

#### ANNUAL INFORMATION FORM

#### FOR THE YEAR ENDED MARCH 31, 2020

www.medicenna.com

Unless otherwise indicated, all information in the Annual Information Form is presented as at and for the year ended March 31, 2020

May 14, 2020

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#### INTRODUCTION AND FORWARD-LOOKING STATEMENTS

The information contained in this Annual Information Form (this "AIF") is stated as at March 31, 2020, unless otherwise indicated.

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

All amounts are in Canadian dollars, unless otherwise indicated.

This AIF contains forward-looking statements within the meaning of applicable securities laws. 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 that are not clearly historical in nature are forward-looking, and the words such as "plan", "expect", "is expected", "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", "might", "shall" or "will" be taken, occur or be achieved and similar expressions are generally intended to identify forward-looking statements. Forward-looking statements in this AIF include, but are not limited to, statements with respect to the Company's:

- requirements for, and the ability to obtain, future funding on favourable terms or at all;
- business strategy;
- expected future loss and accumulated deficit levels;
- projected financial position and estimated cash burn rate;
- expectations about the timing of achieving milestones and the cost of the Company's development programs;
- observations and expectations regarding the effectiveness of MDNA55 and the potential benefits to patients;
- expectations about the Company's products' safety and efficacy;
- expectations regarding the Company's ability to arrange for the manufacturing of the Company's products and technologies;
- expectations regarding the progress, and the successful and timely completion, of the various stages of the regulatory approval process;
- ability to secure strategic partnerships with larger pharmaceutical and biotechnology companies;
- strategy to acquire and develop new products and technologies and to enhance the safety and efficacy of existing products and technologies;
- plans to market, sell and distribute the Company's products and technologies;
- expectations regarding the acceptance of the Company's products and technologies by the market;
- ability to retain and access appropriate staff, management, and expert advisers;
- expectations with respect to existing and future corporate alliances and licensing transactions with third parties, and the receipt and timing of any payments to be made by the Company or to the Company in respect of such arrangements; and
- strategy with respect to the protection of the Company's intellectual property.

All forward-looking statements reflect the Company's beliefs and assumptions based on information available at the time the assumption was made. These forward-looking statements are not based on historical facts but rather on management's expectations regarding future activities, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. By its nature, forward-looking information involves numerous assumptions, inherent risks and uncertainties, both general and specific, known and unknown, that contribute to the possibility that the predictions, forecasts, projections or other forward-looking statements will not occur. Factors which could cause future outcomes to differ materially from those set forth in the forward-looking statements include, but are not limited to:

- the effect of continuing operating losses on the Company's ability to obtain, on satisfactory terms, or at all, the capital required to maintain the Company as a going concern;
- the ability to obtain sufficient and suitable financing to support operations, preclinical development, clinical trials, and commercialization of products;
- the risks associated with the development of novel compounds at early stages of development in the Company's intellectual property portfolio;
- the risks of reliance on third-parties for the planning, conduct and monitoring of clinical trials and for the manufacture of drug product;
- the risks associated with the development of the Company's product candidates including the demonstration of efficacy and safety;
- the risks related to clinical trials including potential delays, cost overruns and the failure to demonstrate efficacy and safety;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling patients;
- risks associated with the Company's inability to successfully develop companion diagnostics for the Company's development candidates;
- delays or negative outcomes from the regulatory approval process;
- the Company's ability to successfully compete in the Company's targeted markets;
- the Company's ability to attract and retain key personnel, collaborators and advisors;
- risks relating to the increase in operating costs from expanding existing programs, acquisition of additional development programs and increased staff;
- risk of negative results of clinical trials or adverse safety events by the Company or others related to the Company's product candidates;
- the potential for product liability claims;
- the Company's ability to achieve the Company's forecasted milestones and timelines on schedule;
- financial risks related to the fluctuation of foreign currency rates and expenses denominated in foreign currencies;
- the Company's ability to adequately protect proprietary information and technology from competitors;
- risks related to changes in patent laws and their interpretations;
- the Company's ability to source and maintain licenses from third-party owners; and
- the risk of patent-related litigation and the ability to protect trade secrets,

all as further and more fully described under the section of this AIF titled "Risk Factors". 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. The forward looking information in this AIF does not include a full assessment or reflection of the unprecedented impacts of the COVID-19 pandemic occurring in the first quarter of 2020 and the ongoing and developing resulting indirect global and regional economic impacts. The Company is currently experiencing uncertainty related to the rapidly developing COVID-19 situation. It is anticipated that the spread of COVID-19 and global measures to contain it, will have an impact on the Company, however it is challenging to quantify the potential magnitude of such impact at this time. The Company is regularly assessing the situation and remains in contact with its partners, clinical sites and investigators, contract research organizations, contract development and manufacturing organizations and suppliers to assess any impacts and risks.

Although the forward-looking statements contained in this AIF 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 AIF 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.

#### CORPORATE STRUCTURE

#### **Corporate Information**

Medicenna, formerly A2 Acquisition Corp. ("A2"), is the resulting issuer following a "threecornered" amalgamation involving A2, 1102209 B.C. Ltd. ("A2 Sub"), a wholly owned subsidiary of A2 incorporated pursuant to the *Business Corporations Act* (British Columbia) ("BCBCA"), and Medicenna Therapeutics Inc. ("MTI"), completed on March 1, 2017.

A2 was formed by articles of incorporation under the *Business Corporations Act* (Alberta) ("ABCA") on February 2, 2015, and following its initial public offering, was a capital pool company ("CPC") listed on the TSX Venture Exchange ("TSXV"). As a CPC, A2 had no assets other than cash and did not carry on any operations other than identifying and evaluating opportunities for the acquisition of an interest in assets or businesses for the completion of a qualifying transaction.

On March 1, 2017, A2 completed its qualifying transaction in accordance with the policies of the TSXV by way of reverse takeover of A2 by the shareholders of MTI (the "Qualifying Transaction"). In addition, on March 1, 2017 and prior to the completion of the Qualifying Transaction, the Company amended its articles as a result of (a) implementing a consolidation (the "Consolidation") of its pre-Qualifying Transaction common shares (the "A2 Shares") on the basis of one new common share of the Company (each, a "Common Share") for every fourteen A2 Shares (1:14) and (b) changing its name to Medicenna Therapeutics Corp.

On August 2, 2017 Medicenna graduated to the main board of the Toronto Stock Exchange ("TSX"). On November 13, 2017, Medicenna continued under the *Canada Business Corporations Act* ("CBCA").

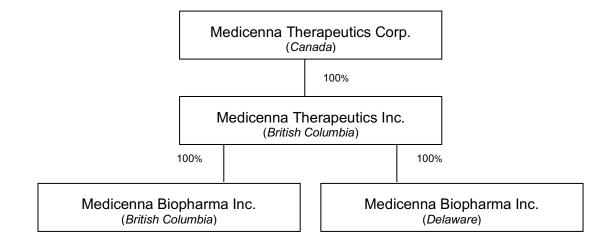
Medicenna's head and registered office is located at 2 Bloor Street W, 7<sup>th</sup> Floor, Toronto, Ontario, M4W 3E2.

#### Intercorporate Relationships

MTI is a wholly owned subsidiary of Medicenna and was incorporated pursuant to the provisions of the BCBCA on October 31, 2011. MTI has two wholly owned subsidiaries: Medicenna Biopharma Inc. (British Columbia) and Medicenna Biopharma Inc. (Delaware). MTI's head office is located at 2 Bloor Street W, 7<sup>th</sup> Floor, Toronto, Ontario, M4W 3E2, and its registered office is at 439 Helmcken Street, Vancouver, British Columbia, V6B 2E6.

Medicenna Biopharma Inc. (British Columbia) was incorporated under the BCBCA on October 5, 2012. Its registered office is located at 439 Helmcken Street, Vancouver, British Columbia, V6B 2E6 and its head office is at 2 Bloor Street W, 7<sup>th</sup> Floor, Toronto, Ontario, M4W 3E2.

Medicenna Biopharma Inc. (Delaware) was incorporated in the State of Delaware on July 1, 2014. Its registered office is located at 1209 Orange Street, Wilmington, New Castle County, Delaware 19801 and its head office is at 1700 Post Oak Blvd, Suite 600, Houston, Texas 77056. The following organizational chart demonstrates the corporate structure of the Company:



#### GENERAL DEVELOPMENT OF THE BUSINESS

Year ended March 31, 2018

In April 2017, the Company announced that it had treated the first patient in its Phase 2b clinical trial of MDNA55 for the treatment of recurrent glioblastoma ("rGBM").

On August 1, 2017, the Common Shares graduated to the main board of the TSX, the premier stock exchange in Canada.

On October 10, 2017, new clinical data were presented by John H. Sampson, MD, PhD, Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University at the 2017 Congress of Neurological Surgeons ("CNS") (Boston, MA), demonstrating successful delivery in brain cancer patients and a reassuring safety profile for MDNA55 as well as a substantially higher proportion of the target tissue being covered then in previous similar trials. In some cases, close to 100% of the tumor and the 1 cm margin around it (at risk for tumor spread) had been successfully covered.

On October 18, 2017, the Common Shares were quoted for trading on the OTC marketplace under the symbol "MDNAF".

In November 2017, further drug distribution and safety data were presented by Dr. Krystof Bankiewicz, MD, PhD, Kinetics Foundation Chair in Translational Research and Professor in Residence of Neurological Surgery at the University of California San Francisco, at the Annual Meeting of the Society for Neuro-Oncology ("SNO") (San Francisco, CA), on the first 15 patients in the study confirming earlier results presented at the CNS.

In October 2017, Medicenna was issued a U.S. Patent related to our Superkine platform. U.S. Patent 9,738,696, issued to Leland Stanford Junior University ("Stanford") and licensed exclusively to Medicenna, covers the composition of engineered IL-4 Superkines.

#### Year ended March 31, 2019

On May 2, 2018, Medicenna announced that half of the patients in the ongoing Phase 2b study of MDNA55 in rGBM had been recruited and the data demonstrated solid safety results and early signals of efficacy based on the findings of the Safety Review and Clinical Advisory Committees, comprised of key opinion leaders and study investigators. Following the recruitment milestone, the protocol was amended to implement optimal methodologies for treatment of the remaining patients.

On August 2, 2018, Medicenna announced preliminary preclinical data on MDNA109, the only interleukin-2 ("IL-2") in development with high affinity to the CD122 receptor to boost cancer fighting T cells, showing that fusions of MDNA109 with inactive protein scaffolds are long-acting and provide the convenience of easier dosing without sacrificing its safety and efficacy.

On August 10, 2018, Medicenna received US\$1,219,871 from the Cancer Prevention and Research Institute of Texas ("CPRIT") for the reimbursement of previously incurred expenses.

On October 22, 2018, the Company presented results and participated in a poster discussion session at the European Society for Medical Oncology ("ESMO") Congress held in Munich. Based on interim data from patients treated at low doses implemented during the first half of the Phase 2b study of MDNA55, the presentation highlighted the benefits of using advanced imaging modalities in order to help tumor response evaluation and identify pseudo-progression in some patients which ultimately translates into tumor shrinkage, and potential treatment benefit.

On October 31, 2018, Medicenna provided an interim update from the ongoing Phase 2b clinical trial of MDNA55 for the treatment of rGBM. These results were superseded by data reported at subsequent dates.

On December 5, 2018, Medicenna received a US\$1.2 million reimbursement of past expenses from CPRIT.

On December 21, 2018, the Company closed a short-form prospectus offering of 4,000,000 units for gross proceeds of \$4,000,000. Each such unit was issued at a price of \$1.00 per unit and consisted of one Common Share and one-half common share purchase warrant of the Company. Each whole warrant entitles the holder to purchase one Common Share at an exercise price of \$1.20 until December 21, 2023. In addition, 280,000 broker warrants, allowing holders to acquire one Common Share at an exercise price of \$1.20 until December 21, 2023. Were issued pursuant to the offering.

On February 6, 2019, Dr. Moutih Rafei, PhD (Associate Professor, Department of Pharmacology and Physiology, Université de Montréal), presented new results on MDNA109 and its long acting variants. The presentation outlined that MDNA109 (a) is an engineered IL-2 Superkine exhibiting 1000-fold enhanced affinity toward the CD122 receptor, (b) has best-in-class potency toward cancer killing effector T cells, (c) was not immunogenic in-vivo and (d) potently synergized with anti-PD-1 or anti-CTLA-4 checkpoint inhibitors to eliminate tumors in the majority of tumor-bearing mice.

On February 7, 2019 Medicenna presented new clinical study results in a podium presentation entitled "The IL4 Receptor as a Biomarker and Immunotherapeutic Target for Glioblastoma: Preliminary Evidence with MDNA55, a Locally Administered IL-4 Guided Toxin", by John H. Sampson, MD, PhD, Robert H. and Gloria Wilkins Distinguished Professor and Chair of

Neurosurgery at Duke University, during the 5<sup>th</sup> Annual Immuno-Oncology 360° Conference held in New York, NY. These data were subsequently updated as described below.

Year ended March 31, 2020

On April 30, 2019, the Company announced completion of enrolment in the MDNA55 Phase 2b clinical study for the treatment of rGBM.

On May 1, 2019, Medicenna received US\$757,940 from CPRIT for reimbursement of past expenses.

On June 3, 2019, a poster entitled "MDNA55: A Locally Administered IL4 Guided Toxin as a Targeted Treatment for Recurrent Glioblastoma" was presented at the 55th Annual Meeting of the American Society of Clinical Oncology ("ASCO") held in Chicago, IL. The presentation by Dr. Dina Randazzo, of Duke University School of Medicine and a Principal Investigator, focused on the development of a new biomarker test for the interleukin-4 receptor ("IL4R") that may enable better selection and superior treatment outcomes for patients with rGBM.

On June 18, 2019, Dr. Fahar Merchant presented results from the Phase 2b MDNA55 clinical trial for rGBM at the Inaugural Immuno-Oncology Pharma Congress in Boston, MA. The presentation highlighted disease control in up to 83% of the patients, according to immunotherapy Response Assessment in Neuro-Oncology ("iRANO") criteria, which measure tumor response relative to the largest tumor size post-treatment (nadir). In addition, safety data from the Phase 2b clinical trial showed a similar safety profile to previous MDNA55 trials, with no systemic toxicities, no clinically significant laboratory abnormalities and no drug-related deaths.

On June 20, 2019, Medicenna presented a poster entitled "Engineering a long-acting CD122 biased IL-2 superkine displaying potent anti-tumoral responses". The presentation by Dr. Moutih Rafei, Associate Professor, Department of Pharmacology and Physiology, Université de Montréal, highlighted that MDNA109-LA (a precursor of MDNA19) when combined with checkpoint inhibitors (a) demonstrated durable tumor control with strong memory response; (b) enhancing activation of naive CD8 T cells and natural killer ("NK") cells (responsible for attacking tumor cells) and (c) attained long term tumor control with fewer treatment cycles and a less frequent dosing regimen.

On June 26, 2019, the Company reported preclinical data on MDNA55 which showed promising results in ovarian cancer models.

On July 9, 2019, Medicenna announced the receipt of US\$1,915,372 from CPRIT reimbursement of past expenses.

On July 31, 2019, the Company announced the selection of MDNA19 (formerly, MDNA109-LA1) as our second immuno-oncology clinical candidate for the treatment of cancer. MDNA19 is a bestin-class long-acting IL-2 developed from our Superkine platform that has shown unique ability to selectively stimulate cancer killing immune cells without the limitations seen with other long-acting IL-2 programs.

On September 24, 2019, Medicenna announced the appointment of Ms. Karen Dawes to our Board of Directors. Ms. Dawes is an experienced and highly regarded leader in the life sciences industry with extensive strategic expertise and considerable commercial background.

On September 25, 2019, the Company presented updated efficacy results from the Phase 2b clinical trial (MDNA55-05) in the first 33 rGBM patients enrolled in the study. MDNA55 is a potent immunotherapy agent, as it potently targets the IL4R, which is overexpressed in glioblastoma ("GBM"), as well as non-cancerous cells that make up the brain tumor microenvironment ("TME"). The data imply that targeting the TME, particularly in GBM, is critical where almost half of the tumor mass is made up of the TME – a cancer swamp that hides the tumor from the immune system. The TME is emerging as one of the key reasons why glioblastoma is extremely aggressive, and continues to be one of the most difficult cancers to treat. Since MDNA55 can simultaneously kill both the tumor cells and the TME by targeting the IL4R, the results to date indicate that MDNA55 could emerge as a new treatment for this deadly disease.

On September 26, 2019, Medicenna announced the publication of a peer-reviewed article in the August 2019 edition of *Nature Communications*, providing independent third-party validation of Medicenna's IL-2 Superkine platform, MDNA109.

On September 30, 2019, the Company announced the presentation of new preclinical data from its IL-2 Superkine program to support the differentiating characteristics of long-acting MDNA109 variants and their potency *in vitro* and *in vivo* from other long-acting IL-2 programs.

On October 17, 2019, Medicenna completed a public offering raising total gross proceeds of \$6,900,000. The Company issued 5,307,693 units at a price of \$1.30, each such unit consisting of one Common Share and one-half common share purchase warrant. Each such whole warrant is exercisable at a price of \$1.75 until October 17, 2022.

On November 21, 2019, the Company announced new positive results on drug distribution from the Phase 2b clinical trial of MDNA55. Implementing new advances in convection-enhanced delivery ("CED"), that were previously not available allows us to bypass the blood-brain barrier and deliver high concentrations of MDNA55 directly to the tumor and the at-risk area immediately surrounding it, without exposure to the rest of the body. Delivering MDNA55 to where it needs to be, along with the ability to continuously monitor distribution using real-time imaging, allows us to dramatically improve drug delivery and maximize tumor coverage.

On November 25, 2019, Medicenna announced the presentation of updated clinical results from the Phase 2b trial of MDNA55, by Dr. John Sampson at the 24<sup>th</sup> SNO annual meeting. Dr. Sampson discussed updated efficacy results from the Phase 2b clinical trial of MDNA55 in rGBM patients using the IL4R as an immunotherapy target.

On December 12, 2019, Medicenna announced a presentation by Dr. Fahar Merchant at the Inaugural Glioblastoma Drug Development Annual Summit. The presentation reported subgroup analysis from the first 40 patients treated with MDNA55 in a Phase 2b clinical trial for patients with rGBM.

On January 8, 2020, the Company announced receipt of \$1.3 million in proceeds from the exercise of previously issued warrants.

On January 13, 2020, Medicenna announced results from a retrospective study of subjects with rGBM who matched eligibility requirements of subjects enrolled in the MDNA55-05 clinical trial (Synthetic Control Arm, "SCA") receiving standard therapies and compared their survival versus subjects treated with MDNA55, in the Phase 2b rGBM clinical. The SCA comprised 81 rGBM patients receiving standard therapies including Avastin<sup>®</sup>, Iomustine and temozolomide ("TMZ") with similar baseline features as patients treated in the MDNA55 trial such as age, tumor size,

ineligibility for surgery, lack of isocitrate dehydrogenase ("IDH") mutations, IL4R expression and other parameters known to affect survival. When comparing IL4R High groups across the two populations, a 150% survival advantage is seen in patients who received MDNA55.

On March 17, 2020, the Company closed a public offering of 11,290,323 Common Shares at a price of \$3.10 per share for gross proceeds of approximately \$35 million.

On March 25, 2020, Medicenna presented preclinical data, including non-human primate ("NHP") data from its IL-2 Superkine program, highlighting data from the long-acting variant MDNA19, engineered to have enhanced binding to CD122 without binding to CD25. This allows MDNA19 to specifically activate naive CD8 T cells and NK cells with minimal stimulation of regulatory T cells ("Tregs"), thereby circumventing toxicity and demonstrating potential for best-in-class features which was supported by the NHP data.

