



RAKOVINA THERAPEUTICS INC.

MANAGEMENT'S DISCUSSION AND ANALYSIS

**FOR THE THREE AND NINE MONTHS ENDED
SEPTEMBER 30, 2023**

RAKOVINA THERAPEUTICS INC.

Management's Discussion and Analysis

For the three and nine months ended September 30, 2023

The following management's discussion and analysis ("MD&A") for the three and nine months ended September 30, 2023 should be read in conjunction with the unaudited interim condensed consolidated financial statements of Rakovina Therapeutics Inc. ("Rakovina" or the "Company") for the three and nine months ended September 30, 2023 and the annual audited consolidated financial statements and accompanying notes for the year ended December 31, 2022 (the "Annual Financial Statements"), which have been prepared by management in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). Our IFRS accounting policies are set out in note 2 of the Annual Financial Statements and all dollar amounts are expressed in Canadian dollars unless otherwise noted.

This MD&A is dated November 27, 2023

FORWARD-LOOKING STATEMENTS

Certain statements and information in this MD&A contain forward-looking statements or forward-looking information under applicable Canadian securities legislation that may not be based on historical fact, including, without limitation, statements containing the words "believe", "may", "plan", "will", "estimate", "continue", "anticipate", "intend", "expect", "predict", "project", "potential", "ongoing", "could", "would", "seek", "target" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions.

Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as factors that we believe are appropriate. Forward-looking statements in this MD&A include, but are not limited to, statements relating to:

- the initiation, timing, cost, progress and success of our research and development programs;
- our ability to safely dose, re-dose, formulate and develop drug candidates;
- our ability and our current and potential future partners' ability to advance product candidates into, and successfully complete, clinical trials;
- the expected therapeutic benefits, effectiveness and safety of our product candidates, including our belief that our approach may reduce the risk, time and cost of developing therapeutics by avoiding some of the uncertainty associated with certain research and pre-clinical stages of drug development;
- our ability to obtain funding for our operations, including funding for research and commercial activities;
- our ability to obtain marketing approval for any of our products and to achieve profitability;
- our ability to establish and maintain relationships with collaborators with acceptable development, regulatory and commercialization expertise and the benefits to be derived from such collaborative efforts;
- our ability to enter into agreements or partnerships with pharmaceutical or biotechnology companies that have sales and marketing capabilities, which will enable us to increase our returns from our product candidates or to further accelerate development of our product candidates;
- the manufacturing capacity of third-party manufacturers for our product candidates;
- the implementation of our business model and strategic plans;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our expectations regarding federal, provincial and foreign regulatory requirements;
- the timing of, and our ability and our collaborator's ability, and the costs of obtaining and maintaining, regulatory approvals in the United States, Canada and other jurisdictions for our product candidates;
- the rate and degree of market acceptance and clinical utility of our future products, if any;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to engage and retain the consultants or employees required to grow our business;
- the compensation that is expected to be paid to consultants or employees of the Company;
- our future financial performance and projected expenditures;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available;
- our expectations regarding the kt-2000 series, kt-3000 series and kt-4000 series candidates;
- our expectations regarding the size and growth of the cancer therapeutics and PARP-inhibitor markets; and estimates of our expenses, future revenue, capital requirements and our needs for additional financing.

Such forward-looking statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Rakovina as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our

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actual results, performance, achievements, prospects or opportunities to be materially different from any future results, performance or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this MD&A, the Company has made various material assumptions, including, but not limited to: (i) obtaining positive results of preclinical research and clinical trials; (ii) obtaining regulatory approvals; (iii) assumptions regarding general business and economic conditions; (iv) assumptions regarding the cost and timing of each study; (v) that the Company's current positive relationships with third parties will be maintained; (vi) the availability of financing on reasonable terms; (vii) the Company's ability to attract and retain skilled consultants; (viii) assumptions regarding market competition; (ix) the products and technology offered by the Company's competitors and (x) the Company's ability to protect patents and proprietary rights.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the heading "*Risk Factors*". Should one or more of these risks or uncertainties, or a risk that is not currently known to us, materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A and we do not intend, and do not assume any obligation, to update these forward-looking statements except as required by applicable securities laws. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.

COMPANY OVERVIEW

Rakovina Therapeutics Inc. (the "Company" or "Rakovina") was incorporated under the *Business Corporations Act* (British Columbia) on May 6, 2019 under the name "Vincero Capital Corp." On February 7, 2020, the Company listed its shares on the TSX Venture Exchange ("TSX-V") as a capital pool company ("CPC") (as defined in the TSX-V Policy 2.4 – *Capital Pool Companies*). On March 25, 2021, the Company completed a qualifying transaction with NewGen Therapeutics Inc. by way of a "three-cornered" amalgamation.

On April 1, 2021 following the completion of the Qualifying Transaction, the common shares of the Company (the "Common Shares") resumed trading on the TSX-V under the symbol "RKV". The Company's first financial year-end subsequent to the completion of the Qualifying Transaction was December 31, 2021. Subco has been identified for accounting purposes as the acquiror, and accordingly the reporting entity is considered to be a continuation of Subco and the net assets of Vincero are deemed to have been acquired by Subco.

