



Medicenna Reports Second Quarter Fiscal 2023 Financial Results and Operational Highlights

November 4, 2022

- Results from low and mid-dose escalation cohorts in Phase 1/2 ABILITY study show tumor control in 5 of 14 evaluable patients, including a confirmed partial response in pancreatic cancer

- \$40 million in cash, cash equivalents, and marketable securities at September 30, 2022, provides runway into Q2 calendar 2024 including completion of ABILITY study

- Management hosting conference call and webcast today at 8:30 am ET

TORONTO and HOUSTON, Nov. 04, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced its financial results and operational highlights for the quarter ended September 30, 2022. All dollar amounts are in Canadian currency unless otherwise noted.

"Achievements this quarter have substantively bolstered our clinical dataset and balance sheet, providing support for MDNA11's best-in-class potential and runway through completion of the ABILITY study," said Fahar Merchant, PhD, President and CEO of Medicenna. "We are particularly encouraged with promising signs of MDNA11's monotherapy activity in multiple patients with aggressive cancers that are typically resistant to immunotherapy. Continued deepening of tumor reduction leading to a confirmed partial response in a fourth-line pancreatic cancer patient is especially heartening, suggesting that MDNA11 may provide durable clinical benefits in immunologically 'cold' tumors. That these data were generated in ABILITY's low and mid-dose escalation cohorts, which is designed primarily to assess safety and pharmacokinetics rather than efficacy, adds to our enthusiasm as we evaluate higher doses and move towards key readouts expected from the trial over the coming quarters."

Program highlights for the quarter ended September 30, 2022, along with recent developments include:

MDNA11: IL-2 Superkine Program

In September 2022, Medicenna reported new [anti-tumor activity data](#) from the first four (low and mid) dose escalation cohorts of the Phase 1/2 ABILITY study of MDNA11, the Company's "beta only," long-acting IL-2 super-agonist. These data support MDNA11's single-agent potential in advanced solid tumors unresponsive to established treatments, as a confirmed partial response (PR) was achieved in a fourth-line (4L) metastatic pancreatic cancer patient who previously failed chemo- and checkpoint inhibitor therapies. The confirmatory scan for this patient showed further tumor reduction compared to prior scans, suggesting durable anti-cancer activity following MDNA11 monotherapy. Overall, five of fourteen (36%) evaluable patients have achieved tumor control (PR or stable disease (SD)) in the ABILITY study's first four dose escalation cohorts. This includes a 3L metastatic melanoma patient that achieved SD with a 10 µg/kg dose and has maintained SD for more than a year while escalating to a 60 µg/kg dose.

Patients in the ABILITY study's first four dose-escalation cohorts (n=14) failed up to four lines of systemic therapy prior to enrolling in the trial, including eleven (79%) who relapsed on, could not tolerate, or did not respond to at least one prior immunotherapy with a checkpoint inhibitor. All patients in the trial's dose escalation phase are treated with MDNA11 monotherapy via intravenous infusion every two weeks. With no dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues observed to-date, the trial is currently enrolling patients in its fifth dose-escalation cohort (two 30 µg/kg "priming" doses of MDNA11 followed by fixed doses of 90 µg/kg).

Clinical Trial Collaboration and Supply Agreement with Merck

In September 2022, Medicenna announced that it had entered into a [clinical trial collaboration and supply agreement](#) with Merck (known as MSD outside the United States and Canada) to evaluate MDNA11 in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD1 therapy, in the ongoing Phase 1/2 ABILITY study. Under the terms of the agreement, Medicenna will sponsor the study and Merck will supply KEYTRUDA®. The two companies will establish a Joint Development Committee to optimally advance the study's combination arm, which will proceed alongside its single-agent expansion phase.

Preclinical IL-4/IL-13 Super-Antagonists and BiSKITs™ Programs

Medicenna continues to conduct preclinical studies exploring the potential of its novel Superkines and BiSKITs (Bifunctional SuperKine ImmunoTherapies) as part of its ongoing efforts to build a diverse pipeline. In September 2022, preclinical data on Fc-MDNA413, a long-acting IL-4/IL-13 super-antagonist, and MDNA223, a next generation BiSKIT consisting of an anti-PD1 antibody linked to an IL-2 super-agonist, were presented at the [10th Annual Meeting of the International Cytokine & Interferon Society \(Cytokines 2022\)](#).

Intellectual Property

The US Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,117,943, titled "Superagonists and Antagonists of Interleukin-2" increasing the patent estate to 50 issued patents and 62 patent applications filed. This patent provides intellectual property (IP) protection for methods of treating leukemia using IL-2 muteins that have an increased binding capacity for IL-2Rβ and a decreased binding capacity for IL-2Rγc. Unlike MDNA109, such IL-2 superkines act as IL-2 partial agonist and antagonists (MDNA209 platform) in applications where inhibition of IL-2 and/or IL-15 functions is useful (e.g., adult T cell leukemia, auto-immune diseases, graft versus host disease, etc).

Financing

In August 2022, Medicenna raised [gross proceeds of approximately US\\$20 million](#) through an underwritten public offering. In addition to strengthening the Company's balance sheet, the offering added new healthcare focused institutional investors to Medicenna's shareholder base.

Expected Upcoming Milestones

New safety, pharmacokinetic (PK), and pharmacodynamic (PD) data from the ABILITY study's first four dose escalation cohorts will be presented next

week at the Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting.

