

On November 17, 2023, Medicenna Therapeutics Corp. (MDNA.T) announced longer term follow up results from the Phase 2b trial of bizaxofusp (formerly MDNA55) was presented at the Society for Neuro-Oncology (SNO) 2023 Annual Meeting. The trial enrolled and treated 44 patients with recurrent glioblastoma (rGBM) with a single dose of bizaxofusp. In addition, a separate analysis of 81 rGBM patients who had received standard of care at major clinical centers was used as a matched External Control Arm (ECA). The data showed that a single treatment with a high dose of bizaxofusp or patients expressing high levels of the IL4R target increased median overall survival (mOS) by 100% compared to the ECA (14.5 months vs. 7.2 months), with 1-year OS increased by 370% and 2-year OS increased by 50%. The company has designed a Phase 3 clinical trial where all patients will be administered a high dose of bizaxofusp and compared to a hybrid external control arm and is actively pursuing partnerships to further advance the drug.

SUMMARY DATA

52-Week High	**$1.13**
52-Week Low	**$0.22**
One-Year Return (%)	**-27.54**
Beta	**0.88**
Average Daily Volume (sh)	**104,742**
Shares Outstanding (mil)	**70**
Market Capitalization ($mil)	**31**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**24**
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 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of $CAD)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	0 A	0 A	0 A	0 A	0 A
2024	0 A	0 A	0 E	0 E	0 E
2025					0 E
2026					0 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2023	-$0.08 A	- $0.01 A	-$0.02 A	-$0.05 A	-$0.16 A
2024	-$0.04 A	-$0.05 A	-$0.06 E	-$0.07 E	-$0.22 E
2025					-$0.25 E
2026					-$0.24 E

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WHAT'S NEW

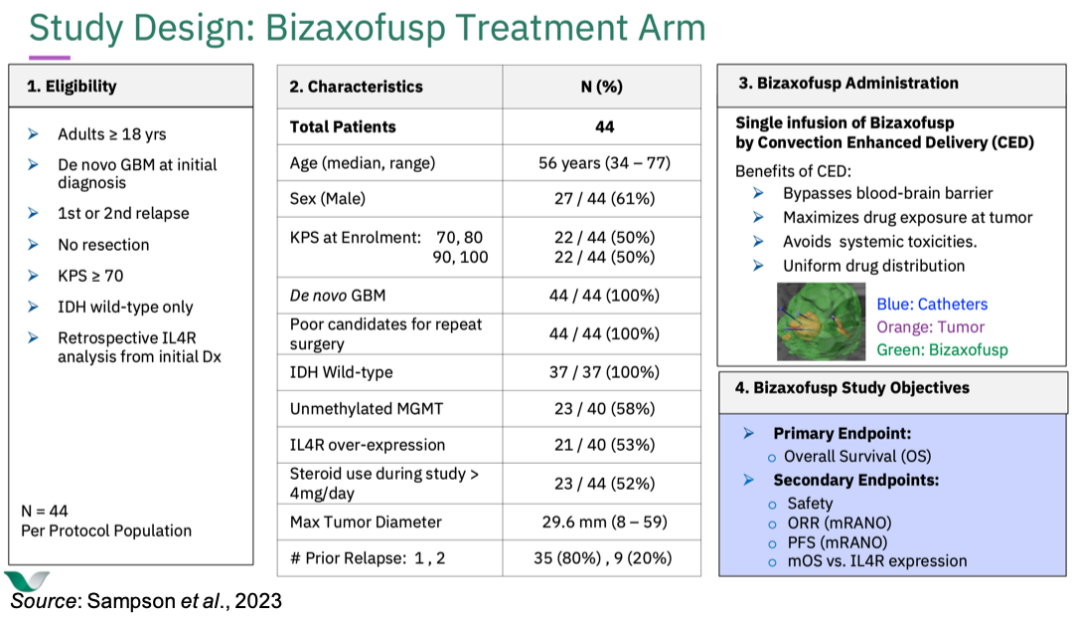
Business Update

Long-Term Overall Survival Data Presented at SNO

On November 17, 2023, Medicenna Therapeutics Corp. (MDNA.T) announced that longer term follow up results from the Phase 2b clinical trial of bizaxofusp (formerly MDNA55) in patients with recurrent glioblastoma (rGBM) were presented at the Society for Neuro-Oncology (SNO) 2023 Annual Meeting. A copy of the presentation can be found here. Bizaxofusp is an IL-4 Empowered Superkine 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). A cartoon representation of the compound is shown in the following figure.

