



Medicenna Therapeutics Reports Fiscal Year 2024 Financial Results and Operational Highlights

June 27, 2024

Increased cash balance to \$37 million following a \$20 million investment by RA Capital extending runway into mid-2026

MDNA11 continues to exhibit compelling deep and durable single agent activity and best-in-class potential relative to other IL-2 therapies in clinical development

Results presented at the Annual Meeting of the AACR showed single agent MDNA11 response rate of 29% (4/14) in patients with checkpoint resistant tumors

Combination dose escalation with pembrolizumab (KEYTRUDA) continues to enroll patients at the MDNA11 monotherapy expansion dose (90 µg/kg, Q2W) having cleared safety at 60 µg/kg, Q2W

Approval of Clinical Trial Application by the European Medicines Agency expands the ABILITY-1 study of MDNA11 to Cancer Centers in the EU

Updated MDNA11 monotherapy expansion and combination escalation results to be presented at medical conferences in H2 of 2024

TORONTO and HOUSTON, June 27, 2024 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA, OTCQB: MDNAF), a clinical-stage immunotherapy company focused on the development of Superkines, today reported financial results and corporate highlights for the fiscal year ended March 31, 2024, as well as anticipated corporate milestones.

"Over the past year, we have continued to demonstrate best-in-class potential of MDNA11, having shown durable single-agent efficacy in end-stage cancer patients who have failed immunotherapies while maintaining an acceptable safety profile," said Fahar Merchant, Ph.D., President and CEO of Medicenna. "We are encouraged by the 29% response rate observed in the study to date, including durable complete regression of target and non-target lesions in a pancreatic cancer patient who remains in remission and a melanoma patient that continues to show durable complete response of the target lesions. On the back of these data, we are delighted with the recent financial backing by RA Capital Management, which has strengthened our balance sheet by \$20 million, extending our cash runway into mid-2026. We are also pleased to see acceptable safety profile of MDNA11 in combination with pembrolizumab, which continues to enroll patients at the higher dose used in the MDNA11 monotherapy expansion arm as well as the recent approval by EMA of our application to expand the ABILITY-1 study in Europe. We look forward to sharing new clinical data from the monotherapy dose expansion as well as the combination arms of the study at medical conferences during the second half of 2024."

Program highlights for the fiscal year ended March 31, 2024, along with recent developments, include:

MDNA11: IL-2 Superkine Program

Clinical activity highlights include:

Deep and Durable Anti-tumor Activity with Single-Agent MDNA11

- 29% response rate (N=4/14) and 50% clinical benefit rate (4 patients with partial responses, 3 patients with stable disease > 24 weeks) in high-dose phase 2 eligible patients who failed checkpoint inhibitor therapy
- A pancreatic cancer patient with 100% regression of target and non-target lesions for over 104 weeks and continues to show remission 4 months after stopping treatment
- A melanoma patient who is continuing on MDNA11 treatment shows 100% regression of target lesions with continued regression of non-target lesions
- 2 of 2 MSI-High patients and 2 of 4 evaluable dose expansion patients have had a partial response
- Previously reported patients with partial responses and stable disease continue on the study further supporting the durability of MDNA11

The monotherapy expansion arm is enrolling patients with metastatic melanoma, non-melanoma skin cancers and MSI-H/dMMR tumors. Combination escalation arm of the ABILITY-1 study is enrolling patients with advanced solid tumors who progressed following earlier lines of treatment.

Monotherapy: Acceptable Safety Profile

- Complete Phase 1 monotherapy dose escalation data was presented and affirmed that MDNA11 has an acceptable safety profile.
- No dose limiting toxicity (DLT) was reported with no evidence of vascular leak syndrome (VLS). Vast majority (95 %) of treatment-related adverse events (TRAEs) were of grade 1-2 and resolved within 48 hours; grade 3 TRAEs mainly constituted asymptomatic transient LFT elevations; no grade 4 or 5 events were reported.

- Repeat administration of MDNA11 at the target doses showed further improvement in tolerability.

Monotherapy: Pharmacodynamic Analysis Showed Potent and Durable Systemic Immune Activation

- Significant increases in stemness, central and effector memory and markers of enhanced effector function in circulating CD8⁺ T and NK cells, all of which are critical for achieving meaningful and durable anti-cancer response.
- Analysis of gene expression signatures from pre-treatment and on-treatment paired biopsies show that cancer promoting pathways were degraded while immune-related pathways against cancer cells were enhanced following MDNA11 treatment.

