Algernon Pharmaceuticals Inc.

MANAGEMENT'S DISCUSSION AND ANALYSIS For the years ended August 31, 2022 and 2021

Dated November 21, 2022

Management's Discussion and Analysis

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 November 21, 2022. 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 statements with "forward-looking information" ("forward-looking statements") within the meaning of applicable securities laws. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "expects" or "does not expect", "is expected", "estimated", "intends", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases or statements that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. In particular and without limitation, this MD&A contains forward-looking statements pertaining to the following:

- 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.

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.

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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 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 and the Company's website at www.sedar.com and <a href="

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.

All the research and development work are carried out by the Company's 100% Canadian own subsidiary, Nash Pharmaceuticals Inc. ("Nash Pharma"), including through Nash's wholly owned subsidiary, Algernon Research Pty Ltd. 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 2 clinical trials (human).

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As at August 31, 2022, the Company has an accumulated deficit of \$25,186,887 (2021 - \$23,546,345) and for the year then ended incurred a net loss of \$6,054,356 (2021 - \$7,734,080). 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 raise 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 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. The 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 pancreatic and small cell lung cancer. 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 is conducting 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. On May 6, 2020, the Company received ethics approval from the Royal Brisbane & Women's Hospital, Human Research Ethics Committee. 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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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.

Since all of Algernon's lead compounds are genericized, 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:

On June 13, 2022, the Company announced that its Phase 2 proof-of-concept study of Ifenprodil for IPF and chronic cough had reached database lock meaning all data from the trial is now finally reported, cleaned and locked in the database.

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 is has been issued a patent from the Canadian Intellectual Property Office, No. 3101853, for the treatment of interstital lung disease with Ifenprodil, entitled "Compositions and Methods for Treating Idiopathic Pulmonary Fibrosis."

On July 5, 2022, the Company disclosed that as part of its intellectual property patent applications filed in early calendar 2021 for N,N-Dimethyltryptamine ("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_{2 A} and sigma-1 receptors; key receptors in the brain that are activated by DMT.

On July 7, 2022, the Company provided an update on its planned Phase 1 clinical human study of DMT and on July 11, 2022 provided an update on its CKD research program with Repirinast. Details of these updates are include in the "Business Development" section.

On July 18, 2022, the Company announced positive topline data showing that it has met the co-primary endpoint in its Phase 2 proof of concept study evaluating Ifenprodil for the potential treatment of IPF and chronic cough. In the study, 65% of patients had stable or improved forced vital capacity ("FVC") over the 12-week treatment period with statistical significance when compared to an anticipated placebo effect of 40%. FVC is the amount of air that can be forcibly exhaled from one's lungs after taking the deepest breath possible.

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For the chronic cough part of the study's primary endpoint, 30% of subjects achieved the endpoint of a 50% reduction in the average number of coughs per hour over 24 hours from baseline to week 12. While this primary cough study endpoint did not achieve statistical significance when compared to an anticipated placebo effect of 25%, the secondary endpoint of actual changes (reduction) in cough counts did. Specifically, subjects experienced a 24% relative reduction from baseline in mean cough count, and a 38% relative reduction from baseline in median cough count in their 24-hour cough count per hour at week 12 (p=0.0344). In addition, 75% of subjects saw improvements in their cough over 12 weeks.

On July 28, 2022, the Company announced additional results from the Phase 2 proof of concept study evaluating Ifenprodil for the potential treatment of IPF and chronic cough. After further review of the topline data, Ifenprodil was shown to be much more effective at reducing cough in patients than initially reported.

On September 1, 2022, the Company announced positive results from the full data set of its Phase 2a Study evaluating NP- 120 ("Ifenprodil") for the potential treatment of idiopathic pulmonary fibrosis ("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.

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 will be 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.

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 announces it has filed a request for Orphan Designation with the FDA for the use of Ifenprodil as a treatment for IPF.

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.

Business Development

The Company concluded several feasibility studies to determine the disease, drug compound and best geographical location to run its first phase 2 study.

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 upcoming phase 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. The Company began screening patients on July 7, 2020 and enrolled its first patient on August 5, 2020.

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On October 8, 2021, the Company announced it filed a pre-IND meeting request with the FDA for an Ifenprodil Phase 2 chronic cough study. The decision to expand its Ifenprodil research program was based on positive trending interim data received by the Company from the chronic cough part of its 20-patient Phase 2 IPF and chronic cough study being conducted in Australia and New Zealand.

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.

On January 14, 2022, the Company announce that it has received positive feedback from the FDA of its pre-IND meeting for its investigation of Ifenprodil for the treatment of chronic cough.

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.

On May 5, 2022, the Company announced that the last patient has completed the treatment period in its Phase 2 proof of concept study of Ifenprodil for IPF and chronic cough. Topline data became available in July 2022.