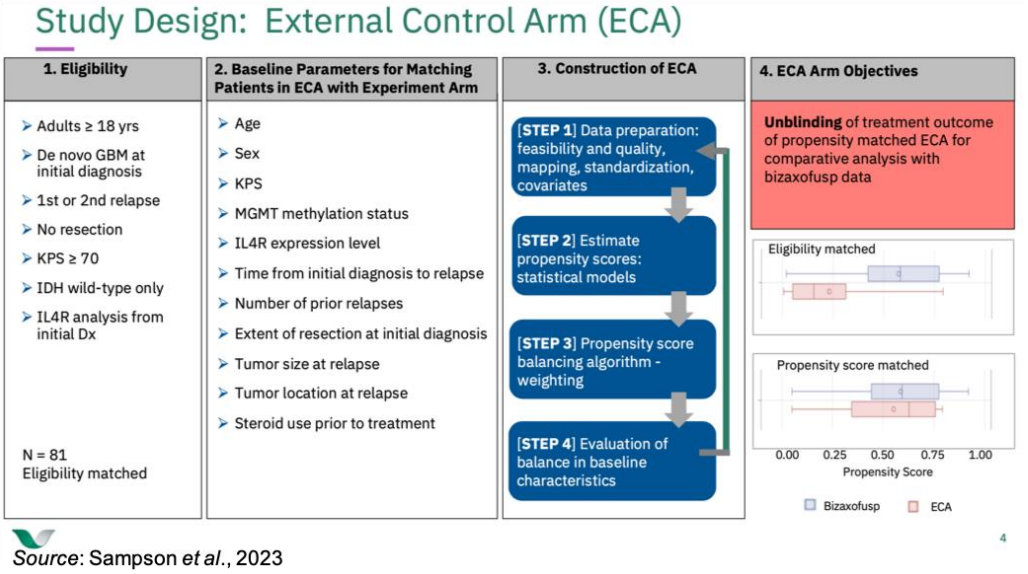


An overview of the study is presented below. A total of 44 patients were treated with a single infusion of bizaxofusp by convection enhanced delivery. The primary endpoint was overall survival with secondary endpoints examining safety, overall response rate (ORR), progression-free survival (PFS), and median overall survival (mOS) in relation to IL-4 expression.



Source: Sampson *et al.*, 2023

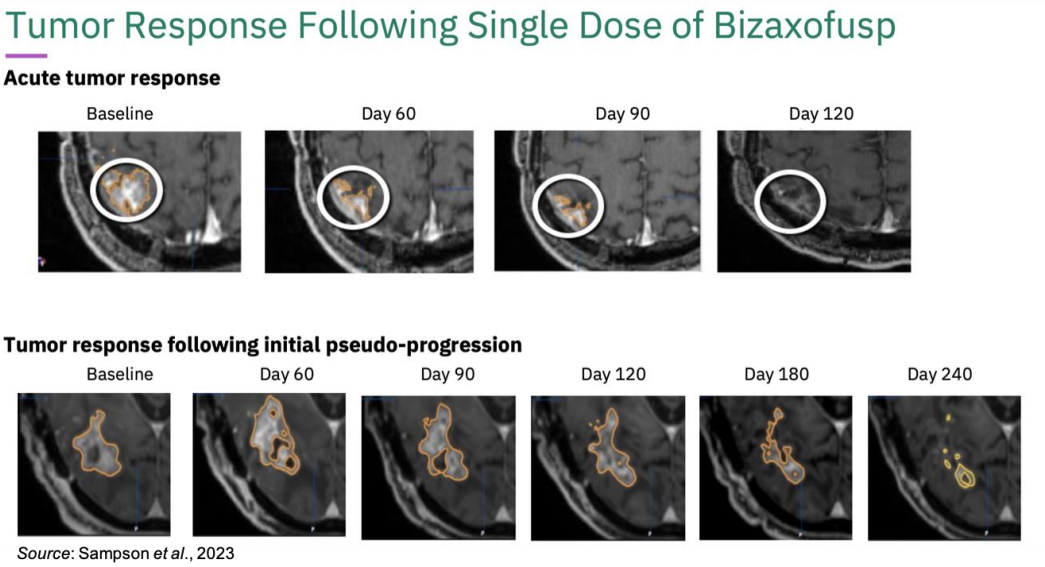
In the Phase 2b trial, an external control arm (ECA) was established as a comparator to the treatment arm using the same inclusion and exclusion criteria used for recruiting patients to the bizaxofusp arm. The following slide gives characteristics of the ECA and how it was put together using data from multiple clinical trial centers. The patients in the ECA were matched on eligibility and 11 prognostic characteristics known to impact survival of rGBM patients. A propensity score weighting was then used to balance the baseline characteristics between the bizaxofusp cohort and the ECA. Propensity scoring is a statistical method utilized to better align a treated group and an observational cohort.