Following completion of the Qualifying Transaction, the Company continued to conduct the biotechnology business previously conducted by Subco until March 23, 2021, when Subco and a subsidiary of the Company were amalgamated, with Amalco being the successor entity. The Company has acquired certain rights to three classes of novel preclinical small-molecule drug candidates with established *in vitro* proof-of-concept data. The Company has acquired worldwide rights, excluding the People's Republic of China, Hong Kong and Taiwan, to develop and commercialize the kt-2000 series under the terms of a purchase and patent assignment agreement dated March 19, 2021 between Subco and NewGen. The Company has also been granted an exclusive option to patents claiming prototype kt-3000 and kt-4000 series drug candidates under the terms of an Evaluation and Option Agreement with the inventor of the kt-2000 series. The Company is conducting lead optimization research on all three series in collaboration with the University of British Columbia ("UBC") under the terms of a collaborative research agreement. The Company's head office and registered and records office is located at Suite 105, 1008 Beach Avenue, Vancouver, British Columbia, V6E 1T7.

The Company, through its wholly owned subsidiary Rakovina Research Ltd., is principally engaged in the research and development of new cancer treatments based on DNA-damage response inhibitors ("DDRi"). The DNA-damage response ("DDR") systems are responsible for detecting and repairing damage to the DNA within our cells. Such damage can occur naturally due to errors during DNA replication or can be caused by exposure to mutagens such as ultraviolet light or toxins within the environment. The DDR systems within our cells are essential for cellular survival.

Approximately seventy-five percent of solid tumors harbor a defect in one or more DDR systems. Such defects can allow a mutation to avoid detection and become entrenched in the cell leading to the formation of a tumor. When this occurs, the cancerous cell loses the function of the defective DDR system(s) and becomes highly reliant on alternative DDR pathways or survival. This dependency may create opportunities for targeting by novel pharmaceutical therapies.

There are currently four "first-generation" FDA approved DDR-targeting drugs known as PARP inhibitors. Each of these drugs target a subset of enzyme family called poly ADP-ribose polymerases ("PARP"). PARP a key component of a DDR pathway called base excision repair ("BER"), which repairs single strand breaks in DNA. If not repaired, single-

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strand DNA breaks can evolve to lethal double-strand DNA breaks which must be repaired by other systems such as the homologous repair ("HR") system.

First-generation PARP inhibitors ("PARPi") target cancers that harbor a mutation in the BRCA gene. BRCA mutations represent a defect in the HR system that significantly reduces a cancer cell's ability to repair lethal double-strand DNA breaks. Cells with an HR-defect become heavily reliant on the BER system's single-strand repair mechanism for survival, and thus are uniquely susceptible to treatment with a targeted therapy such as a PARP-inhibitor which blocks or suppresses BER.

PARPi have become an important component of standard treatment in certain breast, ovarian and prostate cancers that harbor BRCA mutations. While PARP-inhibitors have greatly improved treatment outcomes for these patients, scientists and clinicians have also gained an understanding of their limitations. Such limitations include a limited ability to combine with other therapies due to toxicity, poor penetration of the central nervous system ("CNS") to treat CNS metastases, the emergence of resistance to treatment and limited utility in cancers not harboring a HR-defect. Recent research in the field is focused on the development of next-generation DDRi to address these limitations and further improve treatment outcomes.

Since inception, Rakovina Therapeutics has been conducting lead-optimization and preclinical research in the development of next-generation DDRi in collaboration with the University of British Columbia ("UBC") pursuant to a research collaboration agreement (the "UBC Collaboration Agreement"). The UBC Collaboration Agreement provides us with access to a world class research infrastructure at the Jack Bell Research Center and Robert Ho Research Center in Vancouver, British Columbia including capabilities in molecular pathology, cell imaging, mass spectrometry, protein production and biophysics as well as a vivarium for the conduct of *in vivo* pharmacology and toxicology research. In addition, an associated clinical trial unit has capability and experience in running Phase 1 thru Phase 3 human clinical trials in the cancer field. The research is led by the Company's president, Mads Daugaard, who is also a professor at UBC. The Company's goal is to advance multiple drug candidates into human clinical trials and obtain marketing approval for new cancer therapeutics from Health Canada, the United States Food and Drug Administration and similar international regulatory agencies.

To date, our lead-optimization research conducted has focused on the development of three novel series of DDRi drug candidates (kt-2000, kt-3000, and kt-4000). The aim of our lead-optimization research is to select lead candidates that demonstrate potential superiority to first-generation DDRi to address significant unmet medical needs in the treatment of cancer for advancement to human clinical trials.

In general, milestones in drug discovery and lead-optimization include establishing superiority of novel drug candidates benchmarked against select FDA-approved anti-cancer therapeutics in relevant *in vitro* and *in vivo* models and confirming preclinical safety, biodistribution and pharmacokinetic profiles within acceptable parameters for medicines in the oncology field.

The primary goal of our lead optimization research program will be realized by selecting one or more lead clinical candidates from the kt-2000, kt-3000 and/or kt-4000 series by achieving the following milestones:

1. Identification of one or more lead drug candidates that meet the proprietary benchmark target product profile demonstrating potential superiority to first-generation DDRi to address significant unmet medical needs in the treatment of cancer; and
2. Demonstration of an acceptable safety, biodistribution and pharmacokinetic profile to support advancement of a lead drug candidate to pivot human clinical trials.