In March 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. We continue to monitor the COVID-19 situation, which is rapidly developing. The Company operates in a virtual manner and current operations have not been impacted in any material way by the health crisis. However, the pandemic does have an impact on our third party vendors which could result in the interruption of operations and result in development delays including the timing of the End of Phase 2 clinical study meeting for MDNA55 with the US FDA, the ongoing pre-clinical and future clinical activities related to MDNA19 or MDNA11. We have required all of our employees to work from home and are asking business partners to engage us by telephone or video conference where possible, eliminating business travel and requiring self-isolation for employees travelling outside of Canada. As the COVID-19 health crisis further develops, we will continue to rely on guidance and recommendations from local health authorities, Health Canada and the Centers for Disease Control and Prevention to update our policies.

#### Subsequent Events

On April 15, 2020, Medicenna announced the closing of the full over-allotment option to purchase an additional 1,693,548 Common Shares of Medicenna at a price of \$3.10 per share, in connection with the public offering of Common Shares of Medicenna that was completed on March 17, 2020.

On May 4, 2020, Medicenna announced that it will be presenting two abstracts at the American Society of Clinical Oncology Virtual Scientific Program to be held from May 29 to May 31, 2020. The first abstract has been selected for a poster discussion and will provide new data on tumor response as well as survival outcomes compared to a matched SCA. The second abstract will present preclinical data including non-human primate data for MDNA11, one of Medicenna's IL2 Superkine candidates.

#### Significant Acquisitions

Except as set forth herein, the Company has not completed any significant acquisitions for which disclosure would be required under Part 8 of National Instrument 51-102 as at the date hereof.

#### NARRATIVE DESCRIPTION OF THE BUSINESS

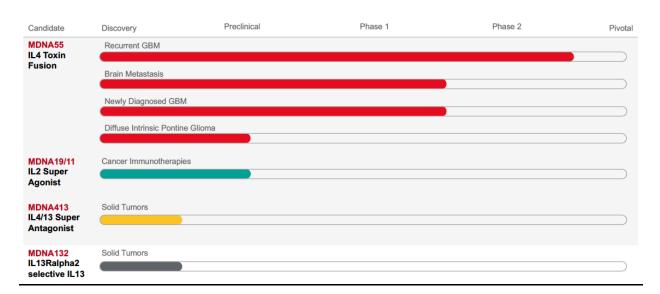
#### Overview

Medicenna is a clinical stage immuno-oncology company developing novel, highly selective versions of IL-2, interleukin-4 ("IL-4") and interleukin-13 ("IL-13") tunable cytokines, called "Superkines". These Superkines can be developed either on their own as short or long-acting therapeutics or fused with cell killing proteins in order to generate Empowered Cytokines™ ("ECs") that precisely deliver potent toxins to the cancer cells without harming adjacent healthy cells. Medicenna's mission is to become the leader in the development and commercialization of targeted ECs and Superkines for the treatment of a broad range of cancers. The Company seeks to achieve its goals by drawing on its expertise, and that of world-class collaborators, in order to develop a unique set of the rapeutic Superkines. Compared to naturally occurring cytokines – that bind to multiple receptor types on many cell types - Superkines are engineered with unique specificity toward defined target cell subsets to enable precise activation or inhibition of relevant immune cells in order to improve therapeutic efficacy and safety. Superkines can also be fused with other types of proteins such as antibodies to generate novel "immunocytokines" or combined with other treatment modalities such as checkpoint inhibitors, chimeric antigen receptor T cells ("CAR-Ts") or oncolvtic viruses to stimulate tumor-killing immune cells or overcome the immunosuppressive tumor microenvironment.

Medicenna has completed enrolment in a Phase 2b clinical trial of MDNA55, Medicenna's lead EC, for the treatment of rGBM, the most common and uniformly fatal form of brain cancer. MDNA55 is a fusion of a circularly permuted version of IL-4, fused to a potent fragment of the bacterial toxin Pseudomonas exotoxin ("PE"), that is designed to preferentially target tumor cells that over-express the IL4R. MDNA55 has now been studied in 5 clinical trials in 132 patients, including 112 patients with rGBM, in which it has shown indications of superior efficacy when compared to the current standard of care ("SOC"). MDNA55 has secured Orphan Drug Status from the United States Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") as well as Fast Track Designation from the FDA for the treatment of rGBM and other types of high grade glioma. Medicenna announced on April 30, 2019 that patient enrollment was complete in the Phase 2b clinical trial of MDNA55 after treating 46 patients with rGBM. Medicenna announced preliminary top line data from the study on June 18, 2019 and additional survival data in December 2019 and January 2020. Medicenna plans to have an End of Phase 2 ("EOP2") meeting with the FDA in 2020. This timeline is later than previously disclosed as additional time was required to collect further data to be included in the submission package as recommended by the Company's regulatory advisors in order to strengthen the submission.

Complementing Medicenna's lead clinical asset (MDNA55), the Company has built a deep pipeline of promising preclinical Superkine candidates such as IL-2 agonists (MDNA109), IL-2 antagonists (MDNA209), dual IL-4/IL-13 antagonists (MDNA413) and IL-13 Superkine (MDNA132) all in-licensed from Stanford. The most advanced of these programs is the MDNA109 platform, which is in preclinical development and is the only engineered IL-2 Superkine designed to specifically target CD122 (IL-2R $\beta$ ) with high affinity without CD25 dependency. The lead candidates from the IL-2 Superkine platform are MDNA19 and MDNA11 (formerly known as MDNA109-LA1) which, unlike native IL-2 (Proleukin) have superior pharmacokinetic ("PK") properties, lack CD25 binding in order to improve safety, potently stimulate effector T cells, reverse NK cell anergy and act with exceptional synergy when combined with checkpoint inhibitors. Medicenna is working towards initiating a Phase 1 clinical study for MDNA19 or MDNA11 mid-2021.

#### **Our Product Candidates**

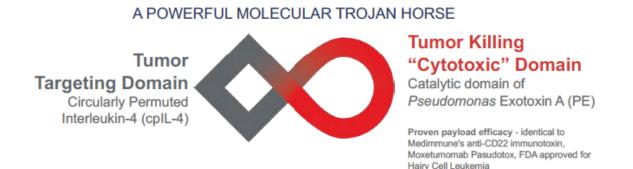


#### MDNA55

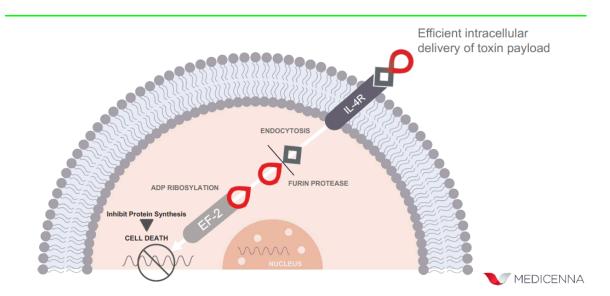
MDNA55 is a novel, locally acting, anti-cancer therapeutic being developed by Medicenna for the treatment of tumors of the brain in adults, of which GBM is the most aggressive type. GBM is also the most common form of adult brain cancer, with 27,500 new cases diagnosed each year and the second most common cause of brain cancer deaths. MDNA55 has obtained Fast Track Designation from the FDA as well as Orphan Drug Designation from the FDA and the EMA.

#### MDNA55: Structure and Mechanism of Action

MDNA55 is a targeted fusion protein being developed by Medicenna for the treatment of tumors that over-express the IL4R. MDNA55 (below) consists of a high-affinity circularly permuted variant of IL-4 (cpIL-4) fused with a truncated version of PE.



# MDNA55 binds with high affinity to IL-4R overexpressed on the surface of tumor cells and is endocytosed. Following cleavage and activation by furin-like proteases found in the endosome of cancer cells, the catalytic domain of the truncated PE is released into the cytosol where it induces cell death via ADP-ribosylation of elongation factor-2 (below).



Expression levels of IL4R are low on the surface of healthy and normal cells, but increase 10- to 100-fold on cancer cells. This differential expression of IL4R therefore provides MDNA55 a wide therapeutic window.

The IL4R is an ideal target for the development of cancer therapeutics, as it is frequently and intensely expressed on a wide variety of human carcinomas. However, the IL4R target is currently under-exploited. Analysis of over 2,000 biopsies show IL4R over-expression in 20 different cancers affecting over a million cancer patients every year. Furthermore, the IL-4/IL4R bias is a marker for highly aggressive forms of cancer, plays a central role in the establishment of an immunosuppressive TME and is generally associated with poor survival outcomes. By disrupting this pro-tumoral IL-4/IL4R axis, MDNA55 directly interferes with multiple networks that support cancer.

#### Glioblastoma

GBM is an aggressive brain tumor characterized by rapid proliferation of undifferentiated cells, extensive infiltration, and a high propensity to recur. It is a rapidly progressing and universally fatal cancer. First-line treatment for primary GBM generally includes surgical resection of the bulk tumor to the maximal extent possible, followed by radiotherapy, often in combination with chemotherapy consisting of TMZ. The approval of TMZ represented a breakthrough in treatment; the drug offers improvements in overall survival ("OS"), although the actual benefits are modest. When used in combination with radiotherapy following surgery, TMZ provided a median survival of 58.4 weeks for newly diagnosed GBM patients compared to 48.4 weeks for radiotherapy alone. TMZ is less effective in GBM patients who harbor unmethylated O6-methylguanine-methyltransferase ("MGMT") promoters in the tumor tissue; more than half of GBM patients have unmethylated MGMT promoters. In practice, even patients without MGMT promoter methylation are prescribed TMZ because of a lack of approved treatment alternatives.

#### Recurrent Glioblastoma (rGBM)

Unlike treatment of newly diagnosed GBM, no consensus exists regarding the optimal treatment of rGBM. Recurrence rates for newly diagnosed GBM patients treated with the current SOC is high, even in completely resected patients.

Drugs currently approved in the United States for treatment of rGBM are Gliadel® and bevacizumab (Avastin<sup>®</sup>). In a Phase 3 study, placing a Gliadel implant directly into the tumor cavity after surgical resection of the tumor, 56% of rGBM treated subjects survived 6 months and the median survival was 26 weeks. However, the majority of patients with rGBM are not candidates for additional surgery, resulting in a large unmet need for this patient population.

Avastin<sup>®</sup> is an anti-angiogenic antibody that targets the vascular endothelial growth factor receptors. It is indicated as a single agent for adult patients with rGBM but has not been shown to improve disease-related symptoms or survival. Avastin<sup>®</sup> was granted accelerated approval on the basis of an objective response rate ("ORR") of 28% following an open label Phase 2 study in 85 patients receiving Avastin<sup>®</sup> only. In 2013, Avastin<sup>®</sup> completed its confirmatory trial in newly diagnosed GBM patients and did not meet its primary endpoint of overall survival. Based on the results of this trial, Genentech, for Avastin<sup>®</sup>, did not receive approval in the European Union for newly diagnosed GBM; however, Avastin<sup>®</sup> remains indicated in the United States and Japan for rGBM.

#### Rationale for Development of MDNA55 for rGBM

MDNA55 is being initially developed for the treatment of rGBM. Using current treatment paradigms, most GBM patients experience tumor recurrence/progression after standard first line treatment. Treatment options for patients with rGBM are very limited and the outcome is generally unsatisfactory. Specifically, chemotherapy regimens for recurrent or progressive GBM have been unsuccessful, producing toxicity without benefit. As overall survival remains dismal, novel anti-cancer modalities, with greater tumor specificity, more robust cytotoxic mechanisms and novel delivery techniques are needed for the treatment of recurrent GBM.

MDNA55 is one such novel therapeutic that provides a targeted treatment approach whereby tumor cells are more sensitive to the toxic effects of the drug than normal cells. When combined with a novel precision delivery to the brain using CED, treatment with MDNA55 could be an ideal approach for the treatment of rGBM and other brain tumors that over-express the IL4R. Cells that do not express the IL4R target do not bind to MDNA55 and are, therefore, not subject to the effects of the toxic payload.

Many features of MDNA55 make it a potentially attractive choice for the treatment of recurrent GBM:

- 1. The majority of cancer biopsy and autopsy samples from adult and pediatric primary and metastatic brain cancers, including rGBM, have been shown to over-express the IL4R with little or no IL4R expression in normal adult and pediatric brain tissue.
- MGMT positive cancer cells (harboring unmethylated MGMT promoters) are common in GBM, making them resistant to TMZ. However, MGMT positive cancer tumors are extremely sensitive to MDNA55, suggesting that MDNA55 could provide a treatment option for GBM patients who would not benefit from TMZ.
- 3. GBM has a robust immunosuppressive TME and may comprise up to 40% of the tumor mass. It has been shown that malignant gliomas have a T-helper cell type-2 ("Th2") bias and are heavily infiltrated by myeloid derived suppressor cells ("MDSCs") and tumor associated macrophages ("TAMs") and that the IL-4/IL4R bias mediates their immunosuppressive functions. Furthermore, IL4R is up-regulated on glioma-infiltrating myeloid cells but not in the periphery or in normal brain. Thus, purging Th2 cells, MDSCs,

and TAMs using MDNA55 may alleviate the immune block associated with cancer (in a manner similar to immunomodulators such as ipilumimab, pembrolizumab or nivolumab), thereby promoting anti-tumor immunity and aid in long-term disease control.

The MDNA55 program therefore offers a promising approach to address serious unmet needs for brain cancer patients. Furthermore, MDNA55 is the only treatment in development that has the potential to simultaneously target the bulk tumor and the immunosuppressive TME. Accordingly, we are of the view that MDNA55 has the potential of altering the treatment paradigm for many brain cancer patients.

#### **Convection Enhanced Delivery of MDNA55**

As with most protein therapeutics, MDNA55 does not cross the blood-brain barrier, and therefore must be delivered directly to the tumor (also known as intra-tumoral therapy) via local one time infusion procedure called CED. Medicenna's development platform includes rights to all oncology indications for MDNA55 as well as novel image guided CED of MDNA55. These technologies are protected by patents either owned or exclusively licensed by Medicenna.

#### **Development History of MDNA55**

The targeting domain and payload for Medicenna's lead candidate, MDNA55, were developed in the laboratories of Dr. Ira Pastan at the National Cancer Institute (NCI) and Dr. Raj Puri at Center for Biologics Evaluation and Research, at the FDA. The targeting domain (IL-4) was engineered to improve the binding affinity of IL-4 to the IL4R and thereby increase potency of MDNA55. The payload domain (pseudomonas toxin) of MDNA55 was engineered in order to remove off-target binding components further improving safety. Preclinical and clinical development of MDNA55 for the treatment of brain as well as other non-brain tumors is described in over 50 publications.

In March 2013, Medicenna acquired all clinical, regulatory and material assets for MDNA55 from Sophiris Bio Inc. (formerly Protox Therapeutics, Inc.) ("Sophiris"). The acquisition was comprised of two Investigational New Drug Applications ("IND") with the FDA, Fast Track Designation from the FDA, Orphan Drug Designations from the FDA and the EMA, clinical data from 72 patients enrolled in three different brain cancer studies, clinical data from 14 patients enrolled in a Phase 1 solid tumor study and all cell banks and reference material required to manufacture MDNA55. Subsequent to the purchase agreement with Sophiris, Medicenna and the National Institutes of Health ("NIH") entered into license agreements (the "NIH License Agreements") covering composition, methods of use, combination therapy and delivery of MDNA55. A summary of the clinical trials related to the treatment of high grade gliomas is provided below.

Three clinical trials were previously conducted with MDNA55 in 72 patients with recurrent high grade glioma (66 rGBM and 6 recurrent anaplastic astrocytoma ("rAA") patients). In a majority of the patients, MDNA55 was delivered only once by intratumoral infusion using CED via ventricular catheters.

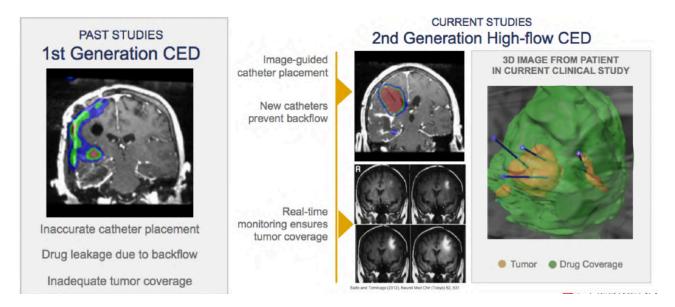
A Phase 1 single centre investigator initiated study (United States) was conducted in a single United States site enrolling nine subjects with rGBM. Doses evaluated ranged from 0.2 to  $6.0 \mu g/mL$  (total dose 6 to 720  $\mu g$ ). One subject remained disease free at >18 months after the procedure; 6 out of 8 subjects had partial to extensive tumor necrosis confirmed by pathology. Most subjects had transient increased intracranial pressure treated readily with craniotomy.

A Phase 1 sponsor initiated multi-centre study (Germany and United States) was carried out in 31 subjects of whom 25 subjects had rGBM and six subjects had rAA. Treatment with MDNA55 using intratumoral CED infusion was dose escalated from 240 to 900  $\mu$ g. In approximately 40% of the subjects, anti-MDNA55 antibodies were observed. Systemic toxicity was not observed. Although not designed to measure efficacy, results showed MDNA55 administration was followed by rapid tumor necrosis with an ORR (i.e.  $\geq$ 50% decrease in tumor size) of 56%. These data compare favourably with an ORR of 5% with current therapies and ORR of 28% achieved by Avastin<sup>®</sup>. These results, including a complete response rate (100% decrease in tumor size) of 20% following a single treatment with MDNA55 were encouraging given that nearly half of the subjects enrolled in the trial had multiple relapses and had poor prognosis due to late stage of the disease. Furthermore, catheter placement and CED of MDNA55 were not optimized at that time.

In the Phase 2a multi-centre study (United States and Germany), MDNA55 was administered by intratumoral infusion via CED in 32 subjects with rGBM at doses of 90 µg, 240 µg or 300 µg. Approximately 3 weeks post-infusion, surgical resection was performed and therefore tumor response analysis was not performed. Tissue samples pre- and post-treatment were adequate for assessment in 10 to 32 subjects. Seven subjects showed a marked reduction in tumor cellularity post-treatment. Of these seven cases, five showed little or no cellular tumor in the resection samples, while the other two had at least a 75% reduction of cellular tumor. The remaining three subjects showed no change compared to baseline. These results, although preliminary, were consistent with ORR observed in the earlier studies. As in the previous studies, systemic toxicity was not observed.

#### Improvements in CED Technology for MDNA55

Since the above mentioned clinical trials, there have been many improvements to the CED technology. This includes use of newly developed techniques for high precision placement of catheters into the tumor bed as well as novel stepped design catheters that prevent backflow of MDNA55 during treatment. Furthermore, by co-infusion of an MRI contrast agent with MDNA55, drug distribution can be monitored in real-time ensuring complete coverage of the tumor bed and the tumor margins. Unlike previous clinical trials, each of these improvements has facilitated highly accurate targeting and uniform distribution of MDNA55 to regions of active tumor growth in the current clinical trial.



Medicenna has obtained an exclusive license from the NIH to patents covering CED and the use of a surrogate tracer for real-time monitoring of MDNA55 delivery and distribution.