Source: Sampson *et al.*, 2023

Safety data showed that bizaxofusp was well tolerated and there were no systemic or clinically significant laboratory abnormalities reported. Treatment related adverse events were primarily neurological or an aggravation of pre-existing neurological deficits due to rGBM.

The presentation included two examples of tumor response, which are shown below. An acute tumor response is shown where the tumor begins shrinking following a single dose of bizaxofusp and by Day 120 the tumor is almost completely gone. A tumor response following pseudoprogression is also shown. Pseudoprogression is a phenomenon where a tumor appears to be getting larger following treatment, however the increase in size on radiographic imaging is due to an inflammatory response to treatment and not due to an increase in tumor mass prior to a decrease in size.

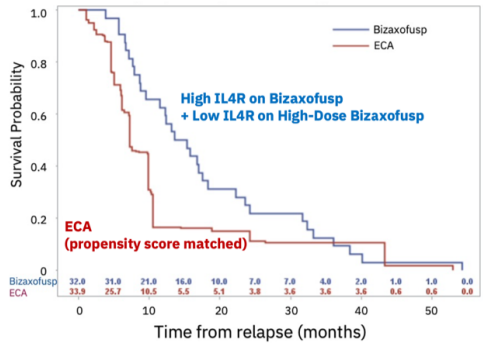


Source: Sampson *et al.*, 2023

The overall survival data is shown below. In patients that will be part of the planned Phase 3 trial (i.e., all patients receiving high dose bizaxofusp, irrespective of IL-4R expression) treatment with bizaxofusp resulted in a 100% increase in mOS compared to the ECA (14.5 months vs. 7.2 months). In addition, 62.5% of bizaxofusp-treated patients were alive at one year compared to only 16.7% in the ECA cohort while 25% of bizaxofusp-treated patients were alive at two years compared to 16.1% in the ECA.

The data showed an even greater effect on OS rate, with 1-year survival increased by 370% and 2-year survival increased by 50% when compared to the ECA.

Bizaxofusp Doubled mOS Irrespective of IL4R Expression vs ECA



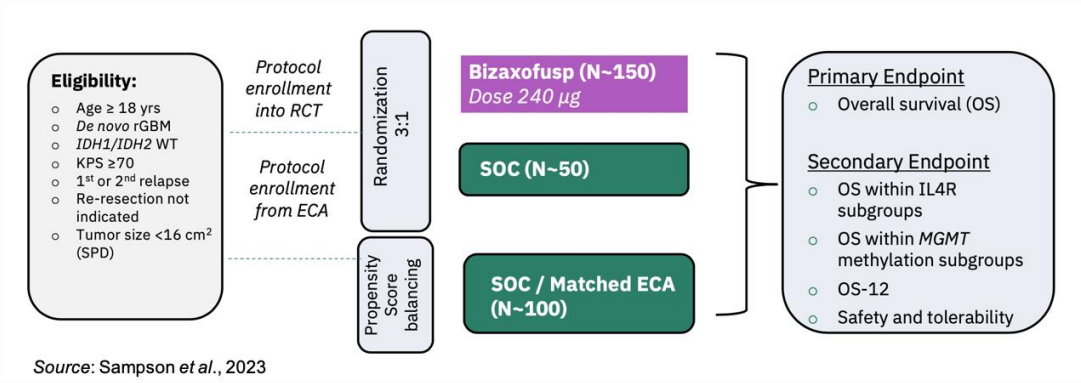
- OS increased by 370% at 1 year
- OS at 2 years improved by > 50%

	Bizaxofusp	ECA
OS-12 (%) (95% CI)	62.5 (43.5, 76.7)	16.7 (2.4, 42.1)
OS-24 (%) (95% CI)	25.0 (11.8, 40.7)	16.1 (2.1, 39.8)
mOS* (months)	14.5	7.2

* P = 0.2142 (Log-rank test)

Source: Sampson *et al.*, 2023

Lastly, the company has designed a Phase 3 protocol with the FDA and includes a hybrid control arm, with 50 patients treated with standard of care and approximately 100 patients making up a matched ECA cohort, as shown in the following image.



