

# Management's Discussion and Analysis

For the Three and Nine Months Ended December 31, 2023

DATE OF REPORT: February 14, 2024

## MANAGEMENT'S DISCUSSION AND ANALYSIS

The following management's discussion and analysis ("MD&A") has been prepared as at February 14, 2024 for the three and nine months ended December 31, 2023 and should be read in conjunction with the unaudited interim condensed consolidated financial statements of Medicenna Therapeutics Corp. for the three and nine months ended December 31, 2023, and the audited annual consolidated financial statements and accompanying notes for the year ended March 31, 2023 (the "Annual Financial Statements"), which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). Our IFRS accounting policies are set out in note 2 of the Annual Financial Statements and all dollar amounts are expressed in Canadian dollars unless otherwise noted.

All references in this MD&A to "the Company", "Medicenna", "we", "us", or "our" and similar expressions refer to Medicenna Therapeutics Corp. and the subsidiaries through which it conducts its business, unless otherwise indicated.

## FORWARD-LOOKING STATEMENTS

This MD&A contains forward-looking statements within the meaning of applicable securities laws. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on current beliefs, expectations, or assumptions regarding the future of the business, future plans and strategies, operational results and other future conditions of the Company. These statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. All statements contained herein other than statements of historical fact regarding the prospects of the Company's industry or its prospects, plans, financial position or business strategy may constitute forward-looking statements and can generally be identified by the use of forward-looking words, such as "seek", "plan", "expect", "is expected", "continue", "predict", "potential", "budget", "scheduled", "estimate", "forecast", "contemplate", "intend", "anticipate", or "believe" or variations (including negative variations) of such words and phrases, or statements that certain actions, events or results "may", "could", "would", "should", "might", "shall" or "will" be taken, occur or be achieved and similar expressions are generally intended to identify forward-looking statements.

By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other forward-looking statements will not be achieved. The Company cautions readers not to place undue reliance on these statements as a number of important factors could cause the actual results to differ materially from the beliefs, plans, objectives, expectations, anticipations, estimates and intentions expressed in such forward-looking statements. 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. Risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, as applicable, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information and statements include, but are not limited to, the risks described under the heading "Risks and Uncertainties" in this MD&A, the Company's annual report on Form 20-F for the fiscal year ended March 31, 2023 (the "Annual Report on Form 20-F") filed with the U.S. Securities and Exchange Commission on June 27, 2023.

Forward-looking statements in this MD&A include, but are not limited to:

- the therapeutic potential, clinical development and related milestones of the Company's Superkines and Empowered Superkines including MDNA11, the BiSKITs<sup>™</sup> platform, the T-MASK<sup>™</sup> platform and bizaxofusp (formerly MDNA55);
- the timely completion of the milestones related to the MDNA11 ABILITY Study (as defined below);
- the impact of the delay on clinical data;

- the clinical trial collaboration and supply agreement ("CTCSA") with Merck (known as MSD outside the United States and Canada);
- statements related to the potential extensions of the term of patents;
- a potential strategic partnership to facilitate bizaxofusp's further development and commercialization; and
- the use of proceeds from public equity offerings and the necessity for the Company to have recourse to such public equity offerings.

Although the Company has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended, including the following:

- the lack of product revenue and inability to continue operations and research and development without sufficient funding;
- the Company's requirements for, and our ability to obtain, future funding on favorable terms or at all;
- the Company's history of losses and expectations of future losses;
- the Company's inability to complete development of or the inability to commercialize (if approved)
- the Company's product candidates, which are in the early stages of development;
- the expense, length and uncertainty of clinical drug development programs;
- the inability to achieve publicly announced milestones according to schedule, or at all;
- the risk that competitors may develop and market products that are more effective that the Company's product candidates or that the products developed by competitors may render the Company's product candidates obsolete or uncompetitive;
- the Company's inability to secure a partnership for bizaxofusp (formerly MDNA55);
- the costs and uncertainty associated with extensive government regulation;
- the potential negative results from clinical trials or studies, adverse safety events or toxicities involving the Company's products used alone or in combination with other products of collaborators;
- the Company's ability to manage the unique risks and uncertainties related to developing biologics which could have a negative impact on future results of operations;
- the risk that preliminary and interim data from our clinical trials that we may announce or publish from time to time may change as patient data are further examined, audited or verified and more patient data become available;
- the value of the "Fast Track" designation granted to bizaxofusp and that it may not actually lead to a faster development or regulatory review or approval process and could be withdrawn by the United States Food and Drug Administration ("FDA");
- the unfavorable pharmacokinetic ("PK") or pharmacodynamic ("PD") properties of MDNA11 and MDNA19 used alone or in combination with other products of collaborators;
- the potential of the pre-clinical products of the Company;
- the risk of product liability claims;
- the Company's inability to enroll subjects in clinical trials or complete clinical trials on a timely basis;
- the failure of our product candidates to receive the marketing approval or market acceptance necessary for commercial success or to maintain any ongoing regulatory requirements it may be subject to;
- the potential for environmental exposure to hazardous or radioactive materials that are used in the Company's discovery and development process;
- the disruption in the availability of key components for ongoing clinical studies that could delay clinical studies, product testing and regulatory approval of the Company's product candidates;
- the Company's reliance on third parties for the planning, conduct and monitoring of preclinical and clinical trials and for the manufacture of drug product;
- the Company's reliance on contract manufacturers over whom the Company has limited control;
- the loss of license rights due to breach of license agreements;

- the conditions and restrictions of the Cancer Prevention and Research Institute of Texas ("CPRIT") grant;
- the ability to protect the Company's intellectual property and proprietary technology;
- the ability for the Company to obtain patent's term extensions;
- the potential involvement in intellectual property litigation;
- the risk that third parties on whom we rely for product development may not adequately protect the Company's trade secrets;
- the risk of product liability claims;
- the limitations surrounding intellectual property rights;
- the volatility in the price of our common shares ("Common Shares");
- the dilution of investor's voting power and reductions in earnings per share owing to future issuances of equity or the conversion of securities into Common Shares;
- the fact that future profits will likely be used for the continued growth of the Company's business and not for the payment of dividends;
- the Company's treatment as a passive foreign investment company and potential adverse U.S. federal income tax consequences associated with such treatment;
- the difficulty U.S. investors may face in bringing actions against the Company for violations of U.S. federal or state securities laws and challenges in enforcing the judgments of U.S. courts against the Company and its directors and executive officers;
- the Company's status as a foreign private issuer under applicable U.S. securities laws;
- the potential for the Company to lose its status as a foreign private issuer;
- changes in government regulations that could impact our business and operations;
- failure to comply with the U.S. Foreign Corrupt Practices Act, the Canadian Corruption of Foreign Public Officials Act and other global corruption and anti-bribery laws;
- failure to comply with healthcare laws;
- the ability of the Company's significant shareholders to assert a material influence over the Company's operations and governance;
- the adverse impact of factors outside our control, such as global health pandemics, natural disasters, geopolitical conflict and macroeconomic challenges;
- the Company's ability to successfully manage its growth;
- the failure of any acquired business, product, service or alliance to yield expected benefits;
- the Company's dependence upon certain key personnel, the loss of whom could adversely affect our ability to achieve our business objectives;
- changes in government regulations that could impact our business and operations;
- foreign currency exchange risks relating to the relative value of the United States dollar;
- the failure of our disclosure controls and procedures to detect all errors or prevent all incidences of fraud;
- the failure to maintain an effective system of internal controls;
- the vulnerability of the computer and information systems of the Company, its consultants and contractors, and third parties on which the Company relies, to security breaches or failure; and
- the pursuit of opportunities for further research and development or additional business opportunities.