On June 13, 2022, the Company announced that its Phase 2 proof-of-concept study of Ifenprodil for IPF and chronic cough had reached database lock meaning all data from the trial is now finally reported, cleaned and locked in the database.

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 is has been issued a patent from the Canadian Intellectual Property Office, No. 3101853, for the treatment of interstital lung disease with Ifenprodil, entitled "Compositions and Methods for Treating Idiopathic Pulmonary Fibrosis."

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.

Management's Discussion and Analysis

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.

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.

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).

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.

The full results of the trial will be presented at the 21st International Colloquium on Lung and Airway Fibrosis in Reykjavik, Iceland in October 2022, and will also be discussed at the 9th American Cough Conference in Reston, Virginia in June 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 announces it has filed a request for Orphan Designation with the FDA for the use of Ifenprodil as a treatment for IPF.

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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.

The Company has decided to focus on the continued investigation of Ifenprodil for IPF with cough after hitting its key co-primary endpoint in its Phase 2a study of IPF with chronic cough. In the trial, patients receiving Ifenprodil experienced no worsening of their lung function, and significant improvements in the frequency of their IPF-associated cough. In addition, improvements in patient-reported measures of cough severity and quality of life were observed. The drug was also confirmed to be safe and well tolerated in the study.

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.

On September 7, 2021, 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.

On October 13, 2021, the Company announced that it had filed a scientific advice meeting request with the MHRA for a Phase 1/2a stroke study with DMT.

On November 1, 2021, the Company announced that it had 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 November 19, 2021, the Company that it has received positive feedback at a scientific advice meeting from the MHRA. The scientific advice meeting was related to the Company's planned Phase 1/2a stroke study with DMT.

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.

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The Company also announces it 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 in the U.K. in the latter part of 2022, after the Phase 1 trial has been completed.

On January 19, 2022, the Company announced that it has filed a combined Clinical Trials of Investigational Medicinal Products ("CTIMP") and Ethics Approval application, with the MHRA. This was accomplished via the combined review service, which provides for a single application route for its planned Phase 1 clinical human study of DMT.

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.

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_{2 A} and sigma-1 receptors; key receptors in the brain that are activated by DMT.

On July 7, 2022, the Company provided an update on its planned Phase 1 clinical human study of DMT.

The Company is currently working to complete the IVF that will be used in the Phase 1 DMT study and has retained the CHDR and its affiliated pharmacy at the Leiden University Medical Center in the Netherlands, to complete the work. The Company is planning to begin the Phase 1 study in September of 2022.

The Company announced earlier that it had filed for a CTIMP application with the MHRA via the combined review service, which provides for a single application route for both clinical trial authorization and ethics approval. The key feedback provided by the MHRA focussed on the IVF of DMT for administration.

The original plan was to complete the IVF in the onsite pharmacy at HMR prior to the Phase 1 DMT study beginning. However, to meet the specifications requested by the MHRA, it was determined that a new vendor would be needed that had additional technical cGMP-suite capabilities.

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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.

The primary focus of Algernon's planned 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.

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 Stichting Beoordeling Ethiek Biomedisch Onderzoek ("BEBO"), an independent Medical Research Ethics Committee ("MREC"). The trial will be conducted at the 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.

The Company plans to begin screening shortly and dose the first subject of the study in calendar Q4, 2022.

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.

Chronic Kidney Disease

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

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Repirinast was originally developed by Mitsubishi Tanabe Pharma ("Mitsubishi") and was sold and marketed in Japan under the brand name RometTM for the treatment of asthma. RometTM 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.

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

On July 11, 2022, the Company provided an update on its CKD research program Repirinast.

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 previously announced It had retained Ausun to manufacture its own supply of cGMP grade Repirinast. Ausun has now developed and optimized a new synthetic route to Repirinast. The last major step on a full- scale engineering batch has been completed, and final material for toxicology studies and formulation development is expected to be delivered in late July 2022. Ausun has also developed and validated all analytical methods for testing.

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.

Pancreatic Cancer

On June 3, 2021, the Company announced a new clinical research program for pancreatic cancer ("PC") and Ifenprodil. Ifenprodil demonstrated a significant anti-tumour effect in a PC animal model which was reported in a paper published in the Dove Press Journal, Clinical Pharmacology: Advances and Applications.

The Company plans to file a pre-IND application with the US FDA in the near future.

Small Cell Lung Cancer

On August 11, 2021, the Company announced that it has initiated an Ifenprodil SCLC research program and appointed Dr. William North, professor emeritus at Dartmouth College and cancer research pioneer, as lead consultant. In a study published in January 2019, entitled "Small-Cell Lung Cancer Growth Inhibition: Synergism Between NMDA Receptor Blockade and Chemotherapy", Ifenprodil in combination with chemotherapeutic agent topotecan, produced clear additive effects that completely blocked tumor growth.

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On September 22, 2021, the Company announced that it has filed a pre-IND meeting request with the FDA for its investigation of Ifenprodil for the treatment of SCLC.