Source: Sampson *et al.*, 2023

The long-term follow up data for bizaxofusp are really encouraging, particularly the large increase in 1-year survival with no reports of systemic or clinically significant laboratory findings. Medicenna continues to actively pursue partnerships to advance bizaxofusp into a Phase 3 clinical trial.

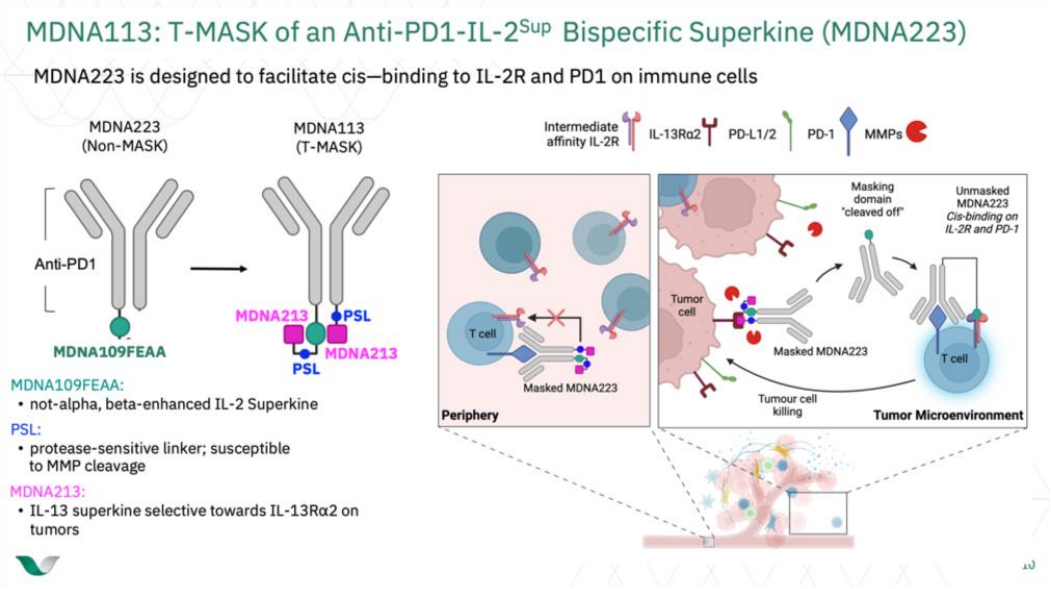
T-MASK Platform Showcased at SITC

On November 3, 2023, Medicenna announced that the company presented proof-of-concept data on the company's T-MASK (**T**argeted **M**etalloprotease Activated **S**uper**K**ine) platform technology with the development candidate MDNA113 at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC). A copy of the presentation can be found here.

The T-MASK platform involves fusion of a dual IL-13 tumor targeting/masking domain linked to an IL-2 Superkine via a matrix metalloprotease (MMP) sensitive linker (PSL). The potential advantages of this technology include:

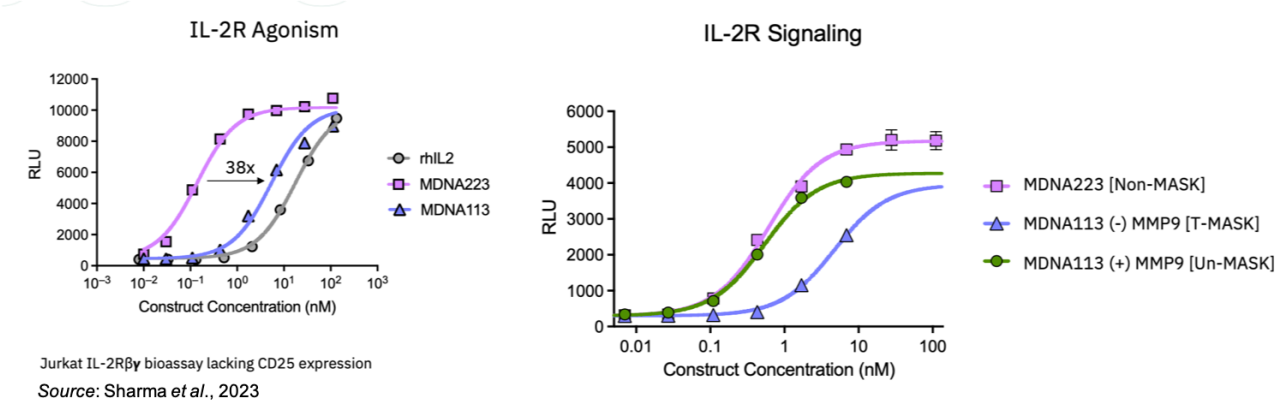
- The tunable blockade of IL-2R agonism to reduce immune cell stimulation in peripheral tissues, which could lead to a decrease in systemic side effects
- Tumor targeting to IL-13Rα2 expressing cancers, a receptor that is highly expressed in a number of tumor types but is not expressed in healthy tissue
- Cleavage and release of the IL-13 domain restores IL-2R agonism in the tumor microenvironment (TME)

MDNA113 is a T-MASK of an IL-2-anti-PD-1 bispecific Superkine (MDNA223). The following image shows a cartoon representation of MDNA223, the non-masked molecule, and MDNA113, which contains the IL-13Rα2-selective Superkine MDNA213 that 'masks' the IL-2 Superkine (MDNA109FEAA) through a PSL. The images on the right show how prior to cleavage of the PSL the IL-2 domain of the molecule is unable to interact with T cells in the periphery, however upon cleavage of the PSL the 'unmasked' IL-2 domain is able to interact with T cells in the TME, resulting in cis-binding on PD-1 and IL-2R.



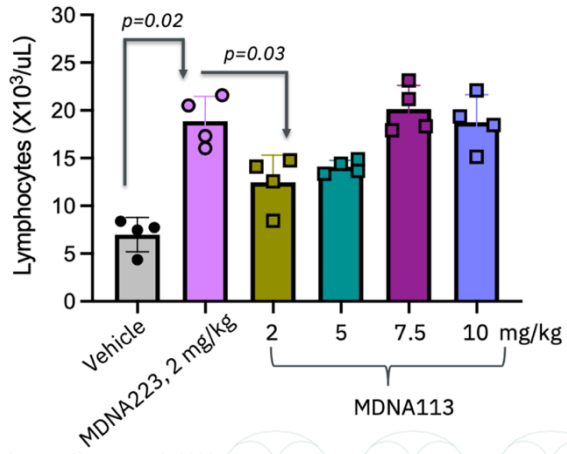
Source: Sharma *et al*., 2023

MDNA113 shows reduced IL-2R agonism compared to MDNA223, as shown in the following figure on the left. While MDNA223 shows enhanced IL-2R agonism from being a 'not-alpha, beta-enhanced' IL-2 Superkine, MDNA113 has reduced IL-2R agonism due to the presence of the IL-13 tumor-targeting/masking entity. The figure on the right shows that in the presence of matrix metalloproteinase 9 (MMP9), IL-2R signaling by MDNA113 is restored to a near equivalent level to MDNA223.



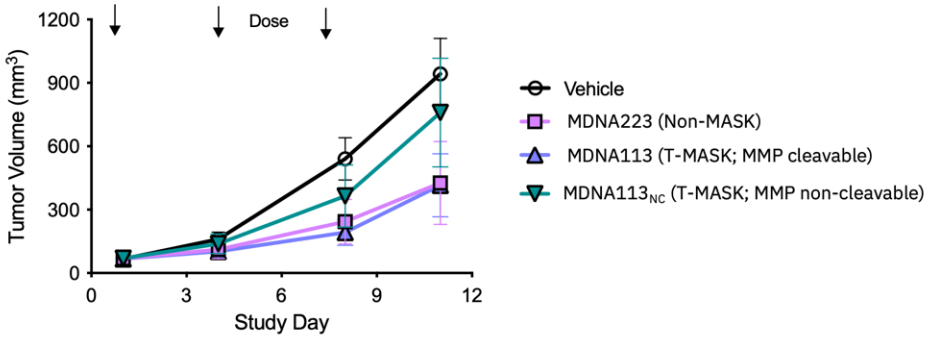
Source: Sharma *et al*., 2023

MDNA113 causes less stimulation of peripheral lymphocyte expansion in mice compared to MDNA223. The following image shows the number of lymphocytes collected from mice following a single IP injection of vehicle, MDNA223 (2 mg/kg), or different doses of MDNA113. There is a statistically significant decrease in lymphocyte expansion when comparing the same dose of MDNA223 and MDNA113. This decrease in lymphocyte expansion can be overcome through an increase in dose of MDNA113. The decreased peripheral activity of MDNA113 should help to decrease the side effect profile of the compound.



