

**Algernon Pharmaceuticals Inc.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**  
**For the nine months ended May 31, 2023**

**Dated July 27, 2023**

Prepared by Management without review by the Company's auditor

# **ALGERNON PHARMACEUTICALS INC.**

## **Management's Discussion and Analysis**

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This Management's Discussion and Analysis ("MD&A") is intended to help the reader understand Algernon Pharmaceuticals Inc., ("Algernon" or the "Company"), its operations, financial performance, current and future business environment and opportunities and risks. This MD&A is intended to supplement and complement the audited consolidated financial statements and notes thereto, prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") for the year ended August 31, 2022 (the "financial statements").

This MD&A is prepared as of July 27, 2023. All dollar figures stated herein are expressed in Canadian dollars, unless otherwise specified.

For the purposes of preparing this MD&A, management, in conjunction with the Board of Directors, considers the materiality of information. Information is considered material if: (i) such information results in, or would reasonably be expected to result in, a significant change in the market price or value of the Company's common shares; or (ii) there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision; or (iii) if it would significantly alter the total mix of information available to investors. Management, in conjunction with the Board of Directors, evaluates materiality with reference to all relevant circumstances, including potential market sensitivity.

### **FORWARD LOOKING INFORMATION**

This MD&A contains forward-looking statements that relate to the Company's current expectations and views of future events. In some cases, these forward-looking statements can be identified by words or phrases such as "may", "might", "will", "expect", "anticipate", "estimate", "intend", "plan", "indicate", "seek", "believe", "predict" or "likely", or the negative of these terms, or other similar expressions intended to identify forward-looking statements. The Company has based these forward-looking statements on its current expectations and projections about future events and financial trends that it believes might affect its financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, among other things, statements relating to:

- the Company's intentions with respect to its business and operations;
- the Company's expectations regarding its ability to raise capital and grow its business;
- the Company's expectations with regard to its marketing and promotional programs;
- the Company's growth strategy and opportunities; and
- anticipated trends and challenges in the Company's business and the industry in which it operates.

Forward-looking information is based on reasonable assumptions, estimates, analysis and opinions of the Company's management in light of its experience and its perception of trends, expected developments, current conditions, as well as other factors that the Company's management believes to be relevant and reasonable in the circumstances at the date of this MD&A, but which may prove to be incorrect. The Company believes that the expectations and assumptions reflected in such forward-looking information are reasonable. Key assumptions upon which the Company's forward-looking information is based include:

- those related to general economic conditions;
- those related to conditions, including competitive conditions, in the market in which the Company operates;
- those related to the Company's use of marketing and promotional materials;
- the Company's ability to obtain requisite licences and necessary governmental approvals;
- the Company's ability to attract and retain key personnel; and
- the impact of the COVID-19 outbreak on the Company's operations.

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Readers are cautioned that the foregoing list is not exhaustive of all factors and assumptions which may have been used. Forward-looking statements are also subject to risks and uncertainties facing the Company's business, any of which could have a material impact on its outlook.

Some of the risks the Company faces and the uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements include:

- the COVID-19 outbreak and its effect on the Company's business;
- the Company's dependence on management, key personnel and consultants;
- the Company's dependence on laboratory developed tests and research skills;
- the Company may require additional financing, which may be dilutive to existing shareholders;
- price volatility of publicly traded securities, including the Company's Common Shares;
- the impact of environmental and safety laws and health regulations and its effect on the Company's business;
- there is no assurance the Company will reach and maintain profitability;
- there is competition in the Company's industry; and
- the Company's directors may have conflicts of interest.

If any of these risks or uncertainties materialize, or assumptions underlying the forward-looking statements prove incorrect, actual results may vary material from those anticipated in those forward-looking statements. The assumptions referred to above and described in greater detail in Appendix 1 under "Risks Related to the Business" should be considered carefully by readers.

The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise, except to the extent required by applicable law. Further information concerning risks and uncertainties associated with these forward-looking statements and the Company's business may be found in the Company's other public filings which are available on the Canadian Securities Administrators' website at [www.sedar.com](http://www.sedar.com) and the Company's website at [www.algernonpharmaceuticals.com](http://www.algernonpharmaceuticals.com).

### **CONFLICTS OF INTEREST**

Certain directors and officers of the Company are, or may become, directors and officers of other companies, and conflicts of interest may arise between their duties as officers and directors of the Company and as officers and directors of such other companies.

### **OVERVIEW**

Algernon Pharmaceuticals Inc. (the "Company" or "Algernon") was incorporated on April 10, 2015 under the British Columbia *Business Corporations Act*. The registered office of Algernon is located at Suite 1500 – 1055 West Georgia Street, Vancouver, British Columbia, V6E 4N7.

Up to December 20, 2022, all the research and development work was carried out by the Company's 100% owned Canadian subsidiary, Nash Pharmaceuticals Inc. ("Nash Pharma"). On January 6, 2020, Nash Pharma established a 100% owned Australian subsidiary, Algernon Research Pty Ltd. ("AGN Research"). Through its ongoing research programs, Nash Pharma is seeking to minimize investment and drug development risk by taking advantage of regulatory approved drugs and discovering alternative clinical uses by accelerating entry into phase II clinical trials (human). On December 9, 2022, the Company established a 100% owned subsidiary incorporated in British Columbia, Algernon NeuroScience Inc. ("AGN Neuro") and on December 20, 2022, AGN Neuro acquired all of the assets of the Company's DMT program and all research and development activities pertaining to DMT will be carried out by AGN Neuro.

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As at May 31, 2023, the Company has an accumulated deficit of \$28,177,235 (August 31, 2022 - \$25,186,887) and for the nine-month period then ended incurred a net loss of \$4,254,809 (May 31, 2022 - \$3,837,179). The Company will need to raise sufficient working capital to maintain operations. Without additional financing, the Company may not be able to fund its ongoing operations and complete development activities. Management anticipates that the Company will continue to raise adequate funding through equity or debt financings, although there is no assurance that the Company will be able to obtain adequate funding on favorable terms. These uncertainties may cast significant doubt on the Company's ability to continue as a going concern. The Company's condensed interim consolidated financial statements have been prepared on a going concern basis, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business and the condensed interim consolidated financial statements do not reflect adjustments, which could be material, to the carrying value of assets and liabilities, which may be required should the Company be unable to continue as a going concern.

#### **BUSINESS MODEL**

Algernon is a drug re-purposing company that investigates safe, already approved drugs, including naturally occurring compounds, for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algernon specifically investigates compounds that have never been approved in the United States ("US") or the European Union ("EU") to avoid off label prescription writing, which can interfere with the normal economic pricing models of newly approved drug treatments.

The Company's early research identified a number of drug candidates that had already been approved for other diseases outside of the US and EU. Only drugs that have not been approved in the US or EU were chosen to avoid off-label prescription writing. The Company is actively investigating new disease areas including: chronic kidney disease ("CKD"), idiopathic pulmonary fibrosis ("IPF") and chronic cough stroke and traumatic brain injury ("TBI"). In addition to these indications, the Company has additional drug candidates it is considering advancing where the Company has performed preclinical studies and filed intellectual property.

The Company's lead candidate is Ifenprodil, which is being investigated by the Company in multiple disease indications. Ifenprodil is an N-methyl-D-aspartate ("NMDA") receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B). Ifenprodil prevents glutamate signalling. The NMDA receptor is found on many tissues including lung cells and T-cells, neutrophils. Ifenprodil (brand name Cerocral) was initially developed by Sanofi in the 1990s in the French and Japanese markets for the treatment of circulatory disorders. Although no longer available in France, the drug is highly genericized and sold in Japan and South Korea.

NMDA receptors also regulate the signalling of mTOR a serine/threonine kinase, which has been identified as a therapeutic target for many types of cancers. Their expression on several human cancer cell lines represents a potential therapeutic avenue to control dysregulated growth, division, and invasiveness.

The Company is investigating Ifenprodil for IPF and chronic cough and completed a Phase 2 study in Australia and New Zealand. The purpose of this proof-of-concept trial was to determine the efficacy of Ifenprodil in the preservation of lung function in IPF patients (including biomarkers of fibrosis) and its associated cough. The Phase 2 IPF and chronic cough trial began on August 5, 2020, and the full data set from the trial was announced on September 1, 2022.

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On January 9, 2023, the Company announced it is planning a 180 patient, 90-day Phase 2b clinical study Ifenprodil for chronic cough to begin in calendar Q3 of 2023. Ifenprodil represents a novel first- in-class potential treatment for chronic cough and is thought to interfere with central signalling in the brain, suppressing the urge to cough. The decision to advance the study is based on positive data previously reported, from the Company's Phase 2a study of IPF and chronic cough, where Ifenprodil showed a significant improvement in mean objective 24- hour and waking cough counts in patients after 4 and 12 weeks.

On February 1, 2021, the Company announced it had established a clinical research program for the treatment of stroke focused on DMT. DMT is a known psychedelic compound that is part of the tryptamine family. Repurposing DMT from its psychedelic effects to a new potential treatment for stroke could have a positive impact on the millions of people that suffer the debilitating consequences of a stroke each year. The Company's decision to investigate DMT and move it into human trials for stroke is based on multiple independent, positive preclinical studies demonstrating that DMT helps promote neurogenesis as well as structural and functional neural plasticity. These are key factors involved in the brain's ability to form and reorganize synaptic connections, which are needed for healing following a brain injury.

The Company is conducting a Phase 1 clinical study of an intravenous formulation ("IVF") of DMT for the treatment of stroke in the Netherlands at the Centre for Human Drug Research ("CHDR") in Leiden. The Company commenced screening subjects on November 16, 2022 and dosed the first subject in the clinical study in January 2023, with dosing in the first cohort completed in February 2023, the second cohort completed in April 2023 and third cohort completed in June 2023.

The Company also reported that the safety review committee has confirmed that there were no safety or tolerability issues with the highest dose, which was able to maintain plasma DMT concentrations at targeted levels and which was below the established psychedelic dose. The psychedelic dose of DMT was previously identified as 0.2 mg/kg by Dr. Rick Strassman, DMT researcher and author of the book *DMT: The Spirit Molecule* (2001) and Algernon consultant, in his ground-breaking DMT human studies in the early 1990s. Algernon is the first company to test DMT at single escalating concentrations with an IV dose for a 6-hour duration.

On February 21, 2023, the Company announced that it has added a new clinical research program for the treatment of TBI with DMT and plans to be the first company globally to investigate DMT for TBI in humans and is planning a Phase 2 clinical trial.

Additionally, On February 23, 2022, the Company announced that it awarded a contract to Zhejiang Ausun Pharmaceutical CO, LTD ("Ausun") of China to begin the manufacturing of a cGMP supply of its repurposed drug Repirinast and has initiated a new CKD research program.

Since Algernon's lead compounds in IPF and chronic cough and CKD were sold outside of the US and EU, there is historical data available on each compound's mechanism of action as it relates to the disease it was originally developed to treat. The Company has decided not to pursue independent confirmation as to whether these known pathways are involved in the specific biochemical interaction that produced the pharmacological effect seen in the Company's animal model research.

#### **Research and Development**

Key Research Milestone Summary:

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On September 1, 2022, the Company announced positive results from the full data set of its Phase 2a Study evaluating Ifenprodil for the potential treatment of IPF and chronic cough. The full data set included additional secondary measures of efficacy, including both objective measurement of lung function and patient-reported outcomes of both IPF and cough. All of the data showed positive results, including statistically significant improvements in measures of cough.

On September 12, 2022, the Company announced it received approval to conduct a Phase 1 clinical study of an intravenous formulation ("IVF") of DMT for the treatment of stroke in the Netherlands from the Stichting Beoordeling Ethiek Biomedisch Onderzoek ("BEBO"), an independent Medical Research Ethics Committee ("MREC"). The trial is being conducted at the Centre for Human Drug Research ("CHDR") in Leiden. DMT is a known psychedelic compound that is part of the tryptamine family. The Company commenced screening subjects on November 16, 2022 and dosed the first subject in the clinical study in January 2023.

On September 19, 2022, the Company announced its decision to advance its investigation of Ifenprodil for IPF with cough as its key indication. As a result, the Company further announced that it had filed a request for Orphan Drug Designation ("ODD") with the United States Food and Drug Administration ("FDA") for the use of Ifenprodil as a treatment for IPF. The Company received ODD for Ifenprodil as a treatment for IPF on December 5, 2022.

On October 24, 2022, the Company entered an Investigator-Initiated Clinical Trial Agreement ("CTA") with Yale University ("Yale") for the investigation of multiple intravenous doses of DMT for the treatment of depression. The trial's principal investigator is Professor Deepak Cyril D'Souza, an experienced researcher with DMT and other controlled substances.

On January 9, 2023, the Company announced it is planning a 180 patient, 90-day Phase 2b clinical study of Ifenprodil for chronic cough to begin in calendar Q3 of 2023. Ifenprodil represents a novel first-in-class potential treatment for chronic cough and is thought to interfere with central signalling in the brain, suppressing the urge to cough. The decision to advance the study is based on positive data previously reported, from the Company's Phase 2a study of IPF and chronic cough, where Ifenprodil showed a significant improvement in mean objective 24-hour and waking cough counts in patients after 4 and 12 weeks.

On January 11, 2023, the Company announced that it has appointed Dr. Peter Dicpinigaitis MD, Professor of Medicine at the Albert Einstein College of Medicine, in New York, as a medical consultant to the Company's chronic cough research program. Dr. Dicpinigaitis will be advising the Company on its planned 180 patient, Phase 2b chronic cough study of Ifenprodil.