On November 24, 2021, the Company announced that it has received positive feedback from the FDA of its pre-IND meeting for its investigation of Ifenprodil for the treatment of SCLC.

As a result of the feedback, the Company is not planning to conduct any additional pre-clinical research and will immediately move to file an IND application to begin its Phase 1 SCLC study as soon as possible. Based on the feedback from the meeting, the Company plans to use its current Ifenprodil finished product inventory for the study. The FDA meeting also produced very helpful guidance on the protocol design and endpoints for the planned SCLC study.

The Company is planning to conduct its Phase 1 study in patients with recurrent SCLC and, as a result, preliminary efficacy signals may be observed in the data.

The Company also plans to apply for orphan drug designation for Ifenprodil to treat patients with SCLC. The U.S. Orphan Drug Act grants special status to a drug for the treatment, diagnosis or prevention of a rare disease or condition.

The Company is planning the following milestones:

Calendar Year 2022/23

Q4/22

- Begin Phase 1 Study DMT/Stroke
- Ifenprodil IPF/chronic cough Pre-IND meeting

Q1/23

Begin Phase 1 Ifenprodil bioequivalence study for new once-daily formulation

Q2/23

- Begin Phase 2b Study Ifenprodil IPF/chronic cough
- Ifenprodil IPF/chronic cough IND Filing and fast track application
- Data from Phase 1 Study DMT/Stroke
- · Begin Phase 1 Study Repirinast/CKD

Q4/23

Data from Phase 1 Study Repirinast/CKD

Regulatory Regimes (Canada, the EU and the U.S) & Drug Scheduling Regulations

Canada

Certain psychoactive compounds, such as DMT, are considered controlled substances under the Controlled Drugs and Substances Act ("CDSA"). DMT and any salt thereof, is listed under Schedule III of the CDSA. The possession, sale or distribution of controlled substances is prohibited unless specifically permitted by the government. Penalties for contravention of the CDSA related to Schedule I substances are the most punitive, with Schedule II being less punitive than Schedule I, Schedule III being less punitive than Schedule I and II and so forth. A party may seek government approval for a Section 56 Exemption to allow for the possession, transport or production of a controlled substance for medical or scientific purposes, as discussed in further detail below under the heading "Regulatory Approvals Required for Studies – Canada."

Management's Discussion and Analysis

Health Canada regulates all health products in Canada, and a health product may only be sold in Canada with the permission of Health Canada. During its evaluation of the safety, efficacy and quality of each health product, Health Canada determines whether a drug should be a controlled substance, a prescription drug or a non-prescription drug. A substance may be deemed a controlled substance but also a prescription drug. As discussed above, scheduling the substance in the CDSA means that there are criminal consequences to possessing the drug unlawfully. If Health Canada determines that a drug requires a prescription, it is placed on the Health Canada Prescription Drug List ("PDL"). DMT is not currently on the PDL.

After Health Canada determines if a drug may be sold in Canada and if it requires a prescription, the individual provinces, territories and the National Association of Pharmaceutical Regulatory Authorities ("NAPRA") decide where it may be sold, under advisement from the National Drug Scheduling Advisory Committee. NAPRA maintains a harmonized list referred to as the National Drug Schedules. NAPRA may decide to be more restrictive in scheduling drugs, but never less restrictive than has already been determined at the federal level.

United States

As explained in further detail below, DMT is currently a restricted drug under the CSA. In the United States, clinical trials involving restricted drugs must adhere to the CSA and its implementing regulations, which are enforced by Drug Enforcement Administration ("DEA") under a legislative, regulatory, and enforcement structure and process. State regulations of controlled substances frequently change, so it is important to be aware of the regulatory nuances of each state in which a trial is conducted. There are three agencies – the US FDA, the National Institute on Drug Abuse, and the DEA –involved in the scheduling of controlled substances, including both narcotic drugs and psychotropic substances. Controlled substances are categorized by the DEA according to five schedules, based upon eight factors, including: 1) actual or relative potential for abuse; 2) scientific evidence of pharmacological effect, if known; 3) state of current scientific knowledge about the drug; 4) history and current pattern of abuse; 5) scope/duration/significance of abuse; 6) what, if any, risk to public health; 7) psychic or physiological dependence liability; and 8) whether the substance is an immediate precursor of an already controlled substance.

DMT is listed as a Schedule I substance under the United States Code of Federal Regulations Title 21 – Food and Drugs 21 Part 1308.11 and assigned DEA Controlled Substances Code Number 7435. Schedule I substances are described as those that have the following findings:

- the drug or other substance has a high potential for abuse;
- the drug or other substance has no currently accepted medical use in treatment in the United States; and
- there is a lack of accepted safety for use of the drug or other substance under medical supervision.