We recently published a manuscript in the Journal of Clinical Cancer Research describing our lead pre-clinical candidate from the kt-3000 series, kt-3283. These data demonstrate kt-3283's potential to treat cancers that are resistant to first-generation PARPi.

kt-3000 Series

The kt-3000 series drug candidates are a patented, novel class of bi-functional small-molecule drug candidates designed to potently inhibit PARP and histone deacetylase (HDAC), an enzyme involved in DNA-replication and the initiation of DNA-damage response mechanisms. FDA-approved HDAC inhibitors (HDACi) are employed in the treatment of certain blood cancers.

Published research demonstrates that inhibiting HDAC restores sensitivity to PARPi by preventing activity of the BRCA gene. The combination of a PARP-inhibitor and an HDAC-inhibitor has shown promise in the laboratory but has been highly toxic in the clinical setting.

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By targeting dual mechanisms in a single molecule, we believe that kt-3000 series drug candidates have the potential to overcome clinical resistance that arises in response to PARP inhibitor treatment without the toxicity observed when combining two separate treatments.

We have presented preclinical data at peer reviewed scientific meetings demonstrating that select kt-3000 candidates retain anti-cancer activity despite the activation of resistance genes compared to an FDA-approved PARP-inhibitor, which loses potency upon re-establishment of BRCA activity.

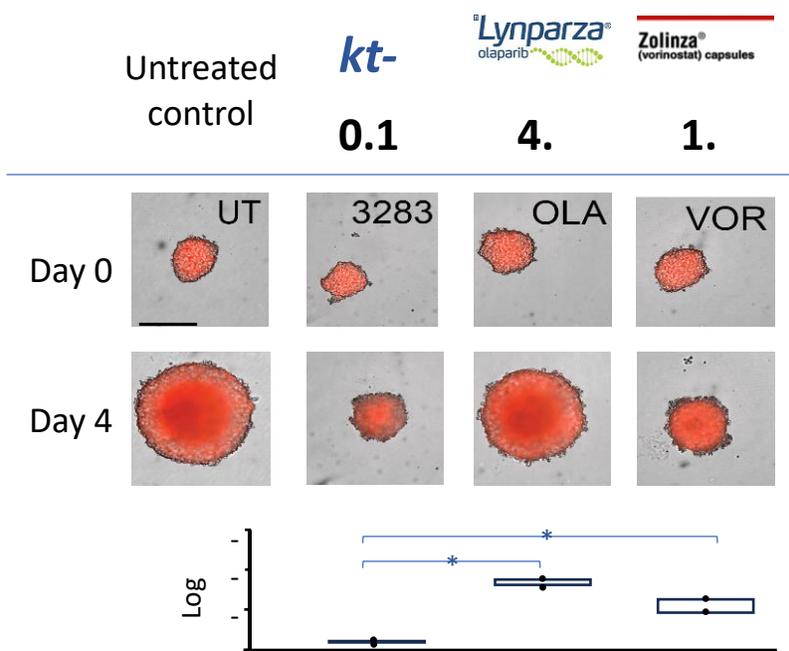
Select kt-3000 series drug candidates have been advanced to pilot toxicology and pharmacology studies. Lead candidates are being evaluated in in vivo models to support future regulatory filings to allow initiation of human clinical trials. Additional kt-3000 series analogues will also be synthesized and evaluated as potential lead candidates.

Lead pre-clinical candidate: kt-3283

kt-3283 is a novel small-molecule drug candidate that demonstrates potent bi-functional PARPi and HDACi activity in pre-clinical models. We recently published a paper in the Journal of Clinical Cancer Research demonstrating that kt-3283 achieves higher efficacy than treatment with single-agent PARP or HDAC inhibitors in pre-clinical models.

These data indicate the dual activity of kt-3283 is 10-times more potent than an FDA-approved PARPi against BRCA-mutant (HR-deficient) cancer cells *in vitro*. Against HR-proficient cancer cell-lines kt-3283 demonstrated 30- to 80-times greater potency than an FDA-approved PARPi, and 30- to 60-times more potent than an FDA-approved HDACi.

In an animal model, kt-3283 inhibited growth and metastasis of aggressive HR-proficient Ewing sarcoma cells in the lungs of mice. FDA-approved PARPi (Lynparza®) and FDA-approved HDACi (Zolinza®) failed to inhibit tumor growth in the same model.



In HR-proficient cell-cycle assays, kt-3282 demonstrates potent S/G2M arrest indicating supporting potential superiority to single-agent Lynparza or Zolinza and the combination of Lynparza + Zolinza, which demonstrated only moderate G2/M cycle arrest.

We believe that our research provides proof-of-concept to support the continued advancement of a lead candidate from the kt-3000 series toward human clinical trials based on the potential to address unmet medical needs in the treatment of Ewing sarcoma and potentially other cancers including leukemia, breast cancer, liver cancer, glioblastoma, prostate cancer and anaplastic thyroid cancer.

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kt-2000 Series

The kt-2000 series candidates are a patented class of next-generation oral, small molecule PARP inhibitors with established *in vitro* and *in vivo* proof of concept. Based on research completed to date, the kt-2000 series lead candidates demonstrate potency comparable to FDA approved PARP-inhibitors and potent anti-cancer activity in preclinical animal models.

The kt-2000 lead candidates are being optimized around potential differentiating factors and competitive advantages, including PARP-1 selectivity and the ability to cross the blood brain barrier. Current FDA-approved PARP inhibitors have limited ability to treat cancer that metastasizes to the brain and exhibit toxicity that has been associated with PARP-2 inhibition. We believe a potent PARP-1 selective, brain-penetrating kt-2000 series drug candidate may provide a significant improvement over the current standard of care.