#### Phase 2b Study Outline for Glioblastoma at First Recurrence or Progression

The Phase 2b trial with MDNA55 using enhanced CED delivery is a multi-center, open-label, single-arm study in up to 52 patients (at least 46 intent-to-treat ("ITT") patients evaluable for survival and 35 patients evaluable for response), with first or second recurrence or progression of GBM after surgery or radiotherapy ± adjuvant therapy or other experimental therapies.

The primary endpoint of the study is median overall survival (mOS) comparing an expected null survival rate of 8.0 months (based on historical control) with an alternative pursue rate of 11.5 months (1-sided alpha = 0.10 and 80% power for approximately 46 ITT or per protocol subjects). The secondary endpoint is objective response rate (ORR) assessed by the modified Response Assessment in Neuro-Oncology (mRANO)-based criteria incorporating advanced imaging modalities according to a null response rate of 6% with an alternative pursue rate of 18% (1-sided alpha = 0.10 and 80% power for at least 35 subjects evaluable for response). IL4R expression levels in tumor biopsies and their potential impact on patient outcomes following treatment with MDNA55, were retrospectively evaluated.

#### Phase 2b Study Update

In April 2017, we treated the first rGBM patient in the Phase 2b clinical trial of MDNA55 and enrolled patients at eight clinical sites across the United States with enrolment in the study (46 ITT patients) completed in April 2019.

While the Company previously targeted completion of the Phase 2b by not later than Q4 2018, the protocol amendments announced in September 2017 and May 2018, and described below, resulted in slower than anticipated patient recruitment.

On September 28, 2017, we announced that based on encouraging drug distribution and safety data observed we implemented an amended protocol incorporating enhanced drug delivery procedure which was used for the treatment of the remaining patients. The amended protocol allowed higher doses and volumes of MDNA55 as well as an increase in the total expected study size – from 43 patients under the original protocol to up to 52 total planned patients. This protocol amendment was based on a planned safety analysis following a unanimous recommendation from MDNA55's Safety Review Committee. Of the up to 52 patients to be treated in the study we required at least 46 of those patients to be evaluable for survival and at least 35 subjects evaluable for response. We met our threshold enrolment requirements in April 2019 with 46 patients treated (ITT population) of which 44 patients met all the protocol eligibility requirements (per protocol population).

On October 10, 2017, clinical data were presented by Principal investigator John H. Sampson MD, PhD, (Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University in Durham, NC) at the 2017 CNS (Boston, MA), demonstrating successful delivery of MDNA55 in rGBM patients and a reassuring safety profile. Furthermore, the data showed that a substantially higher proportion of the target tissue was being covered then in previous similar trials. In some cases, close to 100% of the tumor and the 1cm margin around it (at risk for tumor spread) had been successfully covered.

Additional clinical data from the Phase 2b rGBM clinical trial of MDNA55 were presented at the 22<sup>nd</sup> Annual Meeting of the SNO held in San Francisco in November 2017. Dr. Krystof Bankiewicz, MD, PhD, Professor in Residence of Neurological Surgery at the University of California San Francisco, provided an update on drug distribution and safety data from the first 15 patients treated in the study. The oral and poster presentations at the SNO conference outlined that through a process of real-time image guided delivery together with the ability to monitor and adjust infusion parameters, drug delivery was dramatically improved with significant enhancement in target coverage. A previous CED study in rGBM, without the advances implemented by Medicenna, [ref: J Neurosurg. 2010 Aug;113(2):301-9], was able to achieve, on average, coverage of only 20% of the target volume. In contrast, in the current study, a comparable estimate for coverage of the tumor and a 1 cm high-risk margin around it showed approximately 65% coverage with the figure rising to 75% for the tumor area alone, with some patients achieving near 100% coverage of the target volume.

It was reported on May 2, 2018 that half the patients in the study had been recruited and the data to date demonstrated solid safety results and early signals of efficacy based on the findings of the Safety Review and Clinical Advisory Committees, comprised of key opinion leaders and study investigators. Following the Safety Review, Medicenna amended the protocol at the recommendation of clinical advisors to further improve the chances for demonstrating increased therapeutic benefit for patients. The amendment allowed the implementation of optimal methodologies including more personalized dosing based on the tumor load, incorporation of advanced imaging modalities to measure treatment responses more reliably, use of sub-therapeutics dose of Avastin<sup>®</sup> in patients that could not tolerate steroid use to control edema and inflammation and allowing investigators to administer a second dose of MDNA55 where appropriate.

Review of some patients who had been withdrawn from the study, believing that their disease had progressed, found that the apparent increases in tumor volumes, seen on brain scans, were, in fact, due to tissue necrosis, inflammation and edema. This is a known effect of immunotherapeutic agents such as MDNA55, called pseudo-progression, which poses a challenge to patient retention, management and data interpretation. When evaluating images from such patients, using multi-modal imaging, Medicenna found evidence of biological activity of MDNA55 suggesting that these patients were benefiting from the treatment, and in multiple cases following withdrawal from the study, surgical resection showed significant tumor necrosis. This amendment allowed a biopsy and/or advanced multi-modal imaging to more accurately discriminate between necrosis/inflammation and true disease progression. These tools would encourage subjects to remain in the study, where appropriate, giving time for the pseudo-progression to resolve and increase the likelihood of clinical responses.

Following the amended protocol as announced on May 2, 2018 and after receiving the necessary regulatory and site approvals patient enrolment was resumed at higher doses provided that the pre-established maximum tolerated dose (MTD) of 240 µg was not to be exceeded.

The protocol amendments announced September 28, 2017 and May 2, 2018 resulted in increased timelines for completion of the MDNA55 Phase 2b clinical trial due to an increase in the original number of patients as well as a slowdown of patient recruitment while the necessary regulatory reviews and approvals were completed.

On October 22, 2018, the Company presented results and participated in a poster discussion session at the ESMO Congress held in Munich. Based on interim data from patients treated at low doses implemented during the first half of the Phase 2b study of MDNA55, the presentation

highlighted the benefits of using of advanced imaging modalities in order to help tumor response evaluation and identify pseudo-progression in some patients which ultimately translates into tumor shrinkage, and potential treatment benefit.

On October 31, 2018, Medicenna provided an interim update from the ongoing Phase 2b clinical trial of MDNA55 for the treatment of rGBM. These results were superseded by data reported on February 7, 2019 as described below.

On February 7, 2019, Medicenna presented new clinical study results in a podium presentation entitled "The IL4 Receptor as a Biomarker and Immunotherapeutic Target for Glioblastoma: Preliminary Evidence with MDNA55, a Locally Administered IL-4 Guided Toxin", by John H. Sampson, MD, PhD, Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University, during the 5<sup>th</sup> Annual Immuno-Oncology 360° Conference held in New York, NY. These results have subsequently been superseded by more complete data presented in late 2019 and January 2020.

On April 30, 2019, Medicenna announced that enrolment in the study was complete with 46 evaluable patients (ITT population) of which 44 patients were subsequently identified as meeting protocol eligibility requirements without major deviations (per protocol population).

On June 3, 2019, a poster entitled "MDNA55: A Locally Administered IL4 Guided Toxin as a Targeted Treatment for Recurrent Glioblastoma" was presented at the 55th Annual Meeting of the ASCO held in Chicago, IL. The presentation by Dr. Dina Randazzo, of Duke University School of Medicine and a Principal Investigator, focused on the development of a new biomarker test for the IL4R that may enable better selection and superior treatment outcomes for patients with rGBM. These data were subsequently updated, as described below.

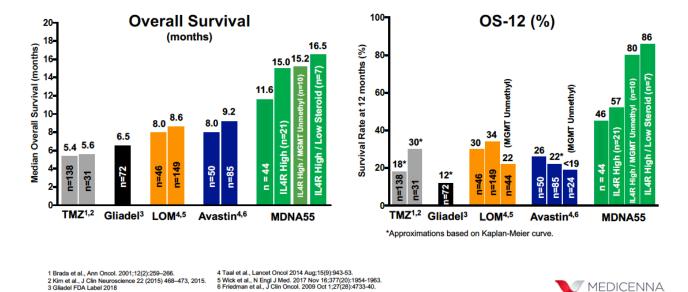
On June 18, 2019, Dr. Fahar Merchant presented results from the Phase 2b MDNA55 clinical trial which recently completed enrollment (n=46) at the Inaugural Immuno-Oncology Pharma Congress in Boston, MA. The presentation highlighted disease control in up to 83% of the patients according to iRANO criteria, which measure tumor response relative to the largest tumor size post-treatment (nadir). Use of advanced imaging techniques (such as perfusion and diffusion MRI) was able to show underlying tissue response amidst inflammation and edema in some subjects. In addition, safety data from the Phase 2b clinical trial show a similar safety profile to previous MDNA55 trials, with no systemic toxicities, no clinically significant laboratory abnormalities and no drug-related deaths.

On September 25, 2019, the Company presented updated efficacy results from the Phase 2b clinical trial MDNA55-05 in rGBM patients using the IL4R as an immunotherapy target, as it is overexpressed in glioblastoma as well as in cells that make up the brain tumor microenvironment. The data imply that targeting the TME, particularly in GBM, is critical where almost half of the tumor mass consists of non-cancerous cells that make up the TME – a cancer swamp that hides the tumor from the immune system. The TME is emerging as one of the key reasons why glioblastoma is extremely aggressive, and continues to be one of the most difficult cancers to treat. Since MDNA55 can simultaneously kill both the tumor cells and the TME by targeting the IL4R, the results to date continue to show that MDNA55 is likely to emerge as a new treatment for this deadly disease. These data were subsequently updated in November and December 2019 and January 2020.

On November 25, 2019, Medicenna announced the presentation of updated clinical results presented by Dr. John Sampson from our Phase 2b trial of MDNA55 at the 24<sup>th</sup> SNO annual

meeting. The presentation highlighted that with a single treatment with MDNA55, the median overall survival ("mOS") in IL4R High subjects (n=21) was 15 months showing a survival advantage of up to nine months when compared to approved therapies (mOS of 5.4 to 9.2 months with temozolomide, Avastin<sup>®</sup> and lomustine), among the 38 evaluable subjects, irrespective of IL4R expression, 82% of the subjects experienced tumor shrinkage or stabilization from nadir. The mOS of patients showing tumor control (n=31) was significantly longer when compared to patients with progressive disease (mOS of 15 months vs. 8.4 months, respectively; p-value of 0.0112) and updated analysis included the first 40 subjects treated with MDNA55 continuing to show an overall survival rate at 12 months ("OS-12") of 45%, irrespective of IL4R expression, and OS-12 of 58% in patients showing a treatment response (n=32). This is an improvement of up to 150% when compared to approved therapies for rGBM (OS-12 is 18-34%).

On December 12, 2019, the Company announced data presented by Dr. Fahar Merchant at the Inaugural Glioblastoma Drug Development Annual Summit. The presentation reported subgroup analysis from the first 40 patients treated with MDNA55 in the Phase 2b clinical trial. The presentation highlighted that the patient characteristics in the clinical study excluded patients that are known to have a much better prognosis, such as patients that were, (a) eligible for surgery to remove the tumor. (b) had a lower grade of brain cancer at initial diagnosis (only de novo GBM patients were enrolled), and (c) had a known mutation associated with better prognosis (IDH mutation). Furthermore, the presentation emphasized that despite enrolling only patients known to have a very poor prognosis, patients actually did much better and were surviving significantly longer following only one treatment with MDNA55, particularly in patients with high expression of the IL4R target. Of particular interest, subjects receiving lower doses of steroids (<4 mg of concurrent steroid per day) showed a trend towards improved survival, particularly in the IL4R High group, with a mOS of 16.5 months with 88% of patients being still alive at 12 months. In patients resistant to approved chemotherapy Temodar (rGBM with unmethylated MGMT promoter), MDNA55 treatment in IL4R High patients had a median overall survival of 15.2 months and a 12 month survival rate of 69% versus 22% for lomustine and less than 19% for Avastin<sup>®</sup>.



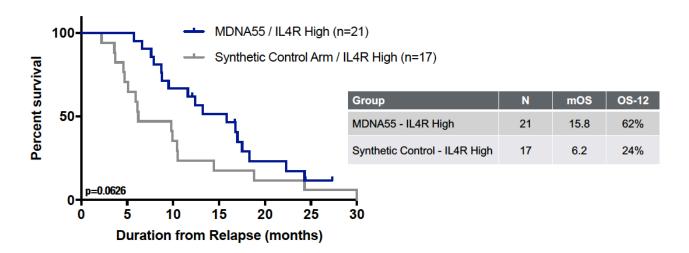
On January 13, 2020, Medicenna announced that it had completed a retrospective study on subjects with rGBM who matched eligibility requirements of subjects enrolled in the MDNA55-05 clinical trial. The study was conducted to compare the survival of subjects treated with MDNA55

in the Phase 2b rGBM clinical trial versus matched patients (SCA) recently treated using other standard therapies. The SCA comprised 81 rGBM patients receiving standard therapies including Avastin<sup>®</sup>, lomustine and TMZ with similar baseline features as patients treated in the MDNA55 trial such as age, tumor size, ineligibility for surgery, IL4R expression and other parameters known to affect survival.

Key data from the study are summarized below and have been computed from the date of relapse rather than from the date of treatment in results previously reported by the Company:

- When comparing IL4R High groups across the two populations, a 150% survival advantage is seen in patients who received MDNA55.
  - IL4R High subjects treated with MDNA55 (n=21) had a mOS of 15.8 months versus
    6.2 months in the SCA (n=17), a survival advantage of an impressive 9.6 months.
  - o OS-12 was 62% in the MDNA55 arm versus 24% in the SCA.
- Regardless of IL4R status, subjects treated with MDNA55 (n=44 subjects comprising the complete per protocol analysis population) demonstrated 112% increase in OS-12 over subjects in the SCA (n=81).
  - OS-12 for the MDNA55 arm was 53% versus 25% in the SCA.
  - o mOS in the MDNA55 arm was 12.4 versus 7.7 months in the SCA.

Survival – IL4R High Groups



Medicenna plans to have an EOP2 meeting with the FDA in 2020 to discuss the results of the MDNA55 Phase 2b clinical study and the development pathway forward, including the possibility of seeking accelerated approval in patients with IL4R positivity which is considered to display a more aggressive form of rGBM. This date is later than previously anticipated due to additional information being prepared in order to strengthen the submission to the FDA as recommended by regulatory consultants.

The Company expects the completion of clinical development of MDNA55 to full approval (including a pivotal Phase 3 clinical trial), if undertaken by Medicenna, to last until at least 2022, with a projected aggregate cost of up to approximately \$75 million, incremental to the current cash on hand. It is anticipated that following the successful completion of the Phase 2b clinical trial and a successful EOP2 meeting with the FDA the Company will work to out-license the program to one or more partners who would fund or co-fund Phase 3 clinical development of MDNA55 as well as prepare the program for commercialization and its subsequent launch in various countries where approval has been granted. In addition to development and regulatory approval of MDNA55, the Company and/or its partner may also have to develop and commercialize a companion diagnostic to test for IL4R expression prior to treatment with MDNA55. See "Risk Factors" below

#### Potential Market: MDNA55

The incidence of primary brain cancer in the 7 major markets ("7MM") (United States, UK, Japan, Italy, Spain, France and Germany) exceeded 52,000 with over 37,000 deaths. Of the primary brain cancers, GBM is the most common, aggressive and with one of the worst prognoses of all cancers. GBM accounts for 52% of all primary brain tumors and although treatment options include surgery, radiation and chemotherapy, the 5-year survival rate is less than 10%. The incidence of GBM in the 7MM is expected to increase from 27,500 in 2012 to 32,000 in 2022 with therapeutic sales projected to reach US\$1.4 billion by 2022.

Treatment options for rGBM are severely limited. With the exception of Avastin<sup>®</sup>, providing no survival benefits, no universal SOC exists for rGBM. Avastin<sup>®</sup> has not been approved by the EMA for newly diagnosed GBM or rGBM, although it has been granted accelerated approval by the FDA for rGBM. Management believes that MDNA55 is currently well positioned for the rGBM indication, when used either as monotherapy or in combination with other approved therapies. Line extension for metastatic brain cancer, newly diagnosed GBM and pediatric gliomas has the potential to increase MDNA55 revenues.

#### MDNA55 Competition: Emerging Therapies for Adult GBM

The SOC for newly diagnosed GBM, consisting of surgery, radiotherapy and concurrent TMZ followed by adjuvant TMZ has not changed for over a decade. The lack of effective treatment options extends to a shortage of approved targeted therapies for GBM. Development of novel agents for the treatment of GBM is therefore an active area of research, and multiple agents and drug classes are being assessed for GBM.

Northwest Biotherapeutics' DCVax-L, an autologous dendritic cell vaccine, is one of the furthest along in development for GBM. DCVax-L is being evaluated in newly diagnosed GBM patients who have received a complete surgical resection and received radiotherapy and concurrent TMZ. Northwest has completed a Phase 3 clinical trial in patients with newly diagnosed GBM and expects to announce top-line data in mid-2020.

DNAtrix's DNX-2401, an oncolytic immunotherapy, has completed enrolment in a Phase 2 clinical trial in collaboration with Merck which evaluated the efficacy and safety of DNX-2401 in combination with pembrolizumab (KEYTRUDA), Merck's anti-PD-1 therapy. Adult subjects diagnosed with GBM or gliosarcoma that have experienced disease progression after initial treatment were candidates for the trial. Interim data were presented in November 2019 and DNAtrix has disclosed plans to initiate a Phase 3 clinical study.

Delmar Pharmaceuticals' product VAL-083 is a "first-in-class" small molecule chemotherapeutic and is enrolling patients in a Phase 2 clinical trial of VAL-083 in patients with MGMT unmethylated, bevacizumab-naive rGBM. The study is expected to be completed in 2020.

Ziopharm Oncology has a controlled IL-12 platform, or Ad-RTS-hIL-12 plus veledimex (Ad+V), which completed a Phase 1 clinical studies in both a monotherapy and in combination with a PD-1 inhibitor, for the treatment of recurrent or progressive glioblastoma multiforme in adults in 2019 and subsequently announced the initiation of a Phase 2 clinical trial in mid-2019. Interim data related to the Phase 1 clinical trials were released in November 2019.

Istari Oncology is enrolling patients in a Phase 2 multi-institutional, dose refinement trial that includes a chemotherapy component found to be beneficial in the Phase 1 study. The trial is testing PVSRIPO which is an oncolytic poliovirus delivered by way of intratumoral administration for the treatment of rGBM. The clinical trial involves 62 GBM patients and should be completed in 2020. In addition, Istari is evaluating D2C7-IT, an antibody-directed immune conjugate, in a dose escalation Phase 1 study in 24 recurrent GBM patients.

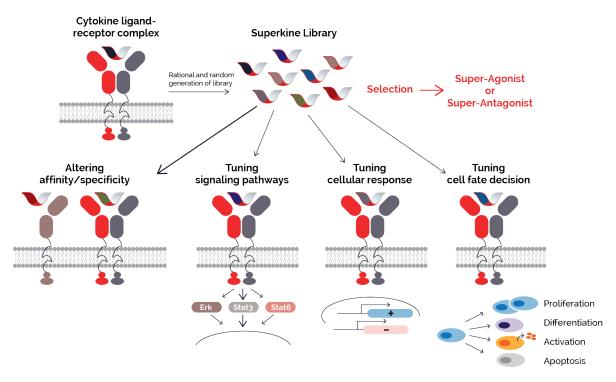
In mid-stage development, Agenus is developing a heat shock protein (gp96) peptide complex (HSPPC-96), an intradermal, autologous, cancer vaccine. Designated as the Prophage G series, Prophage G-100 is applied in newly diagnosed GBM patients and G-200, in rGBM. Phase 2 results for the Prophage G series vaccines demonstrate that the agent may hold promise in a very select group of patients.