No prescriptions may be written for Schedule I substances, and such substances are subject to production quotas which the DEA imposes. All principal investigators or sub-investigators (typically a member of a university or CRO) involved in a clinical trial using a controlled substance must obtain both federal and state authorizations. DEA registration and state licensure are required at the general physical location where the controlled substances for the clinical trial will be dispensed and/or stored overnight. In some cases, it may be possible to dispense the study drug at a satellite location with a separate license and registration if there is no overnight storage at that satellite location.

Management's Discussion and Analysis

Federal registration is granted by the DEA. DEA "Practitioner" registration is valid for three years although Schedule I substances such as DMT require a DEA "Researcher" registration, valid for one year only, and in this situation, the research protocol must be formally approved by the US FDA prior to registration with the DEA. All practitioners who participate in a clinical trial as a principal investigator or sub-investigator must also be authorized by the state in which they practice prescribing, dispense, administer, and conduct research with controlled substances. In most cases, these activities are authorized when a license is granted to the practitioner by the local Institutional Review Board. However, some states require a separate, state-issued controlled substance license and other states have a separate state-controlled substances authority that requires practitioners to obtain a separate registration, in addition to their board license.

Europe

The International Narcotics Control Board ("INCB"), a United Nations ("UN") entity, monitors enforcement of restrictions on controlled substances. The INCB's authority is defined by three international UN treaties -the UN Single Convention on Narcotic Drugs of 1961, the UN Psychotropic Convention of 1971 (referred to herein as the UN71), and the UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, which contains provisions related to the control of controlled substance precursors. European Union ("EU") Member States, including Finland, that have agreed to abide by the provisions of these treaties, each create responsible agencies and enact laws or regulations to implement the requirements of these conventions. Specific EU legislation establishing different classes of controlled substances is limited to EU regulations that define classes of precursors, or substances used in the illicit manufacture of controlled substances, including Regulation (EC) No. 273/2004 of the European Parliament and the Council of February 11, 2004 and the Council Regulation (EC) No. 111/2005 of December 22, 2004. While EU legislation does not establish different classes of narcotic drugs or psychotropic substances, the Council Decision 2005/387/JHA of May 10, 2005, can provoke a Council Decision requiring EU member state to put a drug under national controls equivalent to those of the INCB. DMT is currently classified as a Schedule I substance under the UN71; the EU member states, including Finland, have agreed to the following in respect of Schedule I substances:

- (a) prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them;
- (b) require that manufacture, trade, distribution and possession be under a special licence or prior authorization;
- (c) provide for close supervision of the activities and acts mentioned in paragraphs (a) and (b);
- (d) restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;
- (e) require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein; and
- (f) prohibit export and import except when both the exporter and importer are the competent authorities or agencies of the exporting and importing country or region, respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose.

Management's Discussion and Analysis

As classification of controlled substances may vary among different EU member states, sponsors must be aware of the prevailing legislation in each country where a clinical trial may be conducted. Prior to operating or conducting any pre-clinical or clinical studies in any other EU member state, the Company will investigate the specific regulatory requirements of such EU member state. As referenced above, a licence is required for individuals and entities who wish to produce, dispense, import, or export Schedule I substances (including DMT), but the specific requirements vary from country to country. Currently, DMT is classified in Finland as a narcotic under the Finnish Narcotics Act (373/2008) and as such the production, manufacture, import, export, distribution, trade, handling, possession and use of DMT are prohibited.

Regulatory Approvals Required for Studies (Canada, the EU and the U.S)

Regulatory approvals are required for clinical (human) studies for all investigational products in all member countries of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, which includes the United States, Canada and EU member states.

Canada CDSA

In order to conduct any scientific research, including pre-clinical (animal) and clinical (human) trials using a controlled substance (such as DMT) in Canada, an exemption under Section 56 of the CDSA is required. This exemption allows the holder to possess and use the controlled substance without being subject to the restrictions set out in the CDSA, subject to obtaining any additional approvals such as ethics and clinical trial approvals.

Specifically, the final approved clinical study protocol and a Health Canada issued No Objection Letter are required to obtain an exemption under subsection 56(1) of the CDSA to conduct clinical investigations with DMT in Canada.

Canada FDR

Products that contain a controlled substance such as DMT cannot be made, transported or sold without proper authorization from the government. A party can apply for a dealer's license under Part J of the Canada Food and Drug Regulations ("Canada FDR"), which allows the party to produce, assemble, sell, provide, transport, send, deliver, import or export a restricted drug (as listed in Part J in the Canada FDR—which includes DMT), assuming compliance with all relevant laws (the CDSA and Canada) and subject to any restrictions placed on the license by Health Canada. To qualify as a licensed dealer, a party must meet all regulatory requirements mandated by the regulations including having compliant facilities, compliant materials and staff that meet the qualifications under the regulations of a senior person in charge and a qualified person in charge.