Research and development activity over the next 12 months will focus on investigation and optimization of multiple lead candidates from the kt-2000 series in preclinical models. Additional kt-2000 series analogues will also be synthesized and evaluated as potential lead candidates.

kt-4000 Series

The kt-4000 drug candidates are a patented rationally designed class of small-molecule drug candidates that have been engineered to cause targeted DNA-damage to a tumor cell's DNA while simultaneously inhibiting the tumor's DNA damage response. The kt-4000 series DDR inhibitors molecular structure includes a potent moiety which cause targeted breaks in a tumor cell's DNA strands while also inhibiting DNA-damage repair mechanisms leading to cancer cell death.

We have presented preclinical data at a peer-reviewed scientific meeting demonstrating that select kt-4000 drug candidates cause double-strand DNA breaks while inhibiting PARP-mediated repair resulting in cell-cycle arrest and cancer cell death in a manner distinct from first-generation PARPi.

We believe that kt-4000 series drug candidates have the potential to expand the general utility of DDR-inhibitors to treat tumors that have become or are inherently resistant to first-generation DDRi. During the next 12 months, suitable candidates will be further evaluated in preclinical models.

RECENT ACHIEVEMENTS & HIGHLIGHTS

- On November 27, 2023, we announced the appointment Prof. Artem Cherkasov, Professor in the Department of Urologic Sciences, Faculty of Medicine at the University of British Columbia, and Senior Scientist at the Vancouver Prostate Centre and Canada Research Chair in Precision Cancer Drug Design, to our Scientific Advisory Board.
- On November 20, 2023, we announced the appointment of Prof. Petra Hamerlik, Chair of Translational Neuro-Oncology at the University of Manchester and former CNS Cancer Bioscience Lead at AstraZeneca plc, to our Scientific Advisory Board.
- During the past quarter, we have continued preclinical research activities with the aim of advancing a lead candidate from our kt-3000 series program into human clinical trials during 2024.
- In October 2023, we presented additional data from our kt-3000 series at the AACR-NCI-EORTIC Molecular Targets and Therapeutics Meeting. These data demonstrate the potential of kt-3000 series drug candidates to treat cancers that are resistant to first-generation PARPi and potential to address unmet medical needs in the treatment of a range of cancers including leukemia, breast cancer, liver cancer, glioblastoma, prostate cancer, Ewing sarcoma and anaplastic thyroid cancer.
- In July 2023, we published a peer reviewed manuscript in the Journal of Clinical Cancer Research describing pre-clinical data for a kt-3000 lead candidate, kt-3283, as a potential treatment for Ewing sarcoma, a rare childhood tumor.
- On May 29, 2023, we closed a non-brokered private placement of unsecured convertible debenture units of the Company (the "Debenture Units") for aggregate gross proceeds to the Company of \$1,514,000. Proceeds will be used for research and development expenses primarily to advance its lead kt-3000 dual function DNA-damage response inhibitor program toward human clinical trials and for general working capital purposes.
- On April 19, 2023, we presented new preclinical *in vitro* and *in vivo* data demonstrating the potential of our kt-3000 series against treatment-resistant Ewing sarcoma, a rare childhood tumor, at the annual meeting of the American Association of Cancer Research (AACR).

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- On March 30, 2023, we announced the engagement of Red Cloud Securities and Proactive Investors Nort America Inc as part of our evolving strategy to improve trading liquidity and increase awareness of our next-generation cancer therapy development pipeline.
- On March 23, 2023, we announced the extension of the expiry of 11,414,750 common share purchase warrants from March 24, 2023, to March 24, 2024. The exercise price of each warrant remains at \$0.40.
- On March 22, 2023, we announced the approval of up to \$122,865 in non-dilutive funding from the National Research Council of Canada industrial Research Assistance Program.
- On March 17, 2023, we presented new preclinical data describing progress in our lead optimization activities for our novel kt-3000 series at the EACR-AACR Basic and Translational Research Conference.
- On January 26, 2023, we announced that our president & chief scientific officer presented an address at the 6th Annual DDR-Inhibitors Summit describing research results supporting the activity of kt-3000 series drug candidate in pre-clinical models of Ewing sarcoma.

SELECTED FINANCIAL INFORMATION

The selected statements of net loss and comprehensive loss data for the periods presented and the selected statement of financial position data as of the dates presented are derived from the unaudited interim condensed consolidated financial statements.

Statements of financial position data:

| | As at September 30, 2023 | As at December 31, 2022 |
|---------------------------|-----------------------------|----------------------------|
| | \$ | \$ |
| Cash and cash equivalents | 813,328 | 896,831 |
| Working capital | 990,548 | 962,553 |
| Intangible assets | 4,650,180 | 5,051,160 |
| Total assets | 5,824,463 | 6,120,761 |
| Total liabilities | 1,497,611 | 107,048 |
| Deficit | (10,202,548) | (8,312,386) |
| Total equity | 4,326,852 | 6,013,713 |