Diffusion Pharmaceuticals has a small molecule that enhances oxygen delivery to hypoxic tissues (Trans sodium crocetinate, "TSC"). Since GBM is a highly hypoxic tumor, increased oxygenation is thought to enhance standard of care chemoradiation therapy. TSC is currently being investigated in a Phase 3 clinical trial in patients in newly diagnosed GBM.

#### Superkines

Developed by scientists at Stanford, Medicenna has exclusively licensed an impressive library of tunable cytokines, which we call Superkines. These cytokines include IL-2, IL-4 and IL-13, which are known to be engaged in modulating nearly 2,000 different types of human ailments.

Our Superkines have been engineered to bind to different receptor sub-types with variable specificity and affinity with the additional capacity to tune signaling pathways, cellular responses and cell fate. Further, by fusing Superkines to payloads, antibodies or inactive protein scaffolds, Medicenna is able to generate ECs, immunocytokines and long-acting Superkines, respectively, providing additional functionality, targeted delivery and improved pharmacokinetics. Superkines can also be combined with other immunotherapies such as CAR-T cells, checkpoint inhibitors and oncolytic viruses to provide a cytokine boost by stimulating tumor-killing immune cells or inhibiting immunosuppressive cells of the tumor microenvironment.



#### **IL-2 Superkines**

IL-2 was one of the first effective immunotherapies developed to treat cancer due to its proficiency at expanding T cells, the central players in cell-mediated immunity. Originally discovered as a growth factor for T cells, IL-2 can also drive the generation of activated immune cells, immune memory cells, and immune tolerance.

In contrast, IL-2 induced overstimulation of immune cells can lead to an imbalance in the ratio of effector and regulatory T cells, resulting in autoimmune diseases.

Part of the reason for this is due to the nature of the IL-2 receptor. The IL-2 receptor is composed of three different subunits, IL-2R $\alpha$  (also known as CD25), IL-2R $\beta$  (CD122) and IL-2R $\gamma$  (CD132). The arrangement of these different proteins determines the response to IL-2 signaling.

The IL-2 $\beta$  and IL-2 $\gamma$  components together make a receptor capable of binding IL-2, but only moderately so. When all three components are together, including IL-2R $\alpha$ , the receptor binds IL-2 with a much higher affinity. This complete receptor is usually found on regulatory T cells, which dampens an ongoing immune response. The lower affinity receptor, composed of just the IL-2 $\beta$  and IL-2 $\gamma$  components, is more often found on "naive" immune cells, which are awaiting instructions before seeking out cancer cells.

Altering IL-2's propensity for binding these receptors could encourage greater immune cell activation or block the function of regulatory cells. Medicenna's MDNA109 and MDNA209 platforms take advantage of this dynamic by binding to specific receptors and either activating or blocking them.

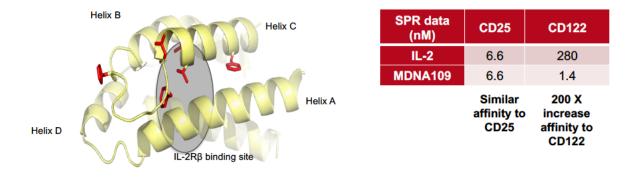
MDNA209 can be used to induce the opposite effect. This Superkine mimics the shape of IL-2 and is also up to 200-1000 times more likely to bind IL-2R $\beta$ . But rather than triggering IL-2 signaling, MDNA209 acts as an antagonist, blocking the receptor and preventing it from

transmitting the signal. This could be used for diseases such as such as multiple sclerosis where it is essential to prevent T cells from becoming activated and attacking healthy tissue. Limited work on MDNA209 has been initiated but development timelines have not been established at this time.

#### MDNA109 Platform Development

MDNA109 is an enhanced version of IL-2 that binds up to 200-1000 times more effectively to IL-2R $\beta$ , thus greatly increasing its ability to activate and proliferate the immune cells needed to fight cancer. Because it preferentially binds IL-2R $\beta$ , MDNA109 drives effector T cell responses over regulatory T cells. Mutations in the core of IL-2 improve affinity to CD122 on CD8 T cells and NK Cells, as CD122 affinity is key for the activation of immune cells responsible for cancer killing (CD8+ T cells, naive T cells, NK cells).

## Exploiting a natural conformational switch to engineer an interleukin-2 'superkine'

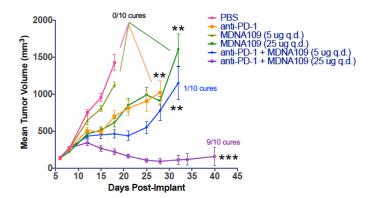


Levin, Bates, and Ring et. al, Nature, 2012

Additionally, MDNA109 reverses NK cell anergy and acts with exceptional synergy when combined with checkpoint inhibitors.

### MDNA109 Synergizes with Anti-PD-1 Immunotherapy

Combination Therapy Produces Robust Dose-Dependent Responses in MC38 Colon Cancer Model



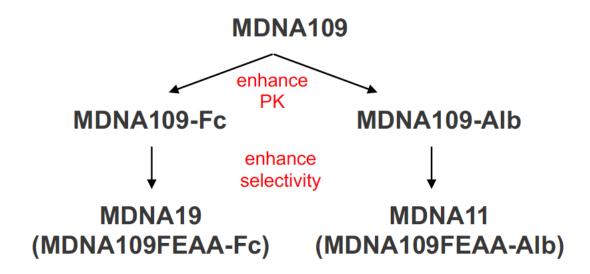
- MDNA109 and anti-PD-1 are not fully efficacious alone
- Dose-dependence observed with monotherapy and anti-PD-1
- Combination treatment sufficient to cure most mice
- Increased efficacy of combination was well-tolerated

C57BL/6 mice were implanted with 10<sup>6</sup> MC38 murine colon tumor cells subcutaneously above hind limb. When tumor reached approximately 125mm<sup>3</sup>, animals were randomized into groups and dosing was initiated by intraperitoneal injections; q.d. = daily. \*\*p=0.01; \*\*\*p=0.001



One of the development challenges with MDNA109 was its short half-life, similar to native IL-2, which would require frequent dosing in a commercial setting. In order to extend the half-life of MDNA109, Medicenna fused inactive protein scaffolds to MDNA109 including Fc-fusions (Fc) and Albumin fusions (Alb) and, on August 2, 2018, we announced preliminary preclinical data on MDNA109, showing that these fusions are long-acting and provided the convenience of easier dosing without sacrificing its safety and efficacy.

Further modifications were made to MDNA109 in its extended half-life forms to enhance pharmacodynamics and further enhance selectivity in order to reduce binding to CD25 which is associated with the toxic side effect profile of Proleukin. These modifications have provided us with two lead candidates in development, MDNA19 and MDNA11.



On February 6, 2019, the Company presented results on MDNA109 and its long acting variants in a podium presentation entitled "Putting Pedal to the Metal: Combining IL-2 Superkine (MDNA109) with Checkpoint Inhibitors", by Moutih Rafei, PhD, Associate Professor, Department of Pharmacology and Physiology, Université de Montréal, at the 5th Annual Immuno-Oncology 360° Meeting in New York, NY.

The results presented demonstrated that MDNA109 exhibited 1000-fold enhanced affinity toward the CD122 receptor and best-in-class potency toward cancer killing effector T cells. When tested *in vivo*, MDNA109 was not immunogenic and led to potent delay in the growth of pre-established B16F10 melanoma tumors compared to IL-2. Likewise, significant delay in the growth of pre-established MC38 and CT-26 colon cancer was observed in syngeneic mice receiving MDNA109, whereas its co-administration with anti-PD1 checkpoint inhibitor eliminated tumors in 90% of MC38 tumor-bearing mice. Furthermore, MDNA109 in combination with anti-CTLA-4 antibody, complete responses were observed in a majority of mice in the CT26 model. When cured animals were re-challenged on the counter-lateral flank with CT26 tumor cells, tumor growth was blocked at the secondary site clearly suggesting the generation of potent memory responses. Additional results on long-acting MDNA109 variants with impaired CD25 binding demonstrated abrogation of regulatory T cell activation at therapeutic doses in order to mitigate peripheral side effects, which are dependent on CD25 binding.

Medicenna presented a poster entitled "Engineering a long-acting CD122 biased IL-2 superkine displaying potent anti-tumoral responses" at the Inaugural Immuno-Oncology Pharma Congress, held from June 18-20, 2019 during World Pharma Week in Boston, MA. Highlights from the presentation by Dr. Moutih Rafei included the following: (a) When MDNA109-LA was co-administered with the immune-checkpoint blocker anti-cytotoxic T-Lymphocyte-Associated Protein ("CTLA") in a colon cancer mouse model, 67% of animals with pre-established tumors remained tumor-free for over 100 days. When these animals received a second and third rechallenge of the tumor without further treatment, 100% and 75% remained tumor free, respectively, demonstrating a strong memory response. (b) A long-acting variant, MDNA19, engineered to mitigate Treg activation by abolishing binding to the CD25 had 50-fold decreased Treg activity and 6-fold higher activity towards naive CD8 T cells for an overall 300-fold preferential activation of cancer killing T cells than recombinant IL-2. (c) In addition, binding affinity studies using surface plasmon resonance confirmed absence of CD25 binding by MDNA19. (d) To further validate the potency of MDNA19 mice with pre-established aggressive B16F10 melanoma tumors showed potent tumor control with a weekly dosing schedule.

On September 26, 2019, Medicenna announced the publication of a peer-reviewed article in the August 2019 edition of *Nature Communications* providing independent third-party validation of Medicenna's IL-2 Superkine platform, MDNA109. The publication, titled "A next-generation tumor-targeting IL-2 preferentially promotes tumor infiltrating CD8+ T cell response and effective tumor control", describes the safety, efficacy, pharmacokinetics, immunogenicity as well as efficacy profile in different tumor models of long-acting variants of MDNA109 including fusions to antibodies to create tumor targeted immunocytokines. The work reported in the publication is covered by Medicenna's patents and patents in-licensed by the Company.

On September 30, 2019, Medicenna announced the presentation by Dr. Minh To, Director of Preclinical Development at Medicenna, of preclinical data to support the differentiating characteristics of long-acting MDNA109 variants and their potency *in vitro* and *in vivo* from other long-acting IL-2 programs.

Highlights from the presentation included:

- High potency towards naive effector T cells but diminished potency on unwanted regulatory T cells (Tregs). Of the long-acting MDNA109 variants, MDNA19 is superior in having decreased binding to CD25 and increased affinity to CD122, therefore selectively activating cancer killing CD8 T cells instead of tumor protecting Tregs.
- Potent effects as monotherapy with improved PK characteristics. In CT26 (mouse colon cancer) and B16F10 (mouse melanoma) models, treatment with long acting variants of MDNA109 (biweekly for 2 weeks or once weekly for 2 or 3 weeks) potently inhibited tumor growth. These data suggest that long-acting MDNA109 variants could lead to potent therapeutic effects with a dosing schedule similar to that used for immune checkpoint inhibitors. In addition, the results also confirm that different protein scaffolds may be used to extend the half-life of MDNA109 and can provide similar tumor control as MDNA19.
- Compelling preclinical synergism with immune checkpoint inhibition. In a pre-established colon cancer CT26 model, long-acting MDNA109 variants co-administered with the immunecheckpoint blocker anti-cytotoxic T-Lymphocyte-Associated Protein (CTLA), showed significant tumor growth inhibition with as many as 89% of animals remaining tumor-free for over 175 days.
- Strong Memory Response. Furthermore, tumor free animals receiving a second and third rechallenge of the tumor without further treatment remained tumor free in up to 100% of mice, demonstrating development of a strong memory response with the ability to prevent tumor relapses.

On March 25, 2020, Medicenna announced preclinical data, including NHP data from MDNA19, during a conference call and webcast.

The presentation highlighted data from the long-acting variant MDNA19, engineered to have enhanced binding to CD122 without binding to CD25 and included:

- Kinetic studies in NHP showed a dose-dependent upregulation of Ki67 in CD8 T cells lasting for almost two weeks post-MDNA19 administration, with no apparent side effects.
- When administered to NHP, MDNA19 increases the absolute number of circulating CD8 T cells in the absence of Treg and eosinophil stimulation (the latter being a major source of IL-5 production which is responsible for triggering vascular leak syndrome and associated toxicity)
- MDNA19 administration as a monotherapy in syngeneic mice with pre-established CT26 colon cancer led to 60% survival and induction of strong and long-lasting memory responses correlating with resistance to subsequent re-challenges.
- Furthermore, MDNA19 treatment of B16F10 tumors favoured activation of CD8 T cells over Tregs in the tumor microenvironment driving a strong therapeutic effect.

Medicenna has commenced GLP and GMP related manufacturing activities with the intention of starting IND enabling studies in the second half of calendar 2020 and initiating a Phase 1/2a clinical trial in mid 2021. These timelines are later than what was previously disclosed as additional optimization to the molecules in development was necessary to to further enhance Medicenna's long acting MDNA109 program as potentially best in class.

Additional funding will be required to achieve the Company's business objectives with respect to the completion of the clinical development (Phase 2b and 3 clinical trials) and commercialization of MDNA19 or MDNA11. The Company expects the completion of clinical development of MDNA19 or MDNA11, if undertaken by Medicenna, to last until at least 2027, with a projected aggregate cost of approximately \$125 million, incremental to the current funds available to the Company. It is anticipated that following the completion of a Phase 1/2a clinical trial, the Company will either license the program to one or more partners who would continue the clinical development or raise additional capital at that time. Additional time and capital would also be required to obtain pre-market approval for MDNA19 or MDNA11 and to complete business development, marketing and other pre-commercialization activities related to commercial launch.

#### IL2 Superkine Competition

The development of next-generation IL-2 agonists for cancer immunotherapy is an area of intense interest within the biotechnology industry. The Company is aware of several IL-2 agonists in various stages of clinical development as noted in the table below.

Developer	Name	Stage
Nektar Therapeutics	NKTR-214	Phase 3
Roche	RG7461	Phase 2
Alopexx	DI-Leu16-IL2	Phase 2
Philogen	Darleukin	Phase 2
Apeiron	Hu14.18-IL2	Phase 1
Alkermes	ALKS 4230	Phase 1/2
Cue Biopharma	CUE-101	Phase 1
Sanofi (formerly Synthorx)	THOR-707	Phase 1
Neoleukin	NL-201	Preclinical
Pivotal Biosciences	PB101	Preclinical
BioNTech	BNT151	Preclinical
Ascendis Pharma	Transcon IL-2	Preclinical

Many of the programs in development that are ahead of Medicenna are engineered variants of IL-2 that each attempt to reduce CD25 binding and extend the therapeutic window of native IL-2. To our knowledge Medicenna is the only IL-2 product in development which significantly reduces CD25 binding while also increasing CD122 binding which increases efficacy. In addition to these benefits our candidates MDNA19 and MDNA11 also increase the half-life to allow for dosing every 2 or 3 weeks.

#### IL-4 and IL-13 Superkines

Medicenna's IL-4 and IL-13 Superkines are engineered versions of wild type cytokines which possess enhanced affinity and selectivity for either the Type 1 or Type 2 IL4R. This selectivity is achieved through mutations of the IL-4 or IL-13 proteins to enhance affinity for binding to specific IL4R subunits. Additional mutations have also been engineered to modulate their bioactivity, resulting in Superkines with enhanced signaling (super-agonists) or the ability to block signaling (super-antagonists).

One promising IL-13 Superkine antagonist is MDNA413. Compared to wild type IL-13, MDNA413 has been engineered to have 2,000-fold higher selectivity for the Type 2 IL4R and which potently blocks IL-4 and IL-13 signaling (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 tumour microenvironment, which shields the cancer from the immune system.

Another promising IL-13 Superkine is MDNA132. Unlike MDNA413, MDNA132 is an IL-13 ligand that has been engineered to increase affinity for IL13R alpha2 overexpressed on certain solid tumors while exhibiting sharply decreased affinity for IL13R alpha1. Medicenna believes MDNA132 has superior targeting compared to other IL-13 variants in development, and is an attractively differentiated targeting domain for inclusion in new and exciting field of immuno-oncology based on the CAR-T platform.

Limited work on MDNA413 and MDNA132 were completed in the past three years and development timelines for MDNA413 and MDNA132 have yet to be established.

#### Trends

The Company anticipates that its current level of cash and cash equivalents and marketable securities, including the over-allotment exercised subsequent to the year end, will be sufficient to execute its current planned expenditures for more than the next 24 months without further financing being obtained. This estimate assumes continued development of MDNA55 to the End of Phase 2 regulatory meeting with the FDA, completion of non-GLP and GLP pre-clinical studies, GMP manufacturing for pre-clinical and clinical studies of MDNA19 or MDNA11 as well as initiation and completion of Phase 1/2a clinical studies for MDNA11 or MDNA19. It does not factor in any future warrant exercises or reimbursement from CPRIT.

Based on the above, Medicenna currently anticipates an increase in expenditures relating to Medicenna's preclinical programs, specifically the MDNA109 platform as it moves toward the clinic in 2021. However, expenditures on the MDNA55 clinical trial are expected to decrease as the clinical development is complete and additional development will not begin without additional funding being obtained. Accordingly, cash burn is projected to increase over the next 12 months and the Company has sufficient capital to execute its planned operations for more than the next 24 months.

#### Intellectual Property and Partnerships

Medicenna regards its intellectual property rights as one of the foundation blocks upon which it continues to build a successful biopharmaceutical development company. Medicenna has established a strong and defensive intellectual property position to protect its proprietary technologies. To date, Medicenna has 16 patent families providing patent protection in the US and in contracting states to the Patent Corporation Treaty. The company has a total of eleven issued patents and several patent applications pending in the United States, as well as a number of granted and pending applications worldwide.

Patent families owned or licensed by Medicenna related to MDNA55 (granted US cases listed):

- 1. Method for Convection Enhanced Delivery of Therapeutic Agents (U.S. Patent No. 7,371,225)
- 2. Targeted Cargo Protein Combination Therapy (U.S. Patent No. 9,629,899)
- 3. IL-4 Fusion Formulations for Treatment of Central Nervous System Tumors

- 4. Treating Cancer Stem Cells Using Targeted Cargo Proteins
- 5. ILR4 as a Biomarker in Cancer (patent pending)

Expiry dates for the above patents and related family members range from 2023 to 2040.

In addition to the above patent protection, MDNA55 has market exclusivity via Orphan Drug Designation in the United States (7 years) and Europe (10 years) for the treatment of GBM, as well as, Biologics Data Exclusivity in the United States (12 years), Europe (10 years), Canada (8 years) and other markets where similar means of exclusivity are available.

Patent families owned or licensed by Medicenna related to the Superkine and Empowered Superkine platforms (granted US cases listed):

- 1. Superagonists and Antagonists of Interleukin-2 (U.S. Patent No. 9,428,567 and U.S. Patent No. 10,183,980)
- 2. Superkines and Synthekines: Repurposed Cytokines with New and Enhanced Signaling Activities (U.S. Patent No. 9,738,696)
- 3. Therapeutic IL-13 Polypeptides (U.S. Patent No. 9,512,194, U.S. Patent No. 9,732,133, and U.S. Patent No. 10,227,389)
- Interleukin-4 Receptor-Binding Fusion Proteins and Uses Thereof (Pro-apoptotic Fusions) (U.S. Patent No. 10,093,708)
- 5. Interleukin-4 Receptor Binding Fusion Proteins and Uses Thereof (Anti-apoptotic Fusions) (U.S. Patent No. 10,106,592)
- 6. IL-13 Superkine: Immune Cell Targeting Constructs and Methods of Use Thereof
- 7. IL-2 Fusion Proteins and Uses Thereof
- 8. Superagonists, Partial Agonists and Antagonists of Interleukin-2 (U.S. Patent No. 10,150,802)
- 9. IL-13 Superkine: Immune Cell Targeting Constructs and Methods of Use Thereof (patent pending)
- 10. IL-2 Superagonists in Combination with Anti-PD-1 Antibodies
- 11. Uses and Methods for Oncolytic Virus Targeting of IL-4/IL-13 and Fusions (patent pending)

Expiry dates for the above patents and related family members range from 2031 to 2039. Medicenna has Biologics Data Exclusivity for the above programs in the United States (12 years), Europe (10 years), Canada (8 years) and in other markets where similar means of exclusivity are available.