United States

The DEA has a streamlined application process for researchers who wish to conduct clinical trials using a Schedule I substance not currently approved for medical use (such as DMT). Schedule I substances are defined as drugs, substances, or chemicals with no accepted medical use and a high potential for abuse. Applicants must provide information about their qualifications, research protocol, and institution where the research will take place; complete requirements are outlined in the United States Code of Federal Regulations Title 21 –Food and Drugs 21 Part 1301.18.

Management's Discussion and Analysis

Europe

Refer to the discussion above under the heading "Drug Scheduling – Europe" for a general description of the regulatory requirements to conduct research and clinical and pre-clinical studies using a Schedule I substance such as (DMT) in one of the EU member states. The specific regulatory processes and approvals required may vary among different EU member states and are set forth in the respective legislation of each country, including Finland.

Clinical Studies and Market Authorization Regulations (Canada, the EU and the U.S)

The Company's goal is to ultimately get market authorization from Health Canada, the US FDA and the European Medicines Agency (the "EMA") to sell any DMT products it creates in Canada, the United States and Europe. However, prior to doing so, the Company will need to go through the clinical trial regulatory process. The next stage would be the market authorization regulatory process, following the completing of phase 1, 2 and 3 clinical studies, associated nonclinical studies and preparation of manufacturing documentation. Set forth below is a description of the regulatory regimes in Canada, the United States and the European Union that the Company will be subject to as it moves through both: (i) the clinical study regulatory processes; and the (ii) market authorization regulatory process in respect of the any future DMT products and may be produced.

Canada -Health Canada

Clinical Study Regulatory Process

In Canada, a CTA is composed of three modules:

- Module 1 contains administrative and clinical information about the proposed trial, and includes the Investigator's Brochure, which details all safety, preclinical and clinical data for the drug under study. Other components of Module 1 are the clinical study synopsis and full protocol, informed consent documents, clinical trial site information, and letters of access;
- Module 2 contains common technical document summaries, including Chemistry, Manufacturing and Control ("CMC") information about the drug product(s) to be used in the proposed trial; and
- Module 3 contains additional supporting quality information including literature references.

The modules are organized and numbered consistently in an internationally adopted format, the Common Technical Document ("CTD"). Adhering to the CTD format facilitates evaluation by Health Canada and ensures consistency of documents in subsequent stages of the drug authorization process. Additional documents including a Clinical Trial Site Initiation Form, Qualified Investigator Undertaking and a Research Ethics Board Attestation must be completed for each clinical trial site. Once prepared, the Clinical Trial Application is sent to the Therapeutic Products Directorate at the Health Product and Food Branch ("HPFB") of Health Canada for review. The review process is 30 days, although during the current COVID-19 pandemic environment, Health Canada is able to extend review timelines for non COVID-19 related studies to 45 days.

Health Canada invites sponsors to request a pre-CTA consultation meeting. Such consultations may be particularly useful for new active substances or applications that will include complex issues that may be new to Health Canada. The Company has applied to Health Canada to hold a pre-CTA consultation meeting with Health Canada to discuss proposed clinical trials for on DMT.

Management's Discussion and Analysis

Market Authorization Regulatory Process (Canada, the EU and the US)

The HPFB is the national authority that regulates, evaluates, and monitors the safety, efficacy, and quality of therapeutic and diagnostic products available to Canadians. When a manufacturer decides that it would like to market a drug in Canada, the company must first file a "New Drug Submission" ("NDS") with one of the Directorates (e.g. Therapeutic Products Directorate) within the HPFB. The NDS contains information and data about the drug's safety, effectiveness, and quality. It includes the results of the preclinical and clinical studies, whether done in Canada or elsewhere, details regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects.

The HPFB performs a thorough review of the submitted information, sometimes using external consultants and advisory committees. HPFB evaluates the safety, efficacy, and quality data to assess the potential benefits and risks of the drug. HPFB reviews the labelling information that the sponsor proposes to provide to health care practitioners and consumers about the drug (e.g. the drug label, product monograph, patient brochure). If, at the completion of the review, the conclusion is that the benefits outweigh the risks and that the risks can be mitigated, the drug is issued a Notice of Compliance, as well as a Drug Identification Number which permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada.

In addition, Health Canada laboratories may test certain biological products before and after authorization to sell in Canada has been issued. This is done through its Lot Release Process, in order to monitor safety, efficacy and quality. This process is predominantly utilized for biologic products seeking a marketing license. Once a drug is on the market, regulatory controls continue. The manufacturer (license holder) and distributors of the drug must report any new information received concerning serious side effects including failure of the drug to produce the desired effect. The manufacturer (license holder) must also notify HPFB about any studies that have provided new safety information and request approval for any major changes to the manufacturing processes, dose regime or recommended uses for the drug.

HPFB conducts market surveillance, monitors adverse reaction reports, investigates complaints and problem reports, and manages recalls, should the necessity arise. In addition, HPFB licenses most drug production sites and conducts regular inspections as a condition for licensing.