The forward-looking information in this MD&A does not include a full assessment or reflection of the negative effect of adverse economic conditions, including a potential recession, and related inflationary cost pressures, higher interest rates, financial and capital market volatility and labor challenges; the negative effect of adverse conditions associated with the continued evolution of the COVID-19 pandemic and geopolitical events; a declining level of business and consumer spending; regulatory initiatives, proceedings and decisions, government consultations and government positions that affect us and influence our business; and the efforts of the Company to mitigate such conditions or events.

All forward-looking statements reflect the Company's beliefs and assumptions based on information available at the time the assumption was made.

Although the forward-looking statements contained in this MD&A are based upon what the Company's management believes to be reasonable assumptions, the Company cannot assure readers that actual results will be consistent with these forward-looking statements.

Any forward-looking statements represent the Company's estimates only as of the date of this MD&A and should not be relied upon as representing the Company's estimates as of any subsequent date. The Company undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events, except as may be required by securities laws.

## **COMPANY OVERVIEW**

Medicenna Therapeutics is a clinical-stage immunotherapy company developing engineered cytokines, called Superkines, designed to improve the specificity, function and safety profile of unmodified interleukins ("IL"). Medicenna's Superkine Platform transforms Superkines into multi-functional therapies that modulate, dampen, amplify or fine-tune the immune system. Medicenna's mission is to harness the power of directed evolution to develop novel immunotherapies that have the potential to revolutionize the treatment landscape in oncology and other immune-related diseases.

Medicenna owns diverse platforms licensed from Stanford University ("Stanford") to develop a pipeline of Superkine candidates: IL-2 agonists, IL-2 antagonists and partial agonists of IL-2. Additional assets from Stanford also include several super-agonists of IL-4 and IL-13 and dual IL-4/IL-13 antagonists. These Superkines can be developed either on their own as short or long-acting therapeutics or fused with cell-killing proteins to generate Empowered Superkines can also be fused with a large variety of proteins, antibodies, checkpoint inhibitors, and even other Superkines to incorporate two synergistic therapeutic activities into one molecule, creating novel <u>Bi</u>-specific <u>SuperKine ImmunoTherapies</u> and <u>Targeted Metalloprotease Activated SuperKines</u>, referred to by Medicenna as BiSKITs<sup>TM</sup> and T-MASK<sup>TM</sup>, respectively.

Medicenna's most advanced candidate is MDNA55, or bizaxofusp, for the treatment of recurrent glioblastoma ("rGBM"), the most common and uniformly fatal form of brain cancer. Bizaxofusp is a fusion of a circularly permuted version of IL-4, fused to a potent fragment of the bacterial toxin, Pseudomonas exotoxin ("PE"), and is designed to preferentially target tumor cells that over-express the interleukin 4 receptor ("IL-4R"). Bizaxofusp has successfully completed a Phase 2b trial for rGBM and holds FastTrack and Orphan Drug status from the U.S. Food and Drug Administration ("FDA") and FDA/European Medicines Agency ("EMA"), respectively. In addition, FDA has recommended Medicenna to proceed with a novel, practical and cost-effective Phase 3 clinical trial for approval of bizaxofusp, where a majority of patients enrolled in the control arm will comprise of clinical data compiled from cancer registries of matched rGBM patients previously treated with other approved therapies (External Control Arm). Medicenna plans to further develop bizaxofusp with a potential partner.

Our second clinical program is MDNA11, a next-generation long-acting "beta-enhanced, not-alpha" IL-2 super-agonist. MDNA11 comprises a molecule of human albumin that accumulates in tumors and augments MDNA11's half-life. MDNA11 is currently being evaluated in the ABILITY-1 ("A Beta-only IL-2 ImmunoTherapY") Phase 1/2 study in patients with melanoma and other solid cancers. The ABILITY-1 study is a global, multi-center, open-label clinical trial that will assess the safety, tolerability and anti-tumor activity of MDNA11 as a monotherapy or in combination with pembrolizumab (Keytruda®) under a clinical collaboration with Merck. MDNA11 has successfully completed Phase 1 dose-escalation portion of the study with a favourable safety profile and demonstrated early signs of efficacy in the monotherapy setting. The monotherapy recommended dose for expansion ("RDE") for MDNA11 has been established and enrollment in the phase 2 dose-expansion portion of the ABILITY-1 trial is currently underway. In addition, Medicenna has also commenced the dose-escalation portion of the trial in combination with Merck's pembrolizumab, the world's biggest selling therapeutic.

Our earlier stage candidates from the BiSKITs<sup>™</sup> and T-MASK<sup>™</sup> platforms are in pre-clinical development and are expected to enter first in human clinical trials in 2025.

# **RECENT ACHIEVEMENTS & HIGHLIGHTS**

The following are the achievements and highlights for the three months ended December 31, 2023 through to the date hereof:

- On February 14, 2024, the Company reported promising clinical data from the on-going monotherapy escalation and expansion arms of the ABILITY-1 study. In addition to previously announced tumor response data, a third patient in the study has also shown a partial response. Amongst 13 patients, all having previously failed or resistant to immune checkpoint inhibitors ("ICI"), receiving high doses of MDNA11 (≥ 60 µg/kg) with tumor types being evaluated in the monotherapy expansion cohort, the response rate, clinical benefit rate, and tumor control rate increased to 23% (3 partial responses), 46% (3 PRs and 3 patients with stable disease for ≥ 24 weeks), and 69% (3 PRs and 6 SDs), respectively, with concomitant shrinkage of target lesions in all patients with stable disease.
- On February 14, 2024, the Company announced that the Board of Directors approved the transition of Dr. Humphrey Gardner from CMO to consultant. Dr. Arash Yavari, Chair of Medicenna's Development Advisory Committee, will lead the clinical activities as Director of Clinical Strategy.
- On February 14, 2024, the Company announced that the Board of Directors approved the appointment of David Hyman, CA, CBV as CFO of the Company. Mr. Hyman is an experienced financial professional with over 25 years of experience spanning public practice, capital markets, private equity and industry. For the past five years, Mr. Hyman has provided fractional and full time CFO services to multiple public and private companies, including two early-stage pharmaceutical companies.
- On February 13, 2024, the Company announced that it had dosed the first patient in the combination arm of the ABILITY-1 clinical trial, evaluating potential synergistic effect of MDNA11 when administered with KEYTRUDA<sup>®</sup> (pembrolizumab). The study will evaluate the safety, tolerability, recommended combination dose for expansion ("cRDE") and therapeutic activity of MDNA11 when combined with pembrolizumab in the dose-escalation and dose-expansion arms of the clinical trial.
- On January 12, 2024, the Company announced that its Board of Directors approved the appointment of MNP LP as the auditor of the Company.
- On January 9, 2024, the Company announced the initiation of enrollment in the combination arm of the Phase 1/2 ABILITY study evaluating MDNA11 with KEYTRUDA<sup>®</sup>. The combination portion of the study is designed to evaluate the potential for a synergistic effect of MDNA11 with KEYTRUDA<sup>®</sup> in patients with advanced solid tumors.
- On December 19, 2023, the Company announced the commencement of trading on the OTCQB Venture Market in the United States.
- On November 17, 2023, the Company announced that a poster presentation and an oral summary highlighting longer term follow up results from the Phase 2b clinical trial of bizaxofusp, the Company's first-in-class IL-4R targeted therapy for the treatment of patients with rGBM, was presented by Dr. Steven Brem, M.D. (Medical Director, Centre for Precision Surgery, Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania) at the 2023 Annual Meeting of the Society for Neuro-Oncology ("SNO") held in Vancouver, Canada.
- On November 6, 2023, Medicenna announced encouraging single-agent activity from the dose escalation and evaluation portion of the ABILITY-1 study in advanced cancer patients receiving doses ≥ 60 µg/kg of MDNA11 (N = 15) who had previously failed immune check-point inhibitor therapies. The results included ongoing partial responses with 100% and 70% reduction of target lesions in pancreatic and melanoma cancer patients, respectively, in addition to durable stable disease in 3 melanoma patients (> 20 to 80 weeks). This data was presented at the 38<sup>th</sup> Annual Meeting of the Society for

Immunotherapy of Cancer ("SITC") held in San Diego. See *Research & Development Update – MDNA11* for clinical updates.