#### **CPRIT** Agreement

In February 2015, the Company was awarded a grant by CPRIT whereby the Company is eligible to receive up to US\$14,100,000 on eligible expenditures over a three-year period related to the development of the Company's Phase 2b clinical program for MDNA55. In October 2017 the Company was granted a one year extension to the grant, allowing expenses to be claimed over a four-year period ending February 28, 2019. On February 4, 2019 the Company was approved for a further six-month extension until August 31, 2019 and on July 25, 2019 an additional sixmonth extension was granted to February 28, 2020 and on January 6, 2020 an additional sixmonth extension was granted to August 28, 2020. The Company does not anticipate requiring any additional extensions to the timelines.

Ongoing program funding from CPRIT is subject to a number of conditions including the satisfactory achievement of milestones that must be met to release additional CPRIT funding, evidence that the Company has raised 50% matching funds and maintaining substantial functions of the Company related to the project grant in Texas as well as using Texas-based subcontractors and collaborators wherever possible. There can be no assurances that the Company will continue to meet the necessary CPRIT criteria or that CPRIT will continue to advance additional funds to the Company.

If the Company is found to have used any grant proceeds for purposes other than intended, is in violation of the terms of the grant, or relocates its MDNA55 related operations outside of the state of Texas, then the Company is required to repay any grant proceeds received.

Under the terms of the grant, the Company is also required to pay a royalty to CPRIT, comprised of 3-5% of revenues on net sales of MDNA55 until aggregate royalty payments equal 400% of the grant funds received, at which time the ongoing royalty will be 0.5%.

#### **Business Strategy**

Medicenna's strategy to reduce risk is to diversify the assets in Medicenna's pipeline based on their stage of development, mechanism of action and target product profile. To achieve this goal, we in-licensed the Superkine platform from Stanford. These candidates, namely IL-2, IL-4 and IL-13 Superkines, of which the lead preclinical program is based on the IL-2 super-agonist platform, MDNA109are expected to enable the company to develop a library of cytokine candidates. The resulting early stage preclinical product candidates derived from the Superkine and EC platforms have a different mechanism of action and target product profile compared to MDNA55, Medicenna's late stage candidate. By adopting a balanced approach, Medicenna is less reliant on a single product in Medicenna's pipeline, with greater upside potential through opportunities to partner or develop on its own, multiple products. Medicenna believes that establishing a pipeline of drug candidates with distinct mechanisms of actions targeting multiple disease indications mitigates development risk. Medicenna intends to achieve its business strategy by focusing on the following key areas:

 Maximize the potential clinical and commercial success of Medicenna's drug candidates by pursuing development programs based on sound scientific rationale for multiple disease indications where there are significant unmet clinical needs. In the near-term, Medicenna's focus will be to advance MDNA55 for the treatment of rGBM through to EOP2 meeting with the FDA as well advance the MDNA109 platform into IND enabling studies followed by Phase 1/2a clinical development;

- 2. Optimize the therapeutic potential of Medicenna's drug candidates by selecting subpopulations of patients who stand an improved chance of responding to treatment and employing the latest technologies and strategies for optimizing drug delivery;
- 3. Establish collaborations and relationships with leading scientific and clinical centres to effectively maximize the success of Medicenna's drug development programs; and
- 4. Assess strategic alliances with select pharmaceutical and/or biotechnology companies where such alliances may enable successful development and commercialization of Medicenna's drug candidates while maximizing its return on investment. Medicenna may conduct transactions with established strategic partners on a regional or worldwide basis to accelerate product development, improve Medicenna's marketing strength and enhance its capability of bringing products to the markets worldwide.

Medicenna will continue to seek sources of non-dilutive funding as well as additional funds through equity financings and/or through collaborative arrangements with pharmaceutical and/or biotechnology companies for any of Medicenna's products and technologies under development. Cash resources are carefully managed and focused on priority programs and initiatives. Accordingly, some initiatives may not be pursued or advanced in the near term as a prudent measure to preserve cash.

#### **Regulatory Process**

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of biological products, such as those Medicenna is developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Securing final regulatory approval for the manufacture and sale of biological products in the United States, Europe, Canada and other commercial territories, is a long and costly process that is controlled by that particular territory's regulatory agency. The regulatory agency in the United States is the FDA, in Canada it is Health Canada, and in Europe it is the EMA. Other regulatory agencies have similar regulatory approval processes, but each regulatory agency has its own approval processes. Approval in the United States, Canada or Europe does not assure approval by other regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country.

None of Medicenna's products have been completely developed or tested and, therefore, Medicenna is not yet in a position to seek final regulatory approval to market any of Medicenna's products. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and will require significant additional capital. See "*Risk Factors*" below.

#### United States Government Regulation

In the United States, the FDA regulates drugs under the *Federal Food, Drug, and Cosmetic Act* ("FDCA"), and its implementing regulations, and biologics under the FDCA and the *Public Health Service Act* ("PHSA"), and its implementing regulations. FDA approval is required before any new

unapproved drug or biologic or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. If Medicenna fails to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, Medicenna may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, civil monetary penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on Medicenna.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices ("GLP") regulations;
- completion of extensive CMC (chemistry, manufacturing and control) to produce drug in accordance with current Good Manufacturing Practices ("cGMP");
- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board ("IRB") or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application ("NDA") or biologics license application ("BLA") after completion of all pivotal clinical trials;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with cGMP;
- a potential FDA audit of the preclinical research and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the product in the United States

The preclinical research, including production of cGMP material, clinical testing and approval process require substantial time, effort, and financial resources, and Medicenna cannot be certain that any approvals for Medicenna's product candidates will be granted on a timely basis, if at all.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human clinical trials. The IND also includes description of the manufacturing process and testing of the batch, results of animal studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

#### **Clinical Trials**

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices ("GCP"), which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site's IRB or ethics committee, before the trials may be initiated, and the IRB or ethics committee must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is introduced into healthy human subjects with the target disease or condition. These studies are designed to evaluate safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and where possible, to gain early evidence on effectiveness.
- Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling.
- Phase 4. In some cases, the FDA may condition approval of an NDA or BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical trials.

Clinical trial sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB or ethics committee, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

The clinical trial process can take years to complete, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Results from one trial are not necessarily predictive of results from later trials. Medicenna may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

### Submission of an NDA or BLA to the FDA

Assuming successful completion of all required preclinical studies and clinical testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs and BLAs is subject to an application user fee. For the year 2020, the application user fee exceeds US\$2.943 million. This fee is typically increased annually. Applications for orphan drug products are exempted from the NDA and BLA application user fee, unless the application includes an indication for other than a rare disease or condition.

An NDA or BLA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, and may also come from a number of alternative sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational new drug product to the satisfaction of the FDA.

Once an NDA or BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an NDA or BLA for a novel drug (in which no active ingredient has been approved in any other application) to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

### The FDA's Decision on an NDA or BLA

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA will issue either an approval letter or a complete response letter ("Complete Response Letter"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. In order to satisfy deficiencies identified in a Complete Response Letter, additional clinical data and/or additional Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing may be required for the product candidate. Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA could also approve the NDA or BLA with a risk evaluation and mitigation strategy, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of Medicenna's products under development.

### Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of Medicenna's product candidates, some of Medicenna's United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Medicenna may apply for restoration of patent term for one of Medicenna's currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

### **Companion Diagnostics**

In its August 6, 2014 guidance document entitled "In Vitro Companion Diagnostic Devices," the FDA defines an "IVD companion diagnostic device" to be an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. Use of an IVD companion diagnostic device is considered essential when its use is required in the labeling of a therapeutic product, for example, to select appropriate patients for a product or those who should not use the product, or to monitor patients to achieve safety or effectiveness. In most circumstances, the IVD companion diagnostic device should be approved or cleared by FDA under the device authorities of the FDCA contemporaneously with the therapeutic product's approval under section 505 of the FDCA for a drug or section 351 of the PHSA for a biological product. FDA expects the therapeutic product sponsor to address the need for an approved or cleared IVD companion diagnostic device in its therapeutic product development plan. The therapeutic product sponsor may develop its own IVD companion diagnostic device, partner with a diagnostic device sponsor to develop an IVD companion diagnostic device, or explore modifying an existing IVD diagnostic device to develop a new intended use. The FDA explains if a diagnostic device and a therapeutic device are studied together to support their respective approvals, both products can be studied in the same investigational study that meets both the requirements of the Investigational Device Exemption, regulations and the IND regulations.

### Specialized Skill and Knowledge

Medicenna's business requires personnel with specialized skills and knowledge in the fields of basic and applied immunotherapy and immunology, oncology in general, the treatment of GBM, as well as drug delivery to the brain. Medicenna has subcontracted out several key functions to highly specialized individuals and companies to conduct the preclinical development of MDNA19 and MDNA11, manufacturing of MDNA19 and/or MDNA11 as well as MDNA55, the clinical program and regulatory activities associated with the EOP2 meetings with the FDA. These programs are overseen by Medicenna's Chief Executive Officer, Head of Clinical Development and Chief Development Officer, to ensure proper and timely completion of the required activities. Medicenna worked with world renowned brain cancer treatment centres for Medicenna's Phase 2b clinical trial of MDNA55. In addition, some of the leading experts in North America and Europe with respect to drug delivery to the brain, contribute towards Medicenna's clinical and regulatory efforts.

#### Employees

As at March 31, 2020, Medicenna had 7 full-time employees and two part-time consultants, including four holding PhD degrees, one holding an MD and other employees holding M.Sc. and MBA degrees or CPA designations.

Medicenna's employees are not governed by a collective bargaining agreement. Medicenna depends on certain key members of its management and scientific staff and the loss of services of one or more of these persons could adversely affect the Company.

Medicenna also uses consultants and outside contractors to carry on many of Medicenna's activities, including preclinical testing and validation, formulation, assay development, manufacturing, clinical and regulatory affairs, toxicology and clinical trials.

#### Legal Proceedings

To Medicenna's knowledge, there have not been any legal or arbitration proceedings, including those relating to bankruptcy, receivership or similar proceedings, those involving any third party, and governmental proceedings pending or known to be contemplated, which may have, or have had in the recent past, significant effect Medicenna's financial position or profitability.

To Medicenna's knowledge, there have been no material proceedings in which any director, any member of senior management, or any of Medicenna's affiliates is either a party adverse to Medicenna or any of Medicenna's subsidiaries or has a material interest adverse to Medicenna or any of Medicenna's subsidiaries.

#### **RISK FACTORS**

An investment in the Common Shares involves a high degree of risk and should be considered speculative. An investment in the Common Shares should only be undertaken by those persons who can afford the total loss of their investment. Investors should carefully consider the risks and uncertainties set forth below, as well as other information described elsewhere in this AIF. The risks and uncertainties below are not the only ones the Company faces. Additional risks and uncertainties not presently known to Medicenna or that Medicenna believes to be immaterial may also adversely affect Medicenna's business. If any of the following risks occur, Medicenna's business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Further, if Medicenna fails to meet the expectations of the public market in any given period, the market price of Medicenna's Common Shares could decline. Medicenna operates in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of Medicenna's control.

#### Risks Related to the Company's Business and the Company's Industry

## <u>The Company has no sources of product revenue and will not be able to maintain operations and research and development without sufficient funding.</u>

The Company has no sources of product revenue and cannot predict when or if it will generate product revenue. The Company's ability to generate product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop the product candidates, obtain regulatory approval, and commercialize products, including any of the current product candidates, or other product candidates that may be developed, in-licensed or acquired in the future. The Company does not anticipate generating revenue from the sale of products for the foreseeable future. The Company expects research and development expenses to increase in connection with ongoing activities, particularly as MDNA55 is advanced through clinical trials and the MDNA109 platform (MDNA19 or MDNA11) is advanced towards the clinic.

The Company will require significant additional capital resources to expand its business, in particular the further development of its proposed products. Advancing its product candidates or acquisition and development of any new products or product candidates will require considerable resources and additional access to capital markets. In addition, the Company's future cash requirements may vary materially from those now expected.

The Company can potentially seek additional funding through corporate collaborations and licensing arrangements, through public or private equity or debt financing, or through other transactions. However, if clinical trial results are neutral or unfavourable, or if capital market

conditions in general, or with respect to life sciences companies such as Medicenna, are unfavourable, the Company's ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. Additional financing that it may pursue may involve the sale of the Common Shares or financial instruments that are exchangeable for, or convertible into, the Common Shares, which could result in significant dilution to its shareholders. If sufficient capital is not available, the Company may be required to delay the implementation of its business strategy, which could have a material adverse effect on its business, financial condition, prospects or results of operations.

#### <u>The Company is highly dependent upon certain key personnel and their loss could adversely</u> affect the its ability to achieve its business objective.

The loss of Dr. Fahar Merchant, the President and Chief Executive Officer, Rosemina Merchant, the Chief Development Officer, or other key members of the scientific and operating staff could harm the Company. Employment agreements exist with Dr. Merchant and Ms. Merchant, although such employment agreements do not guarantee their retention. The Company also depends on scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability. In addition, the Company believes that future success will depend in large part upon its ability to attract and retain highly skilled scientific, managerial, medical, clinical and regulatory personnel. Agreements have been entered into with scientific and clinical collaborators and academic partners in the ordinary course of business as well as with physicians and institutions who recruited patients into the MDNA55 clinical trial and will recruit patients into future clinical trials. Notwithstanding these arrangements, there is significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. The loss of the services of any of the executive officers or other key personnel could potentially harm the Company's business, operating results or financial condition.

If the Company breaches any of the agreements under which it licenses rights to product candidates or technology from third parties, it can lose license rights that are important to its business. The Company's current license agreements may not provide an adequate remedy for breach by the licensor.

The Company is developing MDNA55, the MDNA109 platform (MDNA19 and MDNA11) and other earlier stage preclinical and discovery drug candidates pursuant to license agreements with NIH and Stanford (collectively, the "Licensors"). The Company is subject to a number of risks associated with its collaboration with the Licensors, including the risk that the Licensors may terminate the license agreement upon the occurrence of certain specified events. The license agreement requires, among other things, that the Company makes certain payments and use reasonable commercial efforts to meet certain clinical and regulatory milestones. If the Company fails to comply with any of these obligations or otherwise breach this or similar agreements, the Licensors or any future licensors may have the right to terminate the license in whole. The Company can also suffer the consequences of non-compliance or breaches by Licensors in connection with the license agreements. Such non-compliance or breaches by such third parties can in turn result in breaches or defaults under the Company's agreements with other collaboration partners, and the Company can be found liable for damages or lose certain rights, including rights to develop and/or commercialize a product or product candidate. Loss of the Company's rights to the licensed intellectual property or any similar license granted to it in the future, or the exclusivity rights provided therein, can harm the Company's financial condition and operating results.

<u>Clinical drug development involves a lengthy and expensive process with an uncertain outcome,</u> results of earlier studies and trials may not be predictive of future trial results, and the Company's product candidates may not have favourable results in later trials or in the commercial setting.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. In the case of MDNA55, the promising results seen in the Phase 2b clinical study may not be replicated in a randomized, controlled Phase 3 clinical study. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. This is applicable to the MDNA109 platform (MDNA19 and MDNA11) as the promising preclinical data may not be replicated in a clinical setting. Favourable results in early trials may not be repeated in later trials. There is no assurance the FDA, the EMA or other similar government bodies will view the results as the Company does or that any future trials of its proposed products for other indications will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy triats despite having progressed through preclinical studies and initial clinical trials.

The Company will be required to demonstrate through larger-scale clinical trials that any potential future product is safe and effective for use in a diverse population before it can seek regulatory approvals for commercial sale of its product. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical and post-approval trials. If MDNA55 fails to demonstrate sufficient safety and efficacy in future clinical trials, the Company's operations and financial condition will be adversely impacted.

# If the Company's competitors develop and market products that are more effective than the Company's existing product candidates or any products it may develop, or if they obtain marketing approval before it does, the Company's products may be rendered obsolete or uncompetitive.

Technological competition from pharmaceutical companies, biotechnology companies and universities is intense and is expected to increase. Many of the Company's competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Company does. Our future success depends in part on our ability to maintain a competitive position, including our ability to further progress MDNA55 and the MDNA109 platform (MDNA19 and MDNA11) through the necessary preclinical and clinical trials towards regulatory approval for sale and commercialization. Other companies may succeed in commercializing products earlier than we are able to commercialize our products or they may succeed in developing products that are more effective than our products. While the Company will seek to expand its technological capabilities in order to remain competitive, there can be no assurance that developments by others will not render its products non-competitive or that the Company or its licensors will be able to keep pace with technological developments. Competitors have developed technologies that could be the basis for competitive products. Some of those products may have an entirely different approach or means of accomplishing the desired therapeutic effect than the Company's products and may be more effective or less costly than its products. In addition, other forms of medical treatment may offer competition to the products. The success of the Company's competitors and their products and technologies relative to its technological capabilities and competitiveness could have a material adverse effect on the future preclinical and clinical trials of its products, including its ability to obtain the necessary regulatory approvals for the conduct of such trials.

# The Company is subject to the restrictions and conditions of the CPRIT agreement. Failure to comply with the CPRIT agreement may adversely affect the Company's financial condition and results of operations.

The Company has obtained a grant from CPRIT to fund a portion of its operations to date. The CPRIT grant is subject to the Company's compliance with the scope of work outlined in the CPRIT agreement and demonstration of its progress towards achievement of the milestones set forth in the CPRIT agreement. If the Company fails to comply with the terms of the CPRIT agreement, it may not receive the remaining US\$1.4 million tranche of the CPRIT grant or it may be required to reimburse some or the entire CPRIT grant. Further, the CPRIT grant may only be applied to a limited number of allowable expenses. Failure to obtain the remaining tranche of the CPRIT grant or being required to reimburse all or a portion of the CPRIT grant may cause a halt or delay in ongoing operations, which may adversely affect the Company's financial condition and operating results.

# The Company relies and will continue to rely on third parties to plan, conduct and monitor preclinical studies and clinical trials, and their failure to perform as required could cause substantial harm to the Company's business.

The Company relies and will continue to rely on third parties to conduct a significant portion of clinical development and planned preclinical activities. Preclinical activities include *in vivo* studies providing access to specific disease models, pharmacology and toxicology studies, and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relationship with third parties, or if the Company is unable to provide quality services in a timely manner and at a feasible cost, any active development programs could face delays. Further, if any of these third parties fails to perform as expected or if their work fails to meet regulatory requirements, testing could be delayed, cancelled or rendered ineffective.

# The Company relies on contract manufacturers over whom the Company has limited control. If the Company is subject to quality, cost or delivery issues with the preclinical and clinical grade materials supplied by contract manufacturers, business operations could suffer significant harm.