United States -US FDA

Clinical Study Regulatory Process

Current U.S. Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor (which is typically a research and development company or drug manufacturer) will want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the US FDA. During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies. US FDA's role in the development of a new drug begins when the drug's sponsor, having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

Management's Discussion and Analysis

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies, consisting of preclinical data to permit an
 assessment as to whether the product is reasonably safe for initial testing in humans. Also
 included are any previous experience with the drug in humans (often foreign use);
- Manufacturing Information, pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This is equivalent to the CMC data referenced above for Health Canada applications, and is assessed to ensure that the company can adequately produce and supply consistent batches of the drug; and
- Clinical Protocols and Investigator Information, including detailed protocols for proposed clinical studies to assess whether the initial trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an Institutional Review Board, and to adhere to the investigational new drug regulations.

Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, the US FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

The US FDA invites sponsors to request a pre-IND consultation meeting in advance of application submission. This fosters early communications between sponsors and new drug review divisions to provide guidance on the data necessary to warrant IND submission. The Company has requested a pre-IND consultation meeting to discuss its proposed clinical trials on DMT.

Market Authorization Regulatory Process (Canada, the EU and the U.S)

The US FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical products in the United States to ensure that such medical products distributed domestically are safe and effective for their intended uses. In addition, the US FDA regulates the export of medical products manufactured in the United States to international markets and the importation of medical products manufactured abroad. Unless an exemption applies, each new or significantly modified medical product a company seeks to commercially distribute in the United States will require US FDA approval. The US FDA approval process is conducted through the submission of a New Drug Application ("NDA").

The process can be expensive, and lengthy (6-12 months), and require payment of significant user fees, unless an exemption is available. Significant reductions in fees are available through the Small Business Fee Waiver/Reduction program. Drug companies seeking to sell a drug in the United States must first test it. The company then sends the Centre for Drug Evaluation and Research ("CDER") at the US FDA the evidence from these tests to prove the drug is safe and effective for its intended use, using the NDA. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company's data and proposed labeling.

Management's Discussion and Analysis

If this independent and unbiased review establishes that a drug's health benefits outweigh its known risks, the drug is approved for sale. The center does not actually test drugs itself, although it does conduct limited research in the areas of drug quality, safety, and effectiveness standards. The US FDA drug approval process takes place within a structured framework that includes: (i) analysis of the target condition and available treatments; (ii) assessment of benefits and risks from clinical data; and (iii) strategies for managing risks.

In some cases, the approval of a new drug is expedited. Accelerated approval can be applied to promising therapies that treat a serious or life-threatening condition and provide therapeutic benefit over available therapies. The US FDA also employs several approaches to encourage the development of certain drugs, especially drugs that may represent the first available treatment for an illness, or ones that have a significant benefit over existing drugs. These approaches, or designations, are meant to address specific needs, and a new drug application may receive more than one designation, if applicable. Each designation helps ensure that therapies for serious conditions are made available to patients as soon as reviewers can conclude that their benefits justify their risks. Designations include: (i) fast track; (ii) breakthrough therapy; and (iii) priority review.

Europe -EMA

Clinical Study Regulatory Process

The Investigational Medicinal Product Dossier ("IMPD") is one of several regulatory documents required for conducting a clinical trial of a pharmacologically API (active product ingredient) intended for one or more European Union Member States. The IMPD includes summaries of information related to the quality, manufacture, and control of any Investigational Medicinal Product (including reference product and placebo) ("IMP"), and data from non-clinical and clinical studies. Guidance concerning IMPDs is based on Regulation (EU) No 536/2014 on Clinical Trials on Medicinal Products for Human Use (the "Regulation") and on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (also commonly referred to as the "Clinical Trials Directive"). The Regulation came into force in 2016, harmonizing the laws, regulations and administrative provisions of the Member States relating to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. European Member States have transformed the requirements outlined in the Clinical Trials Directive into the respective national laws.

The content of the IMPD may be adapted to the existing level of knowledge and the product's phase of development. When applying for a clinical trial authorization, a full IMPD is required when little or no information about an API has been previously submitted to competent authorities, when it is not possible to cross-refer to data submitted by another sponsor and/or when there is no authorization for sale in the European Union. However, a simplified IMPD may be submitted if information has been assessed previously as part of a Marketing Authorization or a clinical trial to that competent authority. Although the format is not obligatory, the components of an IMPD are largely equivalent to clinical trial applications in Canada and the U.S. The IMPD need not be a large document as the amount of information to be contained in the dossier is dependent on various factors such as product type, indication, development phase etc.

The assessment of an IMPD is focused on patient safety and any risks associated with the IMP. Whenever any potential new risks are identified the IMPD must be amended to reflect the changes. Certain amendments are considered substantial in which case the competent authority must be informed of the substantial amendment. This may be the case for changes in IMP impurities, microbial contamination, viral safety, transmissible spongiform encephalopathies (e.g. mad cow disease) and in some particular cases to stability when toxic degradation products may be generated.