- On November 3, 2023, the Company presented preclinical data on its first-in-class IL-13Rα2 targeted candidate, MDNA113, from its T-MASK platform, which delivers a masked bispecific anti-PD1-IL2 Superkine to IL-13Rα2 expressing tumors (annual incidence of over 2 million)<sup>1</sup> where it is activated by cancer specific enzymes. This data was presented at the 38<sup>th</sup> Annual Meeting of the SITC held in San Diego. See *Research & Development Update T-MASK Platform* for research updates.
- On November 2, 2023, the trading of the Company's common shares on the Nasdaq Capital Market ("Nasdaq") was suspended as a result of the Company's failure to comply with the US\$1.00 per share minimum bid price requirement. Form 25-NSE was filed with the United States Securities and Exchange Commission, which removed the Company's securities from listing and registration on Nasdaq (the "Nasdaq Delisting"). As of December 19, 2023, the Company's common shares continue to trade on the Toronto Stock Exchange and on the OTCQB in the United States, as noted above.
- On October 27, 2023, Medicenna announced that it was delisted from the Nasdaq as the Company did not meet the listing requirements, that it is reducing its presence in the US to conserve cash, and that Jeff Caravella, Chief Financial Officer, and Brent Meadows, Chief Business Officer, departed the Company, effective October 26, 2023.
- On October 25, 2023, Medicenna announced dosing of the first patient in the Phase 2 monotherapy dose expansion portion of the ABILITY-1 Study.
- On October 3, 2023, new preclinical data characterizing MDNA223, an anti-PD1-IL-2 BiSKIT<sup>™</sup> (Bifunctional SuperKine for ImmunoTherapy), including its synergy when combined with STING agonists were presented at the 2023 AACR Special Conference in Cancer Research: Tumor Immunology and Immunotherapy, held in Toronto, Canada. See Research & Development Update – BiSKITs Platform for research updates.

# FINANCING UPDATE

# Nine months ended December 31, 2023

# 2023 At-The-Market Facility

On February 17, 2023, the Company entered into a sales agreement with Oppenheimer & Co. Inc., acting as sales agent (the "2023 ATM Agreement"), pursuant to which the Company may, from time to time sell, through at-the-market offerings on the Nasdaq such number of Common Shares as would have an aggregate offering price of up to US\$10.0 million (the "2023 ATM Facility"). During the nine months ended December 31, 2023, the Company did not issue any Common Shares pursuant to the 2023 ATM Facility. Further to the Nasdaq delisting in November 2023, the 2023 ATM Agreement was terminated.

# <u>Warrants</u>

During the nine months ended December 31, 2023, no warrants were exercised.

On July 5, 2023, the warrants issued on October 17, 2019, in correlation with a public offering, were due to expire on July 17, 2023 and were extended to October 17, 2024.

On December 18, 2023, the warrants issued on December 21, 2018 were due to expire on December 21, 2023 and were extended to July 31, 2024.

<sup>&</sup>lt;sup>1</sup> https://www.wcrf.org/cancer-trends/worldwide-cancer-data/

# **RESEARCH & DEVELOPMENT UPDATE**

# Our Pipeline of Superkines



## Bizaxofusp (formerly named MDNA55) for the treatment of recurrent Glioblastoma ("rGBM")

Glioblastoma ("GBM") is one of the most complex, deadly, and treatment-resistant cancers. It is expected that in the US and Canada, there will be at least 15,000 new diagnoses of GBM with more than 10,000 individuals succumbing to the disease within one year. Five-year survival rate for GBM patients is only 6.9 percent; these survival rates and mortality statistics have remained virtually unchanged for decades.

Despite first being identified in the scientific literature in the 1920's, there have only been four drugs and one device ever approved by the USFDA specifically for the treatment of GBM. Unfortunately, none have succeeded in significantly extending patient lives beyond a few extra months for newly diagnosed GBM and a few extra weeks for patients with rGBM. GBM is also one of the more expensive cancers to treat, often leaving patients and families with major financial hardship in addition to the burden of the disease. Given the limitation of all current therapeutics, development of novel approaches for treating GBM and rGBM remains a great unmet need.

Bizaxofusp is a genetically engineered fusion of a circularly permuted version of IL-4 to a potent catalytic component of the bacterial toxin, Pseudomonas exotoxin, which effectively arrests protein synthesis leading to cell death. The IL-4 component is engineered and designed to preferentially target tumor cells that over-express the interleukin 4 receptor ("IL-4R"). The drug is delivered only once locally into the tumor, using a minimally invasive technique, bypassing the blood-brain barrier. Bizaxofusp holds a FastTrack and Orphan Drug status from the FDA and FDA/EMA, respectively.

Bizaxofusp has successfully completed a Phase 2b (N=44) trial for nonresectable rGBM where it demonstrated compelling Overall Survival ("OS") benefit versus Standard of Care ("SOC"). The Phase 2b clinical trial was conducted in a multi-center, open-label, single-arm study in patients with first or second recurrence or progression of GBM after surgery or radiotherapy ± adjuvant therapy or other experimental therapies. Results were published in June 2023 issue of NeuroOncology (doi: 10.1093/neuonc/noac285).

# Phase 2b Results Published as the Cover Story in Neuro-Oncology



A separate analysis collected rGBM survival and prognostic data from eligibility matched 81 patients who had contemporaneously received treatment at major clinical centres using current SOC. These data from patient registries were used to establish a matched External Control Arm ("ECA"). Blinded survival data from propensity matched ECA (established by matching with bizaxofusp-treated population based on 11 different prognostic factors using propensity scoring methods) were then used as a control arm versus survival data from the Phase 2b bizaxofusp trial. Survival follow-up has concluded, and final study results were presented at the 28<sup>th</sup> Annual Meeting of the Society of NeuroOncology in Vancouver on November 16-19, 2023. Key findings from the presentation are shown in the figure below and include:

- Bizaxofusp doubled mOS irrespective of IL-4R expression (IL-4R high + IL-4R low treated with high dose bizaxofusp; proposed Phase 3 population) compared to propensity matched ECA (14.5 months vs. 7.2 months).
- Compared to propensity matched ECA, bizaxofusp increase OS by 370% at year 1 and by more than 50% at year 2.

#### **Bizaxofusp Doubles Overall Survival in Phase 3 Population vs ECA**



OS Increased by 370% at 1 Year | OS at 2 Years Improved by >50%



## Bizaxofusp Shows Compelling Overall Survival Benefit Over Standard or Care

Following the End of Phase 2 (EOP2) meeting, the FDA endorsed an innovative open-label hybrid Phase 3 registration trial that allows use of a substantial number of patients (two-thirds) from a propensity matched ECA to support marketing authorization of bizaxofusp for rGBM (see the graphic below).