Combination with KEYTRUDA®: Enrolling in Cohort 2 in the Absence of DLTs in the First Dose Cohort

- In February 2024, the company announced dosing of the first patient in the Phase 1 combination escalation portion of the ABILITY-1 Study
- Dose escalation in combination with KEYTRUDA® is now enrolling at the next higher dose of MDNA11 90 µg/kg Q2W and 400 mg pembrolizumab Q6W (priming MDNA11 30 & 60 µg/kg) following absence of any DLT at 60 µg/kg

The company expects to report additional data from the ongoing monotherapy expansion and combination arms of the ABILITY-1 study at medical conferences in the second half of calendar 2024.

Bizaxofusp (formerly MDNA55): Empowered IL-4 Superkine Program

The Company is currently pursuing partnership opportunities for its phase-3 ready IL-4 Superkine for recurrent glioblastoma (rGBM). Bizaxofusp, which holds both FastTrack and Orphan drug status from the FDA and FDA/EMA, respectively, is Medicenna's Phase 3-ready asset for rGBM which has been tested in 118 patients with high grade gliomas (including 112 patients with rGBM).

On June 1st, 2024, the Company presented survival follow-up, and updated final Phase 2b study results for bizaxofusp at the 2024 ASCO Annual Meeting in Chicago.

Clinical activity highlights include:

- In the Phase 2b study, a single treatment with bizaxofusp in unresectable rGBM patients achieved significant survival benefit (mOS of 13.5 vs. 7.2 months, $p=0.009$) and reduced risk of death by almost half (hazard ratio: 0.54, 95% confidence interval: 0.34-0.83) versus a propensity score (PS) balanced external control arm (ECA).
- Bizaxofusp significantly increased median overall survival (mOS) by 88% ($p = 0.009$) and improved overall survival at 1 and 2 years by 180% and 290%, respectively.
- Tumor control was associated with a significant increase in mOS following treatment with bizaxofusp and consequently, may be an early surrogate of survival benefit in future studies.

With the compelling survival benefit with bizaxofusp in rGBM, the most aggressive form of brain cancer which lacks a standard of care, Medicenna is seeking Breakthrough Therapy Designation with the FDA.

The proposed Phase 3 trial design incorporating a hybrid external control arm has been accepted by the FDA. Medicenna is currently working toward securing alignment with the EMA thereby enabling data from a single Phase 3 registrational trial being sufficient to file for approval in the EU and USA.

Pre-clinical Pipeline Programs

- On April 9, 2024, at the 2024 AACR Annual Meeting, the Company presented preclinical data on its first-in-class IL-13R2 targeted candidate, MDNA113, from its T-MASK™ platform, which specifically delivers a masked bispecific anti-PD1-IL2 Superkine to IL-13R2 expressing tumors (affecting over 2 million cancer patients annually) where it is activated by cancer specific enzymes.

These data demonstrated that the T-MASK™ platform exemplified by MDNA113, facilitates tumor targeting and minimizes systemic toxicity while maximizing therapeutic activity at the tumor site.

Operational Highlights

On April 30, 2024, the Company closed a \$20 million financing through a private placement with RA Capital Management ("RA"), a multi-stage investment manager based in Boston, MA, by way of a non-brokered private placement (the "Offering"). Pursuant to the terms of the Offering, RA subscribed for 5,141,388 common shares in the capital of the Company (the "Shares") at a price of CA\$1.95 per share and, in lieu of common shares, pre-funded warrants to purchase 5,141,388 common shares at a purchase price of CA\$1.94 per pre-funded warrant, for total net proceeds to the Company of approximately CA\$20 million.

Expected Upcoming Milestones

- Topline MDNA11 monotherapy expansion data to be presented at medical conferences in H2 of calendar 2024.
- Clinical update and combination escalation data from the ABILITY-1 Study evaluating MDNA11 with KEYTRUDA expected in H2 of calendar 2024.
- Potential for Breakthrough Therapy Designation (BTD) for bizaxofusp. With compelling longer term survival benefit with bizaxofusp in rGBM patients, as presented at the ASCO meeting held in April 2024, Medicenna will seek to apply for BTD with the FDA.
- Seek alignment with the European Medicines Agency (“EMA”) for the Phase 3 registration trial of bizaxofusp.

Annual Financial Results

As of March 31, 2024, cash and cash equivalents were \$17.0 million, compared to \$33.6 million on March 31, 2023. These funds, in combination with the \$20 million in proceeds from the Offering, are expected to provide the Company with sufficient capital to execute its current planned expenditures to mid-2026 based on its current plans and projections.