Updated anti-tumor activity data from the ABILITY study's escalation cohorts are expected in calendar Q1-2023.

Early anti-tumor activity data from the ABILITY study's single agent expansion phase are expected in mid-2023.

Early anti-tumor activity data from the ABILITY study's combination arm are expected in Q4-2023.

Though these milestones represent a brief delay compared to prior guidance, we believe that taking the extra time necessary to recruit an optimized patient population in the current and future cohorts will allow us to potentially increase the impact of the data from these dose cohorts from a scientific and value-creation perspective.

Financial Results

Medicenna had cash, cash equivalents, and marketable securities of \$40 million at September 30, 2022. These funds provide the Company with sufficient capital to execute its current planned expenditures through the completion of the ABILITY study, important upcoming catalysts as described above, and into Q2 calendar 2024 based on its current plans and projections.

Net loss for the quarter ended September 30, 2022, was \$0.9 million, or (\$0.01) per share, compared to a loss of \$8.2 million, or (\$0.15) per share for the quarter ended September 30, 2021. The significant decrease in net loss for the quarter ended September 30, 2022, compared with the quarter ended September 30, 2021, was primarily a result of a foreign exchange gain of \$1.9 million on our USD cash balances due to the strength of the US dollar during the current quarter, a non-cash gain of \$1.8 million related to the change in valuation of a non-cash warrant liability associated with the August 2022 financing as well a reduction in R&D expenses in the current year period.

Research and development expenses of \$2.4 million were incurred during the quarter ended September 30, 2022, compared with \$6.3 million incurred in the quarter ended September 30, 2021. The decrease in research and development expenses in the current fiscal year's quarter is primarily attributed to costs associated with the development of MDNA11 incurred in the prior year including GMP manufacturing and IND enabling studies for which no comparable expenses were incurred in the current year. The reduction in MDNA11 development expenses was partially offset by higher clinical costs in the current year period.

General and administrative expenses of \$2.4 million were incurred during the quarter ended September 30, 2022, compared with \$2.0 million during the quarter ended September 30, 2021. The increase in general and administrative expenses is primarily attributed to one-time transaction costs of \$0.7 million related to the warrant liability derivative associated with the August 2022 financing for which there was no comparable expense in the prior year period.

Medicenna's condensed consolidated interim financial statements for the quarter ended September 30, 2022 and the related management's discussion and analysis (MD&A) will be available on SEDAR at www.sedar.com and EDGAR at www.sec.gov.

Conference Call and Webcast

Medicenna will host a conference call and webcast today at 8:30 am ET. To access the call please dial 1-877-407-9716 from the United States or 1-201-493-6779 internationally and refer to conference ID: 13733195. To access the live webcast, visit this [link to the event](#). Following the live webcast, an archived version of the call will be available on Medicenna's website.

About the Phase 1/2 ABILITY Study

The ABILITY (A Beta-only IL-2 ImmunoTherapY) study is designed to assess the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced, relapsed, or refractory solid tumors. The trial includes an MDNA11 monotherapy arm, as well as a combination arm designed to evaluate MDNA11 with KEYTRUDA® (pembrolizumab). Approximately 100 patients are expected to be enrolled into the ABILITY Study. Following establishment of the recommended Phase 2 dose (RP2D) and optimal treatment schedule in the study's dose escalation phase, Medicenna plans to conduct a dose expansion phase that will enroll patients with renal cell carcinoma, melanoma, and other solid tumors in monotherapy and combination settings. For more information, see [ClinicalTrials.gov](https://clinicaltrials.gov/Identifier/NCT05086692) Identifier: [NCT05086692](https://clinicaltrials.gov/Identifier/NCT05086692).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Medicenna

Medicenna is a clinical stage immunotherapy company focused on the development of 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 CD122 (IL-2 receptor beta) binding without CD25 (IL-2 receptor alpha) affinity thereby preferentially stimulating cancer killing effector T cells and NK cells. Medicenna's early-stage BiSKITs™ program, (Bifunctional SuperKine ImmunoTherapies) is designed to enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's IL-4 Empowered Superkine, MDNA55, has been studied in 5 clinical trials including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. MDNA55 has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of applicable securities laws that relate to the future operations of the Company, plans and projections and other statements that are not historical facts including, but not limited to, statements related to the clinical potential, development of MDNA11 and the expected timing and milestones for the presentation of new data related thereto, cash runway, the clinical trial collaboration and supply agreement with Merck (known as MSD outside the United States and Canada) to evaluate MDNA11 in combination with KEYTRUDA® (pembrolizumab), the potential of the Superkines and BiSKITs (Bifunctional SuperKine ImmunoTherapies), the diversification of the pipeline and planned expenditures. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expect", "believe", "seek", "potentially" and similar expressions. All statements other than statements of historical fact, included in this release, including, but not limited to, MDNA11's ultimate treatment potential and statements on the future plans and objectives of the Company, are forward-looking statements that are subject to risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated 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 and Annual Report on Form 20-F of the Company and in other

filings made by the Company with the applicable securities regulators from time to time in Canada and the United States.

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. 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.

Further Information

For further information about the Company please contact:

Elizabeth Williams, Chief Financial Officer, 416-648-5555, ewilliams@medicenna.com

Investor Contact

For more investor information, please contact:

Dan Ferry, Managing Director, LifeSci Advisors, 617-430-7576, daniel@lifesciadvisors.com



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