Source: Sharma *et al.*, 2023

Unmasking MDNA113 results in similar anti-tumor activity to MDNA223. The following graph shows tumor growth in a MC38 mouse model when the mice were treated intratumorally with MDNA223, MDNA113, or an MDNA113 molecule with an uncleavable PSL. MDNA113 and MDNA223 both decrease tumor growth in a manner greater than the unmasked MDNA113 molecule. These results show that the same level of efficacy can be achieved with MDNA113 with decreased peripheral activity when compared to MDNA223.



Avg tumor volume of 40 mm³ at initiation of dosing;
Dose of 15 ug/tumor by IT injection

Source: Sharma *et al.*, 2023

Financial Update

On November 14, 2023, Medicenna announced financial results for the second quarter of fiscal year 2024, which ended September 30, 2023. As expected, the company did not report any revenues for the second quarter of fiscal year 2024. Net loss for the second quarter of fiscal year 2024 was CAD$3.7 million, or $0.05 per share, compared to a net loss of CAD$0.9 million, or $0.01 per share, for the second quarter of fiscal year 2024. R&D expenses for the current quarter were approximately CAD$3.1 million, compared to approximately CAD$2.4 million for the second quarter of fiscal year 2023. The increase was primarily due to increased licensing and patent legal fees along with higher clinical costs for the ABILITY study. G&A expenses in the second quarter of fiscal year 2024 were CAD$2.3 million, compared to CAD$2.4 million for the second quarter of fiscal year 2023. The decrease was primarily due to an increase in public company expenses, salaries, and benefits partially offset by the one-time transaction costs associated with warrant derivative.

As of September 30, 2023, Medicenna had approximately CAD$25.7 million in cash, cash equivalents, and marketable securities. We estimate that the company is funded through key milestones in the ABILITY trial and into the first quarter of calendar 2025. Subsequent to the end of the quarter, Medicenna's common stock ceased trading on the Nasdaq, a move that the company estimates will result in significant financial savings. As of November 14, 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 92.6 million.

Conclusion

With such encouraging data from the Phase 2b trial of bizaxofusp we are confident that Medicenna will be able to enter into a development partnership to advance the compound into a Phase 3 trial. We look forward to updates from the company regarding the partnering process. The T-MASK technology looks to be a novel mechanism to get enhanced anti-tumor activity in the tumor microenvironment while mitigating systemic side effects and we anticipate additional updates from the company as it advances that program toward the clinic. With no changes to our model our valuation remains at $9.00 per share.

PROJECTED FINANCIALS

Medicenna Therapeutics Corp. In Canadian Dollars	FY 2023 A	Q1 FY24 A	Q2 FY24 A	Q3 FY24 E	Q4 FY23 E	FY 2024 E	FY 2025 E	FY 2026 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	$9.3	$2.8	$3.1	$2.5	$2.9	$11.3	$10.5	$11.0
General & Administrative	$7.0	$1.6	$2.3	$2.0	$2.2	$8.2	$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)	($4.5)	($5.4)	($4.5)	($5.1)	($19.5)	($18.5)	($19.5)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($6.3)	($1.6)	($1.7)	($0.2)	($0.2)	($3.7)	($0.4)	($0.4)
Pre-Tax Income	($10.0)	($2.9)	($3.7)	($4.3)	($4.9)	($15.8)	($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)	$0.5	($0.0)	($0.0)	$0.4	($0.2)	($0.2)
Net Income	**($10.1)**	**($2.9)**	**($3.2)**	**($4.3)**	**($4.9)**	**($15.4)**	**($18.3)**	**($19.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.16)**	**($0.04)**	**($0.05)**	**($0.06)**	**($0.07)**	**($0.22)**	**($0.25)**	**($0.24)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	64.7	69.6	69.6	70.0	70.0	69.8	72.0	80.0

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

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