The Company is conducting a Phase 1 clinical study of an intravenous formulation ("IVF") of DMT for the treatment of stroke in the Netherlands at the Centre for Human Drug Research ("CHDR") in Leiden. The Company commenced screening subjects on November 16, 2022 and dosed the first subject in the clinical study in January 2023, with dosing in the first cohort completed in February 2023, the second cohort completed in April 2023 and third cohort completed in June 2023.

The Company also reported that the safety review committee has confirmed that there were no safety or tolerability issues with the highest dose, which was able to maintain plasma DMT concentrations at targeted levels and which was below the established psychedelic dose.

On February 21, 2023, the Company announced that it has added a new clinical research program for the treatment of TBI with DMT and plans to be the first company globally to investigate DMT for TBI in humans and is planning a Phase 2 clinical trial.

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The Company appointed global TBI expert Dr. Andrew Maas as a scientific and medical advisor and Dr. David L. Brody, MD, PhD to help guide its TBI research program.

### **Business Development**

#### **IPF & Chronic Cough**

On December 10, 2019, the Company announced the selection of Ifenprodil for its lead phase 2 trial for IPF and chronic cough. On January 17, 2020, the Company appointed Novotech as the contract research organization ("CRO") for the Company's phase 2 IPF and chronic cough study which would be conducted in Australia.

The Company began to work towards achieving both regulatory and ethics approval to run the IPF and chronic cough study, which has been received resulting in the Company beginning to screen patients on July 7, 2020 and enrolling the first patient on August 5, 2020.

The Company has also retained Organic Consultants, Inc. (dba Cascade Chemistry) to produce the active pharmaceutical ingredient ("API") of Ifenprodil. Algernon made the decision to scale-up 'current good manufacturing practice' ("cGMP") manufacturing of Ifenprodil to support its IPF and Chronic Cough clinical program. The Company has manufactured its first multi-kilogram batch of cGMP material produced. Stability testing of the API is on-going. The Company filed a pre-Investigational New Drug ("IND") application with the US Food and Drug Administration ("FDA") to seek guidance on the use of Algernon's planned new propriety injectable and slow release formulation. The FDA advised that for the toxicology program of a new intravenous formulation, a single animal 30-day study would be acceptable. The Company's estimated cost of manufacturing of finished product is approximately \$500,000.

The Company announced in September 2021, that it had received positive trending interim data from the chronic cough part of its 20-patient Phase 2 IPF and chronic cough study. The interim analysis examined 24-hour total and waking cough counts measured using an ambulatory cough monitor at baseline and after 4 and 12 weeks of treatment with 20 mg of Ifenprodil, three times daily. The data showed a trend to a relative reduction in cough count when compared to each patient's baseline measurement control.

The data showed a trend to a relative reduction in cough count when compared to each patient's baseline measurement control. In October 2021, the Company submitted a request to the FDA for a pre-IND meeting on the investigation of Ifenprodil for a planned Phase 2 trial for treatment of refractory chronic cough based on the positive trending interim data.

The Company received positive feedback from the FDA of its pre-IND meeting for its investigation of Ifenprodil for the treatment of chronic cough in January 2022. The FDA meeting produced helpful guidance on the Phase 2b protocol design that was submitted by the Company as well as the endpoints that had been selected. The FDA also requested standard genotoxicity testing be completed prior to beginning the Phase 2b study, which the Company estimates will take approximately 90 days to complete.

On February 4, 2022, the Company announced that it completed enrollment in its Phase 2 Ifenprodil IPF and chronic cough study and on May 5, 2022, the Company announced that the last patient has completed the treatment period. On June 13, 2022, the study had reached database lock meaning all data from the trial is now finally reported, cleaned and locked in the database.

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On June 21, 2022, the Company announced that patients from multiple sites participating in its Phase 2 proof-of-concept study of Ifenprodil for IPF and chronic cough, being conducted in Australia and New Zealand, have requested ongoing supply of Ifenprodil for their personal use beyond the study's treatment period. The Company is helping the clinical sites obtain additional supply of the drug through the Australian Governments Special Access Scheme, a mechanism which allows patients to access unapproved therapeutic goods.

On June 22, 2022, the Company announced that it has been issued a patent from the Canadian Intellectual Property Office, No. 3101853, for the treatment of interstitial lung disease with Ifenprodil, entitled "Compositions and Methods for Treating Idiopathic Pulmonary Fibrosis."

On July 18, 2022, the Company announced top line data indicating that the study's IPF co-primary endpoint, preservation of lung function determined by no worsening of FVC over 12 weeks, had been met. The Company further reported on July 28, 2022 significant reductions in geometric mean cough counts after both 4 and 12 weeks of treatment and on September 1, 2022, the Company announced positive results from the full data set of its Phase 2a Study evaluating Ifenprodil for the potential treatment of IPF and chronic cough. The full data set includes additional secondary measures of efficacy, including both objective measurement of lung function and patient-reported outcomes of both IPF and cough. All of the data showed positive results, including statistically significant improvements in measures of cough.

#### **IPF Data**

Secondary endpoints focused on pulmonary fibrosis, as indicated by key measures, were consistent with the preservation of lung function as measured by key indications, specifically:

Unchanged diffusing capacity for carbon monoxide (DLCO) over twelve weeks (change from baseline 0.00,  $p > 0.99$ , 95% CI -3.14, 3.14). DLCO estimates the ability of the lungs to transfer oxygen between alveolar gas and red blood cells.

No change in the modified Medical Research Council (mMRC) dyspnea scale over twelve weeks. The mMRC scale is a self-rating tool to measure the degree of disability imposed by breathlessness on day-to-day activities.

An increase of 7.0 points in the King's Brief Interstitial Lung Disease Questionnaire (K-BILD) ( $p = 0.1209$ , 95% CI -2.03, 16.03). The K-BILD is a self-administered health-status questionnaire developed in patients with interstitial lung diseases (higher scores are better).

#### **Cough Data**

Secondary endpoints focused on cough showed significant improvements, namely:

A reduction of 23.6 mm from baseline in the cough visual analogue scale (VAS) ( $p = 0.0005$ , 95% CI -35.22, -11.94). The cough VAS is a patient-reported subjective assessment of cough severity (lower scores are better).

An improvement of 10.05 points in the mean score on the Leicester Cough Questionnaire (LCQ) ( $p = 0.0296$ , 95% CI 1.12, 18.99). The LCQ is a self-completed quality of life measure of chronic cough (higher scores are better).

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Ifenprodil was well tolerated with a high overall compliance rate (average >90%). As reported with the top line data, no new safety concerns were identified.

On September 19, 2022, the Company announced its decision to advance its investigation of Ifenprodil for IPF with cough as its key indication. As a result, the Company further announced that it had filed a request for ODD with the FDA for the use of Ifenprodil as a treatment for IPF. The Company received ODD for Ifenprodil as a treatment for IPF on December 5, 2022.

Supporting the development and evaluation of new treatments for rare diseases through orphan designation is a priority for the FDA and other jurisdictions (Europe) that have similar orphan programs. Orphan designation qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and a potential seven years of market exclusivity after approval. The designation is available only for rare diseases, defined by the FDA as those which affect fewer than 200,000 patients in the United States, which the Company's research indicates that IPF may qualify.

IPF is a type of chronic lung condition characterized by a progressive and irreversible decline in lung function and scarring (fibrosis) of the lungs. There is no cure for IPF and there are currently no procedures or medications that can remove the scarring from the lungs. At least 70%-85% of patients with IPF are affected by a dry non-productive cough, which can often get worse on exertion.

On January 9, 2023, the Company announced it is planning a 180 patient, 90-day Phase 2b clinical study of Ifenprodil for chronic cough to begin in calendar Q3 of 2023. Ifenprodil represents a novel first-in-class potential treatment for chronic cough and is thought to interfere with central signalling in the brain, suppressing the urge to cough. The decision to advance the study is based on positive data previously reported, from the Company's Phase 2a study of IPF and chronic cough, where Ifenprodil showed a significant improvement in mean objective 24-hour and waking cough counts in patients after 4 and 12 weeks.

On January 11, 2023, the Company announced that it has appointed Dr. Peter Dicipinigaitis MD, Professor of Medicine at the Albert Einstein College of Medicine, in New York, as a medical consultant to the Company's chronic cough research program. Dr. Dicipinigaitis will be advising the Company on its planned 180 patient, Phase 2b chronic cough study of Ifenprodil.

The Company presented its Phase 2a Ifenprodil cough data at the 9<sup>th</sup> American Cough Conference (ACC) which was held June 9-10, 2023 in Reston, Virginia. The ACC is the world's leading educational meeting for healthcare professionals involved in the research and management of patients with cough.

#### **DMT/Stroke**

On February 1, 2021, the Company announced it had established a clinical research program for the treatment of stroke focused on DMT. Repurposing DMT from its psychedelic effects to a new potential treatment for stroke could have a positive impact on the millions of people that suffer the debilitating consequences of a stroke each year. The Company's decision to investigate DMT and move it into human trials for stroke is based on multiple independent, positive preclinical studies demonstrating that DMT helps promote neurogenesis as well as structural and functional neural plasticity. These are key factors involved in the brain's ability to form and reorganize synaptic connections, which are needed for healing following a brain injury.

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The Company confirmed in its own preclinical study, that DMT increased the growth of cortical neurons by 40% with statistical significance in one arm of the study, when compared to control. Algernon also reported that the increased growth was achieved with a sub hallucinogenic dose.

The Company has established the optimum peak stimulation period of 6 hours for neuron outgrowth by DMT in its pre-clinical in vitro study conducted by Charles River Laboratories. Algernon also confirmed that the increased growth was achieved with a sub-hallucinogenic dose.

On December 8, 2021, the Company announced that it has completed the manufacturing of its cGMP of DMT at Canadian manufacturer Dalton Pharma Services. The Company believes it has produced a sufficient supply of cGMP DMT to complete its planned Phase 1 and Phase 2 clinical trials.

The Company has appointed Dr. Anthony Rudd and Dr. Robert Simister, both from the U.K., as medical consultants to the Company's DMT stroke clinical research program. Both Dr. Rudd and Dr. Simister have extensive backgrounds in stroke management as well as clinical care and stroke research. Their primary responsibility will be to help guide the Company's Phase 2 acute stroke and post stroke therapy clinical trials planned to begin after the Phase 1 trial has been completed.

On January 24, 2022, the Company disclosed that as part of its intellectual property patent applications filed in early 2021 for DMT, the Company included novel salt forms of DMT. A novel salt form of a drug is a new and separate structure from the original compound and is considered a new composition of matter.

Many drug compounds' core structures can often be paired with a salt. Different salts can improve the core drug in several ways, including improved efficacy, safety/tolerability, and stability.

The Company believes that it has maximized its intellectual property position around DMT, which includes filing patent applications for new novel salt forms, as outlined herein, as well as dosing, formulation, and method of use patent applications for stroke rehabilitation.

On July 5, 2022, the Company disclosed that as part of its intellectual property patent applications filed in early calendar 2021 for DMT, the Company included nicotinate and pamoate as novel salt forms of DMT. The Company also announces that in its own binding study of nicotinate and pamoate, the salts showed, when compared to fumarate, the most studied form of DMT, that they had similar binding to the 5-HT<sub>2A</sub> and sigma-1 receptors; key receptors in the brain that are activated by DMT.

After working to identify qualified vendors that could perform the needed work in the required time period, the Company selected CHDR and the IVF work is in progress. In addition to its fill finish cGMP-suite services, CHDR is also a world class clinical trial center, performing approximately 60 early-phase clinical studies per year.

On September 12, 2022, the Company announced it received approval to conduct a Phase 1 clinical study of an IVF of DMT for the treatment of stroke in the Netherlands from the BEBO, an independent MREC. The trial is being conducted at the CHDR in Leiden. The Company commenced screening subjects on November 16, 2022 and dosed the first subject in the clinical study in January 2023.

On February 16, 2023, dosing of the first cohort in the Phase 1 clinical study of DMT was completed noting that the safety review committee has approved moving the study forward with the next cohort at an escalated dose after observing no safety or tolerability issues.

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The Company is conducting a Phase 1 clinical study of an intravenous formulation ("IVF") of DMT for the treatment of stroke in the Netherlands at the Centre for Human Drug Research ("CHDR") in Leiden. The Company commenced screening subjects on November 16, 2022 and dosed the first subject in the clinical study in January 2023, with dosing in the first cohort completed in February 2023, the second cohort completed in April 2023 and third cohort completed in June 2023.

The Company also reported that the safety review committee has confirmed that there were no safety or tolerability issues with the highest dose, which was able to maintain plasma DMT concentrations at targeted levels and which was below the established psychedelic dose.

The primary focus of the Phase 1 DMT study is to investigate prolonged intravenous infusion of DMT, for durations which have never been clinically studied. The resulting data generated will help the Company to plan both its Phase 2 acute stroke and rehabilitation studies more effectively.

The Company's decision to investigate DMT and move it into human trials for ischemic stroke is based on multiple independent, positive preclinical studies demonstrating that DMT helps mitigate tissue damage and promote neurogenesis as well as structural and functional neural plasticity. These are key factors involved in the brain's ability to form and reorganize synaptic connections, which are needed for healing following a brain injury. The Company also confirmed in its own murine cortical neuron outgrowth preclinical study, that DMT, in sub-psychedelic doses, increased the growth of cortical neurons by up to 40% compared to control.

Since there have already been several Phase 1 studies successfully conducted on DMT, the Company is not anticipating any serious adverse events or safety issues arising from its study. The reason that the Company is planning to conduct a Phase 1 study and not directly advance DMT into a Phase 2 study is that it is investigating prolonged intravenous infusion of DMT, for durations which have never been clinically studied. The resulting data generated will help the Company to plan both its Phase 2 acute stroke and rehabilitation studies more effectively.