Statements of net loss and comprehensive loss data:

| | Three months ended Sept 30, 2023 | Three months ended Sept 30, 2022 | Nine months ended Sept 30, 2023 | Nine months ended Sept 30, 2022 |
|--|--|--|---------------------------------------|---------------------------------------|
| | \$ | \$ | \$ | \$ |
| Research and development | 426,852 | 548,369 | 1,252,165 | 1,451,462 |
| General and administrative | 163,416 | 178,981 | 568,496 | 713,158 |
| Interest income | (7,425) | (10,474) | (18,393) | (21,082) |
| Interest expense | 45,793 | - | 61,721 | - |
| Accretion expense | 18,313 | - | 24,575 | - |
| Foreign exchange gain (loss) | 19 | (996) | 1,598 | 270 |
| Net loss and comprehensive loss | 646,968 | 715,880 | 1,890,162 | 2,143,808 |
| Basic and diluted loss per share | (0.01) | (0.01) | (0.03) | (0.03) |
| Weighted average shares outstanding (basic and diluted) | 69,829,500 | 69,829,500 | 69,829,500 | 69,829,500 |

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RESULTS OF OPERATIONS

Research and development expenses

| | Three months ended Sept 30, 2023 \$ | Three months ended Sept 30, 2022 \$ | Nine months ended Sept 30, 2023 \$ | Nine months ended Sept 30, 2022 \$ |
|-----------------------------------|--|--|---|---|
| Contract research - UBC Agreement | 108,500 | 152,250 | 369,250 | 456,750 |
| Amortization | 135,129 | 135,129 | 400,980 | 400,980 |
| Consulting | 84,576 | 75,247 | 260,076 | 249,195 |
| Chemistry and Manufacturing | 83,733 | 112,206 | 127,721 | 130,754 |
| Share-based payments | 12,620 | 42,889 | 57,994 | 146,234 |
| Patent and legal fees | 2,294 | 30,648 | 36,144 | 67,549 |
| | 426,852 | 548,369 | 1,252,165 | 1,451,462 |

Research and development expenses of \$426,852 and \$1,252,165 were incurred during the three and nine months ended September 30, 2023, compared with \$548,369 and \$1,451,462 incurred in the three and nine months ended September 30, 2022.

The decrease in R&D expenses during the three months ended September 30, 2023 relative to the three months ended September 30, 2022 is primarily due to the following:

- A decrease in Contract research costs related to the UBC contract from \$152,250 during the three months ended September 30, 2022 to \$108,500 for the three months ended September 30, 2023. The decrease was expected as the UBC contract was structured with lower payments during the final twelve months of the initial three-year term.
- A decrease in chemistry and manufacturing from \$112,206 for the three months ended September 30, 2022 to \$83,722 for the three months ended September 30, 2023. The decrease is primarily related to timing of chemistry and manufacturing expenses as overall activity levels have remained relatively constant throughout the year.
- A decrease in Patent and legal fees from \$30,648 for the three months ended September 30, 2022 to \$2,294 for the three months ended September 30, 2023. Patent and legal fees are not incurred equally throughout the year which can result in quarter over quarter variances that are not indicative of changing activity levels.
- A decrease in Share-based payment expense from \$42,889 for the three months ended September 30, 2022 to \$12,620 for the three months ended September 30, 2023. The decrease is due to the amortization of the fair value of stock options granted to officers, directors and advisors that are directly involved with the research and development activities of the Company which decreases over time as options vest.

The decrease in R&D expenses during the nine months ended September 30, 2023 relative to the nine months ended September 30, 2022 is primarily due to the following:

- A decrease in Contract research costs related to the UBC contract from \$456,750 during the nine months ended September 30, 2022 to \$369,250 for the nine months ended September 30, 2023. The decrease was expected as the UBC contract was structured with lower payments during the final twelve months of the initial three-year term.
- A decrease in Patent and legal fees from \$67,549 for the nine months ended September 30, 2022 to \$36,144 for the nine months ended September 30, 2023. Patent and legal fees are not incurred equally throughout the year which can result in quarter over quarter variances that are not indicative of changing activity levels.
- A decrease in Share-based payment expense from \$146,234 for the nine months ended September 30, 2022 to \$57,994 for the nine months ended September 30, 2023. The decrease is due to the amortization of the fair value of stock options granted to officers, directors and advisors that are directly involved with the research and development activities of the Company which decreases over time as options vest.

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General and administrative expenses

| | Three months ended Sept 30, 2023 | Three months ended Sept 30, 2022 | Nine months ended Sept 30, 2023 | Nine months ended Sept 30, 2022 |
|--------------------------|--|--|---------------------------------------|---------------------------------------|
| | \$ | \$ | \$ | \$ |
| Legal and professional | 16,356 | 36,811 | 112,640 | 250,387 |
| Corporate communications | 46,994 | 18,610 | 143,166 | 90,824 |
| Share-based payments | 12,848 | 19,870 | 33,416 | 70,070 |
| Consulting | 39,000 | 39,000 | 117,000 | 117,020 |
| Director fees | 25,683 | 30,186 | 80,620 | 95,099 |
| Rent | 10,500 | 10,500 | 31,500 | 28,000 |
| Other expenses | 12,035 | 24,004 | 50,154 | 61,758 |
| | 163,416 | 178,981 | 568,496 | 713,158 |

General and administrative expenses of \$163,416 and \$568,496 were incurred during the three and nine months ended September 30, 2023, compared with \$178,981 and \$713,158 incurred in the three and nine months ended September 30, 2022.