# Phase 3 Trial with Hybrid External Control Arm ("ECA") to be Conducted in Collaboration with Potential Partner



#### Hybrid with ECA: The First Time FDA has Endorsed Inclusion of an ECA in a Phase 3 Trial for Brain Cancer

In order to add additional value to the bizaxofusp program Medicenna is planning to seek Breakthrough Therapy Designation from the FDA and is also seeking alignment from the EMA for the FDA-endorsed Phase 3 trial design in the coming months.

Medicenna is pursuing strategic partnerships to assist with additional clinical development of bizaxofusp, as well as preparing the program for commercialization and its subsequent launch in various countries where marketing authorization has been granted. Medicenna estimates that the total costs of completion of a pivotal registrational trial, associated regulatory and manufacturing activities and preparing bizaxofusp for commercial launch to be approximately \$60 to \$80 million USD.

Through confidential primary market research conducted for the Company, bizaxofusp has a market potential of more than US\$800M annually for GBM alone. In addition, metastatic IL-4R positive brain tumors account for ~US\$4B market.

# <u>MDNA11</u>

MDNA11 is a long-acting albumin-fusion, beta-enhanced not-alpha IL-2 super agonist designed to preferentially activate anti-cancer immune cells (CD8+ T and NK) over immunesuppressive (pro-cancer) Tregs. Fusion with human albumin augments MDNA11's half-life and promote its accumulation in tumors. MDNA11 is currently being evaluated in the ABILITY Phase 1/2 study in patients with melanoma and other solid cancers. The ABILITY Study is a global, multi-center, open-label study that assesses the safety, tolerability and anti-tumor activity of MDNA11 as monotherapy or in combination with pembrolizumab (Keytruda®). The figure below describes the ABILITY Phase 1/2 study.

# ABILITY Phase 1/2 Study Schema: MDNA11 Monotherapy and in Combination with Pembrolizumab



On August 9, 2023, Medicenna held a R&D day webcast where Dr. Arash Yavari, Chair of the Company's Development Advisory Committee ("DAC"), presented a clinical update on the monotherapy dose escalation portion of the ABILITY Study. Key findings from the dose escalation portion of the ABILITY Study include:

- <u>Favorable safety profile</u>: MDNA11 was generally well tolerated across cohorts, with majority of adverse events (AEs) being grade 1 or 2, with no grade 4 or 5 AEs.
- <u>Promising single-agent activity and durable tumor control</u>: Several patients exhibited encouraging evidence of single-agent activity with clinical benefit observed in 7 of 19 evaluable patients (37%).

- <u>Confirmed partial response to single-agent MDNA11 in a highly aggressive tumor type</u>: A patient in cohort 4 (60µg/kg dose) with metastatic pancreatic ductal adenocarcinoma (PDAC), who had failed to respond to multiple prior systemic therapies, continues to show tumor shrinkage of all metastatic lesions in the liver after each successive scan. The most recent scan showed an 80% decrease in total tumor size with complete regression of 2 out of 3 lesions. This patient continues on study treatment with MDNA11.
- Prolonged stable disease in metastatic melanoma progressed on prior immune checkpoint inhibition: A patient in cohort 2 (commenced on 10 μg/kg dose and subsequently increased to 30, 60 and 90 μg/kg), having failed prior immunotherapy, experienced stable disease for 84 weeks.
- Pharmacodynamic data on effector anti-tumor immune cells continue to support the mechanistic rationale for MDNA11's promising anti-tumor activity, with MDNA11 inducing robust expansion of a population of potent activated CD8<sup>+</sup>T cells and increasing NK cells, but with limited expansion of Tregs which can suppress anti-tumor immunity.

Based on the totality of the dose escalation data, a Recommended Dose for Expansion ("RDE") of 90  $\mu$ g/kg given every other week by IV infusion has been chosen for the monotherapy expansion phase of the trial.

Selection of specific cancers for evaluation in the monotherapy dose expansion phase was determined based on clinical data available from the ABILITY-1 Study, discussions with Medicenna's Clinical Advisory Board ("CAB") and other expert KOLs, and an understanding of the immunobiology of the selected tumor types and the potential for MDNA11 monotherapy in the post-checkpoint inhibitor setting. The following tumor types will be recruited in the dose expansion phase of the study:

- Melanoma (Cutaneous, Mucosal or Acral).
- Non-Melanoma Skin Cancers (cSCC, BCC, MCC).
- Microsatellite Instability-High (MSI-H) or deficient DNA mismatch repair (dMMR) cancers. This
  population was selected to determine if the response achieved in the PDAC patient may have been
  due to the MSI-H profile. The PDAC patient unequivocally progressed on pembrolizumab, which is
  approved for MSI-H cancers.

On October 25, 2023, Medicenna reported that the first patient was dosed in the monotherapy dose expansion portion of the study. Preliminary data from the monotherapy dose expansion part of the study are expected to be presented in the first half of calendar 2024.

Enrolment for combination dose escalation with KEYTRUDA<sup>®</sup> commenced end of calendar 2023 with the first patient for combination dose escalation being dosed on February 7, 2024.

At the 38<sup>th</sup> Annual Meeting of the SITC held in San Diego from November 1-5, 2023, Medicenna presented further updates from the Phase 1/2 ABILITY Study. Key clinical data are summarized and shown graphically below:

- MDNA11 continues to demonstrate encouraging single-agent activity from the dose escalation and evaluation portion of the ABILITY-1 study, including ongoing partial response with 100% reduction of target and non-target lesions in one pancreatic cancer patient and a second patient with metastatic melanoma demonstrating a 70% reduction of target lesion at week 12.
- MDNA11 showed durable stable disease in 3 melanoma patients for longer than 5 months, with one
  patient showing durable stable disease for 18 months, with concomitant shrinkage of target lesions,
  following prior failure with immune check-point therapies.
- At dose levels above 60 μg/kg, MDNA11 achieved a disease control rate of 33.3% (2 PRs and 3 durable SDs in 15 patients) irrespective of tumor type.
- MDNA11 is generally well tolerated with no dose-limiting toxicities and vascular leak syndrome reported in any of the monotherapy dose escalation cohorts.

- Vast majority (95.6%) of treatment related adverse events were grade 1-2 severity and resolved within 48 hours; grade 3 TRAEs mainly constituted transient LFT elevations; no grade 4 or 5 events were reported.
- Pharmacodynamic response showed robust expansion and activation (CD25 and OX40) of CD8+ T cells with some expansion of NK cells and limited increase in number of immune-suppressive Treg cells, in all dose cohorts and particularly at 90 μg/kg.
- Target dose of 90 μg/kg (following 2 step-up doses of 30 and 60 μg/kg) Q2W by IV infusion was chosen as the Recommended Dose for Expansion (RDE) in the monotherapy expansion portion of the ABILITY study.

#### 2 Partial Responses (PR) and 3 Durable Stable Diseases (SD) with Single-agent MDNA11 (Data cutoff as of October 26, 2023) – Additional, updated data are presented below



Deep Shrinkage of Tumor Lesions with Single-agent MDNA11











Following the SITC presentation, additional follow-up data from MDNA11 monotherapy further confirms single agent activity. Key updates are shown in the below figures and include:

- PDAC PR patient continues to show complete resolution of all baseline lesions.
- Melanoma PR patient shows further deepening of tumor shrinkage.
- A new melanoma patient with iPR (PR as per iRECIST) showed pseudo-progression (at week 8) with a iPR (at week 12). Additional data will be presented at medical conferences in H1 2024.
- Amongst 13 patients, all having previously failed or resistant to immune checkpoint inhibitors ("ICI"), receiving high doses of MDNA11 (≥60 µg/kg) and with tumor types being evaluated in the monotherapy expansion cohort, the response rate, clinical benefit rate, and tumor control rate increased to 23% (3 partial responses), 46% (3 PRs and 3 patients with stable disease for ≥24 weeks), and 69% (3 PRs and 6 SDs), respectively, with concomitant shrinkage of target lesions in all patients with stable disease.