For the year ended March 31, 2024, the Company reported total operating costs of \$18.7 million compared to total operating costs of \$16.3 million for the year ended March 31, 2023. The increase is related to an increase in general and administrative expenses (\$0.7 million) and research and development expenses (\$1.5 million) as discussed further below.

Net loss for the year ended March 31, 2024, was \$25.5 million or \$0.37 per share compared to a loss of \$10.0 million or \$0.16 per share for the year ended March 31, 2023. The increase in net loss for the year ended March 31, 2024 was primarily a result of an increase in the fair value of the derivative warrant liability of \$8.0 million compared to a decrease of \$4.3 million in the prior year. The significant increase in fair value of the warrant derivative is due to the 111% increase in the Company’s share price year-over-year, as share price is a key variable in the valuation of the derivative liability.

Research and development expenses of \$10.8 million were incurred during the year ended March 31, 2024, compared with \$9.3 million incurred in the year ended March 31, 2023. The increase in research and development expenses in the current fiscal year is primarily attributed to increased clinical costs related to the expansion of the MDNA11 ABILITY-1 with new clinical sites added in South Korea, the commencement of the combination arm with Keytruda, and an increase in salaries and benefits due to the addition of research staff during the period.

General and administrative expenses of \$7.8 million were incurred during the year ended March 31, 2024, compared with \$7.0 million during the year ended March 31, 2023. The increase in G&A expenses in the current year primarily relates to increased salaries and benefits in fiscal 2024 related to the addition and subsequent restructuring of executive staff in the US as the Company refocused its operations to Canada following its delisting from Nasdaq. This transition is anticipated to result in cost savings in future periods.

Medicenna’s financial statements for the year ended March 31, 2024 and the related management’s discussion and analysis (MD&A) will be available on SEDAR at www.sedarplus.ca.

About Medicenna

Medicenna is a clinical-stage immunotherapy company focused on developing novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first-in-class Empowered Superkines. Medicenna’s long-acting IL-2 Superkine, MDNA11, is a next-generation IL-2 with superior affinity toward CD122 (IL-2 receptor beta) and no CD25 (IL-2 receptor alpha) binding, thereby preferentially stimulating cancer-killing effector T cells and NK cells. Medicenna’s IL-4 Empowered Superkine, bizaxofusp (formerly MDNA55), has been studied in 5 clinical trials enrolling over 130 patients, including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. Bizaxofusp has obtained FastTrack and Orphan Drug status from the FDA and FDA/EMA, respectively. Medicenna’s early-stage BiSKITs™ (Bifunctional SuperKine ImmunoTherapies) and the T-MASK™ (Targeted Metalloprotease Activated SuperKine) programs are designed to enhance the ability of Superkines to treat immunologically “cold” tumors.

For more information, please visit www.medicenna.com, and follow us on [Twitter](#) and [LinkedIn](#).

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Forward-Looking Statements

This news release contains forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, express or implied statements regarding the future operations of the Company, estimates, plans, strategic ambitions, partnership activities and opportunities, objectives, expectations, opinions, forecasts, projections, guidance, outlook or other statements that are not historical facts, such as statements on the Company’s cash runway, the clinical performance and potential, safety profile of MDNA11 and bizaxofusp (MDNA55), the reporting of additional results, anticipated corporate milestones, partnership efforts and cost savings following the Nasdaq delisting. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented. Forward-looking statements are often identified by terms such as “will”, “may”, “should”, “anticipate”, “expect”, “believe”, “seek”, “potentially” and similar expressions. Forward-looking statements are based on a number of assumptions believed by the Company to be reasonable at the date of this news release. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such statements will prove to be accurate. These statements are subject to certain risks and uncertainties and may be based on assumptions that could cause actual results and future events to differ materially from those anticipated or implied in such statements. Important factors that could cause actual results to differ materially from the Company’s expectations include the risks detailed in the latest annual information form of the Company and in other filings made by the Company with the applicable securities regulators from time to time in Canada.

The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and

other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management, may prove to be incorrect and actual results may differ materially from those anticipated or implied in forward-looking statements. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. The forward-looking statements contained in this news release are made as of the date hereof and except as required by law, we do not intend and do not assume any obligation to update or revise publicly any of the included forward-looking statements.

This news release contains hyperlinks to information that is not deemed to be incorporated by reference in this news release.

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