The net decrease in general and administrative expenses during the three months ended September 30, 2023 relative to the three months ended September 30, 2022 is primarily due to the following:

- A decrease in legal and professional expense from \$36,811 for the three months ended September 30, 2022 to \$16,356 for the three months ended September 2023. The decrease is primarily due to non-recurring legal expenses incurred in the prior period related to US shareholder registration matters.
- An increase in corporate communications expense from \$18,610 for the three months ended September 30, 2022 to \$46,994 for the three months ended September 2023. The increase is primarily attributable to the addition of ongoing marketing and liquidity service contracts relative during the second quarter to enhance trading liquidity and increase general market awareness of the Company.

The net decrease general and administrative expenses during the nine months ended September 30, 2023 relative to the nine months ended September 30, 2022 is primarily due to the following:

- A decrease in legal and professional expense from \$250,387 for the nine months ended September 30, 2022 to \$112,640 for the nine months ended September 2022. The decrease is primarily due to non-recurring legal expenses incurred in the prior period related to the completion and filing of the company's base shelf prospectus, and non-recurring financial advisory services incurred during the prior period.
- The reduction in legal and professional expenses were partially offset by an increase in corporate communications expense from \$90,824 for the nine months ended September 30, 2022 to \$143,166 for the nine months ended September 30, 2023. The increase is primarily attributable to the addition of marketing and liquidity service contracts during the second quarter to enhance trading liquidity and increase general market awareness of the Company.

Total cash expenses related to research and development and general and administrative expenses were \$429,671 and \$1,328,271 for the three and nine months ended September 30, 2023, respectively, versus \$529,462 and \$1,547,336, respectively, for the prior comparative period. The decrease in cash expenses relative to the comparative period is primarily due to a period over period decrease in legal and professional fees as discussed above.

SUMMARY OF QUARTERLY RESULTS

| | Sept 30, 2023 | Jun 30, 2023 | Mar 31, 2023 | Dec 31, 2022 | Sep 30, 2022 | Jun 30, 2022 | Mar 31, 2022 | Dec 31, 2021 |
|--|------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| | \$ | \$ | \$ | \$ | \$ | \$ | \$ | \$ |
| Net Loss | (646,968) | (601,404) | (641,790) | (647,426) | (715,880) | (715,975) | (711,953) | (751,353) |
| Basic and diluted loss per share | (0.01) | (0.01) | (0.01) | (0.01) | (0.01) | (0.01) | (0.01) | (0.01) |

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During the three and nine months ended September 30, 2023, the Company reported a net loss of \$646,968 and \$1,890,162, respectively, versus a net loss of \$715,880 and \$2,143,808 for the three and nine months ended September 30, 2022, respectively.

The net loss of \$646,968 incurred during the three months ended September 30, 2023 is consistent with the prior four quarters and is primarily attributable to research and development expenses of \$426,852 and general and administrative expenses of \$163,416.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity and Capital Resources

The Company's capital currently consists of equity and working capital. Its principal source of cash is from the issuance of common shares, warrants and convertible debt. The Company's capital management objectives are to safeguard its ability to continue as a going concern and to have sufficient capital to be able to further its research and development activities.

The Company does not have any externally imposed capital requirements to which it is subject. The Company manages the capital structure and adjusts it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Company may attempt to issue new shares.

The Company's capital needs are for funds to support its scientific research and development activities, including staffing, lead compound optimization, administrative costs and for working capital. The Company expects that its existing cash and cash equivalents as of September 30, 2023, will enable it to fund operating requirements for the next 12 months. The Company intends to raise additional capital during the first half of 2024 to progress its lead program into human clinical trials. However, there is no assurance that the financing will be obtained on terms favorable to the Company or at all. If the financing is not obtained, the Company may be required to take additional measures to address its liquidity needs, including reducing operating expenses or seeking alternative sources of financing.

The process of drug development can be costly, and the timing and outcomes of research related activities is uncertain. The assumptions upon which we have based our estimates are routinely evaluated and may be subject to change. The actual amount of our expenditures will vary depending upon several factors including but not limited to the design, timing and duration of lead optimization studies, the progress of our research and development programs, and the level of financial resources available.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2023 and 2022:

| | September 30, 2023 | September 30, 2022 |
|---|---------------------------|--------------------|
| | \$ | \$ |
| Cash used in operating activities | (1,484,695) | (1,466,931) |
| Cash provided by financing activities | 1,401,192 | 2,150 |
| Cash provided by investing activities | - | - |
| Net (decrease) / increase in cash and cash equivalents | (83,503) | (1,464,781) |

The Company realized a net cash outflow of \$83,503 for the nine months ended September 30, 2023, compared to a net cash outflow of \$1,464,781 for the nine months ended September 30, 2022. The variances in the cash flow for the nine months ended September 30, 2023, compared to September 30, 2022 were as follows:

Cash Flows Used in Operating Activities

Net cash used in operating activities was \$1,484,695 during the nine months ended September 30, 2023 compared to \$1,466,931 for the nine months ended September 30, 2022. The slight increase in cash used in operating activities for the current period primarily reflects cash used to increase non-cash working capital partially offset by a decrease in cash used to fund the net loss after adjusting for non-cash items. The increase in non-cash working capital related to an increase in prepaid expenses for marketing and liquidity services contracts.

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Cash Flows From Financing Activities

Net cash provided by financing activities was \$1,401,192 during the nine months ended September 30, 2023 compared to \$2,150 for the nine months ended September 30, 2022. Cash provided from financing activities of \$2,150 during the nine months ended September 30, 2022 was due to the exercise of 21,500 agent options. Cash provided from financing activities during the nine months ended September 30, 2023 was related to the convertible debenture issuance which closed on May 29, 2023.