Compelling Single-Agent Activity in Heavily Pre-treated Patients with Advanced Solid Tumors (Data cut-off as of February 5<sup>th</sup>)



On February 13, 2024, Medicenna reported that the first patient was dosed in the combination dose escalation with KEYTRUDA<sup>®</sup>. Preliminary data from the combination escalation part of the study are expected to be presented in the first half of calendar 2024.

In addition to general clinical expenses, which are distributed amongst the various clinical projects, \$12.4 million is currently estimated to be allocated to the Phase 2 monotherapy dose expansion and Phase 2 combination trial with KEYTRUDA<sup>®</sup>.

# IL-4 and IL-13 Superkines in preclinical development

Medicenna's IL-4 and IL-13 Superkines, licensed from Stanford, are engineered cytokines which possess enhanced affinity and selectivity for either the Type 1 or Type 2 IL-4 receptors or dedicated IL13 receptors such as IL13R $\alpha$ 2. This selectivity is achieved through mutations of the IL-4 or IL-13 cytokines to enhance affinity for binding to specific IL4R or IL13R subunits. Additional mutations have also been engineered to modulate their bioactivity, resulting in Superkines with enhanced signalling (super-agonists) or the ability to block signalling (super-antagonists).

# MDNA413 : An IL-4/IL-13 Dual Super-Antagonist

One promising IL-13 Superkine antagonist is MDNA413. Compared to wild-type IL-13, MDNA413 has been engineered to have a 2,000-fold higher selectivity for the Type 2 IL4R and potently blocks IL-4 and IL-13 signalling (Moraga et al., 2015). Blocking of Type 2 IL4R by MDNA413 may be relevant not only for targeting solid tumors that overexpress this receptor, but also the Th2-biased tumor microenvironment, which shields cancer from the immune system.

We believe that MDNA413's ability to block IL-4/IL-13 signalling has the potential to address a significant unmet medical need for effective therapies against immunologically cold tumors which are often resistant to checkpoint inhibitors and other immunotherapeutic agents due to their immunosuppressive tumor microenvironment ("TME").

# MDNA132 and MDNA213: High Affinity Cancer-Specific Targeting Ligands

Another promising IL-13 Superkine is MDNA132, and its variant, MDNA213. Unlike MDNA413, MDNA132 and MDNA213 are IL-13 ligands that have been engineered to increase affinity for IL13R $\alpha$ 2 overexpressed on certain solid tumors while exhibiting sharply decreased affinity for IL13R $\alpha$ 1. Medicenna believes MDNA132 and MDNA213 have superior targeting compared to other IL-13 variants in development and is an attractively differentiated tumor targeting domain for (a) cell-based immunotherapies (such as those using chimeric antigen receptors or CARs); (b) potent payloads used in antibody-drug conjugates ("ADC");

(c) targeted fusion toxins or (d) radiopharmaceuticals. Development timelines for MDNA132 and MDNA213 have yet to be established. MDNA132 and/or MDNA213 are also being evaluated as potential fusion proteins in our BiSKITs<sup>™</sup> and the T-MASK<sup>™</sup> platforms.

On April 17, 2023, we presented new preclinical data characterizing the Interleukin 13 ("IL-13") Superkines, MDNA132 and MDNA213, and a series of next generation IL-13 Superkine therapies, at the AACR Annual Meeting, which took place in Orlando, Florida, from April 14 to 19, 2023. The AACR poster included data demonstrating that both MDNA132 and MDNA213 exhibit highly selective binding to the IL-13 decoy receptor (IL-13R $\alpha$ 2) and, in a murine model, selectively accumulate in the TME for several days. MDNA132 and MDNA213 exhibit high affinity and selectivity for the IL13R $\alpha$ 2, which is overexpressed in various tumors such as pancreatic, prostate, bladder, colorectal, breast and lung cancer but minimally expressed in healthy tissues. A fusion of MDNA213 with a toxin selectively caused cell death in IL-13R $\alpha$ 2 expressing cancer cells in vitro and tumors in vivo. High expression of IL13R $\alpha$ 2 in these tumors is generally associated with more aggressive cancer and poor survival outcomes.

# BiSKITs<sup>™</sup> (Bi-functional SuperKine ImmunoTherapies) Platform

Our BiSKITs<sup>™</sup> platform allows us to develop designer Superkines by fusing them to other proteins, checkpoint inhibitors, antibodies or cytokines to our IL-2, IL-4 and/or IL-13 Superkines in order to combine two distinct and yet synergistic mechanisms of action into one molecule: a BiSKIT<sup>™</sup>.

MDNA223 is a fusion of Medicenna's IL-2 Superkine with an anti-PD1 antibody, designed to maximize antitumor response by concurrently facilitating IL-2R pathway stimulation and PD1 checkpoint blockade on the same effector immune cell as described in the figure below.

#### Cis-binding Facilitates IL-2R Activation and PD-1 Blockade on the Same CD8+ T Cell to Maximize Anti-Cancer Response



On October 3, 2023, we presented a poster at the AACR Special Conference in Cancer Research: Tumor Immunology and Immunotherapy with preclinical data demonstrating that the MDNA223 BiSKIT:

 Showed enhanced IL-2Rbeta selectivity and no binding to IL-2Ralpha, leading to preferential stimulation of CD8+ T cells over Tregs in human PBMCs.

- Retained high affinity to PD-1, generating potent blockade of PD-1/PD-L1 mediated exhaustion of T cells.
- Induced durable proliferation and expansion of CD8+ T cells in the periphery, and enhanced tumor infiltration of functionally active CD8+ T cells.
- Demonstrated superior efficacy and survival benefit in multiple syngeneic tumor models, including "cold" tumors compared to co-administration (combination) of anti-PD1 and IL-2 super-agonist (MDNA19) (see figure below).
- Synergized with agonist of the STING (Stimulator of Interferon Genes) pathway to enhance tumor inhibition and promote an abscopal effect as demonstrated by shrinkage of the untreated tumor on opposite flank.
- Enhanced tumor response while being well-tolerated in a step-up dosing setting.
- The sum of encouraging preclinical data on MDNA223 highlights the potential of Medicenna's BiSKIT platform to broadly deliver effective therapy to otherwise challenging-to-treat 'cold' tumors.

# MDNA223 Shows Superior Efficacy to Combination of MDNA19 (IL-2 agonist) + anti-PD-1



Medicenna is currently screening and optimizing a variety of IL-2/IL-4/IL-13 Superkines as part of our BiSKIT<sup>™</sup> platform. As preparing, submitting, and advancing applications for regulatory approval, developing drugs and drug product and clinical trials are sometimes complex, costly, and time-consuming processes, an estimate of the future costs is not reasonable at this time.