Management's Discussion and Analysis

The Company is planning the Phase I study to obtain preliminary evidence of the safety and efficacy of DMT. The study will occur in the U.K. and the current focus is preparing an IMPD document that includes CMC (Chemistry, Manufacturing and Control) information, an Investigator's brochure (including prior safety, preclinical and clinical data) and a clinical study protocol and supporting information to be submitted to the regulatory authorities, all of which is subject to the risks, delays and related cost implications.

Market Authorization Regulatory Process

Under the centralized authorization procedure, pharmaceutical companies submit a single marketing-authorization application to the EMA, which provides the basis of a legally binding recommendation that will be provided by the EMA to the European Commission, the authorizing body for all centrally authorized products. This allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the European Union on the basis of a single marketing authorization.

EMA's Committee for Medicinal products for Human Use or Committee for Medicinal Products for Veterinary Use carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not, under any particular dosing regime. Although, under European Union law, the EMA has no authority to permit marketing in the different European Union countries, the European Commission is the authorizing body for all centrally authorized products, who takes a legally binding decision based on EMA's recommendation. This decision is issued within 67 days of receipt of EMA's recommendation.

Once granted by the European Commission, the centralized marketing authorization is valid in all European Union Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. European Commission decisions are published in the Community Register of medicinal products for human use. Once a medicine has been authorized for use in the European Union, the EMA and the European Union Member States constantly monitor its safety and take action if new information indicates that the medicine is no longer as safe and effective as previously thought.

The safety monitoring of medicines involves a number of routine activities ranging from: assessing the way risks associated with a medicine will be managed and monitored once it is authorized; continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications; regularly assessing reports submitted by the Company holding the marketing authorization on the benefit-risk balance of a medicine in real life; and assessing the design and results of post-authorization safety studies which were required at the time of authorization. The EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission.

These are called European Union referral procedures; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimization measures or the benefit-risk balance of the medicine. The EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee. This ensures that EMA and the European Union Member States can move very quickly once an issue is detected and take any necessary action, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

Management's Discussion and Analysis

<u>Legislation on controlled substances United Kingdom</u>

In the UK, there are two main "layers" of regulation with which products containing controlled substances must comply. These are:

- i) controlled drugs legislation, which applies to all products containing controlled substances irrespective of the type of product, and
- ii) the regulatory framework applicable to a specific category of products, in this case, pharmaceuticals and food/food supplements.

In the U.K., DMT is considered a Class A drug under the amended Misuse of Drugs Act 1971, and as a Schedule 1 drug under the amended Misuse of Drugs Regulations 2001 (the "MDR").

Class A drugs are highly controlled and considered to be the most potentially harmful. Schedule 1 drugs receive the most restrictive controls. They are considered to have no legitimate or medicinal use, and can only be imported, exported, produced, supplied and the like under a Home Office license.

Even if granted a marketing authorization for SPL026 by the MHRA, DMT would still remain a Schedule 1 drug until rescheduled by the Home Office. Unless and until DMT is rescheduled under the MDR, and unless a statutory exemption were to be passed for SPL026 following the grant of a U.K. marketing authorization and before rescheduling, any prescribing doctors in the U.K. would require a Home Office license to prescribe SPL026. There can be no guarantee that such Home Office licenses would be granted or that rescheduling would be successful.

The amended Misuse of Drugs Act 1971 sets out the penalties for unlawful production, possession and supply of controlled drugs based on three classes of risk (A, B and C). The MDR sets out the permitted uses of controlled drugs based on which Schedule (1 to 5) they fall within. In the United Kingdom, Class A drugs are deemed to be the most dangerous, and so carry the harshest punishments for unlawful manufacture, production, possession and supply. Schedule 1 drugs can only be lawfully manufactured, produced, possessed and supplied under a Home Office licence. While exemptions do exist, none are applicable to the API.

Additional legislation was more recently passed in order to address an increasing prevalence of psychoactive drugs designed to circumvent the Misuse of Drugs Act 1971. The Psychoactive Substances Act 2016 (the "PSA") prohibits certain activities regarding any psychoactive substance, defined in the PSA as a substance that produces a psychoactive effect, which by stimulating or depressing the central nervous system affects a person's mental functioning or emotional state.

Controlled substances are exempt from the PSA, which therefore does not apply to SPL026. SPL028 and SPL029 may fall within the MDR. If either SPL028 or SPL029 are found to fall outside of the MDR then the PSA may apply, subject to certain exemptions which apply to experimental medicines. Approved medicines are also exempt from the PSA, so the PSA should not apply to SPL028 or SPL029, if approved by the MHRA.

Licensing Requirements

All UK-based facilities involved in the manufacture, analytical testing, release and clinical testing of DMT need to hold appropriate Home Office licenses. All premises that are licensed in the manufacture, analytical testing, release and clinical testing of controlled drugs are required to adhere to detailed security standards.