On October 24, 2022, the Company entered an Investigator-Initiated CTA with Yale for the investigation of multiple intravenous doses of DMT for the treatment of depression. The trial's principal investigator is Professor Deepak Cyril D'Souza, an experienced researcher with DMT and other controlled substances.

As part of the CTA, Algernon will provide cGMP DMT for the study. In return, Algernon will jointly own IP around the clinical use of DMT arising from the study developed jointly by Algernon and Yale, and the option to negotiate licenses to both IP developed jointly and IP developed solely by Yale. (This is subject to rights reserved by the United States Government in conjunction with publicly funded research). In addition, the Company will receive data from the study, which may assist in its DMT stroke research program.

#### **DMT/TBI**

On February 21, 2023, the Company announced that it has added a new clinical research program for the treatment of TBI with DMT and plans to be the first company globally to investigate DMT for TBI in humans and is planning a Phase 2 clinical trial.

The Company's decision to investigate DMT for TBI is based on several factors, specifically:

- There are many commonalities between stroke and TBI where DMT has demonstrated benefit in several preclinical studies, including: neuroinflammation, mitochondrial dysfunction, reactive oxygen species, excitotoxicity, and spreading depolarizations.

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- DMT is an agonist of sigma-1, a part of the body's natural defense against physiological stresses, which is elevated following TBI. DMT increases brain derived neurotropic factor (BDNF), a protein which plays a key role in neuroplasticity. Natural levels of BDNF in the brain are decreased following TBI; however, expression of TrkB mRNA, the receptor to which BDNF binds, is increased as the brain seeks to compensate for the injury. Studies have shown that exercise-induced increases in BDNF generally improve recovery following TBI, and that blocking the effects of BDNF attenuate the improvement. Furthermore, increased levels of BDNF following TBI are correlated with improved cognitive function.
- On-going symptoms of TBI are often psychological and cognitive; a number of psychedelic drugs, including DMT, have already shown therapeutic potential in clinical trials in some of these conditions.
- In TBI, classified as mild according to the Glasgow coma scale, up to 50% of TBI patients have symptoms that have not resolved after 6 months. Millions of mild TBIs occur each year, and that number is expanding with increased access to motor vehicles in the developing world and the associated increase in accidents. There are currently no drugs approved for treatment of TBI of any severity.

The Company appointed global TBI expert Dr. Andrew Maas as a scientific and medical advisor and Dr. David L. Brody, MD, PhD to help guide its TBI research program.

Dr. Maas is Emeritus Professor of Neurosurgery at the Antwerp University Hospital and University of Antwerp. He holds positions as past Chairman of the Neurotraumatology Committee of the World Federation of Neurosurgical Societies (WFNS) and the International Neurotrauma Society, and is Co-Chairman of the European Brain Injury Consortium. He has a vast experience as a general neurosurgeon and has specific research interests in TBI and neuro-intensive care.

Dr. Brody, MD, PhD is a board-certified neurologist with both a research and a clinical specialization in TBI and neurodegenerative diseases. Dr. Brody was the Norman J. Stupp Professor of Neurology at the Washington University School of Medicine in St. Louis. Dr. Brody was also the Washington University site director for the National Football League (NFL) Neurological player care program. His research focuses on accelerating implications for better diagnosis, treatment and outcomes of traumatic brain injury.

#### **Chronic Kidney Disease**

On February 23, 2022, the Company announced that it awarded a contract Ausun of China to begin the manufacturing of a cGMP supply of its repurposed drug Repirinast and has initiated a new CKD research program. Ausun has now developed and optimized a new synthetic route to Repirinast. Ausun has also developed and validated all analytical methods for testing.

Repirinast was originally developed by Mitsubishi Tanabe Pharma ("Mitsubishi") and was sold and marketed in Japan under the brand name Romet<sup>TM</sup> for the treatment of asthma. Romet<sup>TM</sup> was marketed for over 25 years in Japan. Mitsubishi discontinued manufacturing and sales of the drug in 2013.

Repirinast was approved in Japan for patients with bronchial asthma in 1987, to prevent attacks when administered regularly. A pediatric formulation was also approved in 1990. Unlike most allergy medications, Repirinast does not have a direct antihistaminic effect. The drug acts on mast cells and inhibits the release of chemical mediators by IgE-related antigen antibody interactions.

Repirinast is one of several repurposed drug candidates that were part of Algernon's acquisition of NASH on October 22, 2018.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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On April 26, 2022, the Company announced that Repirinast reduced fibrosis by 56% with statistical significance in a preclinical study investigating NASH in the STAM™ model from SMC Laboratories (Japan).

In a pre-clinical animal model of kidney fibrosis, Repirinast reduced fibrosis by 50% with statistical significance. It also showed an additive improvement when given in combination with Telmisartan, the latter of which is a blood pressure lowering medication and is considered a front line, standard of care treatment for CKD. As part of the new CKD research program, the Company will also investigate the use of Repirinast in acute interstitial nephritis, which causes inflammation of parts of the kidney.

The Company will conduct a bridging sub-acute toxicology study when the Repirinast cGMP synthesis is completed. The sub-acute toxicology study is expected to take approximately 90 days. Once completed, the Company plans to begin a small Phase 1 study in calendar Q2, 2023, to determine the bioavailability of its Repirinast finished product.

On April 17, 2023, the Company announced it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application 17/258,402 entitled "Compositions and Methods for Treating Non-Alcoholic Steatohepatitis" for Repirinast. The Company has also filed corresponding patent applications in Canada, Europe, China and Japan.

On May 31, 2023, the Company announced that it has received a Notice of Allowance from the Japanese Patent Office (JPO) for patent application 2021-522114 entitled "Compositions and Methods for Treating Chronic Kidney Disease" for its lead CKD program drug Repirinast. The Company has also filed corresponding patent applications in the United States, Canada, Europe and China. The invention claims the administration of Repirinast, either alone or in combination with telmisartan, for use in the prophylaxis or treatment of renal fibrosis or kidney disease.

#### **Pancreatic and Small Cell Lung Cancer**

The Company is currently evaluating its cancer programs to determine the next steps for the programs.

Subject to available financing, the Company is planning the following milestones during the remainder of calendar 2023:

##### Calendar Year 2023

###### Q3/23

- Data from Phase 1 Study DMT

###### Q4/23

- Ifenprodil – chronic cough IND Filing and fast track application
- Begin Phase 2a Study DMT Stroke and/or TBI

#### **Medical and Scientific Advisory Board Update**

The Company appointed Dr. Peter Dicipinigaitis MD, Professor of Medicine at the Albert Einstein College of Medicine, in New York, as a medical consultant to the Company's chronic cough research program.

The Company appointed global TBI expert Dr. Andrew Maas as a scientific and medical advisor and Dr. David L. Brody, MD, PhD to help guide its TBI research program.

# ALGERNON PHARMACEUTICALS INC.

## Management's Discussion and Analysis

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### **Corporate**

On September 8, 2022, the Company announced that it will be the Headline Sponsor for Wonderland, the world-leading academic and business gathering in the psychedelic medicine industry, which was held in Miami from November 3-5<sup>th</sup>, 2022 at the Mana Wynwood Convention Centre. The Company delivered two keynote addresses by the Company's CEO Christopher Moreau and including Dr. Rick Strassman, author of the book *DMT: The Spirit Molecule* and Algernon consultant. Wonderland is the world's largest conference in the psychedelic medicine sector. It provided an opportunity to discover the world of psychedelic medicine, and was attended by some of the leading founders, investors, therapists, practitioners, researchers, thought leaders, innovators, and media from around the globe.

On September 21, 2022, the Company announced that it has recently received a cash payment of approximately CDN \$450,000 from a refundable tax credit program from its clinical research work in Australia.

On March 3, 2023, the Company completed a forward split all of its issued and outstanding common shares on the basis of 4 to 1. Unless otherwise noted, all share, options and warrants, and RSU information have been retroactively adjusted to reflect this forward split.

On June 27, 2023, the Company, announced that it has engaged Maxim Group LLC ("Maxim") to provide financial advisory and investment banking services, and to assist in identifying and evaluating potential M&A and strategic opportunities, including the potential spin-off of the Company's Ifenprodil chronic cough research program.

### **Financing**

The Company announced changes to the warrants that it issued on July 4, 2022, pursuant to the July 2022 Offering as a result of the anti-dilution provisions contained in the warrants. The July 2022 Offering consisted of one common share and one warrant (a "Warrant"). Upon issuance, the Warrants were exercisable at a price of \$1.175 per Warrant and included anti-dilution provisions in the case of a down-round financing during the five-year term of the Warrants (a "Dilutive Issuance") to reduce the exercise price of the Warrants and increase the number of shares issuable thereunder, if common shares are sold or issued for a consideration per share less than the Warrant exercise price (subject to certain exceptions).

On August 22, 2022, the Company closed the August 2022 Offering in the amount of 1,495,600 units of the Company at a price of \$0.938 per unit. The August 2022 Offering resulted in a Dilutive Issuance and the exercise price of the Warrants issued in the July 2022 Offering has been reduced to \$0.938 per share and the number of shares issuable under each Warrant has been increased such that the aggregate exercise price payable after taking into account the decrease in the exercise price shall be equal to the aggregate exercise price prior to the adjustment.

Additionally, on December 9, 2022, the Company established Algernon NeuroScience Inc. ("AGN Neuro"), a wholly-owned subsidiary to advance the Company's DMT stroke research program and completed an asset transfer and trademark license agreement, on December 20, 2022, to transfer all of the assets of the DMT research program into AGN Neuro for USD \$20 million resulting in the issuance of 20,000,000 common shares of AGN Neuro to the Company.

AGN Neuro has filed a Form 1-A offering statement with the U.S. Securities and Exchange Commission (the "SEC"), and has obtained qualification from the SEC to raise up to USD \$10 million for AGN Neuro by offering up to 37.5% of its common shares, (including the maximum amount of bonus shares offered under the offering statement) under a Tier II Regulation A+ offering (Reg A+).

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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AGN Neuro adopted a Stock Option Plan (the "AGN Neuro Plan") on December 20, 2022. Under the AGN Neuro Plan, shares of AGN Neuro are authorized for issuance to employees, officers, directors, consultants and Algernon employees in an amount up to 10% of the issued and outstanding common shares of the AGN Neuro. To date, no stock options have been granted under the AGN Neuro Plan.

On December 23, 2022, the Company entered into an equity distribution agreement (the "Distribution Agreement") with Research Capital Corporation (the "Agent"). Under the Distribution Agreement, the Company will be entitled, at its discretion and from time-to-time during the term of the Distribution Agreement, to sell, through the Agent, as sole and exclusive placement agent, such number of Class A common shares of the Company having an aggregate gross sales price of up to \$5.0 million (the "ATM Offering"). The shares will be distributed at market prices or prices related to prevailing market prices from time to time. As a result, prices of the shares sold under the ATM Offering will vary as between purchasers and during the period of distribution. The ATM Offering will be effective until the earlier of the issuance and sale of all of the shares issuable pursuant to the ATM Offering and June 6, 2023, unless terminated prior to such date by the Company or the Agent in accordance with the terms of the Distribution Agreement.

During the nine-month period ended May 31, 2023, the Company issued 109,788 common shares as a result of the exercise of 87,600 Warrants resulting in gross proceeds to the Company of \$102,929.

During the nine-month period ended May 31, 2023, the Company has sold 8,400 shares through the ATM offering with gross proceeds of \$4,641.

During the nine-month period ended May 31, 2023, the Company issued 117,328 common shares to directors and consultants of the Company as a result of the settlement of Restricted Share Units ("RSU's") that vested on January 1, 2023.

On May 5, 2023, the Company closed a rights offering which expired on April 27, 2023 (the "Rights Offering"). At closing, the Company issued 4,753,369 units (the "Rights Offering Units") at the subscription price of \$0.25 per Rights Offering Unit for total gross proceeds of approximately \$1,188,342. Each Rights Offering Unit consists of one common share and one common share purchase warrant (a "Rights Offering Warrant"), with each Rights Offering Warrant being exercisable for one common share at the exercise price of \$0.52 until November 5, 2024, subject to acceleration to a date that is not less than 30 days following delivery of an acceleration notice to the holders of the Rights Offering Warrants if the volume weighted average price of the shares for each of the ten consecutive trading days on the Canadian Securities Exchange (the "CSE") exceeds \$1.04.

Pursuant to a Dealer Manager Agreement entered into by the Company with the soliciting dealer (the "Soliciting Dealer"), the Company paid to the Soliciting Dealer a cash fee of \$42,292, of which \$10,000 of the fee was settled by way of the issuance of 40,000 Rights Offering Units, and a corporate finance fee of \$22,600, which was settled by way of the issuance of 90,400 Rights Offering Units.

The Company also issued to the Soliciting Dealer 165,166 Soliciting Dealer warrants (the "Soliciting Dealer Warrants"). Each Soliciting Dealer Warrant is exercisable for one Rights Offering Unit at the exercise price of \$0.25 until November 5, 2024. The fair value of the Soliciting Dealer Warrants were recorded as a reduction in the value of the shares issued as share issuance costs.

The proceeds of the Rights Offering are expected to be used for working capital and general corporate purposes and administrative expenses.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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On July 26, 2023, the Company issued to Maxim Group LLC ("Maxim") 200,000 common shares at a deemed issue price of \$0.22, being the closing price of the common shares on the CSE on July 13, 2023, as initial compensation for entering into an engagement letter (the "Engagement Letter") pursuant to which Maxim will provide financial advisory and investment banking services, and assist in identifying and evaluating potential M&A and strategic opportunities, including the potential spin-off of the Company's Ifenprodil chronic cough research program. In connection with entering into the Engagement Letter, the Company may be obligated to issue up to an additional 200,000 Common Shares to Maxim in certain circumstances. The Company may also be obligated to pay Maxim a success fee upon the consummation of a successful transaction.