#### T-MASK<sup>™</sup> (Targeted Metallo/protease Activated SuperKine) Platform

Our T-MASK<sup>™</sup> platform involves fusion of a dual IL-13 tumor targeting/masking domain to an IL-2 superkine or IL-2 BiSKIT<sup>™</sup> via a matrix metalloprotease ("MMP") sensitive linker ("PSL"), to provide the following unique features:

- Tunable blockade of IL-2R agonism to reduce peripheral immune stimulation for enhanced tolerability.
- Tumor targeting to IL-13Rα2 highly expressed in a broad range of cancer indications but not normal tissues.
- Cleavage and release of IL-13 tumor-targeting/masking domain by MMPs restores IL-2R agonism within the tumor microenvironment (TME).

Proposed mechanism of action of the T-MASK<sup>™</sup> platform is shown in the figure below for an IL-2 BiSKIT (MDNA223; Anti-PD1-IL-2<sup>SK</sup>)



At the 38<sup>th</sup> Annual Meeting of the SITC held in San Diego from November 1-5, 2023, Medicenna presented preclinical data on characterization of its T-MASK<sup>TM</sup> platform, by evaluating T-MASK<sup>TM</sup> versions of long-acting IL-2 superkine and MDNA223, an anti-PD1-IL-2 BiSKIT<sup>TM</sup>. Key features of the platform and preclinical data presented in the conference are summarized below:

- The IL-13 superkine acts as an effective dual tumor targeting and masking domain to selectively
  deliver potent immune modulators to the tumor microenvironment where they are activated by cancer
  specific enzymes.
- IL-13Rα2 is highly expressed in a broad range of aggressive tumors at an annual rate of more than 2 million cases worldwide and include some of the most immunologically "cold" tumors.<sup>2</sup>
- MDNA113 is a first-in-class IL-13Rα2 targeted therapy that delivers a masked anti-PD1-IL-2 bifunctional superkine to the tumor microenvironment.
- MDNA113 showed reduced potency in IL-2 signaling assays but activity was restored upon MMP cleavage to remove the IL-13 Mask.
- Masking had no effect on blockade of PD1/PD-L1 immune suppressive signaling in vitro.
- Systemic administration of MDNA113 in mice showed reduced peripheral immune cell expansion compared to non-masked version.
- MDNA113 is as effective as its non-masked version at inhibiting tumor growth in mouse cancer models; an uncleavable version of MDNA113 has reduced efficacy as expected (see figure below).
- The level of masking is tunable and avoids complete blockade of the immune modulator thereby retaining good tolerability while achieving adequate immune stimulation during transit to the tumor micro-environment.

<sup>&</sup>lt;sup>2</sup> Sharma A., et al. Journal for ImmunoTherapy for Cancer. 2023; 11 (Suppl 1) <u>https://doi.org/10.1136/jitc-2023-SITC2023.1071</u>

# Effective Tumor Inhibition by MDNA113 Requires Activation by MMP Cleavage Within TME



Medicenna is currently screening and optimizing a variety of IL-2/IL-4/IL-13 Superkines as part of our BiSKITs<sup>™</sup> and T-MASK<sup>™</sup> platforms. Additional funding will be necessary to advance one or more of these product candidates into clinical trials. As preparing, submitting, and advancing applications for regulatory approval, developing drugs and drug product and clinical trials are sometimes complex, costly, and time-consuming processes, an estimate of the future costs is not reasonable at this time.

# SELECTED FINANCIAL INFORMATION

All tabular amounts below are presented in thousands of Canadian dollars, except for per share amounts.

	Three months ended Nine December 31,		Nine mont Dece	Nine months ended December 31,	
	2023	2022	2023	2022	
Statements of loss and comprehensive loss data:	\$	\$	\$	\$	
General and administration	1,786	1,976	5,736	6,266	
Research and development	2,991	2,945	8,937	7,718	
Total operating expenses	4,777	4,921	14,673	13,984	
	(000)	(2.10)	(070)	(500)	
Finance income	(282)	(340)	(970)	(532)	
Change in fair value of warrant derivative	160	(3,747)	(2,547)	(5,547)	
Foreign exchange loss (gain)	322	307	406	(1,713)	
_	200	(3,780)	(3,111)	(7,792)	
Net Loss	(4,977)	(1,141)	(11,562)	(6,192)	
Basic and diluted loss per share	(0.07)	(0.02)	(0.17)	(0.10)	

	As of		
	December 31, 2023	March 31, 2023	
Statement of financial position:			
	\$	\$	
Cash	21,758	33,596	
Total assets	23,268	36,446	
Total liabilities	4,639	6,960	
Working capital	19,184	32,585	
Accumulated deficit	(92,543)	(80,981)	
Total shareholder's equity	18,629	29,486	

The Company has not generated revenue in any of the previous fiscal years, other than income from interest earned on cash and cash equivalents.

For the three and nine months ended December 31, 2023, the Company reported a net loss of \$5.0 million (\$0.07 loss per share), and \$11.6 million (\$0.17 loss per share), compared to a net loss of \$1.1 million (\$0.02 loss per share) and \$6.2 million (\$0.10 loss per share), respectively for the three and nine months ended December 31, 2022. The increase in net loss for the three and nine month period ended December 31, 2023, compared with the period ended December 31, 2022, was primarily related to the non-cash change in fair value of warrant derivate. Variances within the general and administrative and research and development categories are discussed specifically below.

## **RESULTS OF OPERATIONS FOR THE THREE AND NINE MONTHS ENDED DECEMBER 31, 2023**

	Three month	Three months ended		Nine months ended		
	Decer	December 31,		mber 31,		
	2023	2022	2023	2022		
	\$	\$	\$	\$		
Chemistry, manufacturing, and controls	257	146	1,028	686		
Regulatory	27	15	77	52		
Discovery and pre-clinical	216	295	1,102	1,166		
Clinical	1,454	1,221	3,545	2,752		
Salaries and benefits	606	780	1,760	1,839		
Licensing, patent legal fees and royalties	208	303	1,065	739		
Stock based compensation	97	156	399	452		
Research and development tax credits	-	-	(200)	-		
Other research and development expenses	126	29	161	32		
	2,991	2,945	8,937	7,718		

#### Research and Development ("R&D") Expenses

R&D expenses of \$3.0 million and \$8.9 million were incurred during the three and nine months ended December 31, 2023, compared with \$2.9 million and \$7.7 million incurred during the three and nine months ended December 31, 2022.

The increase in R&D expenses in the three and nine months ended December 31, 2023, compared to the three and nine months ended December 31, 2022, is primarily attributable to:

- increased clinical costs during the nine months ended December 31, 2023, relative to the prior year due to the expansion of the MDNA11 ABILITY-1 Study to new clinical sites in US and South Korea.
- increased manufacturing costs during the nine months ended December 31, 2023, relative to the prior year due to one-time labeling and packaging costs of Keytruda for use in the combination portion of MDNA11 ABILITY-1 study.
- increase in licensing, patent legal fees and royalties during the nine months ended December 31, 2023 relative to the prior year due to the timing of royalty and milestone payments.
- The above increases for the nine month period ending December 31, 2023 related to the prior comparative period were partially offset by tax credits related to filed SRED claims.

# General and Administrative ("G&A") Expenses

	Three months ended December 31,		Nine months ended December 31,	
	2023 \$	2022 \$	2023 \$	2022 \$
Public company expenses	1,030	1,213	4,001	3,587
Salaries and benefits	465	429	805	877
Facilities and operations	227	149	603	422
Stock based compensation	62	183	323	724
Transaction costs, warrant derivative	-	-	-	652
Depreciation expense	2	2	4	4
	1,786	1,976	5,736	6,266

G&A expenses of \$1.8 million and \$5.7 million were incurred during the three and nine months ended December 31, 2023, compared with \$2.0 million and \$6.3 million during the three and nine months ended December 31, 2022.