OFF-BALANCE SHEET ARRANGEMENTS

As of the date of this MD&A, the Company does not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Company, including, and without limitation to, such considerations as liquidity and capital resources that have not previously been disclosed.

FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

The Company classifies its financial assets into the following specified categories: "amortized cost"; "fair value through other comprehensive income" ("FVTOCI"); and "fair value through profit or loss" ("FVTPL"). Financial liabilities are designated as FVTPL or classified as loans and borrowings measured at amortized cost. Classification depends on the purpose for which the financial assets and liabilities were acquired or incurred. Management determines the classification of its financial instruments at initial recognition.

Financial instruments consist of cash and cash equivalents, amounts receivable, and accounts payable and accrued liabilities, due to related parties and the liability component of convertible debt.

Fair values

The Company has classified its financial instrument fair values based on the required three level hierarchies:

Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2: inputs other than quoted prices included in Level 1, but that are observable for the asset or liability, either directly or indirectly; and

Level 3: inputs for the asset or liability that are not based on observable market data.

The fair value hierarchy level at which a fair value measurement is categorized is determined on the basis of the lowest level input that is significant to the fair value measurement in its entirety. The Company records cash and cash equivalents at fair value using level 1 inputs. There were no transfers from levels 1, 2 and 3 during the three and nine months ended September 30, 2023.

The fair values of cash and cash equivalents, amounts receivable, and accounts payable and accrued liabilities approximate the carrying values due to the short-term nature of these instruments.

There has been no significant change in the credit risk and concentrations, interest rate risk or liquidity risk during the three and nine months ended September 30, 2022.

Financial risk factors

The Company's risk exposures and the impact on the Company's financial instruments are summarized below:

Credit risk

Credit risk is the risk of loss associated with the counterparty's inability to fulfill its payment obligations. Financial instruments that potentially subject the Company to concentrations of credit risks consist of cash and cash equivalents and amounts receivable. The Company's cash and cash equivalents consists of funds held in a reputable Canadian bank. The amounts receivable is related to GST receivable from the Government of Canada and accrued interest from a reputable Canadian bank. Management actively reviews the risk of the financial institutions and/or the counterparty to underlying financial instruments failing to meet its obligations and adjusts if and when any undue risk is identified. At September 30, 2023, the Company does not believe it is currently exposed to any significant credit risk.

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Interest rate risk

Interest rate risk is the risk that changes in market interest rates may influence the cash flows associated with some financial instruments, known as interest rate cash flow risk, or on the fair value of other financial instruments, known as interest rate price risk. The Company is not exposed to any significant interest rate risk.

Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company currently settles its financial obligations out of cash. The ability to do this relies on the Company's ability to raise equity financing in a timely manner and by maintaining sufficient cash in excess of anticipated needs.

The Company is obligated to the following contractual maturities of undiscounted cash flows at September 30, 2023:

| | Amount | Year 1 | Year 2 | Year 3 | Total |
|---------------------------------|------------------|----------------|----------------|------------------|------------------|
| | \$ | \$ | \$ | and over | \$ |
| | | | | \$ | |
| Trade and other payables | 183,735 | 183,735 | - | - | 183,735 |
| Convertible debt ⁽¹⁾ | 1,514,000 | 181,680 | 181,680 | 1,604,840 | 1,968,200 |
| | <u>1,697,735</u> | <u>365,415</u> | <u>181,680</u> | <u>1,604,840</u> | <u>2,151,935</u> |

⁽¹⁾ The convertible debt and related interest can be settled in common shares of the Company at the option of the holders.

Foreign currency risk

The Company is exposed to foreign currency risk on fluctuations in foreign exchange rates for any cash and cash equivalents, amounts receivable, accounts payable, due to related parties, and accrued liabilities that are denominated in foreign currencies. The Company's foreign currency risk is primarily related to expenses denominated in United States dollars.

DIVIDEND POLICY

Since its incorporation, the Company has not paid any dividend on its common shares. Any future determination to pay dividends is at the discretion of the Company's Board of Directors and will depend on the Company's financial condition, results of operations, capital requirements and other such factors as the Board of Directors of the Company may deem relevant.

RELATED PARTY TRANSACTIONS

The key management personnel of the Company are the Directors, Executive Chairman, President and Chief Scientific Officer, Chief Operating Officer, and Chief Financial Officer. Amounts due to related parties, including amounts due to key management personnel, at the period-end are unsecured, interest free and settlement generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables.

As at September 30, 2023, the Company had amounts due to related parties of \$85,543 (December 31, 2022 - \$79,309) comprised of board fees, management compensation and reimbursable expenses. Compensation to key management personnel for the reporting period is as follows:

| | Three months ended | Three months ended | Nine months ended | Nine months ended |
|------------------------------------|---------------------------|--------------------|--------------------------|-------------------|
| | Sept 30, 2023 | Sept 30, 2022 | Sept 30, 2023 | Sept 30, 2022 |
| | \$ | \$ | \$ | \$ |
| Compensation / short term benefits | 118,278 | 130,939 | 374,197 | 386,196 |
| Board fees | 25,683 | 30,186 | 80,620 | 95,099 |
| Share-based payments | 23,729 | 53,693 | 79,305 | 189,237 |
| | <u>167,690</u> | <u>214,818</u> | <u>534,122</u> | <u>670,532</u> |

For the three and nine months ended September 30, 2023, the Company incurred rent expense of \$10,500, and \$31,500, respectively (2022 - \$10,500 and \$28,000, respectively) to a Director of the Company, pursuant to a short-term lease agreement for office space.