On July 27, 2023, the Company closed a non-brokered private placement for gross proceeds of \$205,000 (the "Offering") of units (the "July 2023 Units") at an issue price of \$0.20 per July 2023 Unit. Each July 2023 Unit will consist of one common share in the capital of the Company and one common share purchase warrant (a "Warrant"). Each Warrant will entitle the holder to acquire one common share (a "Warrant Share") at an exercise price of \$0.25 per Warrant Share for a period of 2 years from the date of issuance (the "Expiry Date"), subject to acceleration of the Expiry Date as described below.

The Warrants are subject to accelerated expiry in the event the volume weighted average trading price of the common shares exceeds \$0.50 for 20 consecutive trading days, the Company may, within 10 business days of the occurrence of such event, deliver a notice to the holders of the Warrants accelerating the Expiry Date of the Warrants to a date that is not less than 30 days following the date of such notice and the issuance of a press release by the Company announcing the acceleration notice (the "Accelerated Exercise Period"). Any unexercised Warrants shall automatically expire at the end of the Accelerated Exercise Period. The Company will use the proceeds of the private placement for working capital purposes.

#### **Use of Proceeds of Offerings**

The Company received gross proceeds totalling \$2,561,314 collectively from the July 2022 Offering and the August 2022 Offering (collectively the "Prior Offerings"). After deducting Agent's Fees and expenses in connection with the Prior Offerings the Company received net proceeds from the Prior Offerings of \$2,055,123.

Additionally, the Company received gross proceeds totalling \$1,188,342 from the Rights Offering completed on May 5, 2023. After deducting the Soliciting Dealer's fees and expenses of the rights offering, the Company received net proceeds of \$1,054,201 which will be used for working capital and general corporate purposes and administrative expenses.

The following table sets out a comparison of how the Company intended to use the net proceeds from the Prior Offerings and its actual use of proceeds from the Prior Offerings as at August 31, 2022, an explanation of variances and the impact of variances on the ability of the Company to achieve its business objectives and milestones.

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

Intended Use of Proceeds of Offerings		Actual Use of Proceeds from Offerings	Variance – (Over)/Under Expenditure	Explanation of Variance and Impact on business objectives
DMT Phase 1 Stroke Trial	\$ 1,250,000	\$ 624,802	\$ 625,198	Trial in progress, offerings completed in Q4 2022
General and Administrative Expenses and Working Capital	\$ 805,123	\$ 1,430,321	(\$ 625,198)	Offerings completed in Q4 2022
TOTAL	\$ 2,055,123	\$ 2,055,123	\$ -	

The Prior Offerings were completed in the fourth quarter of fiscal 2022 and the DMT Phase 1 trial is ongoing at May 31, 2023. Funds will be used to further the DMT Phase 1 stroke trial in fiscal 2023. Additionally, funds were required to complete the IPF and chronic cough study during the nine months ended May 31, 2023.

Although the Company intended to use the proceeds from the Offerings as set forth above, the actual allocation of the net proceeds may vary depending on future developments or unforeseen events.

## RESULTS OF OPERATIONS

### Nine months ended May 31, 2023 and 2022

The Company had a net loss of \$4,254,809 for the nine months ended May 31, 2023 compared to a net loss of \$3,837,179 for the nine months ended May 31, 2022. The Company's significant operating expenses for the nine months ended May 31, 2023 included the following:

- Research and development expenses of \$906,802 (2022 – \$1,478,756)
- Salaries and benefits of \$525,161 (2022 – \$583,240)
- Marketing expenses of \$1,043,005 (2022 – \$390,016)
- Professional fees of \$232,119 (2022 – \$688,602)
- General and administrative expenses of \$186,639 (2022 – \$202,423)
- Shareholder communications expenses of \$175,396 (2022 – \$193,776)
- Share-based payment expenses of \$1,187,023 (2022 – \$301,980)

Research and development expenses totaled \$906,802 for the nine months ended May 31, 2023 (2022 – \$1,478,756) and pertained primarily to the Company's DMT program including the planning stages and initiation of the Phase 1 clinical trial including the completion of the first three phases of the trial. The decrease was mainly due to lower costs during the nine months ended May 31, 2023 in connection with the IPF and chronic cough clinical trial which was fully underway during the nine months ended May 31, 2022, but was substantially complete before the nine months ended May 31, 2023. Additionally, the decrease in expenses also related to preclinical and manufacturing activities of DMT were incurred during the nine months ended May 31, 2022 as the program ramped up.

Salaries and benefits for the nine months ended May 31, 2023 were \$525,161 (2022 – \$583,240). The decrease in salaries and benefits for the nine months ended May 31, 2023 related to severance recorded during the nine months ended May 31, 2022 as a result in the change in the chief financial officer of the Company effective December 1, 2021.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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Marketing expenses were \$1,043,005 for the nine months ended May 31, 2023 (2022 – \$390,016). The increase from the nine months ended May 31, 2022 resulted from additional marketing activities being performed during the nine months ended May 31, 2023, including the Company being the headline sponsor for the 2022 Wonderland Psychedelic Conference in November 2022. Additional promotional activities were performed during the nine months ended May 31, 2023.

Professional fees were \$232,119 for the nine months ended May 31, 2023 (2022 – \$688,602). The decrease for the nine months ended May 31, 2023 is as a result of higher professional fees during the nine months ended May 31, 2022 from the Company's exploration and filings for an uplisting to the NASDAQ.

General and administrative expenses were \$186,639 for the nine months ended May 31, 2023 (2022 – \$202,423) and were consistent with the nine months ended May 31, 2022.

Shareholder communications expenses were \$175,396 for the nine months ended May 31, 2023 (2022 – \$193,776) and were consistent with the nine months ended May 31, 2022.

Share-based payment expenses were \$1,187,023 for the nine months ended May 31, 2023 (2022 – \$301,980) including share-based payment expenses in relation to the stock options granted by the Company on January 1, 2022 and August 31, 2022 and restricted share units ("RSUs") granted by the Company on August 31, 2022. The expense relates to stock options and RSUs that had not vested prior to the period.

#### **Three months ended May 31, 2023 and 2022**

The Company had a net loss of \$1,127,296 for the three months ended May 31, 2023 (Q3 2023) compared to a net loss of \$800,161 for the three months ended May 31, 2022 (Q3 2022). The Company's significant operating expenses for the three months ended May 31, 2023 included the following:

- Research and development expenses of \$460,576 (Q3 2022 – \$87,234)
- Salaries and benefits of \$164,958 (Q3 2022 – \$182,247)
- Marketing expenses of \$155,547 (Q3 2022 – \$123,050)
- Professional fees of \$28,652 (Q3 2022 – \$288,474)
- General and administrative expenses of \$58,822 (Q3 2022 – \$49,822)
- Shareholder communications expenses of \$65,373 (Q3 2022 – \$56,027)
- Share-based payment expenses of \$194,102 (Q3 2022 – \$14,312)

Research and development expenses totaled \$460,576 for the three months ended May 31, 2023 (Q3 2022 – \$87,234) and pertained primarily to the Company's DMT program including the planning stages and initiation of the Phase 1 clinical trial including the completion of the first three phases of the trial. The increase was mainly due to higher costs during the three months ended May 31, 2023 in connection with DMT program.

Salaries and benefits for the three months ended May 31, 2023 were \$164,958 (Q3 2022 – \$182,247) and were consistent with the three months ended May 31, 2022.

Marketing expenses were \$155,547 for the three months ended May 31, 2023 (Q3 2022 – \$123,050) and were consistent with the three months ended May 31, 2022.

Professional fees were \$28,652 for the three months ended May 31, 2023 (Q3 2022 – \$288,474). The decrease for the three months ended May 31, 2023 is as a result of higher professional fees during the three months ended May 31, 2022 from the Company's exploration and filings for an uplisting to the NASDAQ.

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

General and administrative expenses were \$58,822 for the three months ended May 31, 2023 (Q3 2022 – \$49,822) and were consistent with the three months ended May 31, 2022.

Shareholder communications expenses were \$65,373 for the three months ended May 31, 2023 (Q3 2022 – \$56,027) and were consistent with the three months ended May 31, 2022.

Share-based payment expenses were \$194,102 for the three months ended May 31, 2023 (Q3 2022 – \$14,312) including share-based payment expenses in relation to the stock options granted by the Company on January 1, 2022 and August 31, 2022 and restricted share units (“RSUs”) granted by the Company on August 31, 2022. The expense relates to stock options and RSUs that had not vested prior to the period.

#### Summary of Quarterly Results

The following table sets out selected quarterly information of the Company derived from financial statements prepared by management, for those periods reported to date. The Company's condensed consolidated interim financial statements are prepared in accordance with IFRS applicable to interim financial statements and are expressed in Canadian dollars.

Quarter Ended	2023	2023	2022	2022
	May 31 <sup>(1)</sup>	Feb . 28 <sup>(2)</sup>	Nov. 30 <sup>(3)</sup>	Aug. 31 <sup>(4)</sup>
Total revenue	\$ nil	\$ nil	\$ nil	\$ nil
Loss before other items	1,128,030	1,247,795	1,880,320	2,217,642
Net loss	1,127,296	1,247,487	1,880,026	2,217,643
Net loss per share, basic and diluted	0.10	0.13	0.20	0.32

Quarter Ended	2022	2022	2021	2021
	May 31 <sup>(5)</sup>	Feb. 28 <sup>(6)</sup>	Nov. 30 <sup>(7)</sup>	Aug. 31 <sup>(8)</sup>
Total revenue	\$ nil	\$ nil	\$ nil	\$ nil
Loss before other items	801,166	1,836,591	1,201,025	546,036
Net loss	800,161	1,835,992	1,200,560	240,267
Net loss per share, basic and diluted	0.12	0.27	0.18	0.04

<sup>(1)</sup> The Company had a net loss of \$1,127,296 for the quarter ended May 31, 2023 as compared to a net loss of \$1,247,487 for the prior quarter ended February 28, 2023. The decrease in net loss was primarily due to decreases in stock-based compensation expenses during the quarter ended May 31, 2023.

<sup>(2)</sup> The Company had a net loss of \$1,247,795 for the quarter ended February 28, 2023 as compared to a net loss of \$1,880,026 for the prior quarter ended November 30, 2022. The decrease in net loss was primarily due to decreases in research and development expenses and share-based payment expenses during the quarter ended February 28, 2023.

<sup>(3)</sup> The Company had a net loss of \$1,880,026 for the quarter ended November 30, 2022 as compared to a net loss of \$2,217,642 for the prior quarter ended August 31, 2022. The decrease in net loss was primarily due to decreases in research and development expenses and lower salaries and benefits during the quarter ended November 30, 2022, partially offset by higher marketing costs and share-based payment expenses when compared to the quarter ended August 31, 2022.

<sup>(4)</sup> The Company had a net loss of \$2,217,643 for the quarter ended August 31, 2022 as compared to a net loss of \$800,161 for the prior quarter ended May 31, 2022. The increase in net loss was primarily due to increases in research and development as a result of work completed surrounding the DMT program, bonuses accrued during the three months ended August 31, 2022 and an increase in share-based compensation expenses relating to stock options granted during the quarter.

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

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<sup>(5)</sup> The Company had a net loss of \$800,161 for the quarter ended May 31, 2022 as compared to a net loss of \$1,835,992 for the prior quarter ended February 28, 2022. The decrease in net loss was primarily due to decreases in research and development as a result of credits received for research and development work completed and a reduction in share-based compensation expenses relating to stock options granted during the quarter ended February 28, 2022.

<sup>(6)</sup> The Company had a net loss of \$1,835,992 for the quarter ended February 28, 2022 as compared to a net loss of \$1,200,560 for the prior quarter ended November 30, 2021. The increase in net loss was primarily due to increases professional fees pertaining to the Company's potential Nasdaq listing, costs associated with updating the Company's website and share-based compensation expenses relating to stock options granted during the quarter ended February 28, 2022.

<sup>(7)</sup> The Company had a net loss of \$1,200,560 for the quarter ended November 30, 2021 as compared to a net loss of \$240,567 for the prior quarter ended August 31, 2021. The increase in net loss was primarily due to increases in research and development expenses as a result of credit notes issued during the three months ended August 31, 2021 by Novotech, a CRO chosen to conduct the Company's first phase 2 clinical trial, for deposits paid on future work which would no longer take place.

<sup>(8)</sup> The Company had a net loss of \$240,267 for the quarter ended August 31, 2021 as compared to a net loss of \$1,673,993 for the prior quarter ended May 31, 2021. The decrease in net loss was primarily due to decreases in research and development expenses as a result of credit notes issued by Novotech and decreases in share-based payment and a gain on restricted share units cash settlement.

### LIQUIDITY AND CAPITAL RESOURCES

Liquidity risk is the risk that the Company will encounter difficulty in satisfying financial obligations as they become due. The Company manages its liquidity risk by forecasting cash flows from operations and anticipated investing and financing activities. The Company's objective in managing liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements.

At May 31, 2023, the Company had a working capital deficit of \$1,827,370 compared to working capital at August 31, 2022 of \$310,999. This included cash and cash equivalents of \$434,234 (August 31, 2022 - \$1,408,509) available to meet short-term business requirements and current liabilities of \$2,414,375 (August 31, 2022 - \$2,516,099). The Company's accounts payable and accrued liabilities have contractual maturities of less than 30 days and are subject to normal trade terms. The Company has no long-term debt.

At present, the Company has no current operating income. The Company will need to raise sufficient working capital to maintain operations. Without additional financing, the Company may not be able to fund its ongoing operations and complete development activities. The Company intends to finance its future requirements through a combination of debt and/or equity issuance. There is no assurance that the Company will be able to obtain such financings or obtain them on favourable terms. These uncertainties may cast doubt on the Company's ability to continue as a going concern.