G&A expenses in the three and nine month period ended December 31, 2023 decreased relative to the comparative three and nine month periods ended December 31, 2022 primarily due to a reduction in directors and officers liability insurance premiums.

	Dec. 31 2023	Sep. 30 2023	Jun. 30 2023	Mar. 31 2023	Dec. 31 2022	Sep. 30 2022	Jun. 30 2022	Mar. 31 2022
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue	-	-	-	-	-	-	-	-
General and administration	1,786	2,303	1,647	1,385	1,976	1,719	1,919	1,936
Research and development	2,991	3,134	2,812	1,586	2,945	2,362	2,411	1,191
Change in fair value of warrant derivative	160	(960)	(1,747)	1,200	(3,747)	(1,800)	-	-
Net loss	(4,977)	(3,723)	(2,862)	(3,856)	(1,141)	(896)	(4,155)	(3,206)
Basic and diluted loss per share	(0.07)	(0.05)	(0.04)	(0.06)	(0.02)	(0.01)	(0.07)	(0.06)
Total assets	23,268	27,743	31,546	36,446	38,174	42,560	20,140	23,456
Total liabilities	4,026	4,306	4,646	6,960	4,949	8,644	2,147	2,621

# SUMMARY OF QUARTERLY FINANCIAL RESULTS:

R&D expenses have remained relatively constant over the last three quarters as there have been no significant changes in the Company's clinical programs. Refundable tax credits of \$0.7 million contributed to a decrease in R&D expenses during the quarter ended March 31, 2022, and during the quarter ended March 31, 2023. R&D expenses increased in the quarter ended December 31, 2022, the quarter ended June 30, 2023, and quarter ended September 30, 2023, due to timing of activity in the MDNA11 ABILITY Study.

G&A expenses have remained relatively consistent quarter over quarter other than the quarter ended September 30, 2023, which reflects non-recurring legal and recruitment costs related to personnel additions during the quarter.

There was a non-cash change in the fair value of the warrant derivative (gain) loss from the quarter ended September 30, 2022 onwards. The fair value of the warrant derivative will fluctuate quarterly due to volatility of share price, expected dividend yield and expected risk-free interest rate.

# LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has devoted its resources to funding R&D programs, including securing intellectual property rights and licenses, conducting discovery research, manufacturing drug supplies, initiating preclinical and clinical studies, submitting regulatory dossiers, and providing administrative support to R&D activities, which has resulted in an accumulated deficit of \$92.5 million as of December 31, 2023. With current revenues only consisting of interest earned on excess cash, cash equivalents and marketable securities, losses are expected to continue while the Company's R&D programs are advanced.

The Company does not earn any revenue from our product candidates and is therefore considered to be in the development stage. As required, the Company will continue to finance its operations through the issuance of equity or pursue non-dilutive funding sources. The continuation of our research and development activities for bizaxofusp, MDNA11, the BiSKITs<sup>™</sup> and T-MASK<sup>™</sup> platforms and the commercialization of bizaxofusp is dependent upon the ability to successfully finance and complete our research and development programs through a combination of equity financing and revenues from strategic partners. The Company currently has no sources of revenue from strategic partners.

Management has forecasted that the Company's current level of cash will be sufficient to execute its current planned expenditures into Q2 of calendar 2025. The Company has the ability to reduce or eliminate planned expenditures to extend its operating runway if it is unable to obtain additional financing when required. The Company's ability to continue as a going concern beyond the first quarter of 2025 is dependent on its ability to secure additional financing.

These circumstances cast substantial doubt as to the ability of the Company to continue as a going concern and, hence, the appropriateness of the use of accounting principles applicable to a going concern.

The following table summarizes the Corporation's cash flows for the periods indicated:

	Nine Months ended December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	(11,415)	(10,366)
Financing activities	-	24,949
Net increase (decrease) in cash and cash equivalents	(11,415)	14,583

Cash utilized in operating activities for the nine months ended December 31, 2023 was \$11.4 million, compared to the nine months ended December 31, 2022 of \$10.4 million. The increase in cash utilized in the nine months ended December 31, 2023, compared to the nine months ended December 31, 2022 is primarily as a result of increased research and development expenses and changes in working capital.

Cash provided by financing activities for the nine months ended December 31, 2022 is comprised of an underwritten public offering completed on August 10, 2022. Total proceeds from the August 2022 Public Offering, net of issuance costs was \$23.9 million. The remaining cash provided by financing activities was from the 2020 ATM Facility. There was no cash generated from financing activities during the nine months ended December 31, 2023.

# CASH POSITION

At December 31, 2023, the Company had a cash and cash equivalents balance of \$21.8 million, compared to \$33.6 million at March 31, 2023. The Company invests cash in excess of current operational requirements in highly rated and liquid instruments. Working capital on December 31, 2023 was \$19.1 million (March 31, 2023 - \$32.6 million). These funds are expected to provide the Company with sufficient capital to execute its current planned expenditures through the key milestones associated with the ABILITY Study and into calendar Q2 2025 based on its current plans and projections.

The Company does not expect to generate positive cash flow from operations for the foreseeable future due to additional R&D expenses, including expenses related to drug discovery, preclinical testing, clinical trials, chemistry, manufacturing and controls and operating expenses associated with supporting these activities. It is expected that negative cash flow from operations will continue until such time, if ever, that we receive marketing authorization to commercialize any of our product candidates under development and/or royalty or milestone revenue from any such products should they exceed our expenses.

# CONTRACTUAL OBLIGATIONS

# **CPRIT** Assistance

In February 2015, the Company received notice that it had been awarded a grant by the CPRIT whereby the Company was eligible to receive up to US\$14.1 million on eligible expenditures over a three-year period related to the development of the Company's Phase 2b clinical program for bizaxofusp. As of March 31, 2022, all of the US\$14.1 million had been received and the grant with CPRIT was complete.

Under the terms of the grant, the Company is required to pay a royalty to CPRIT, comprised of 3-5% of revenues on net sales of bizaxofusp until aggregate royalty payments equal 400% of the grant funds received at which time the ongoing royalty will be 0.5% of revenues. At this time the royalty is not probable and therefore no liability has been recorded. In addition, the Company must maintain a presence in Texas for three years following completion of the grant.

# Refundable tax credits

In July 2023, the Company received \$0.7 million through our Australian R&D incentive program relating to the year ended March 31, 2023 (March 31, 2022: \$0.7 million). The amount receivable was recorded as a reduction in research and development expenses in the year ended March 31, 2023.

In September 2023, the Company received \$0.1 million through the Canadian scientific research and experimental development (SR&ED) relating to the year ended March 31, 2021. The Company received an additional \$0.2 million of SR&ED funding related to the year ended March 31, 2022 in January 2024. Amounts received for SRED are recorded as a reduction in research and development expenses.

# Intellectual Property

The Company has entered into various license agreements with respect to accessing patented technology. In order to maintain these agreements, the Company is obligated to pay ongoing license fees, patent prosecution and maintenance costs, royalty and other milestone payments, the timing of which is uncertain. As of December 31, 2023, the Company is obligated to pay the following:

- Given the current development plans and expected timelines of the Company, it is assumed that project milestones of US\$1.2 million will be due in the next five years; and
- As part of these license agreements, the Company has committed to make certain royalty payments based on net sales to the FDA, NIH and Stanford.

The Company also maintains a robust portfolio of intellectual property assets that encompasses a diverse range of patents covering novel drug candidates, formulations, and therapeutic methods. Notably, the Company was granted three new patents that further bolster the IP portfolio. These assets are integral to strategic initiatives, providing exclusivity and market differentiation for groundbreaking treatments. The ongoing investment in IP development and enforcement reflects the commitment to sustaining the leadership position and delivering value to shareholders and patients alike.