The Company has limited manufacturing experience and relies on contract development and manufacturing organizations ("CDMOs"), to manufacture MDNA55 for clinical trials and the MDNA109 platform (MDNA19 or MDNA11) for preclinical development. The Company relies on CDMOs for manufacturing, filling, packaging, storing and shipping of drug product in compliance with cGMP, regulations applicable to its products. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. The Company plans to utilize CDMOs that are licensed by both the FDA and the EMA.

There can be no assurances that the CDMOs selected will be able to meet future timetables and requirements. If the Company is unable to arrange for alternative third-party manufacturing sources on commercially reasonable terms or in a timely manner, it may delay the development of the product candidates. Further, contract manufacturers must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. The Company's dependence upon third parties for the manufacture of its products may adversely affect profit margins and ability to develop and deliver products on a timely and competitive basis.

# The Company's future success is dependent primarily on the regulatory approval of a single product.

The Company does not have any products that have gained regulatory approval. Currently, its only clinical product candidate is MDNA55. As a result, the Company's near-term prospects, including its ability to finance its operations and generate revenue, are substantially dependent on its ability to obtain regulatory approval for, and, if approved, to successfully commercialize MDNA55 in a timely manner. The Company cannot commercialize MDNA55 or other future product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, it cannot commercialize MDNA55 or other future product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Although MDNA55 has received Orphan Drug (FDA, EMA) and Fast Track (FDA) designations, there can be no assurance regulatory approval will be granted. Before obtaining regulatory approvals for the commercial sale of MDNA55 or other future product candidates for a target indication, the Company must demonstrate with substantial evidence gathered in preclinical and clinical studies to the satisfaction of the relevant regulatory authorities, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Many of these factors are beyond the Company's control. If the Company, or its potential commercialization collaborators, are unable to successfully commercialize MDNA55, the Company may not be able to earn sufficient revenues to continue its business.

## The Company may not achieve its publicly announced milestones according to schedule, or at all.

From time to time, the Company may announce the timing of certain events expected to occur, such as the anticipated timing of results from clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed. These variations in timing may occur as a result of different events, including the ability to recruit patients in a clinical trial in a timely manner, the nature of results obtained during a clinical trial or during a research phase, problems with a CDMO or a contract research organization ("CRO"), or any other event having the effect of delaying the publicly announced timeline. The Company undertakes no obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of previously announced milestones could have a material adverse effect on the business plan, financial condition or operating results and the trading price of the Common Shares.

# <u>MDNA55 is in the mid stages of clinical development and the MDNA109 platform (MDNA19 and MDNA11) in preclinical development and, as a result, the Company will be unable to predict whether it will be able to profitably commercialize its product candidates.</u>

The Company has not received regulatory approval for the sale of MDNA55 in any market. Accordingly, the Company has not generated any revenues from product sales. A substantial commitment of resources to conduct clinical trials and for additional product development will be required to commercialize all of our product candidates. There can be no assurance that MDNA55, the MDNA109 platform (MDNA19 and MDNA11) or any of our other product candidates will meet applicable regulatory standards, be capable of being produced in commercial quantities

at reasonable cost or be successfully marketed, or that the investment made by the Company in the commercialization of the products will be recovered through sales, license fees or related royalties.

## The Company will be subject to extensive government regulation that will increase the cost and uncertainty associated with gaining final regulatory approval of its product candidates.

Securing final regulatory approval for the manufacture and sale of human therapeutic products in the United States, Canada and other markets is a long and costly process that is controlled by that particular country's national regulatory agency. Approval in the United States, Canada or Europe does not assure approval by other national regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country. Other national regulatory agencies have similar regulatory approval processes, but each is different.

Prior to obtaining final regulatory approval to market a drug product, every national regulatory agency has a variety of statutes and regulations which govern the principal development activities. These laws require controlled research and testing of products, government review and approval of a submission containing preclinical and clinical data establishing the safety and efficacy of the product for each use sought, approval of manufacturing facilities including adherence to cGMP during production and storage and control of marketing activities, including advertising and labelling. There can be no assurance that MDNA55 or the MDNA109 platform (MDNA19 and MDNA11) will be successfully commercialized in any given country. There can be no assurance that the Company's licensed products will prove to be safe and effective in clinical trials under the standards of the regulations in the various jurisdictions or receive applicable regulatory approvals from applicable regulatory bodies.

# <u>Negative results from clinical trials or studies of third parties and adverse safety events involving the targets of the Company's products may have an adverse impact on future commercialization efforts.</u>

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's product candidates, or the therapeutic areas in which the Company's product candidates compete, could adversely affect the share price and ability to finance future development of the Company's product candidates, and the business and financial results could be materially and adversely affected.

## The Company faces the risk of product liability claims, which could exceed its insurance coverage and produce recalls, each of which could deplete cash resources.

The Company is exposed to the risk of product liability claims alleging that use of its product candidate MDNA55, and in the future, the MDNA109 platform (MDNA19 and MDNA11), caused an injury or harm. These claims can arise at any point in the development, testing, manufacture, marketing or sale of product candidates and may be made directly by patients involved in clinical trials of product candidates, by consumers or healthcare providers or by individuals, organizations or companies selling the products. Product liability claims can be expensive to defend, even if the product or product candidate did not actually cause the alleged injury or harm.

Insurance covering product liability claims becomes increasingly expensive as a product candidate moves through the development pipeline to commercialization. Currently the Company maintains clinical trial liability insurance coverage of \$5 million. However, there can be no assurance that such insurance coverage is or will continue to be adequate or available at a cost acceptable to the Company or at all. The Company may choose or find it necessary under its collaborative agreements to increase the insurance coverage in the future but may not be able to secure greater or broader product liability for damages resulting from a product liability claim could exceed the amount of the coverage, require payment of a substantial monetary award from the Company's cash resources and have a material adverse effect on the business, financial condition and results of operations. Moreover, a product recall, if required, could generate substantial negative publicity about the products and business, inhibit or prevent commercialization of other products and product candidates or negatively impact existing or future collaborations.

#### <u>Changes in government regulations, although beyond the Company's control, could have an</u> adverse effect on the Company's business.

The Company depends upon the validity of its licenses and access to the data for the timely completion of clinical research. Any changes in the drug development regulatory environment or shifts in political attitudes of a government are beyond the Company's control and may adversely affect its business. The Company's business may also be affected in varying degrees by such factors as government regulations with respect to intellectual property, regulation or export controls. Such changes remain beyond the Company's control and the effect of any such changes cannot be predicted. These factors could have a material adverse effect on the Company's ability to further develop its licensed products.

# The Company's significant shareholders may have material influence over its governance and operations.

Dr. Fahar Merchant and Ms. Rosemina Merchant (collectively, the "Merchants"), hold a significant interest in the Company's outstanding Common Shares on a fully diluted basis. For as long as the Merchants maintain a significant interest in the Company, they may be in a position to affect the Company's governance and operations. In addition, the Merchants may have significant influence over the passage of any resolution of the Company's shareholders (such as those that would be required to amend the constating documents or take certain other corporate actions) and may, for all practical purposes, be able to ensure the passage of any such resolution by voting for it or prevent the passage of any such resolution by voting against it. The effect of this influence may be to limit the price that investors are willing to pay for the Common Shares. In addition, the potential that the Merchants may sell their Common Shares in the public market (commonly referred to as "market overhang"), as well as any actual sales of such Common Shares.

# If the Company is unable to enroll subjects in clinical trials, it will be unable to complete these trials on a timely basis.

It is anticipated that the COVID-19 pandemic crisis will impact ongoing trial activities across the industry due to the pressure placed on the healthcare system as well as governmental and institutional restrictions. The Company is not currently enrolling patients in a clinical study and does not plan to enrol additional patients until 2021. Should the COVID-19 pandemic continue into 2021 the Company's will need to determine at that time if initiating a clinical trial is feasible

and if so the clinical team will need to work closely with each clinical site and a CRO on a plan to ensure that patient safety and the integrity of data is maintained. It is noted that some clinical sites have paused or slowed enrollment in clinical trials, while other sites, less impacted, are continuing activities as planned.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of subjects to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications the Company is investigating. Furthermore, the Company relies on CROs and clinical trial sites to ensure the proper and timely conduct of its clinical trials, and while it has agreements governing their committed activities, the Company has limited influence over their actual performance.

If the Company experiences delays in the completion or termination of any clinical trial of its proposed products or any future product candidates, the commercial prospects of its product candidates will be harmed and its ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing clinical trials will increase costs, slow down product candidate development and approval process and can shorten any periods during which the Company may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before it does. Delays can further jeopardize the Company's ability to commence product sales, which will impair its ability to generate revenues and may harm the business, results of operations, financial condition and cash flows and future prospects. In addition, many of the factors that can cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of its proposed products or its future product candidates.

## The Company's discovery and development processes involve use of hazardous and radioactive materials which may result in potential environmental exposure.

The Company's discovery and development processes involve the controlled use of hazardous and radioactive materials. The Company is subject to federal, provincial, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although the Company believes that the current safety procedures for handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the Company's resources. The Company is not specifically insured with respect to this liability. Although the Company believes that the Company is in compliance in all material respects with applicable environmental laws and regulations and currently does not expect to make material capital expenditures for environmental control facilities in the near term, there can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws and regulations in the future, or that the operations, business or assets will not be materially adversely affected by current or future environmental laws or regulations.

If the Company is unable to successfully develop companion diagnostics for its therapeutic product candidates, or experience significant delays in doing so, the Company may not achieve marketing approval or realize the full commercial potential of its therapeutic product candidates.

The Company plans to develop companion diagnostics for its therapeutic product candidates. It is expected that, at least in some cases, regulatory authorities may require the development and regulatory approval of a companion diagnostic as a condition to approving a therapeutic product candidate. The Company has limited experience and capabilities in developing or commercializing diagnostics and plans to rely in large part on third parties to perform these functions. The Company does not currently have any agreement in place with any third party to develop or commercialize companion diagnostics for any of its therapeutic product candidates.

Companion diagnostics are subject to regulation by the FDA, Health Canada and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval or clearance prior to commercialization. If the Company, or any third parties that the Company engages to assist, are unable to successfully develop companion diagnostics for the Company's therapeutic product candidates, or experience delays in doing so, the Company's business may be substantially harmed.

<u>Significant disruption in availability of key components for ongoing clinical studies could</u> <u>considerably delay completion of potential clinical trials, product testing and regulatory approval</u> <u>of potential product candidates.</u>

The Company relies on third parties to supply ingredients and excipients for the manufacture and formulation of its drugs, catheters required to deliver the drug to the brain as well as imaging software to accurately place catheters in the tumor ("Components"). Each of the suppliers of these Components in turn need to comply with regulatory requirements. Any significant disruption in supplier relationships could harm the Company's business, including the potential impact of COVID-19. Any significant delay in the supply of a Component, for a potential ongoing clinical study could considerably delay completion of potential clinical trials, product testing and regulatory approval of potential product candidates. If the Company or its suppliers are unable to purchase these Components after regulatory approval has been obtained for the product candidates, or the suppliers decide not to manufacture these Components or provide support for any of the Components, clinical trials or the commercial launch of that product candidate would be delayed or there would be a shortage in supply, which would impair the ability to generate revenues from the sale of the product candidates. It may take several years to establish an alternative source of supply for such Components and to have any such new source approved by the FDA and other regulatory agencies.

### Risks Related to Intellectual Property and Litigation

# The Company's success depends upon its ability to protect its intellectual property and its proprietary technology.

The Company's success depends, in part, on its ability and its licensors' ability to obtain patents, maintain trade secrets protection and operate without infringing on the proprietary rights of third parties or having third parties circumvent its rights. Certain licensors and the institutions that they represent, and in certain cases, have filed and are actively pursuing certain applications for Canadian and foreign patents. The patent position of pharmaceutical and biotechnology firms is uncertain and involves complex legal and financial questions for which, in some cases, certain important legal principles remain unresolved. There can be no assurance that the patent

applications made in respect of the owned or licensed products will result in the issuance of patents, that the term of a patent will be extendable after it expires in due course, that the licensors or the institutions that they represent will develop additional proprietary products that are patentable, that any patent issued to the licensors or the Company will provide it with any competitive advantages, that the patents of others will not impede its ability to do business or that third parties will not be able to circumvent or successfully challenge the patents obtained in respect of the licensed products. The cost of obtaining and maintaining patents is high. Furthermore, there can be no assurance that others will not independently develop similar products which duplicate any of the licensed products or, if patents are issued, design around the patent for the product. There can be no assurance that the Company's processes or products or those of its licensors do not or will not infringe upon the patents of third parties from developing similar and competitive products.

Much of the Company's know-how and technology may not be patentable, though it may constitute trade secrets. There can be no assurance, however, that the Company will be able to meaningfully protect its trade secrets. To help protect its intellectual property rights and proprietary technology, the Company requires employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance that these agreements will provide meaningful protection for its intellectual property rights or other proprietary information in the event of any unauthorized use or disclosure.

#### <u>The Company's potential involvement in intellectual property litigation could negatively affect its</u> <u>business</u>.

Its future success and competitive position depends in part upon its ability to maintain the its intellectual property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications. Even if such patents are issued, there can be no assurance that any patents issued or licensed to the Company will not be challenged. The Company's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes are infringing its rights and by defending claims brought by others who believe that the Company is infringing their rights. In addition, enforcement of its patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Even if such claims are found to be invalid, the Company's involvement in intellectual property litigation could have a material adverse effect on its ability to out-license any products that are the subject of such litigation. In addition, its involvement in intellectual property litigation could result in significant expense, which could materially adversely affect the use or licensing of related intellectual property and divert the efforts of its valuable technical and management personnel from their principal responsibilities, whether or not such litigation is resolved in its favour.

## <u>The Company's reliance on third parties requires it to share its trade secrets, which increases the possibility that a competitor will discover them.</u>

Because the Company relies on third parties to develop its products, it must share trade secrets with them. The Company seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically restrict the ability of the Company's collaborators, advisors, employees and consultants to publish data potentially relating to the Company's trade secrets. The Company's academic collaborators typically have rights to publish data, provided that the

Company is notified in advance and may delay publication for a specified time in order to secure its intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by the Company, although in some cases it may share these rights with other parties. The Company also conducts joint research and development programs which may require it to share trade secrets under the terms of research and development collaboration or similar agreements. Despite the Company's efforts to protect its trade secrets, its competitors may discover its trade secrets, either through breach of these agreements, independent development or publication of information including its trade secrets in cases where the Company does not have proprietary or otherwise protected rights at the time of publication. A competitor's discovery of the Company's trade secrets may impair its competitive position and could have a material adverse effect on its business and financial condition.

# <u>Product liability claims are an inherent risk of the Company's business, and if the Company's clinical trial and product liability insurance prove inadequate, product liability claims may harm its business.</u>

Human therapeutic products involve an inherent risk of product liability claims and associated adverse publicity. There can be no assurance that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. An inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could have a material adverse effect on the Company's business by preventing or inhibiting the commercialization of its products, licensed and owned, if a product is withdrawn or a product liability claim is brought against the Company.

#### <u>Generally, a litigation risk exists for any company that may compromise its ability to conduct the</u> <u>Company's business.</u>

All industries are subject to legal claims, with and without merit. Defense and settlement costs can be substantial, even with respect to claims that have no merit. Due to the inherent uncertainty of the litigation process, the resolution of any particular legal proceeding could have a material adverse effect on the Company's business, prospects, financial condition and results of operations.

### Other Risks

#### Our Common Share price has been volatile in recent years, and may continue to be volatile.

The market prices for securities of biotechnology companies, including ours, have historically been volatile. In the year ended March 31, 2020, our Common Shares traded on the TSX at a high of \$4.86 and a low of \$0.64 per share. A number of factors could influence the volatility in the trading price of our Common Shares, including changes in the economy or in the financial markets, industry related developments, the results of product development and commercialization, changes in government regulations, and developments concerning proprietary rights, litigation and cash flow. Our quarterly losses may vary because of the timing of costs for clinical trials, manufacturing and preclinical studies. Also, the reporting of clinical data or the lack thereof, adverse safety events involving our products and public rumors about such events could cause our share price to decline or experience periods of volatility. Each of these factors could lead to increased volatility in the market price of our Common Shares. In addition, changes in the

market prices of the securities of our competitors may also lead to fluctuations in the trading price of our Common Shares.

# Future sales or issuances of equity securities or the conversion of securities into Common Shares could decrease the value of the Common Shares, dilute investors' voting power, and reduce earnings per share.

The Company may sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance operations, acquisitions or projects, and issue additional Common Shares if outstanding securities are converted into Common Shares, which may result in dilution.

The Company's board of directors will have the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that the Company will issue additional securities to provide such capital.

Sales of substantial amounts of securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of Common Shares upon conversion or exchange of outstanding convertible or exchangeable securities, could adversely affect the prevailing market prices for securities and dilute investors' earnings per share. A decline in the future market prices of the Company's securities could impair its ability to raise additional capital through the sale of securities should it desire to do so.

In the past, following periods of volatility in the market price of a company's securities, shareholders have instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the Company's profitability and reputation.

The market price for the Common Shares may also be affected by the Company's ability to meet or exceed expectations of analysts or investors. Any failure to meet these expectations, even if minor, may have a material adverse effect on the market price of the Common Shares.

# The Company is subject to foreign exchange risk relating to the relative value of the United States dollar.

A material portion of the Company's expenses are denominated in United States dollars. As a result, the Company is subject to foreign exchange risks relating to the relative value of the Canadian dollar as compared to the United States dollar. A decline in the Canadian dollar would result in an increase in the actual amount of its expenses and adversely impact financial performance.

## <u>The Company's disclosure controls and procedures may not prevent or detect all errors or acts</u> <u>of fraud.</u>

The Company's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by the Company in reports it files or submits under applicable securities laws is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified under applicable securities laws. The Company believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not

absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in the Company's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Any failure to maintain an effective system of internal controls may result in material misstatements of the Company's consolidated financial statements or cause the Company to fail to meet the reporting obligations or fail to prevent fraud; and in that case, shareholders could lose confidence in the Company's financial reporting, which would harm the business and could negatively impact the price of the Common Shares.

Effective internal controls are necessary to provide reliable financial reports and prevent fraud. If there is a failure to maintain an effective system of internal controls, the Company might not be able to report financial results accurately or prevent fraud; and in that case, shareholders could lose confidence in the Company's financial reporting, which would harm the business and could negatively impact the price of the Common Shares. While the Company believes that it will have sufficient personnel and review procedures to maintain an effective system of internal controls, no assurance can be provided that potential material weaknesses in internal control could arise. Even if it is concluded that the internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS, as issued by the International Accounting Standards Board (IASB), because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm results of operations or cause a failure to meet future reporting obligations.

# Failure to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), the Canadian Corruption of Foreign Public Officials Act ("CFPOA"), and other global anti-corruption and anti-bribery laws could subject the Company to penalties and other adverse consequences.

The FCPA and the CFPOA, as well as any other applicable domestic or foreign anti-corruption or anti-bribery laws to which the Company is or may become subject generally prohibit corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries.

Compliance with these anti-corruption laws and anti-bribery laws may be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, these laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and physicians and other hospital employees are considered to be foreign officials. Certain payments by other companies to hospitals in connection with clinical trials and other work have been deemed to be improper payments to governmental officials and have led to FCPA enforcement actions.

The Company's internal control policies and procedures may not protect it from reckless or negligent acts committed by the Company's employees, future distributors, licensees or agents. The Company can make no assurance that they will not engage in prohibited conduct, and the Company may be held liable for their acts under applicable anti-corruption and anti-bribery laws. Noncompliance with these laws could subject the Company to investigations, sanctions,

settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, whistleblower complaints, reputational harm, adverse media coverage, and other collateral consequences. Any investigations, actions or sanctions or other previously mentioned harm could have a material negative effect on the Company's business, operating results and financial condition.