#### *Non-GAAP Financial Measure*

The Company uses "working capital" to assess liquidity and general financial strength and is calculated as current assets less current liabilities<sup>(1)</sup>. Working capital does not have any standardized meaning prescribed by IFRS and is referred to as a "Non-GAAP Financial Measure." It is unlikely for Non-GAAP Financial Measures to be comparable to similar measures presented by other companies.

- Working capital is calculated as current assets (May 31, 2023 - \$587,005; August 31, 2022 - \$2,827,098), less current liabilities (May 31, 2023 - \$2,414,375; August 31, 2022 - \$2,516,099).

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

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#### Cash Used in Operating Activities

Operating activities used \$1,980,301 in cash for the nine months ended May 31, 2023 compared to cash used in operating activities of \$1,441,125 for the nine months ended May 31, 2022. The increase in cash used in operating activities was primarily due to the receipt of a significant amount pertaining to the Australian research and development tax credit during the nine months ended May 31, 2022 as a result of high research and development expense levels in Australia during the year ended August 31, 2021 when compared to the year ended August 31, 2022. This decrease in Australian research and development expenses year over year result in a lower Australian research and development tax credit received during the nine months ended May 31, 2023.

#### Cash Used in Investing Activities

The cash used in investing activities for the nine months ended May 31, 2023 was \$53,919 compared to \$95,543 in cash used in investing activities for the nine months ended May 31, 2022 and relates entirely to additions in intangible assets. The difference between the two periods is as a result of the timing of the expenditures and payments relating to these additions.

#### Cash flows from Financing Activities

The Company generated \$1,059,744 in cash flows from financing activities for the nine months ended May 31, 2023 compared to no cash generated from financing activities for the nine months ended May 31, 2022. The cash flows from financing activities for the nine months ended May 31, 2023 are as a result of the net proceeds from the rights offering of \$1,054,201, the issuances of shares as a result of the exercise of warrants totaling \$102,929 and proceeds from shares issued for cash under the ATM financing totaling \$4,525 during the nine months ended May 31, 2023, partially offset by cash spent on financing costs for financing activities that had not closed as of May 31, 2023 totaling \$101,911.

### OUTSTANDING SHARE DATA

As at May 31, 2023 and the date of this report, the Company has:

As at	May 31, 2023	July 27, 2023
Issued and outstanding common shares	14,550,757	15,775,757
Warrants outstanding	7,528,237	8,553,237
Agent warrant units outstanding	290,466	290,466
Stock options outstanding	931,000	931,000
Restricted share units	766,672	766,672

### OFF-BALANCE SHEET ARRANGEMENTS

There are no off-balance sheet arrangements.

### CONTRACTUAL COMMITMENTS

There are no contractual commitments to disclose.

**ALGERNON PHARMACEUTICALS INC.**  
Management's Discussion and Analysis

**INTANGIBLE ASSETS**

	Acquisition of Nash Pharma <sup>(1)</sup>	Trademark Application Costs <sup>(2)</sup>	In-licensed Patents <sup>(3)</sup>	Patent Application Costs <sup>(4)</sup>	Total
<b>Cost</b>					
Balance, August 31, 2021	\$ 4,862,756	\$ 14,432	\$ -	\$ 293,683	\$ 5,170,871
Additions	-	1,291	50,292	105,120	156,703
Write-downs	-	-	-	(36,479)	(36,479)
Balance, August 31, 2022	\$ 4,862,756	\$ 15,723	\$ 50,292	\$ 362,324	\$ 5,291,095
Additions	-	1,129	-	73,826	74,955
<b>Balance, May 31, 2023</b>	<b>\$ 4,862,756</b>	<b>\$ 16,852</b>	<b>\$ 50,292</b>	<b>\$ 436,150</b>	<b>\$ 5,366,050</b>

	Acquisition of Nash Pharma <sup>(1)</sup>	Trademark Application Costs <sup>(2)</sup>	In-licensed Patents <sup>(3)</sup>	Patent Application Costs <sup>(4)</sup>	Total
<b>Accumulated Amortization</b>					
Balance, August 31, 2021	\$ -	\$ -	\$ -	\$ -	\$ -
Amortization	-	(1,572)	(9,598)	(23,766)	(34,936)
Balance, August 31, 2022	\$ -	\$ (1,572)	\$ (9,598)	\$ (23,766)	\$ (34,936)
Amortization	-	(1,203)	(15,599)	(20,257)	(37,059)
<b>Balance, May 31, 2023</b>	<b>\$ -</b>	<b>\$ (2,775)</b>	<b>\$ (25,197)</b>	<b>\$ (44,023)</b>	<b>\$ (71,995)</b>

	Acquisition of Nash Pharma <sup>(1)</sup>	Trademark Application Costs <sup>(2)</sup>	In-licensed Patents <sup>(3)</sup>	Patent Application Costs <sup>(4)</sup>	Total
<b>Net Book Value</b>					
Balance August 31, 2022	\$ 4,862,756	\$ 14,151	\$ 40,694	\$ 338,558	\$ 5,256,159
<b>Balance, May 31, 2023</b>	<b>\$ 4,862,756</b>	<b>\$ 14,077</b>	<b>\$ 25,095</b>	<b>\$ 392,127</b>	<b>\$ 5,294,055</b>

(1) On October 19, 2018, the Company completed the acquisition transaction of Nash Pharma. No amortization was taken on the intangibles acquired as the assets with finite life are not available for use. On an annual basis, the intangibles with finite life including those not available for use, are reviewed for impairment or more frequently if there are indicators of impairment. The Company will impair or write-off the intangible assets related to the acquisition of Nash Pharma when the recoverable value is less than the carrying value. The Nash Pharma intangibles are tested annually for impairment at August 31.

(2) The Company has filed trademark applications for the name "ALGERNON". During the year ended August 31, 2022, the Company changed its estimate in relation to the useful life of trademarks and began to amortize the trademarks over their estimated useful life of ten years. The Company recorded \$1,203 of amortization within general and administrative expenses on the condensed interim consolidated statement of loss and comprehensive loss for the nine months ended May 31, 2023 (2022 - \$nil).

(3) The Company in-licensed an issued patent relating its oncology program, for payments including up-front and annual license fees and patent filing costs reimbursed and is amortizing the patents based on its estimated useful life of 4.75 years. The Company recorded \$15,599 of amortization within research and development expenses on the condensed interim consolidated statement of loss and comprehensive loss for the nine months ended May 31, 2023 (2022 - \$6,554).

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

- (4) The Company has filed new method of use patents for lead compounds for treatment of six new disease areas: NASH, CKD, IBD, IPF, chronic cough and stroke. In addition to method of use, the applications for the stroke lead compounds also includes claims for composition of matter as well as formulations, dosages and devices. The likelihood of the application success is not known. During the year ended August 31, 2022, the Company changed its estimate in relation to the useful life of patent application costs and began to amortize these costs over their remaining estimated useful life representing the remaining months to expiration of the associated patent. The Company recorded \$20,257 of amortization within research and development expenses on the condensed interim consolidated statement of loss and comprehensive loss for the nine months ended May 31, 2023 (2022 - \$nil).

### RELATED PARTY TRANSACTIONS AND KEY MANAGEMENT COMPENSATION

Key management personnel are considered to be those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly. Key management includes senior officers and directors of the Company.

#### Short-term benefits

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2023	Nine months ended May 31, 2022
Christopher Moreau <sup>(1)</sup>	CEO / Director	CEO remuneration	\$ 165,000	\$ 165,000
James Kinley <sup>(2)</sup>	CFO	CFO remuneration	\$ 90,000	\$ 72,500
Michael Sadhra <sup>(3)(4)</sup>	CFO / Director	CFO remuneration	\$ nil	\$ 75,000
Christopher Bryan	VPRO	VPRO remuneration	\$ 97,500	\$ 97,500
Harry Bloomfield KC <sup>(5)</sup>	Chairman/Director	Director fees	\$ 30,501	\$ 23,849
Mark Williams <sup>(6)</sup>	Director	Director fees	\$ 19,500	\$ 12,000
Howard Gutman <sup>(7)</sup>	Director	Director fees	\$ 19,930	\$ 6,367
Raj Attariwala	Director	Director fees	\$ 19,500	\$ 9,500
David Levine <sup>(10)</sup>	Director	Director fees	\$ nil	\$ 3,000
Short-term benefits to key management personnel			\$ 441,931	\$ 464,716

(1) No director fees paid.

(2) Appointed CFO effective December 1, 2021.

(3) No director fees paid.

(4) Resigned as a director effective September 16, 2021 and resigned as CFO effective November 30, 2021.

(5) Appointed to the Board of Directors and as Chairman effective September 7, 2021.

(6) Appointed as a member of the Board of Directors effective September 16, 2021.

(7) Appointed to the Board of Directors effective February 28, 2022.

(8) Did not stand for reelection and ceased to be a member of the Board of Directors on February 28, 2022.

#### Share-based payments

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2023	Nine months ended May 31, 2022
Christopher Moreau	CEO / Director	Stock Option Grant	\$ 46,640	\$ 111,808
James Kinley	CFO	Stock Option Grant	\$ 31,268	\$ 33,277
Christopher Bryan	VPRO	Stock Option Grant	\$ 31,268	\$ 33,277
Harry Bloomfield KC	Chairman/Director	Stock Option Grant	\$ 34,980	\$ 34,940
Mark Williams	Director	Stock Option Grant	\$ 11,660	\$ 22,711
Howard Gutman	Director	Stock Option Grant	\$ 23,320	\$ nil
Raj Attariwala	Director	Stock Option Grant	\$ 11,660	\$ 22,711
David Levine	Director	Stock Option Grant	\$ nil	\$ 22,711
Christopher Moreau	CEO / Director	RSU grant	\$ 258,627	\$ nil
James Kinley	CFO	RSU grant	\$ 129,313	\$ nil
Christopher Bryan	VPRO	RSU grant	\$ 129,313	\$ nil

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

Harry Bloomfield KC	Chairman/Director	RSU grant	\$ 107,761	\$ nil
Mark Williams	Director	RSU grant	\$ 43,104	\$ nil
Howard Gutman	Director	RSU grant	\$ 43,104	\$ nil
Raj Attariwala	Director	RSU grant	\$ 43,104	\$ nil
Share-based compensation to key management personnel			\$ 945,122	\$ 281,435

Related party transactions not included in compensation to key management personnel are as follows:

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2023	Nine months ended May 31, 2022
Bloomfield & Advocats	Company with Harry Bloomfield Chairman / Director as principal <sup>(1)</sup>	Corporate secretarial services	\$ 2,250	\$ nil
Mark Williams	Member of board of directors <sup>(2)</sup>	Scientific consulting fees	\$ 5,000	\$ nil
Pacific Urban Advisory Group Inc.	Company with Michael Sadhra, CFO / Director as a principal <sup>(3)</sup>	Office rent	\$ nil	\$ 9,000

(1) Appointed as a member of the Board of Directors and as Chairman effective September 7, 2021.

(2) Appointed as a member of the Board of Directors effective September 16, 2021.

(3) Michael Sadhra resigned as a director effective September 16, 2021 and resigned as CFO effective November 30, 2021. Beginning December 1, 2021, this former senior officer and director is no longer a related party of the Company

Accounts payable and accrued liabilities include the following amounts due to related parties:

As at	May 31, 2023	August 31, 2022
Key management personnel – bonuses	\$ -	\$ 268,000
Key management personnel – directors fee	5,441	5,244
Key management personnel – consulting fees	-	788
Total	\$ 5,441	\$ 274,032

The amounts recorded within accounts payable and accrued liabilities that are due to related parties are unsecured, non-interest bearing and due on demand.

Prepaid expenses as at May 31, 2023 did not include any amounts (August 31, 2022 - \$32,132) pertaining to prepaid board of directors fees.

### RESEARCH AND DEVELOPMENT PROGRAM

Algermon is a drug re-purposing company that investigates safe, already approved drugs, including naturally occurring compounds, for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algermon specifically investigates compounds that have never been approved in the U.S. or Europe to avoid off label prescription writing, which can interfere with the normal economic pricing models of newly approved drug treatments.

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

The Company's early research identified a number of drug candidates that had already been approved for other diseases outside of the U.S and E.U. Only drugs that have not been approved in the U.S or Europe were chosen to avoid off-label prescription writing. The Company is actively investigating new disease areas including: CKD, IPF and chronic cough and stroke. In addition to these indications, the Company has additional drug candidates it is considering advancing where the Company has performed preclinical studies and filed intellectual property.

All the research and development ("R&D") work are carried out by the Company's 100% owned Canadian subsidiary, Nash Pharma, including through Nash's wholly owned subsidiary, Algernon Research Pty Ltd.

#### The breakdown of the major components of the research and development programs for the nine months ended May 31, 2023.