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The Company entered into a consulting agreement with Jeffrey Bacha, the Executive Chairman of the Company. Pursuant to this consulting agreement, Mr. Bacha is compensated at a rate of \$10,000 per month. During the three and nine months ended September 30, 2023, Mr. Bacha received \$30,000 and \$90,000, respectively (2022 - \$30,000 and \$90,000, respectively) in fees for management services. As of September 30, 2023, the Company has included in its accounts payable and accrued liabilities \$12,386 (December 31, 2022 - \$13,621) due to Mr. Bacha related to management services plus GST (\$10,500) and reimbursable expenses (\$1,886).

The Company entered into a consulting agreement with Daugaard Consulting and Mads Daugaard, the President and Chief Scientific Officer of the Company. Pursuant to this consulting agreement, Mr. Daugaard is compensated at a rate of \$11,970 per month. During the three and nine months ended September 30, 2023, Mr. Daugaard received \$35,910 and \$107,730, respectively (2022 - \$35,910 and \$107,730, respectively) in fees for management services. As of September 30, 2023, the Company has included in its accounts payable and accrued liabilities \$12,569 (December 31, 2022 - \$12,569) due to Mr. Daugaard related to management services plus GST.

The Company entered into a consulting agreement with Langlands & Associates Consulting Inc. and John Langlands, the Chief Operating Officer of the Company. Pursuant to this consulting agreement, Mr. Langlands is compensated at a rate of \$10,666 per month. During the three and nine months ended September 30, 2023, Mr. Langlands received management fees of \$31,998 and \$95,994, respectively (2022 - \$31,998 and \$95,994, respectively) in fees for management services. As of September 30, 2023, the Company has included in its accounts payable and accrued liabilities \$22,400 (December 31, 2022 - \$11,665) due to Mr. Langlands related to management services plus GST.

The Company entered into a consulting agreement with Tandem Innovation Group ("Tandem") and David Hyman, the Chief Financial Officer ("CFO") of the Company. Pursuant to this consulting agreement, Mr. Hyman is compensated at a rate of \$10,000 per month. During the three and nine months ended September 30, 2022, Tandem charged fees of \$30,000 and \$90,000, respectively, (2022 - \$30,000 and \$90,000, respectively) for CFO services. As of September 30, 2023, the Company has included in its accounts payable and accrued liabilities \$10,500 (December 31, 2022 - \$10,500) due to Tandem related to management services plus GST and to Mr. Hyman (\$2,005) for reimbursable expenses.

The Company pays its independent directors a fixed quarterly fee of \$8,750 plus \$1,875 for the audit committee chair and \$1,000 for audit committee members. As of September 30, 2023, the Company has included in its accounts payable \$8,137 (December 31, 2022 - \$8,137) for Al De Lucrezia, \$8,750 (December 31, 2022 - \$9,312) for Dennis Brown, and \$8,795 (December 31, 2022 - \$8,795) for Michael Liggett related to Director fees.

All related party transactions, whether monetary or non-monetary, are conducted in the normal course of business and are measured at fair value, which is the consideration established and agreed to by the related parties.

OUTSTANDING SECURITIES

As at November 27, 2023 the company has the following securities outstanding:

| | # |
|---------------------------------------|-------------------|
| Common shares | 69,829,500 |
| Warrants – Initial financing | 11,414,750 |
| Warrants – Convertible debt financing | 3,028,000 |
| Stock Options | 6,982,500 |
| Total | 91,254,750 |

On May 29, 2023, the Company closed a non-brokered private placement of unsecured convertible debenture units of the Company (the "Debenture Units") for aggregate gross proceeds to the Company of \$1,514,000. Each Debenture unit consists of one \$50,000 unsecured convertible debenture of the company and 100,000 share purchase warrants ("Warrants") with each Warrant entitling the holder thereof to acquire one common share of the Company (a "Warrant Share") at a price of \$0.15 per Warrant Share for a period of 30 months. The debentures are repayable in 30 months (unless earlier converted or redeemed) and will accrue interest at a rate of 12% per annum which is due and payable semi-annually in cash or common shares, at the option of the debenture holder. The Debenture holders will have the right to convert the principal amount of the Debenture into common shares of the Company at a conversion price of \$0.20 per share, which would result in the issuance of 7,570,000 common shares. The Company is entitled to redeem each Debenture starting 12 months following the Closing Date by paying a redemption premium on the outstanding principal amount of Debenture equal to 2%, subject to certain limitations.

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Escrow

As at the date of this report 4,612,500 common shares are held in escrow and will be released on March 31, 2024 based on the Company's escrow agreements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Please refer to the Annual Financial Statements for the year ended December 31, 2022.

There have been no changes to the Company's critical accounting policies and estimates for the three months ended September 30, 2023.

RISKS FACTORS

Investing in our securities involves a high degree of risk. Before deciding to invest in our securities, you should carefully consider the risks described in the Company's Annual Information Form, together with other information included in or incorporated by reference into this MD&A and filed on SEDAR at www.sedar.com. If any of the following risks materialize, the business, financial condition, results of operation and future prospects of the Company will likely be materially and adversely affected. This could cause actual future events to differ materially from those described in forward-looking statements and may cause the trading price of our securities to decline.