## Any future profits will likely be used for the continued growth of the business and products and will not be used to pay dividends on the issued and outstanding shares.

The Company will not pay dividends on the issued and outstanding Common Shares in the foreseeable future. If the Company generates any future earnings, such cash resources will be retained to finance further growth and current operations. The board of directors will determine if and when dividends should be declared and paid in the future based on the Company's financial position and other factors relevant at the particular time. Until the Company pays dividends, which it may never do, a shareholder will not be able to receive a return on his or her investment in the Common Shares unless such Common Shares are sold. In such event, a shareholder may only be able to sell his, her or its Common Shares at a price less than the price such shareholder originally paid for them, which could result in a significant loss of such shareholder's investment.

## The Company may pursue other business opportunities in order to develop its business and/or products.

From time to time, the Company may pursue opportunities for further research and development of other products. The Company's success in these activities will depend on its ability to identify suitable technical experts, market needs, and effectively execute any such research and development opportunities. Any research and development would be accompanied by risks as a result of the use of business efforts and funds. In the event that the Company chooses to raise debt capital to finance any such research or development opportunities, its leverage will be increased. There can be no assurance that the Company would be successful in overcoming these risks or any other problems encountered in connection with any research or development opportunities.

# <u>The Company may acquire businesses or products, or form strategic alliances, in the future, and the Company may not realize the benefits of such acquisitions.</u>

The Company may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that the Company believes will complement or augment its existing business. If the Company acquires businesses with promising products or technologies, the Company may not be able to realize the benefit of acquiring such businesses if the Company is unable to successfully integrate them with its existing operations and company culture. The Company may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent it from realizing their expected benefits or enhancing the Company's business. The Company cannot assure investors that, following any such acquisition, it will achieve the expected synergies to justify the transaction.

#### The Company's success depends on its ability to effectively manage its growth.

The Company may be subject to growth-related risks including pressure on its internal systems and controls. The Company's ability to manage its growth effectively will require the Company to

continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. Inability to deal with this growth could have a material adverse impact on its business, operations and prospects. The Company may experience growth in the number of its employees and the scope of its operating and financial systems, resulting in increased responsibilities for its personnel, the hiring of additional personnel and, in general, higher levels of operating expenses. In order to manage its current operations and any future growth effectively, the Company will also need to continue to implement and improve its operational, financial and management information systems and to hire, train, motivate, manage and retain its employees. There can be no assurance that the Company will be able to manage such growth effectively, that its management, personnel or systems will be adequate to support its operations or that the Company will be able to achieve the increased levels of revenue commensurate with the increased levels of operating expenses associated with this growth.

### If the Company is treated as a passive foreign investment company, United States shareholders may be subject to adverse U.S. federal income tax consequences

Under the U.S. Internal Revenue Code of 1986, as amended (the "Code"), the Company will be classified as a passive foreign investment company ("PFIC") in respect of any taxable year in which either (i) 75% or more of its gross income consists of certain types of "passive income" or (ii) 50% or more of the average quarterly value of its assets is attributable to "passive assets" (assets that produce or are held for the production of passive income). For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, if the Company directly or indirectly owns at least 25% by value of the shares of another corporation, the Corporation will be treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. PFIC status is a factual determination that needs to be made annually after the close of each taxable year, on the basis of the composition of the Company's income, the relative value of its active and passive assets, and its market capitalization. For this purpose, the Company's PFIC status depends in part on the application of complex rules, which may be subject to differing interpretations, relating to the classification of the Company's income and assets. Based on our interpretation of the law, the Company's recent financial statements, and considering expectations about the Company's income, assets and activities, the Company believes that it was a PFIC for the taxable year ended March 31, 2020 and expects that it will be a PFIC for the current taxable year.

If the Company is a PFIC for any taxable year during which a United States shareholder holds the Common Shares, the Company will continue to be treated as a PFIC with respect to such United States shareholder in all succeeding years during which the United States shareholder owns the Common Shares, regardless of whether the Company continues to meet the PFIC test described above, unless the United States shareholder makes a specified election once the Company ceases to be a PFIC. If the Company is classified as a PFIC for any taxable year during which a United States shareholder holds the Common Shares, the United States shareholder may be subject to adverse tax consequences regardless of whether the Company continues to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements. In certain circumstances, a United States shareholder may alleviate some of the adverse tax consequences attributable to PFIC status by making either a "qualified electing fund," ("QEF") election or a mark-to-market election (if the Common Shares constitute "marketable" securities under the Code). If the Company determines that it is a PFIC for this year or any future

taxable year, the Company currently expects that it would provide the information necessary for United States shareholders to make a QEF election.

Each United States shareholder should consult its own tax advisors regarding the PFIC rules and the United States federal income tax consequences of the acquisition, ownership and disposition of the Common Shares.

## <u>The Company's operations could be adversely affected by events outside of its control, such as</u> <u>natural disasters, wars or health epidemics</u>

The Company may be impacted by business interruptions resulting from pandemics and public health emergencies, including those related to COVID-19 coronavirus, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires. An outbreak of infectious disease, a pandemic or a similar public health threat, such as the recent outbreak of the novel coronavirus known as COVID-19, or a fear of any of the foregoing, could adversely impact the Company by causing operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how the Company may be affected if such an epidemic persists for an extended period of time. The Company may incur expenses or delays relating to such events outside of its control, which could have a material adverse impact on its business, operating results and financial condition.

#### <u>It may be difficult for non-Canadian investors to obtain and enforce judgments against the</u> <u>Company because of the Company's Canadian incorporation and presence.</u>

The Company is a corporation existing under the federal laws of Canada. Most of the Company's directors and officers, and several of the experts, are residents of Canada, and all or a substantial portion of their assets, and a substantial portion of the Company's assets, are located outside the United States. Consequently, it may be difficult for holders of the Company's securities who reside in the United States to effect service of process within the United States upon those directors, officers and experts who are not residents of the United States. It may also be difficult for holders of the Company's securities who reside in the United States to realize in the United States upon judgments of courts of the United States predicated upon the Company's civil liability and the civil liability of the Company's directors, officers and experts under the United States federal securities laws. Investors should not assume that Canadian courts (i) would enforce judgments of United States courts obtained in actions against the Company or such directors, officers or experts predicated upon the civil liability provisions of the United States federal securities laws or the securities or "blue sky" laws of any state or jurisdiction of the United States or (ii) would enforce, in original actions, liabilities against the Company or such directors, officers or experts predicated upon the United States federal securities laws or any securities or "blue sky" laws of any state or jurisdiction of the United States. In addition, the protections afforded by Canadian securities laws may not be available to investors in the United States.

#### <u>The Company may lose foreign private issuer status in the future, which could result in significant</u> <u>additional costs and expenses.</u>

The Company may in the future lose foreign private issuer status if a majority of the Common Shares are held in the United States and the Company fails to meet the additional requirements necessary to avoid loss of foreign private issuer status, such as if: (i) a majority of the Company's directors or executive officers are U.S. citizens or residents; (ii) a majority of the Company's assets are located in the United States; or (iii) the Company's business is administered principally in the United States. The regulatory and compliance costs to the Company under U.S. securities laws as a U.S. domestic issuer may be significantly more than the costs incurred as a foreign private issuer.

#### DIVIDENDS

There are no restrictions in the Company's articles preventing the Company from paying dividends. The Company has not declared or paid any dividends since incorporation. The directors of the Company anticipate that the Company will retain all future earnings and other cash resources for the future operation and development of its business, and accordingly, do not intend to declare or pay any cash dividends in the foreseeable future. Payment of any future dividends will be at the discretion of the board of the directors after taking into account many factors including the Company's operating results, financial condition and current and anticipated cash assets.

#### SHARE CAPITAL

#### **Common Shares**

The authorized share capital of the Company consists of an unlimited number of Common Shares of which 48,500,376 Common Shares are issued and outstanding as fully paid and non-assessable as at the date hereof.

Each Common Share carries one vote at all meetings of shareholders, is entitled to receive dividends as and when declared by the directors, and is entitled to a pro-rata share of the remaining property and assets of the Company distributable to the holders of the Common Shares upon any liquidation, dissolution or winding-up of the Company.

#### Convertible Securities

In addition, as at the date hereof, there are issued and outstanding the following convertible securities of the Company, details of which are outlined in the table below:

Security	Number	Exercise or Conversion Price	Expiry Date (dd/mm/yyyy)	
Stock options	4,130,000	\$1.00 to \$2.88	24/02/2024 to 08/11/2029	
Warrants	1,468,000	\$1.20	21/12/2023	
Warrants	1,953,532	\$1.75	17/10/2022	
Broker warrants	163,000	\$2.00	05/05/2021	
Broker warrants	57,500	\$1.20	20/12/2020	
Broker warrants	209,003	\$1.75	17/10/2021	
Broker warrants	845,646	\$3.10	17/03/2022	
Incentive warrants	2,667,083	\$2.00	01/01/2021 to 01/03/2021	

#### MARKET FOR SECURITIES

#### Trading Price and Volume

The Common Shares are listed on the TSX under the symbol "MDNA". The following table shows the price ranges and volumes traded on the TSX for the periods noted:

	TSX			
Month	High (\$)	Low (\$)	Volume (#)	
April 2019	\$0.85	\$0.64	434,380	
May 2019	\$0.96	\$0.66	739,698	
June 2019	\$2.38	\$0.82	2,205,187	
July 2019	\$1.61	\$1.02	936,043	
August 2019	\$1.43	\$1.06	308,067	
September 2019	\$1.88	\$0.94	799,169	
October 2019	\$1.48	\$1.10	785,221	
November 2019	\$2.05	\$1.27	2,702,400	
December 2019	\$3.87	\$1.30	3,524,777	
January 2020	\$3.78	\$2.41	3,596,527	
February 2020	\$4.86	\$2.77	2,365,899	
March 2020	\$4.12	\$2.15	5,105,194	

#### **Prior Sales**

The following securities of the Company (other than Common Shares) were issued during the fiscal year ended March 31, 2020:

Date of Issue	Security	Number	Exercise Price
June 7, 2019	Stock options	200,000	\$1.38
October 17, 2019	Warrants	2,653,846	\$1.75
October 17, 2019	Broker warrants	350,134	\$1.30
November 18, 2019	Stock options	1,030,000	\$1.30
March 17, 2020	Broker warrants	456,016	\$3.10

### BOARD OF DIRECTORS AND MANAGEMENT

The following are the names and municipalities of residence of each of the directors and officers of the Company, the positions and offices held with the Company, their respective principal occupations within the five preceding years and the number and percentage of Common Shares beneficially held by each of them as of the date hereof. Each director will hold office until the next annual meeting of the Company, unless his or her office is earlier vacated in accordance with the CBCA or the by-laws of the Company.

Name, State/ Province and Country of Residence	Positions with the Company and, if Director, Date First Elected	Principal Occupation(s) for Past 5 Years	Number and Percentage of Common Shares Owned <sup>(1)</sup>
<b>Fahar</b> <b>Merchant</b> Toronto, Ontario, Canada	President, Chief Executive Officer and Director October 30, 2011 <sup>(6)</sup>	President and Chief Executive Officer of Medicenna	5,250,000 <sup>(5)</sup> (10.82%)
<b>Albert Beraldo</b> Toronto, Ontario, Canada	Director <sup><math>(2)(4)</math></sup> November 22, 2016 <sup><math>(6)</math></sup>	President of Idoman Ltd. (July 2008 to present)	225,000 (0.09%)
Karen Dawes Palm Beach Gardens, Florida, United States	Director <sup>(2)(4)</sup> September 24, 2019	President, Knowledgeable Decisions, LLC (2003 to present)	25,000 (0.05%)
<b>Chandrakant</b> <b>Panchal</b> Dollard-des- Ormeaux, Quebec, Canada	Director <sup>(2)(3)</sup> November 22, 2016 <sup>(6)</sup>	Chairman, CEO and CSO of Axcelon Biopolymers Corp. (2001 to present)	1,500 (0.00%)
<b>Andrew</b> <b>Strong</b> Houston, Texas, United States	Director <sup>(3)(4)</sup> November 22, 2016 <sup>(6)</sup>	Partner, Pillsbury Winthorp Shaw Pittman LLP (March 2015 to present) President and CEO of Kalon Biotherapeutics LLC (June 2011 to March 2015)	50,000 (0.10%)
<b>Rosemina</b> <b>Merchant</b> Toronto, Ontario, Canada	Chief Development Officer and Director April 25, 2016 <sup>(6)</sup>	Chief Development Officer of Medicenna (October 30, 2011 to present)	5,250,000 <sup>(5)</sup> (10.82%)
<b>Elizabeth</b> <b>Williams</b> Georgetown, Ontario, Canada	Chief Financial Officer, Corporate Secretary	Chief Financial Officer of Medicenna (December 2016 to present)	5,300 (0.00%)

Notes:

- (1) Based on 48,500,376 Common Shares outstanding as of the date hereof.
  (2) Member of the Company's Audit Committee.
  (3) Member of the Company's Corporate Governance and Nominating Committee.

- (4) Member of the Company's Compensation Committee.
- (5) In addition, an aggregate of 5,500,000 Common Shares (representing 11.34% of the outstanding Common Shares) are held by Aries Biologics Inc. Fahar Merchant and Rosemina Merchant each own 50% of the voting shares, and are a director and officer, of Aries Biologics Inc.
- (6) Represents the date the individual was first appointed as director of MTI. Each such director was appointed as director of the Company effective March 1, 2017 in connection with the completion of the Transaction.

#### **Biographies of Executive Officers and Directors**

**Fahar Merchant** – Chairman, President and CEO – Dr. Merchant is a biotech veteran with more than 30 years' experience, a serial entrepreneur and co-founder of Medicenna. Previously he was President and CEO of Protox Therapeutics Inc. (TSXV and TSX; now Sophiris, Nasdaq) where he established a late clinical stage urology company. At Protox Therapeutics Inc. he raised over \$70 million through multiple PIPEs, including a \$35 million investment by Warburg Pincus. In 1992, he co-founded IntelliGene Expressions, Inc., a biologics CDMO, and built it to one of the fastest growing companies in Canada. In 2000, by strategic in-licensing, he co-founded Avicenna Medica, Inc., a clinical stage oncology company that was sold a year later to KS Biomedix (LSE) for \$90 million. Fahar was CTO and Director of KS Biomedix until its acquisition by Xenova (Nasdaq and LSE; now Celtic Pharma). Fahar has closed several transactions valued at over \$300 million. He has a PhD in Biochemical Engineering from Western University.

Albert Beraldo – Director – Mr. Beraldo, CPA, CA, has over 30 years' experience in varying roles within the pharmaceutical/biotechnology industry. Mr. Beraldo has been the President of Idoman Limited since July 2008, a company dedicated to improving the lives of women through the manufacture and distribution of innovative, minimally invasive medical solutions. Mr. Beraldo was the founder and President and Chief Executive Officer of Alveda Pharmaceuticals Inc., a leading supplier of pharmaceuticals to the Canadian health care market, from 2006 until November 2015. Alveda was acquired by Teligent, Inc. (formerly IGI Laboratories, Inc., Nasdaq), a New Jersey-based specialty generic pharmaceutical company. Mr. Beraldo formerly served as President and CEO of Bioniche Pharma Group Limited until 2006. Mr. Beraldo sits on the board of Pure Global Cannabis Inc. (TSXV) and has served as an Independent Director of Telesta Therapeutics Inc. (July 2011 to February 2014). Mr. Beraldo worked in public accounting with Ernst and Whinney until he joined Vetrepharm Canada Inc. as Financial Controller in 1983. Mr. Beraldo obtained a Bachelor of Commerce degree from the University of Windsor and a Chartered Accountant designation from the Canadian Institute of Chartered Accountants.

**Karen A. Dawes** – Director – With 20+ years of commercial and executive management Ms. Dawes has been a key player in the successful development, launch and marketing of products in the Cardiovascular, CNS, Oncology, Metabolic, Infectious Disease and Women's and Men's Health areas, including five blockbuster therapeutics. Karen's industry experience began with 10 years of commercial and executive management at Pfizer, where she gained increasing responsibility in product management, development, and strategy leading to her position as Vice-President, Marketing, Pratt Division. Karen then moved to biotech pioneer Genetics Institute (GI), where, as Chief Commercial Officer, she built the company's initial commercial operations including strategic and operational marketing, sales, medical affairs, public relations, and market research. When GI was acquired by Wyeth, Karen was appointed by the new parent company as Senior Vice-President, Global Strategic Marketing. Subsequently, Karen moved to Bayer Corporation as Division Head for the company's U.S. Pharmaceuticals Division. Ms. Dawes is

currently President of Knowledgeable Decisions, a biopharmaceutical consulting firm focusing on corporate and commercial strategy. Ms. Dawes also serves as the chairperson of the board of directors of RepliGen (NASDAQ: RGEN) and is a member of the board of directors of Assertio Therapeutics, Inc. (NASDAQ: ASRT) and Medicines360. Karen has a combined B.A and M.A from Simmons College and an MBA from Harvard Business School.

**Chandrakant Panchal** – Lead Independent Director – Dr. Panchal is the Founder of Axcelon Biopolymers Corp., a biotechnology company where he is Chairman, CEO and CSO. From 1989 to 1999 he was Co-Founder, President, and CEO of Procyon Biopharma Inc., which he took public on the TSXV in 1998 and later on the TSX in 2000. Thereafter, Dr. Panchal was CSO at Procyon until its merger with Cellpep, Inc (2006). He was then Senior Executive VP of Business Development at the merged entity, Ambrilia Biopharma Inc. During his term at Procyon and Ambrilia, he led several licensing and M&A transactions with pharmaceutical and biotechnology companies relating to cancer and HIV drugs developed by the company. Dr. Panchal sits on the boards of Pure Global Cannabis Inc. (as Chairman) (TSXV:PURE), Canadian Oil Recovery & Remediation Enterprises (TSXV:CVR), Avicanna Inc.(as Lead Director) (TSX:AVCN) and was until recently, a board member of MaRS Innovation and Avivagen (TSXV:VIV). Dr. Panchal obtained a PhD in biochemical engineering from Western University.

**Andrew Strong** – Director - Mr. Strong has been a partner at Pillsbury Winthrop Shaw Pittman since 2015 and leads the Life Sciences Team (Houston, TX). Mr. Strong represents life sciences companies from early stage biotech start-ups to publicly traded and fully integrated pharmaceutical companies. From 2009 to 2011,Mr. Strong served as the General Counsel and Compliance Officer for the Texas A&M University System where he led efforts to secure a multi-billion dollar federal contract to serve as a first line of defense for influenza pandemics and biological threats. As part of that effort, he led the formation of a state-owned biomanufacturing company (Kalon Biotherapeutics) and was subsequently appointed founding CEO of Kalon that would develop and manufacture biologics for clinical and commercial supply for pharmaceutical and biotech companies. In addition to raising capital, Mr. Strong oversaw the successful sale, in 2014, of Kalon to a subsidiary of FUJIFILM Corporation and Mitsubishi Corporation. Mr. Strong has a J.D., Law from South Texas College of Law. Mr. Strong was a Director and Chair of the Compensation Committee for Braemer Hotels & Resorts which is listed on the NYSE from November 2013 to May 2017.