Period ended	May 31, 2023	May 31, 2022
Clinical Trials:		
Phase 2 for IPF and chronic cough	\$ 13,207	\$ 875,264
Phase 1 DMT	749,136	-
Phase 2b/3 multinational COVID study	-	2,676
	762,343	877,940
Preclinical:		
Ifenprodil preclinical and manufacture	13,001	43,253
DMT preclinical and manufacture	23,878	463,361
Repirinast	-	209,198
Oncology preclinical	-	39,277
	36,879	755,089
Management and Ad Hoc scientific support	54,552	97,137
Amortization of intangible assets	35,375	6,554
Total	889,149	1,736,720
Less: Australian R&D Tax Credit	17,653	(257,964)
Total Net Expense	\$ 906,802	\$ 1,478,756

#### SEGMENTED DISCLOSURES

The Company is a Canadian clinical stage pharmaceutical development company that operates in two reportable operating segments: the development of repurposed therapeutic drugs in Canada, and the facilitation of the Company's lead drug candidates into off-label phase II clinical trials (humans) in Australia. All of the Company's expenditures are incurred in both Canada and Australia. Geographical information of the Company's long-term assets are as follows:

As at May 31, 2023, the Company's long-term assets are located as follows:

	Canada	Australia	Total
Restricted cash equivalents	\$ 57,500	\$ -	\$ 57,500
Deferred share issue costs	196,972	-	196,972
Intangible assets	5,294,055	-	5,294,055
	\$ 5,548,527	\$ -	\$ 5,548,527

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

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As at August 31, 2022, the Company's long-term assets were located as follows:

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	Canada	Australia	Total
Restricted cash equivalents	\$ 57,500	\$ -	\$ 57,500
Intangible assets	5,256,159	-	5,256,159
	\$ 5,313,659	\$ -	\$ 5,313,659

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### SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are disclosed in Note 3 of the Company's annual audited consolidated financial statements for the year ended August 31, 2022.

#### Significant Accounting Judgments, Estimates and Assumptions

The preparation of financial statements in accordance with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and reported amounts of revenues and expenses during the reporting period.

Actual outcomes could differ from these estimates, and as such, the estimates and underlying assumptions are reviewed on an ongoing basis.

The Company assesses at each reporting date if the intangible assets have indicators of impairment. In determining whether the intangible assets are impaired, the Company assesses certain criteria, including observable decreases in value, significant changes with adverse effect on the entity, evidence of technological obsolescence and future plans.

The following are the accounting policies subject to such judgments and the key sources of estimation uncertainty that the Company believes could have the most significant impact on the reported results and financial position.

#### *Deferred income taxes*

The Company estimates the expected manner and timing of the realization or settlement of the carrying value of its assets and liabilities and applies the tax rates that are enacted or substantively enacted on the estimated dates of realization or settlement. In assessing the probability of realizing income tax assets, management makes estimates related to expectations of future taxable income, applicable tax opportunities, expected timing of reversals of existing temporary differences and the likelihood that tax positions taken will be sustained upon examination by applicable tax authorities.

The actual amount of income taxes only becomes final upon filing and acceptance of the tax return by the relevant tax authorities, which occurs subsequent to the issuance of the consolidated financial statements.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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#### *Share-based compensation*

The fair value of equity instruments is subject to the limitations of the Black-Scholes option pricing model, as well as other pricing models such as the Geske option pricing model for equity instruments involving compound options that incorporate market data and involve uncertainty in estimates used by management in the assumptions. Because option pricing models require inputs of highly subjective assumptions, including the volatility of share prices, changes in subjective input assumptions can materially affect the fair value estimate. The Company estimates volatility based on the Company's historical share prices, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the entities' expected share price volatility.

#### *Intangible assets – Treatment and Recoverability*

Following initial recognition, the Company carries the value of the intangible assets at cost less accumulated amortization and any accumulated impairment losses. Amortization is recorded on the straight-line basis based upon management's estimate of the useful life and residual value.

Recoverability of the carrying value of intangible assets requires management to determine whether future economic benefits from sale or otherwise are likely. Evaluation may be more complex where activities have not reached a stage that permits a reasonable assessment of the viability of the asset.

Management must make certain estimates and assumptions about future events or circumstances including, but not limited to, the interpretation of research results, as well as the Company's financial ability to continue sales activities and operations.

At each reporting date, the Company assesses if the intangible assets have indicators of impairment. In determining whether the intangible assets are impaired, the Company assesses certain criteria, including observable decreases in value, significant changes with adverse effect on the entity, evidence of technological obsolescence and future plans.

#### *Intangible assets – Assessment of Useful Life*

Intangible assets acquired as a part of the acquisition of Nash Pharma are intangible assets with a finite life that are not available for use. On an annual basis, intangible assets with finite life are reviewed for impairment and the Company impairs or writes off intangible assets when it abandons a drug or determine an amortization policy when a compound is approved.

During the year ended August 31, 2022, the Company changed its estimate in relation to the useful life of trademark application costs and began to amortize trademark application costs over their estimated useful life, estimated to be ten years.

During the year ended August 31, 2022, the Company in-licensed an issued patent relating its oncology program and is amortizing the patents based on its estimated useful life, which represents the remaining life of the patent of 4.75 years.

During the year ended August 31, 2022, the Company changed its estimate in relation to the useful life of patent application costs and began to amortize these costs over their remaining estimated useful life representing the remaining months to the expiration of the associated patent.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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#### *Qualified research and development expenses*

In determining whether the R&D expenses incurred in Australia qualify for the Australian R&D tax credit, the Company must use judgment in assessing whether expenses incurred meet the criteria set forth by the Australian Government. These criteria include, but are not limited to, whether the expenditure was incurred on R&D activities, whether the expense was incurred to acquire or construct a building, and whether the expense relates to a decline in value of depreciating assets used in R&D activities.

#### *Determination of the functional currency*

In concluding that the Canadian dollar is the functional currency of Algernon and Nash Pharma, and the Australian dollar is the functional currency of AGN Research, management considered the currency that mainly influences the cost of providing goods and services in the primary economic environment in which each entity operates, or if there has been a change in events or conditions that determined the primary economic environment.

#### *Going concern*

The assessment of the Company's ability to continue as a going concern and to raise sufficient funds to pay its ongoing operating expenditures and to meet its liabilities for the ensuing year, involves significant judgment based on historical experience and other factors, including expectation of future events that are believed to be reasonable under the circumstances.

Apart from the above, there have been no material revisions to the nature and amount of changes in estimates of amounts reported in its audited consolidated financial statements for the year ended August 31, 2022.

## **FINANCIAL INSTRUMENTS AND RISK MANAGEMENT**

The Company's financial instruments as at May 31, 2023 included cash and cash equivalents, accounts receivable, restricted cash equivalents and accounts payable and accrued liabilities.

The Company classifies its financial instruments into the following categories:

- cash and cash equivalent are classified as financial assets at FVTPL;
- accounts receivable are classified as loans and receivables;
- restricted cash equivalents are classified as financial assets at FVTP; and
- accounts payable and accrued liabilities are classified as financial liabilities, which are measured at amortized cost.

### **Fair Value**

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Financial instruments measured at fair value are classified into one of three levels in the fair value hierarchy according to the relative reliability of the inputs used to estimate the fair values.

1. Level 1 – fair values are based on quoted prices (unadjusted) in active markets for identical assets or liabilities;
2. Level 2 – fair values are based on inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (as prices) or indirectly (derived from prices); or
3. Level 3 – fair values are based on inputs for the asset or liability that are not based on observable market data (unobservable inputs).

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

The Company classified its financial instruments at Level 1 and as follows:

	<b>Financial Assets</b>		<b>Financial Assets</b>		<b>Financial Liabilities</b>	
	Fair Value Through Profit		Measured at Amortized Cost		Measured at Amortized Cost	
<b>May 31, 2023</b>						
Cash and cash equivalents	\$	434,234	\$	-	\$	-
Restricted cash equivalents		57,500		-		-
Accounts receivable		-		255		-
Accounts payable and accrued liabilities	\$	-	\$	-	\$	(2,414,375)
<b>August 31, 2022</b>						
Cash and cash equivalents	\$	1,408,509	\$	-	\$	-
Restricted cash equivalents		57,500		-		-
Accounts receivable		-		481		-
Accounts payable and accrued liabilities	\$	-	\$	-	\$	(2,516,099)

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

#### Credit risk

Credit risk is the risk of loss associated with a counter party's inability to fulfill its payment obligations. The Company's credit risk is primarily attributable to its cash and cash equivalents and accounts receivable. The Company's accounts receivable is mainly comprised of GST receivable, accrued interest receivable from GIC's held with bank, and accrued Australia R&D tax credit receivable. GST receivable and Australia R&D tax credit receivable are not financial instruments as they do not arise from contractual obligations. The Company limits exposure to credit risk on bank deposits by holding demand deposits in high credit quality banking institutions in Canada and Australia. Management believes that the credit risk with respect to receivables is minimal.

#### Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty in satisfying financial obligations as they become due. The Company manages its liquidity risk by forecasting cash flows from operations and anticipated investing and financing activities. The Company's objective in managing liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements. All of the Company's financial obligations are due within one year.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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At May 31, 2023, the Company had a working capital deficit of \$1,827,370 compared to working capital at August 31, 2022 of \$310,999. This included cash and cash equivalents of \$434,234 (August 31, 2022 - \$1,408,509) available to meet short-term business requirements and current liabilities of \$2,414,375 (August 31, 2022 - \$2,516,099).

#### **Market risk**

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises three types of risk: interest rate risk, foreign currency risk, and other price risks. The Company is not exposed to significant interest rate risk and other price risk.

#### **Interest rate risk**

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The risk that the Company will realize a loss as a result of a decline in the fair value of the cash is limited because of the short-term investment nature. The Company's financial asset exposed to interest rate risk consists of cash and cash equivalents and restricted cash equivalents. Restricted cash equivalents consists of GICs held at banking institutions that bear interest prime less 2.90% (August 31, 2022 – 2.65%) and mature one year from the purchase date.

#### **Other price risk**

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices, other than those arising from interest rate risk or foreign currency risk. The Company is not exposed to significant other price risk.

#### **Foreign currency risk**

Foreign currency risk is related to fluctuations in foreign exchange rates. The Company has certain expenditures that are denominated in US dollars ("US\$"), Australian dollars ("AUD\$"), Euros, British Pound Sterling ("GBP") and Swedish Krona ("Krona") and other operating expenses that are mainly in Canadian dollars ("CAD\$").

The Company holds funds in its Australian subsidiary in AUD\$ and may fund additional cash calls to this foreign subsidiary in the future. The Company's exposure to foreign currency risk arises primarily on fluctuations in the exchange rate of the CAD\$ relative to the US\$ and the AUD\$.

As at May 31, 2023, the Company had monetary assets of US\$4,206 or \$5,721 (August 31, 2022 - US\$29,841 or \$39,125) at the CAD\$ equivalent and monetary liabilities of US\$482,165 or \$655,889 (August 31, 2022 - US\$508,797 or \$667,084) at the CAD\$ equivalent. The Company's sensitivity analysis suggests that a change in the absolute rate of exchange in US\$ by 10% will increase or decrease comprehensive loss by approximately \$65,017 (August 31, 2022 - \$62,796).

As at May 31, 2023, the Company had monetary assets of AUD\$68,945 or \$60,768 (August 31, 2022 - AUD\$698,522 or \$627,832) at the CAD\$ equivalent and monetary liabilities of AUD\$469,189 or \$413,544 (August 31, 2022 - AUD\$668,260 or \$600,632) at the CAD\$ equivalent. The Company's sensitivity analysis suggests that a change in the absolute rate of exchange in AUD\$ by 10% will increase or decrease comprehensive loss by approximately \$35,278 (August 31, 2022 - \$2,720).

As at May 31, 2023, the Company had monetary liabilities of \$316,863 Euros or \$459,800 (August 31, 2022 - \$161,764 Euros or \$212,898) at the CAD\$ equivalent. The Company's sensitivity analysis suggests that a change in the absolute rate of exchange in the Euro by 10% will increase or decrease comprehensive loss by approximately \$45,980 (August 31, 2022 - \$21,290).

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### **Management's Discussion and Analysis**

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As at May 31, 2023, the Company had monetary liabilities of GBP\$66,639 or \$112,366 (August 31, 2022 - GBP\$120,000 or \$182,892) at the CAD\$ equivalent. The Company's sensitivity analysis suggests that a change in the absolute rate of exchange in the GBP by 10% will increase or decrease comprehensive loss by approximately \$11,237 (August 31, 2022 - \$18,289).

As at May 31, 2023, the Company had monetary liabilities of \$114,900 Krona or \$14,351 (August 31, 2022 – \$nil Krona or \$nil) at the CAD\$ equivalent. The Company's sensitivity analysis suggests that a change in the absolute rate of exchange in the Krona by 10% will increase or decrease comprehensive loss by approximately \$1,435 (August 31, 2022 - \$nil).

The Company has not entered into any foreign currency contracts to mitigate this risk. Foreign currency risk is considered low relative to the overall financial operating plan.

#### **COVID-19 Pandemic Risk**

Since December 31, 2019, the outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which included the implementation of travel bans, self-imposed quarantine periods and physical distancing, caused material disruption to business globally resulting in an economic slowdown. Global equity markets continue to experience significant volatility and weakness.

The duration and impact of the COVID-19 outbreak is unknown as how it would impact the Company's operations. COVID-19 restrictions in Australia led to temporary site closures and delays in patient screening and enrolment. With recent widespread adoption of vaccination, these restrictions have been lifted, however future site closures in jurisdictions where the Company is conducting clinical trials could result in delays in patient enrolment and screening ultimately delaying the completion of clinical research and development.

It is currently not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company in future periods.

## **RISKS RELATED TO THE BUSINESS**

### ***Limited Operating History***

The Company has a limited history of operations and is considered a development stage company. As such, the Company is subject to many risks common to such enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of its success must be considered in light of its early stage of operations.

### ***Negative Cash Flow for the Foreseeable Future***

The Company has no history of earnings or cashflow from operations. The Company does not expect to generate material revenue or achieve self-sustaining operations for several years, if at all. To the extent that the Company has negative cash flow in future periods, the Company may need to allocate a portion of its cash reserves to fund such negative cash flow.

### ***Going-Concern Risk***

The financial statements have been prepared on a going concern basis under which an entity is considered to be able to realize its assets and satisfy its liabilities in the ordinary course of business. The Company's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing an equity or debt financing or in achieving profitability.

The financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern.