## TRANSACTIONS WITH RELATED PARTIES

Key management personnel, which consists of the Company's officers (President and Chief Executive Officer, Chief Medical Officer, Chief Development Officer, former Chief Financial Officers, and former Chief Business Officer) and directors, earned the following compensation for the following periods:

	Three mo De	Three months ended December 31,		Nine months ended December 31,	
	2023	2022	2023	2022	
	\$	\$	\$	\$	
Salaries and wages	505	331	1,482	836	
Board fees	76	95	253	247	
Stock option expense	119	261	546	972	
	700	687	2,281	2,055	

As at December 31, 2023, the Company had trade and other payables in the normal course of business, owing to directors and officers of \$0.2 million (2022 - \$0.1 million) related to board fees and accrued vacation.

# **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no material undisclosed off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our results of operations, financial condition, revenues or expenses, liquidity, capital expenditures or capital resources that is material to investors.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The significant accounting policies of the Company are described in note 2 of the Annual Financial Statements and available on SEDAR+ at www.sedarplus.ca and included in the Annual Report on Form 20-F filed on EDGAR at www.sec.gov.

Estimates and assumptions are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The determination of estimates requires the exercise of judgement based on various assumptions and other factors such as historical experience and current and expected economic conditions. Actual results could differ from those estimates. Critical judgements in applying the Company's accounting policies are detailed in the Annual Financial Statements, filed on SEDAR+ at www.sedarplus.ca and included in the Annual Report on Form 20-F filed on EDGAR at www.sec.gov.

## FINANCIAL INSTRUMENTS

Financial instruments are defined as a contractual right or obligation to receive or deliver cash on another financial asset. The Company recognizes financial instruments based on their classification. Depending on the financial instrument's classification, changes in subsequent measurements are recognized in net loss or other comprehensive loss.

A description of the financial instruments, their fair value and risk management is included in notes 2, 5 and 6 of the Annual Financial Statements, filed on SEDAR+ at <u>www.sedarplus.ca</u> and included in the Annual Report on Form 20-F filed on EDGAR at <u>www.sec.gov/edgar</u>.

# 2020 PUBLIC OFFERING AND USE OF PROCEEDS

The following table provides an update on the anticipated use of proceeds raised as part of the 2020 public offering of Common Shares (the "2020 Public Offering"), which initially closed on March 17, 2020, along with amounts actually expended. Following completion of the 2020 Public Offering, Medicenna selected MDNA11 as its lead IL-2 candidate over MDNA19 to progress to the clinic and, as such, proceeds from the 2020 Public Offering, which were initially allocated to the development of MDNA19, have been re-directed to the development of MDNA11 in the same proportions. As of December 31, 2023, the following expenditures had been incurred (in thousands of Canadian dollars):

ltem	Amount to Spend (\$)	Spent to Date (\$)	Adjustments (\$)	Remaining to Spend (\$)
Preclinical development	3,300	3,300	-	-
Manufacturing of clinical batch	4,400	4,400	1	-
Clinical development	13,150	13,150		-
General corporate and working				
capital purposes	11,350	11,350	_	-
Total	32,200	32,200	_	-

# 2022 PUBLIC OFFERING AND USE OF PROCEEDS

The following table provides an update on the anticipated use of proceeds raised under an underwritten public offering of units, with each unit consisting of one Common Share and one Common Share purchase warrant, on August 11, 2022 (the "2022 Public Offering"), along with amounts actually spent. As of December 31, 2023, the following expenditures had been incurred (in thousands of US dollars):

ltem	Amount to Spend (\$USD)	Spent to Date (\$USD)	Adjustments (\$USD)	Remaining to Spend (\$USD)
Phase 1/2 MDNA11 ABILITY				
Study	8,000	722	-	7,278
General corporate purposes and pre-clinical development of a				
BiSKIT candidate	8,000	2,128	-	8,872
Total	16,000	2,850	_	13,150

#### **RISKS AND UNCERTAINTIES**

The Company is an immunotherapy company that operates in a highly competitive industry that is dependent on a number of factors that include the Company's capacity to raise additional funding on reasonable terms when necessary, secure partnerships for the development of its product candidates, obtain necessary regulatory approvals and achieve market acceptance, face disruption in availability of key components for ongoing clinical studies, obtain positive results from pre-clinical and clinical studies, successfully develop existing and new products, hire and retain skilled staff and key personnel, rely on third-party providers, protect its intellectual property and face litigation risk in connection thereof. An investment in the Common Shares is subject to a number of risks and uncertainties, including the risks related to the Company being a foreign private issuer.

In addition, the Company may, from time to time, announce or publish preliminary or interim data from its clinical trials. Preliminary and interim data remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary or interim data. Preliminary and interim results of a clinical trial are not necessarily predictive of final results. There can be no assurance that favorable interim or preliminary data will result in favorable final data. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, patient data are further examined and reviewed, more patient data become available, and the Company prepares and issues its final clinical study report. As a result, preliminary and interim data should be viewed with caution until the final, complete data are available. Material adverse changes in the final data compared to the preliminary or interim data could significantly harm the Company's business, prospects, financial condition and results of operations.

An investor should carefully consider these risks, as well as the risks described in the Company's Annual Report on Form 20-F, as well as the other information filed with the securities regulators before investing in the Common Shares. If any of such described risks occur, or if others occur, the Company's business, financial condition and the results of operations could be seriously harmed, and investors could lose all or part of their investment.

There are important risks which management believes could impact the Company's business. For information on risks and uncertainties, please also refer to the "Risk Factors" section of the Company's most recent Annual Report on Form 20-F filed on SEDAR+ at www.sedarplus.ca and EDGAR at www.sec.gov/edgar.

#### DISCLOSURE CONTROLS AND INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company has implemented a system of internal controls that it believes adequately protects the assets of the Company and is appropriate for the nature of its business and the size of its operations. The internal control system was designed to provide reasonable assurance that all transactions are accurately recorded, that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS and that our assets are safeguarded.

These internal controls include disclosure controls and procedures designed to ensure that information required to be disclosed by the Company is accumulated and communicated as appropriate to allow timely decisions regarding required disclosure.

Internal control over financial reporting means a process designed by or under the supervision of the Chief Executive Officer and the Vice President of Finance to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS as issued by the IASB.

The internal controls are not expected to prevent and detect all misstatements due to error or fraud. There were no changes in our internal control over financial reporting that occurred during the three and nine months ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

As of December 31, 2023, the Company's management assessed the effectiveness of our internal control over financial reporting and disclosure controls and procedures using the Committee of Sponsoring Organizations of the Treadway Commission's 2013 framework. Based on their evaluation, the Chief Executive Officer and the Vice President of Finance have concluded that these controls and procedures are effective.

#### OUTSTANDING SHARE DATA

	Number
Common Shares	69,637,469
Warrants	16,185,386
Stock options	8,056,757
Total	92,561,979

As at the date of this report, the Company has the following securities outstanding:

For a detailed summary of the outstanding securities convertible into, exercisable or exchangeable for voting or equity securities of Medicenna as at March 31, 2023, refer to notes 9, 10, and 11 of the Annual Financial Statements of the Company.

#### ADDITIONAL INFORMATION

Additional information relating to the Company, including the Company's Annual Report on Form 20-F, is available under the Company's profile on SEDAR+ at www.sedarplus.ca and EDGAR at www.sec.gov, respectively.