**Rosemina Merchant** – Director and Chief Development Officer – Ms. Merchant has 30 years of experience in the development of biopharmaceuticals. Most recently, Ms. Merchant was Senior VP of Development and Regulatory Affairs at Sophiris and responsible for development of PRX302 for prostate cancer and BPH. She transitioned PRX302, a discovery project to a late stage clinical program in less than 6 years. During that time, she executed multiple clinical trials, managed Canadian and United States regulatory filings and led all CMC related outsourcing activities in the United States and Europe. In 1992, Nina co-founded IntelliGene Expressions, Inc., a biologics CDMO, where she was VP of Manufacturing and Chief Operating Officer. Nina also held a variety of senior level positions at KS Biomedix, Bioniche, GE LifeSciences, Sanofi Pasteur and Alberta Innovates. Her education includes a MESc. in Biochemical Engineering from Western University.

**Elizabeth Williams** – Chief Financial Officer – Ms. Williams, CPA, CA has more than 15 years of experience in biotech, working with publicly listed entities in both Canada and the United States. Ms. Williams has extensive financing experience playing an integral role in raising more than \$150 million in financing by way of public offerings, private placements, rights offerings, at-the-market facilities, warrant exercises, corporate reorganizations and debt (issuance and

redemption). Prior to joining Medicenna, Ms. Williams was the Vice President of Finance and Administration at Aptose Biosciences Inc. (previously Lorus Therapeutics Inc., TSX and Nasdaq), a biotechnology company ("Aptose"). While at Aptose, Ms. Williams held several positions including acting as the Chief Financial Officer during a lengthy transition period and was responsible for a broad range of activities including financings, financial reporting and regulatory compliance. Prior to joining Aptose, Ms. Williams was an Audit Manager at Ernst & Young LLP with a focus on publicly listed multinational companies. Ms. Williams is a Chartered Professional Accountant and Chartered Accountant and received a Bachelor of Business Administration from Wilfrid Laurier University.

### Shareholdings of Directors and Executive Officers

As at the date hereof, the directors and executive officers of the Company as a group beneficially own, directly or indirectly, or exercise control or direction over 16,306,800 or approximately 33.6% of the number of issued and outstanding Common Shares.

### CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

#### **Cease Trade Orders**

To the knowledge of the Company, no director or executive officer of the Company is, or within the ten years prior to the date hereof has been, a director, chief executive officer, or chief financial officer, of any company (including the Company) that was subject to (a) a cease trade order; (b) an order similar to a cease trade order; or (c) an order that denied the relevant company access to any exemption under securities laws, that was in effect for a period of more than thirty consecutive days, issued while that person was acting in such capacity or issued thereafter but resulted from an event that occurred while that person was acting in such capacity.

### **Bankruptcies**

To the knowledge of the Company, no director or executive officer or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company is, or within the ten years prior to the date hereof has been, a director or executive officer of any company (including the Company) that, while that person was acting in such capacity or within a year of that person ceasing to act in such capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets.

To the knowledge of the Company, no director or executive officer or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company has, within the ten years prior to the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement, or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold that person's assets.

#### **Penalties and Sanctions**

No director or executive officer of the Company, or a shareholder holding a sufficient number of securities of Medicenna to affect materially the control of the Company has been subject to (a) any penalties or sanctions imposed by a court relating to securities laws or by a securities

regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

All of the above disclosure also applies to any personal holding companies of any of the persons referred to above.

### CONFLICTS OF INTEREST

Certain of the Company's officers and directors are also officers and/or directors of other, or may otherwise be involved with or consulted by, companies engaged in the biotechnology industry and research business generally and may be presented from time to time with situations or opportunities which give rise to apparent conflicts of interest which cannot be resolved by arm'slength negotiations but only through exercise by the officers and directors of such judgment as is consistent with their fiduciary duties to the Company which arise under applicable corporate law, especially insofar as taking advantage, directly or indirectly, of information or opportunities acquired in their capacities as directors or officers of the Company. Any such conflict is governed by applicable corporate laws, which require that directors act honestly, in good faith and with a view to the best interests of the Company. It is expected that any transactions with officers and directors will be on terms consistent with industry standards and sound business practice in accordance with the fiduciary duties of those persons to the Company, and, depending upon the magnitude of the transactions and the absence of any disinterested board members, may be submitted to the shareholders for their approval.

In addition, the CBCA requires officers and directors to disclose any personal interest which they may have in any material contract or transaction which is proposed to be entered into with the Company and, in the case of directors, to abstain from voting as a director for the approval of any such contract or transaction, unless otherwise permitted under the CBCA.

### LEGAL PROCEEDINGS AND REGULATORY ACTIONS

There are no existing or contemplated material legal proceedings to which Medicenna or a subsidiary of Medicenna is a party or of which any of their respective property is the subject matter and no such proceedings known to Medicenna is contemplated. Medicenna has not had any material penalties or sanctions imposed against it by any legal or regulatory authorities.

#### INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as otherwise set out herein, there are no material interests, direct or indirect, of any director, executive officer, person who beneficially owns, or controls or directs, directly or indirectly, more than 10% of the outstanding Common Shares, or any known associates or affiliates of such persons, in any transaction within the last three completed financial years or during the current financial year which has materially affected or is reasonably expected to materially affect the Company.

#### TRANSFER AGENT

The Company's registrar and transfer agent is TSX Trust Company, located at 301 – 100 Adelaide St. West, Toronto, Ontario, M5H 4H1.

#### MATERIAL CONTRACTS

The Company is not party to any material contract that was entered into either (1) in the last completed fiscal year, or (2) before the most recently completed fiscal year but that is still in effect as of the date hereof, except for contracts entered into in the ordinary course of business and as set out below:

- 1. the warrant indenture dated October 17, 2019 between the Company and TSX Trust Company regarding the provision for issuance of the unit warrants from the October 2019 public offering;
- 2. the warrant indenture dated December 21, 2018 between the Company and TSX Trust Company regarding the provision for issuance of the unit warrants from the December 2018 public offering;
- 3. the license agreements with Stanford made effective as of August 21, 2015, and subsequent amendments;
- 4. the NIH License Agreement and subsequent amendments; and
- 5. the CPRIT grant agreement made effective as of March 1, 2015, and subsequent extensions.

#### INTEREST OF EXPERTS

The Company's registered public accounting firm is Davidson & Company LLP. Davidson & Company LLP has advised that they are independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Chartered Professional Accountants of Ontario (registered name of the Institute of Chartered Accountants of Ontario) and the rules and standards of the Public Company Accounting Oversight Board (United States) and the securities laws and regulations administered by the United States Securities and Exchange Commission.

Except as disclosed herein, no person or company whose profession or business gives authority to a report, valuation, statement or opinion made by the person or company and who is named as having prepared or certified the report, valuation, statement or opinion described in or included in this AIF or a filing made under National Instrument 51-102 by the Company, during, or relating to, the Company's most recently completed financial year holds more than 1% beneficial interest, direct or indirect, in any securities or other property of the Company or of an associate or affiliate of the Company and no such person is expected to be elected, appointed or employed as a director, senior officer or employee of the Company or of an associate or affiliate of the Company.

#### ADDITIONAL INFORMATION

Additional information about us may be found on SEDAR at www.sedar.com. Additional information, including directors' and officers' remuneration and indebtedness, principal holders of our securities, options to purchase securities and securities authorized for issuance under equity compensation plans, is contained in our Management Information Circular for our most recent annual meeting of shareholders. Additional information may also be found in our audited financial statements and related management's discussion and analysis for our most recently completed financial year.

#### SCHEDULE A AUDIT COMMITTEE INFORMATION

#### a) Audit Committee Charter

See Appendix 1 attached hereto.

#### b) Composition of the Audit Committee

The Audit Committee of the Company is currently comprised of Mr. Alberto Beraldo (Chairman), Dr. Chandrakant Panchal and Ms. Karen Dawes. All members of the Audit Committee are considered to be independent and financially literate within the meaning of National Instrument 52-110 – *Audit Committees* ("NI 52-110").

#### c) Relevant Education and Experience

The relevant education and experience of each member of the Audit Committee is provided above, under the heading "Board of Directors and Management". All of the Audit Committee members are independent of management of the Company as required by the TSX and each member is financially literate in that he or she has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements. Each individual has experience managing a company as the President and/or Chief Executive Officer or, in the case of Mr. Beraldo, as both the Chief Executive Officer and chief Financial Officer and, in those roles, reviewing financial statements and reports. Mr. Albert Beraldo, Chairman of the Audit Committee, is the Financial Expert of the Committee and is a CPA, CA with many years of experience as the Chief Financial Officers, each member of the Audit Committee has experience serving on public company boards.

#### d) Audit Committee Oversight

At no time since the commencement of the Company's most recently completed financial period was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the board of directors.

#### e) Reliance on Certain Exemptions

At no time since the commencement of the Company's most recently completed financial period has the Company relied on the following exemptions under NI 52-110: section 2.4 (*De Minimis Non-Audit Services*), section 3.2 (*Initial Plublic Offerings*), section 3.4 (*Events Outside Control of Member*), section 3.5 (*Death, Incapacity or Resignation of Audit Committee Member*), or an exemption from NI-52-110 in whole or in part, granted under Part 8 (*Exemptions*) thereof.

#### f) Pre-Approval Policies and Procedures

The Audit Committee has adopted specific policies and procedures for the engagement of non-audit services, as described in the Audit Committee Charter attached hereto as **Appendix 1** to this Schedule A.

YEAR ENDING	AUDIT FEES	AUDIT RELATED FEES	TAX FEES	ALL OTHER FEES	TOTAL FEES
March 31, 2020	\$49,627	\$14,122	\$5,750	NIL	\$69,499
March 31, 2019	\$48,805	\$5,000	\$20,950	NIL	\$74,755
March 31, 2018	\$49,725	NIL	NIL	NIL	\$49,725

#### g) External Auditor Service Fees

"Audit Fees" refers to the aggregate fees billed by the Company's external auditors for audit services including interim reviews. "Audit Related Fees" refers to aggregate fees billed for assurance and related services by the Company's external auditors that are reasonably related to the performance of the audit or review of the Company's financial statements and not reported under Audit Fees, including the provision of comfort letters and consents, the consultation concerning financial accounting and reporting of specific issues and the review of documents filed with regulatory authorities. "Tax Fees" includes fees for professional services rendered by the Company's external auditors for tax compliance, tax advice and tax planning. "All Other Fees" includes all fees billed by the Company's external auditors for services not covered in the other three categories.

#### APPENDIX 1 AUDIT COMMITTEE CHARTER



#### 1. PURPOSE

The primary function of the audit committee (the "Committee") is to assist the Board of Directors (the "Board") of Medicenna Therapeutics Corp. (the "Company") in fulfilling its oversight of, and recommend appropriate actions with respect to (i) the integrity of the Company's financial statements, accounting and financial reporting processes, system of internal controls over financial reporting and audit process, (ii) the Company's compliance with, and process for monitoring compliance with, legal and regulatory requirements so far as they relate to matters of financial reporting, (iii) the independent auditor's qualifications, independence and performance and (iv) the design, implementation and performance of the Company's internal audit function.

The members of the Committee are not full-time employees of the Company and may or may not be accountants or auditors by profession or experts in the fields of accounting or auditing and, in any event, do not serve in such capacity. Consequently, it is not the duty of the Committee to conduct audits or to determine that the Company's financial statements and disclosures are complete and accurate and are in accordance with generally accepted accounting principles and applicable laws, rules and regulations. These are the responsibilities of management and the external auditors.

#### 2. COMPOSITION

(a) <u>At Least Three Members</u>. The Committee shall be comprised of a minimum of three directors as determined by the Board upon the recommendation of the Corporate Governance and Nomination Committee. All of the members of the Committee shall be "independent" as determined by the Board in compliance with applicable securities laws and applicable rules and guidelines of any stock exchange on which the securities of the Company are listed and any other laws applicable to the Company, including National Instrument 52-110 – *Audit Committees*.

All members of the Committee shall also be "financially literate", meaning the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements. At least one member of the Committee shall be a "financial expert", as such term is defined by the U.S. Securities and Exchange Commission, and have, as determined by the Board, financial sophistication (including past employment experience in finance or accounting, requisite professional certification in accounting, or any other comparable experience or background which results in the individual's financial sophistication, including being or having a been a chief executive officer, chief financial officer or other senior officer with financial oversight responsibilities). The Board shall designate a Committee member as the Chairperson of the Committee, or if the Board does not do so, the Committee members shall appoint a Committee member as Chairperson by a majority vote of the full Committee membership.

(b) <u>Appointment and Removal</u>. The Board shall appoint Committee members and designate the Committee's "financial expert(s)" at the first meeting of the Board following each Annual General Meeting upon the recommendation of the Corporate Governance and Nomination Committee. Such members shall meet the independence, experience and expertise requirements under applicable securities law and the applicable rules and guidelines of any stock exchange on which the securities of the Company are listed and applicable policies of the Board. Members of the Committee shall serve for one year terms and until their successors are appointed. The Board may fill vacancies on the Committee by a majority vote of the authorized numbers of directors, but may remove Committee members only with the approval of a majority of the other independent directors then serving on the full Board.

### 3. MEETINGS, REPORTS AND RESOURCES OF THE AUDIT COMMITTEE

(a) <u>Meetings</u>. In discharging its responsibilities, the Committee shall meet as often as it determines necessary or advisable, but not less frequently than quarterly. The Committee may also hold special meetings or act by unanimous written consent as the Committee may decide. The meetings may be in person or telephone. The Committee shall keep written minutes of its meetings and shall deliver a copy of such minutes to the Board and to the corporate secretary of the Company for inclusion in the Company's minute books, and reports of Committee meetings will be presented at the next regularly scheduled Board meeting. The Committee may meet in separate executive sessions with other directors, the CEO and other Company employees, agents or representatives invited by the Committee. At least annually, the Committee will also meet separately with the independent auditors and/or the held of internal audit (or, if applicable, internal audit service providers), without management present.

(b) <u>Procedures</u>. The Committee may establish its own procedures, including the formation and delegation of authority to subcommittees, in a manner not inconsistent with this charter, the articles, applicable securities laws, or the applicable rules and guidelines of any stock exchange on which the securities of the Company are listed. The Chairperson or majority of the Committee members may call meetings of the Committee. A majority of the authorized number of Committee members shall constitute a quorum for the transaction of Committee business, and the vote of a majority of the Committee members present at the meeting at which a quorum is present shall be the act of the Committee. The Committee shall review and reassess at least annually the adequacy of this charter and recommend to the Board for approval any proposed changes, including any changes necessary to comply with applicable securities laws and applicable rules and guidelines of any stock exchange on which the securities of the Company are listed and any other laws applicable.

(c) <u>Resources</u>. The Committee shall have the authority, in its sole discretion, to (i) engage independent counsel and other advisors as it determines necessary to carry out its duties, (ii) set and pay the compensation for any advisors employed by the Committee, and (iii) communicate directly with the internal and external auditors. The Company shall provide funding, as determined appropriate by the Committee and in the Committee's sole authority, for payment of compensation to any registered public accounting firm engagement for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company; compensation to any advisers employed by the Committee, as it determines necessary to carry out its duties; and ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out the Committee's duties.

### 4. AUTHORITY AND RESPONSIBILITIES

In furtherance of its purpose, the Committee shall have the following authority and responsibilities:

- be directly responsible for appointing and recommending to the Board and the shareholders: (i) the external auditor for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company; and (ii) the compensation of the external auditor;
- (b) be directly responsible for retaining and overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the external auditor regarding financial reporting, with the external auditor reporting directly to the Committee;
- (c) pre-approve all non-audit services to be provided to the Company or its subsidiary entities by the Company's external auditor in accordance with the pre-approval process noted below;
- (d) review the accounting principles and practices to be applied and followed by the Company during the fiscal year and any significant changes from those applied and followed during the previous year;
- review the adequacy of the systems of internal accounting and audit policies, practices and controls established by the Company, and discuss with the auditor the results of its reviews and reports;
- (f) review all litigation and claims involving or against the Company which could materially adversely affect its financial position and which the auditor or any officer of the Company may refer to the Committee;
- (g) ensure that the auditor submits on a periodic basis to the Committee, and review and discusses at least annually with the auditor, a formal written statement delineating all relationships between the auditor and the Company, consistent with applicable auditor independence standards, and to review such statement and to actively engage in a dialogue with the auditor with respect to any disclosed or undisclosed relationships or services that may impact on the objectivity and independence of the auditor, and to review the statement and the dialogue with the Board and recommend to the Board appropriate action to ensure the independence of the auditor;
- (h) obtain written confirmation from the independent auditor that it is objective within the meaning of the Rules of Professional Conduct/Code of Ethics adopted by the provincial institute or order of Chartered Accountants to which it belongs and is an independent public accountant within the meaning of the Independence Standards of the Canadian Institute of Chartered Accountants and as required by applicable law or standards of the Public Company Accounting Oversight Board (the "PCAOB"), or any successor body;
- (i) meet with the auditor at least once per quarter without management present to allow a candid discussion regarding any concerns the auditor may have and to resolve any

disagreements between the auditor and management regarding the Company's financial reporting;

- (j) review the annual consolidated financial statements of the Company and the notes thereto following the examination thereof by the auditor and prior to their approval by the Board and report to the Board thereon;
- (k) review and approve the quarterly financial statements, notes thereto and quarterly management discussion and analysis (MD&A) and related press releases of the Company prior to their release;
- (I) review the annual MD&A, and other public disclosure documents and related press releases, including any prospectus prior to their approval by the directors.
- (m) be satisfied that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements and must periodically assess the adequacy of those procedures;
- establish procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters;
- (o) approve the Whistleblower Policy and review and assess the adequacy of the policy on an annual basis, or more often if deemed appropriate;
- (p) discuss with management and the external auditor any other matters required to be communicated to the Committee by the external auditor under applicable standards of the PCAOB or applicable law or listing standards;
- (q) review and approve the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditor of the Company;
- (r) review, approve and oversee any related-party transactions (as defined in applicable securities laws and stock exchange rules and guidelines);
- (s) review the adequacy of insurance policies maintained by the Company;
- (t) approve the Corporate Disclosure and Trading Policy and review and assess the adequacy of the policy on an annual basis, or more often if deemed appropriate; and
- (u) consider any other matter which in its judgment should be taken into account in reaching its recommendation to the Board concerning the approval of the financial statements.

#### 5. PRE-APPROVAL OF NON-AUDIT SERVICES

The Committee satisfies the pre-approval requirement of item 4(c) of its Responsibilities if:

(a) the aggregate amount of all the non-audit services that were not pre-approved is reasonably expected to constitute no more than five per cent of the total amount of fees

paid by the Company and its subsidiary entities to the Company's external auditor during the fiscal year in which the services are provided;

- (b) the Company or the subsidiary entity of the Company, as the case may be, did not recognize the services as non-audit services at the time of the engagement; and
- (c) the services are promptly brought to the attention of the Committee of the Company and approved, prior to the completion of the audit, by the Committee or by one or more of its members to whom authority to grant such approvals has been delegated by the Committee.

The Committee may delegate to one or more members the authority to pre-approve non-audit services in satisfaction of the requirement of item 4.(c) of its Responsibilities. The pre-approval of non-audit services by any member to whom authority has been delegated pursuant hereto must be presented to the Committee at its first scheduled meeting following such pre-approval.

The Committee satisfies the pre-approval requirement of item 4.(c) of its Responsibilities if it adopts specific policies and procedures for the engagement of the non-audit services, if: (i) the pre-approval policies and procedures are detailed as to the particular service; (ii) the Committee is informed of each non-audit service; and (iii) the procedures do not include delegation of the Committee's responsibilities to management.