### ***The Company may not be successful in its efforts to identify, license or discover additional product candidates.***

Although a substantial amount of the Company's effort will focus on the continued research and pre-clinical and clinical testing, potential approval and commercialization of its existing product candidates, the success of its business also depends in part upon its ability to identify, license or discover additional product candidates. The Company's research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- the Company's research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- the Company may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- the Company's product candidates may not succeed in pre-clinical or clinical testing;
- the Company's product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render the Company's product candidates obsolete or less attractive;

## ALGERNON PHARMACEUTICALS INC.

### Management's Discussion and Analysis

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- product candidates the Company develops may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during the Company's program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occurs, the Company may be forced to abandon its development efforts to identify, license or discover additional product candidates, which could have a material adverse effect on its business, prospects, results of operations and financial condition and could potentially cause the Company to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. The Company may focus its efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

#### ***Violations of laws and regulations could result in repercussions, and psychedelic inspired drugs may never be approved as medicines***

In Canada, under the CDSA, DMT is classified as a Schedule III drug and as such, medical and recreational use is illegal under the Canadian laws. Certain other jurisdictions, including the jurisdictions in which the Corporation has engaged third-party contractors, including Finland (EU) and the United Kingdom, have similarly regulated DMT. There is no guarantee that DMT will ever be approved as medicines in any jurisdiction in which the Company or its third-party contractors operate. The Company's third party contractors will conduct programs involving DMT in strict compliance with the laws and regulations regarding the production, storage and use of DMT. As such, all facilities engaged with such substances by or on behalf of the Company do so under current licenses and permits issued by appropriate federal, state and local governmental agencies. While a portion of the Company's research programs will be focused on using psychedelic inspired compounds, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates and does not intend to have any such involvement. However, a violation of any Canadian laws and regulations, such as the CDSA, or of similar legislation in the other jurisdictions, including Finland (EU) and the United Kingdom, could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which the Company or its third party contractors operate, or by private citizens, or through criminal charges. The loss of the necessary licenses and permits for Schedule III drugs by the Company's third party contractors could have an adverse effect on Algernon's operations.

#### ***None of the Company's product candidates has to date received regulatory approval for their intended commercial sale.***

None of the Company's product candidates has to date received regulatory approval for their intended commercial sale. The Company cannot market a pharmaceutical product in any jurisdiction until it has completed rigorous preclinical testing and clinical trials and passed such jurisdiction's extensive regulatory approval process. In general, significant research and development and clinical studies are required to demonstrate the safety and efficacy of a product candidate before it can be submitted for regulatory approval. Even if a product candidate is approved by the applicable regulatory authority, the Company may not obtain approval for an indication whose market is large enough to recover the Company's investment in that product candidate. In addition, there can be no assurance that we will ever obtain all or any required regulatory approvals for any of our product candidates.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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***The Company relies on contract research organizations consultants to design, conduct, supervise and monitor research due to a lack of internal resources to perform these functions.***

Outsourcing these functions involves risk that third party providers may not perform to the Company's standards, may not produce results in a timely manner or may fail to perform at all. If any contract research organization fails to comply with applicable regulatory requirements, the research and data generated may be deemed unreliable to regulatory authorities. Additional pre-clinical and clinical trials may be required before approval of marketing applications will be given. The Company cannot provide assurance that all third party providers will meet the regulatory requirements for research and pre-clinical trials. Failure of third party providers to meet regulatory requirements could result in repeat pre-clinical and clinical trials, which would delay the regulatory approval process or result in termination of pre-clinical and clinical trials. Any of the foregoing could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

#### ***Reliance on Third Parties for Research***

The Company relies on third parties for the execution of a significant portion of its regulatory, pharmacovigilance medical information, and logistical responsibilities and such third parties may fail to meet their obligations as a result of inadequacies in their systems and processes or execution failure.

The Company also relies on third parties to perform critical services, including preclinical testing, clinical trial management, analysis and reporting, regulatory, pharmacovigilance, medical information and logistical services.

These third parties may not be available on acceptable terms when needed or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner. This non-compliance may be due to a number of factors, including inadequacies in third-party systems and processes or execution failure. The Company may also experience unexpected cost increases that are beyond its control. As a result, the Company may need to enter into new arrangements with alternative third parties that may be costly. The time that it takes the Company to find alternative third parties may cause a delay, extension or termination of its preclinical studies or clinical trials and the Company may incur significant costs to replicate data that may be lost. These third parties may also have relationships with other commercial entities, some of which may compete with Algernon. In addition, if such third parties fail to perform their obligations in compliance with regulatory requirements and the Company's protocols, Algernon's preclinical studies or clinical trials may not meet regulatory requirements or may need to be repeated and its regulatory filings, such as marketing authorizations or new drug submissions, may not be completed correctly or within the applicable deadlines. As a result of Algernon's dependence on third parties, the Company may face delays or failures outside of its direct control in its efforts to develop product candidates.

## **ALGERNON PHARMACEUTICALS INC.**

### **Management's Discussion and Analysis**

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#### ***Regulatory approval risk***

Algernon's and its contract research organization's research and development activities and are and will be significantly regulated by a number of governmental entities, including Health Canada, the EMA, the Home Office in the U.K. and the FDA. Regulatory approvals are required prior to each clinical trial and Company and its contract research organizations may fail to obtain the necessary approvals to commence or continue clinical testing in one or more jurisdictions. The time required to obtain approval by regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials. Any analysis of data from clinical activities Algernon and its contract research organizations perform is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary

by jurisdiction. The Company and its contract research organizations could fail to receive regulatory approval for Algernon's planned research for many reasons, including but not limited to:

- disagreement with the design or implementation of its clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with Algernon's interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a submission to obtain regulatory approval;
- deficiencies in the manufacturing processes or the failure of facilities of collaborators with whom Algernon contracts for clinical supplies to pass a pre-approval inspection;
- changes in the approval policies or regulations that render Algernon's preclinical and clinical data insufficient for approval.

#### ***Psychedelic regulatory risks***

Psychedelic therapy is a new and emerging industry with ambiguous existing regulations and uncertainty as to future regulations. Certain psychedelics may be illegal substances other than when used for scientific or medical purposes. As such, new risks may emerge, and management may not be able to predict all such risks or be able to predict how such risks may result in actual results differing from the results contained in any forward-looking statements. This industry is subject to extensive controls and regulations, which may significantly affect the financial condition of market participants. The marketability of any product may be affected by numerous factors that are beyond the control of the Company and cannot be predicted, such as changes to government regulations, including those relating to taxes and other government levies which may be imposed. Changes in government levies, including taxes, could make future capital investments or operations uneconomic. The psychedelic therapy industry is also subject to numerous legal challenges, which may significantly affect the financial condition of market participants and which cannot be reliably predicted.

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#### ***Decriminalisation of psychedelics***

Despite the current status of DMT as a controlled substance in Canada, the EU, the United Kingdom and United States, there may be changes in the status of DMT under the laws of certain jurisdictions. Possession of psilocybin, for example, was voted to be decriminalised in May 2019 in Denver and in November 2020, voters in Oregon approved the legal medical use of "psilocybin products," including magic mushrooms, to treat mental health conditions in licensed facilities with registered therapists (Measure 109). The legalization of psychedelics with inadequate regulatory oversight may lead to the development of psychedelic tourism in such states in clinics without proper therapeutic infrastructure or adequate clinical research. While drug laws pertaining to DMT are less likely to be as forthcoming, the expansion of such an industry which could put patients at risk may bring reputational and regulatory risk to the entire industry, leading to challenges for Algernon to achieve regulatory approval. The legalization of psilocybin, and potentially other psychedelic compounds (including DMT) in the future may also impact commercial sales for Algernon due to a reduced barrier to entry leading to a risk of increasing competition.

#### ***Enforcing Contracts***

Due to the nature of the business of Algernon and the fact that certain of its contracts involve the possession, manufacture, production or supply of DMT, the use of which is not legal under U.K., EU, U.S. or Canadian law and in certain other jurisdictions, Algernon may face difficulties in enforcing its contracts in the courts in the UK, EU, U.S. or Canada. The inability to enforce any of its contracts could have a material adverse effect on its business, operating results, financial condition or prospects.

In order to manage its contracts with contractors, Algernon will ensure that such contractors are appropriately licensed. Were such contractors to operate outside the terms of these licenses, Algernon may experience an adverse effect on its business, including the pace of development of its product.

#### ***Unfavourable publicity or consumer perception***

The success of the industry in which the Corporation operates may be significantly influenced by the public's perception of psychedelic inspired medicinal applications. There is no guarantee that future scientific research, publicity, regulations, medical opinion, and public opinion relating to psychedelic inspired medicine will be favourable. The industry in which the Company operates is in its early stages and is constantly evolving, with no guarantee of viability. The market for psychedelic inspired medicines is uncertain, and any adverse or negative publicity, scientific research, limiting regulations, medical opinion and public opinion relating to the consumption of psychedelic inspired medicines may have a material adverse effect on the Company's operational results, consumer base and financial results. While the Company is undertaking research programs using psychedelic inspired compounds, and does not advocate for the legalization of any psychedelic substances or deal with psychedelic substances except within laboratory and clinical trial settings conducted within approved regulatory frameworks, any unfavourable publicity or consumer perception regarding psychedelic substances (in addition to psychedelic inspired medicines) could also have a material adverse effect on the Company's operational results, consumer base and financial results.

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### **Management's Discussion and Analysis**

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#### ***The psychedelic therapy industry is difficult to quantify and investors will be reliant on their own estimates of the accuracy of market data***

Because the psychedelic therapy industry is in a nascent stage with uncertain boundaries, there is a lack of information about comparable companies available for potential investors to review in deciding about whether to invest in Algernon and, few, if any, established companies whose business model Algernon can follow or upon whose success Algernon can build. Accordingly, investors will have to rely on their own estimates in deciding about whether to invest in Algernon. There can be no assurance that Algernon's estimates are accurate or that the market size is sufficiently large for its business to grow as projected, which may negatively impact its financial results.

#### ***Failure to follow regulatory requirements***

The Company's prospects must be considered in light of the risks, expenses, shifts, changes and difficulties frequently encountered with companies whose businesses are regulated by various federal, state and local governments. The health care, wellness, workers compensation and similar companies are subject to a variety of regulatory requirements and the regulatory environment is ever changing particularly with recent legislation, the full impact of which is not yet understood as regulations have not been issued. Failure to follow applicable regulatory requirements will have a materially negative impact on the business of the Company. Furthermore, future changes in legislation cannot be predicted and could irreparably harm the business of the Company.

#### ***Additional financing needs***

The Company will require equity and/or debt financing to support on-going operations, to undertake capital expenditures or to undertake acquisitions or other business combination transactions. There can be no assurance that additional financing will be available to the Company when needed or on terms which are acceptable. The Company's inability to raise financing to fund capital expenditures or acquisitions could limit its growth and may have a material adverse effect upon its business, prospects, results of operations and financial condition.

If additional funds are raised through further issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of holders of common shares. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Company to obtain additional capital and to pursue business opportunities, including potential acquisitions.

Because of the early stage of the industry in which the Company will operate, the Company expects to face additional competition from new entrants. To become and remain competitive, the Company will require research and development, marketing, sales and client support. The Company may not have sufficient resources to maintain research and development, marketing, sales and client support efforts on a competitive basis which could materially and adversely affect the business, financial condition and results of operations of the Company.

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#### ***Intellectual Property Rights***

The Company could be adversely affected if it does not adequately protect its intellectual property rights. The Company regards its marks, rights, and trade secrets and other intellectual property rights as critical to its success. To protect its investments and the Company's rights in these various intellectual properties, it may rely on a combination of patents, trademark and copyright law, trade secret protection and confidentiality agreements and other contractual arrangements with its employees, clients, strategic partners, acquisition targets and others to protect proprietary rights. There can be no assurance that the steps taken by the Company to protect proprietary rights will be adequate or that third parties will not infringe or misappropriate the Company's copyrights, trademarks and similar proprietary rights, or that the Company will be able to detect unauthorized use and take appropriate steps to enforce rights. In addition, although the Company believes that its proprietary rights do not infringe on the intellectual property rights of others, there can be no assurance that other parties will not assert infringement claims against the Company. Such claims, even if not meritorious, could result in the expenditure of significant financial and managerial resources.

The Company will rely on trade secrets to protect technology where it does not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect. While commercially reasonable efforts to protect trade secrets will be used, strategic partners, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose information to competitors.

If the Company is not able to defend patents or trade secrets, then it will not be able to exclude competitors from developing or marketing competing products, and the Company may not generate enough revenue from product sales to justify the cost of development of products and to achieve or maintain profitability.

#### ***Pre-clinical and clinical trials, including reliance on third parties to conduct such trials***

The Company's clinical trials for each product candidate may fail to adequately demonstrate the safety and efficacy of that candidate, which could force the Company to abandon its product development plans for that product candidate. Before obtaining regulatory approval for the commercial sale of any of its product candidates, the Company must demonstrate, through lengthy, complex and expensive pre-clinical testing and clinical trials, that each product is both safe and effective for use in each target indication. Clinical trial results are inherently difficult to predict, and the results the Company has obtained or may obtain from third-party trials or from its own trials may not be indicative of results from future trials. The Company may also suffer significant setbacks in advanced clinical trials even after obtaining promising results in earlier studies. Although the Company intend to modify any of its protocols in ongoing studies or trials to address any setbacks, there can be no assurance that these modifications will be adequate or that these or other factors will not have a negative effect on the results of its clinical trials. This could significantly disrupt the Company's efforts to obtain regulatory approvals and commercialize its product candidates. Furthermore, the Company may voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable safety risk to patients, either in the form of undesirable side effects or otherwise. If the Company cannot show that its product candidates are both safe and effective in clinical trials, it may be forced to abandon its business plan.

The Company will rely on third parties to conduct its product development, chemistry activities, as well as pre-clinical and clinical trials. If these third parties do not perform as contractually required or as otherwise expected the Company may not be able to obtain regulatory approval for its product candidates, which may prevent it from becoming profitable.

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***Pre-clinical and clinical trials will be lengthy and expensive. Delays in clinical trials are common for many reasons and any such delays could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales as currently contemplated.***

As part of the regulatory process, the Company would need to conduct clinical trials for any drug candidate to demonstrate safety and efficacy to the satisfaction of the regulatory authorities, including the FDA for the U.S. and Health Canada for Canada should it decide to seek approval in those jurisdictions. Clinical trials are subject to rigorous regulatory requirements and are expensive and time-consuming to design and implement. The Company may experience delays in clinical trials for any of its drug candidates, and the projected timelines for continued development of the technologies and related drug candidates by the Company may otherwise be subject to delay or suspension. Any planned clinical trials might not begin on time; may be interrupted, delayed, suspended, or terminated once commenced; might need to be redesigned; might not enroll a sufficient number of patients; or might not be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including the following:

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the FDA, a data safety monitoring board or committee or by the Company;
- delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites;
- delays in obtaining required monitoring board approval at each site for clinical trial protocols;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new sites;
- delays in obtaining sufficient supplies of clinical trial materials, including comparator drugs;
- delays resulting from negative or equivocal findings of a data safety monitoring board for a trial; or
- adverse or inconclusive results from pre-clinical testing or clinical trials.

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 patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the biologic being studied in relation to other available therapies, including any new biologics that may be approved for the indications we are investigating. Any of these delays in completing our clinical trials could increase costs, slow down the product development and approval process, and jeopardize the Company's ability to commence product sales and generate revenue.

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***The Company may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of its drug candidates.***

Clinical trials may be suspended or terminated at any time for a number of reasons. A clinical trial may be suspended or terminated by the Company, its collaborators, the FDA, or other regulatory authorities because of a failure to conduct the clinical trial in accordance with regulatory requirements or the Company's clinical protocols, presentation of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational biologic, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or negative or equivocal findings of the data safety monitoring board for a clinical trial. The Company may voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable risk to participants. If the Company elects or is forced to suspend or terminate any clinical trial of any proposed product that it develops, the commercial prospects of such proposed product will be harmed and the Company's ability to generate product revenue from such proposed product will be delayed or eliminated. Any of these occurrences could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

***The Company faces product liability exposure, which, if not covered by insurance, could result in significant financial liability.***

The risk of product liability is inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Product candidates and products that we may commercially market in the future may cause, or may appear to have caused, injury or dangerous drug reactions, and expose the Company to product liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, corporate collaborators or others selling such products. If the Company's product candidates during clinical trials were to cause adverse side effects, the Company may be exposed to substantial liabilities. Regardless of the merits or eventual outcome, product liability claims or other claims related to the Company's product candidates may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle related litigation;
- a diversion of management's time and resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of product candidates, if approved.

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The Company intends to obtain clinical trial insurance once a clinical trial is initiated. However, the insurance coverage may not be sufficient to reimburse the Company for any expenses or losses it may suffer. Insurance coverage is becoming increasingly expensive, and, in the future, the Company, or any of its collaborators, may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or at all to protect against losses due to liability. Even if the Company's agreements with any future collaborators entitle it to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise. The Company's inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the commercialization of its product candidates. If a successful product liability claim or series of claims is brought against the Company for uninsured liabilities or in excess of insured liabilities, its assets may not be sufficient to cover such claims and its business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

***In light of the Company's current resources and limited experience, it may need to establish successful third-party relationships to successfully commercialize its future product candidates.***

The long-term viability of the Company's future product candidates may depend, in part, on the Company's ability to successfully establish new strategic collaborations with pharmaceutical and biotechnology companies, non-profit organizations and government agencies. Establishing strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of the Company's financial, regulatory or intellectual property position or based on their internal pipeline; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, the ability of the Company's products to address these areas, or other reasons beyond our expectations or control. If the Company fails to establish a sufficient number of collaborations or government relationships on acceptable terms, it may not be able to commercialize any future drug candidates or generate sufficient revenue to fund further research and development efforts.

Even if the Company establishes new collaborations or obtains government funding, these relationships may never result in the successful development or commercialization of any drug candidates for several reasons, including the fact that:

- the Company may not have the ability to control the activities of its partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of drug candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to the Company's drug candidates or properly maintain or defend our intellectual property rights;
- relationships with collaborators could also be subject to certain fraud and abuse laws if not structured properly to comply with such laws;
- any failure on the part of the Company's partners to perform or satisfy their obligations to the Company could lead to delays in the development or commercialization of drug candidates and affect the Company's ability to realize product revenue; and
- disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time-consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

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If the Company or its collaborators fail to maintain our existing agreements or in the event we fail to establish agreements as necessary, the Company could be required to undertake research, development, manufacturing and commercialization activities solely at its own expense. These activities would significantly increase capital requirements and, given the Company's lack of sales, marketing and distribution capabilities, significantly delay the commercialization of future drug candidates

#### ***Rapid Technological Change***

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes could have a material adverse effect on the Company's business, prospects, results of operations and financial condition. The Company is subject to the risks of companies operating in the medical and healthcare business.

The market in which Algernon competes is characterized by rapidly changing technology, evolving industry standards, frequent new service and product announcements, introductions and enhancements and changing customer demands. As a result, an investment in the common shares of the Company is highly speculative and is only suitable for investors who recognize the high risks involved and can afford a total loss of investment.

#### ***Protection and Enforcement of Intellectual Property Rights***

The Company regards the protection of its copyrights, service marks, trademarks, trade dress and trade secrets as critical to its future success and relies on a combination of copyright, trademark, service mark and trade secret laws and contractual restrictions to establish and protect its proprietary rights in products and services. The Company has entered into confidentiality and invention assignment agreements with its officers and contractors, and nondisclosure agreements with parties with which it conducts business in order to limit access to and disclosure of its proprietary information. There can be no assurance that these contractual arrangements or the other steps taken by the Company to protect its intellectual property will prove sufficient to prevent misappropriation of the Company's technology or to deter independent third-party development of similar technologies.

To date, the Company has not been notified that its technologies infringe the proprietary rights of third parties, but there can be no assurance that third parties will not claim infringement by the Company with respect to past, current or future technologies. The Company expects that participants in its markets will be increasingly subject to infringement claims as the number of services and competitors in the Company's industry segment grows. Any such claim, whether meritorious or not, could be time-consuming, result in costly litigation, cause service upgrade delays or require the Company to enter into royalty or licensing agreements. Such royalty or licensing agreements might not be available on terms acceptable to the Company or at all. As a result, any such claim could have a material adverse effect upon the Company's business, prospects, results of operations and financial condition.

#### ***Litigation Risks***

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which the Company becomes involved be determined against the Company such a decision could adversely affect the Company's ability to continue operating and the market price for the Company's common shares. Even if the Company is involved in litigation and wins, litigation can redirect significant company resources.

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Commercial success of the Company will depend in part on not infringing upon the patents and proprietary rights of other parties and enforcing its own patents and proprietary rights against others. The research and development programs will be in highly competitive fields in which numerous third parties have issued patents and pending patent applications with claims closely related to the subject matter of the Company's programs. The Company is not currently aware of any litigation or other proceedings or claims by third parties that its technologies or methods infringe on their intellectual property.

While it is the practice of the Company to undertake pre-filing searches and analyses of developing technologies, they cannot guarantee that they have identified every patent or patent application that maybe relevant to the research, development, or commercialization of its products. Moreover, the Company can provide no assurance that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

#### ***There may be larger, better financed companies which may become competition for the Company.***

There is high potential that the Company will face intense competition from other companies, some of which can be expected to have longer operating histories and more financial resources and research and manufacturing than the Company. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company. At present, management believes that there are a number of drug development companies, on a global scale, that are advancing compounds for the treatment of NASH, IBD and CKD and are in various stages of development from pre-clinical up to and including Phase 3 human trials.

In regards to its medical device, the Company has certain direct competition from Menssana Research Inc., which is based in New Jersey, U.S. and Owlstone Nanotech Inc., which is based in the United Kingdom. These companies have the financial ability to compete directly with the Company.

Competitive pressures created by any one of these companies, or by the Company's competitors collectively, could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

The Company believes that the principal competitive factors in its market are its ability to develop drug compounds that are more efficacious than the current gold standard treatment of other drugs under development, to protect its intellectual property and to also be the first company to deliver its medical device products to the market on a timely and cost-effective basis.

Better performing drugs and the expansion of existing technologies may increase the competitive pressures on the Company by enabling the Company's competitors to receive regulatory approval to market for certain drugs before its compounds are approved, offer a lower-cost product.

#### ***Reliance on Management***

The success of the Company is dependent upon the ability, expertise, judgment, discretion and good faith of its senior management. While employment/consulting agreements are customarily used as a primary method of retaining the services of key management, these agreements cannot assure the continued services of such persons. Any loss of the services of such individuals could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

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#### ***Dividends***

The Company has no earnings or dividend record, and does not anticipate paying any dividends on the common shares in the foreseeable future. Dividends paid by the Company would be subject to tax and, potentially, withholdings.

#### ***Limited Market for Securities***

The Company's common shares are listed on the CSE. There can be no assurance that an active and liquid market for the common shares will be maintained and an investor may find it difficult to resell any securities of the Company.

#### ***Permits and Licenses***

The operations of the Company may require licenses and permits from various governmental authorities. There can be no assurance that such licenses and permits will be granted.

#### ***Uninsurable Risks***

The business of the Company may not be insurable or the insurance may not be purchased due to high cost. Should such liabilities arise, they could reduce or eliminate any future profitability and result in increasing costs and a decline in the value of the Company.

#### ***The market price of the Company's common shares may be subject to wide price fluctuations***

The market price of the Company's common shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Company and its subsidiaries, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Company and its subsidiaries, general economic conditions, legislative changes, and other events and factors outside of the Company's control. In addition, stock markets have from time to time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Company's common shares.

#### ***The lack of product for commercialization***

If the Company cannot successfully develop, manufacture and distribute its products, or if the Company experiences difficulties in the development process, such as capacity constraints, quality control problems or other disruptions, the Company may not be able to develop market-ready commercial products at acceptable costs, which would adversely affect the Company's ability to effectively enter the market. A failure by the Company to achieve a low-cost structure through economies of scale or improvements in cultivation and manufacturing processes could have a material adverse effect on the Company's commercialization plans and the Company's business, prospects, results of operations and financial condition.

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#### ***The lack of experience of the Company/Management in marketing, selling, and distribution products***

The Company's management's lack of experience in marketing, selling, and distributing our products could lead to poor decision-making which could result in cost-overruns and/or the inability to produce the desired products. Although management of the Company intends to hire experienced and qualified staff, this inexperience could also result in the company's inability to consummate revenue contracts or any contracts at all. Any combination of the aforementioned may result in the failure of the Company and a loss of your investment.

#### ***Risks Associated with Future Acquisitions***

If appropriate opportunities present themselves, the Company intends to acquire businesses, technologies, services or products that the Company believes are strategic. The Company currently has no understandings, commitments or agreements with respect to any other material acquisition and no other material acquisition is currently being pursued. There can be no assurance that the Company will be able to identify, negotiate or finance future acquisitions successfully, or to integrate such acquisitions with its current business. The process of integrating an acquired business, technology, service or product into the Company may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of the Company's business. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could materially adversely affect the Company's business, results of operations and financial condition. Any such future acquisitions of other businesses, technologies, services or products might require the Company to obtain additional equity or debt financing, which might not be available on terms favourable to the Company, or at all, and such financing, if available, might be dilutive.

#### ***Difficulty to Forecast***

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. A failure in the demand for its products to materialize as a result of competition, technological change or other factors could have a material adverse effect on the Company's business, prospects, results of operations and financial condition.

#### ***Conflicts of Interest***

Certain of the directors and officers of the Company are, or may become directors and officers of other companies, and conflicts of interest may arise between their duties as officers and directors of the Company and as officers and directors of such other companies.

#### ***Global Economy Risk***

The ongoing economic slowdown and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by the ongoing global economic risks. As such, the Company is subject to liquidity risks in meeting our development and future operating cost requirements in instances where cash positions are unable to be maintained or appropriate financing is unavailable. These factors may impact the Company's ability to raise equity or obtain loans and other credit facilities in the future and on terms favourable to the Company. If uncertain market conditions persist, the Company's ability to raise capital could be jeopardized, which could have an adverse impact on the Company's operations and the trading price of the Company's shares on the stock exchange.

# **ALGERNON PHARMACEUTICALS INC.**

## **Management's Discussion and Analysis**

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### ***Public Health Crises, including COVID-19***

A local, regional, national or international outbreak of a contagious disease, such as COVID-19, could have an adverse effect on local economies and potentially the global economy, which may adversely affect the Company's ability to conduct operations and may result in shortages of staff and disturbances where the Company or its collaborative partners are enrolling patients in the Company's clinical trials. Such an outbreak, if uncontrolled, could have a material adverse effect on our business, prospects, results of operations and financial condition, including a potential disruption to the supply chain and the manufacture or shipment of both drug substance and finished drug product for our product candidates for preclinical testing and clinical trials and adversely impact our business, financial condition or results of operations. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

### **MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS**

The information provided in this report, including the consolidated financial statements, are the responsibility of Management. In the preparation of this report, estimates are sometimes necessary to make a determination of future values for certain assets or liabilities. Management believes such estimates have been based on careful judgments and have been properly reflected in the accompanying financial statements.

July 27, 2023

On behalf of Management and the Board of Directors,

*"Chris Moreau"*

Director and Chief Executive Officer