Management's Discussion and Analysis

Typically, when controlled drugs are being transported between licensees, responsibility for their security remains with the owner and does not transfer to either the courier or the customer until the drugs arrive at their destination and are signed for. However, where a third party is involved in the transit and/or storage of controlled drugs, even if they are not the legal owners, this party also carries responsibility for their security by virtue of being 'in possession' of them. Under the Home Office guidance, each organisation involved in the movement of controlled drugs should have a standard operating procedure covering their responsibilities, record keeping, reconciliation and reporting of thefts/losses.

Medical and Scientific Advisory Board Update

There are no changes to report.

Financing

On July 4, 2022, the Company issued 309,117 units (the "Units") at a price of \$3.75 per Unit for gross proceeds of \$1,159,189 upon the closing of a marketed public offering (the "July 2022 Offering") with an Agent (the "Agent"). Each Unit consisted of one common share of the Company (a "Common Share") and one Common Share purchase warrant (a "Warrant") of the Company. Each Warrant entitles the holder thereof, subject to adjustment in certain circumstances, to purchase one Common Share (a "Warrant Share") at an exercise price equal to \$4.70 per Warrant Share (the "Warrant Exercise Price") for a period of five years following the date of issuance (the "Expiry Date"), subject to acceleration of the expiry date.

In the event of a down-round financing during the period of five years following closing of the Offering (a "Dilutive Issuance"), the Warrants contain an anti-dilution protection feature, to adjust the Warrant Exercise Price and increase the number of Warrant Shares issuable thereunder if Common Shares are sold or issued for a consideration per share less than the Warrant Exercise Price (subject to certain exemptions), provided, that the exercise price will not be less than \$1.875 (the "Floor Price").

Provided that if, at any time prior to the expiry date of the Warrants, the volume weighted average trading price of the Common Shares on the CSE, or other principal exchange on which the Common Shares are listed, is greater than \$14.10 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 Warrants accelerating the Expiry Date of the Warrants to the 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.

In connection with the July 2022 Offering, the Company issued a total of 10,845 compensation warrants. Each compensation warrant entitles the holder to purchase one common share at a price of \$4.125 until July 4, 2027.

The Company granted to the Agent an option (the "Over-Allotment Option") to increase the size of the Offering by up to an additional number of Units, and/or the components thereof, that in aggregate would be equal to 15% of the total number of the Offered Securities to be issued under the July 2022 Offering, to cover over-allotments, if any, and for market stabilization purposes, exercisable at any time and from time to time up to 30 days following the closing of the July 2022 Offering.

The July 2022 Offering included cash commissions, payable to the Agent, of eight percent and compensation warrants of five percent, including from the exercise, if any, of the Over-Allotment Option, subject to a reduction for certain orders. In connection with the July 2022 Offering, the Company issued a total of 10,845 compensation warrants that entitles the holder to purchase one common share for a price of \$4.125 for a five-year period ending July 4, 2027.

Management's Discussion and Analysis

On certain purchasers, an additional eight percent cash commission and five percent compensation warrants, including from the exercise, if any, of the Over-Allotment Option for certain purchasers, could have been payable due to a prior agreement with an investment bank in the United States.

The net proceeds from the July 2022 Offering of the Units will be used to fund research and development programs, general and administrative expenses and for working capital purposes.

On August 22, 2022, the Company closed its previously announced non-brokered private placement in the amount of 373,900 units of the Company (the "Units") at a price of \$3.75 per Unit for gross proceeds of \$1,402,125 (the "August 2022 Offering"). Each Unit consists of one common share in the capital of the Company (a "Common Share") 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 \$4.25 per Warrant Share until August 22, 2027 (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 \$12.75 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.

In connection with the closing of the August 2022 Offering, the Company paid cash finder's fees in the aggregate amount of \$122,850 and issued a total of 20,480 finder's warrants (the "Finder's Warrants") to eligible finders. The Finder's Warrants are non-transferable Common Share purchase warrants exercisable for one Common Share (a "Finder's Warrant Share") at a price of \$4.125 per Finder's Warrant Share until August 22, 2027 and are subject to the same acceleration provision as the Warrants.

The securities issued and issuable in connection with the closing of the August 2022 Offering will be subject to a statutory hold period of four months plus a day from the date of issuance in accordance with applicable securities legislation.

The Company will use the proceeds from the August 2022 Offering to fund research and development programs, general and administrative expenses and for working capital purposes.

Additionally, the Company announces 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 \$4.70 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 373,900 units of the Company at a price of \$3.75 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 \$3.75 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.

Management's Discussion and Analysis

Corporate

Effective September 7, 2021, Mr. Harry Bloomfield, QC. was appointed as a new member of the Board of Directors and was elected Chairman of the Board;

Effective September 16, 2021, Mr. Michael Sadhra resigned as Director of the Company.

Effective September 16, 2021, Dr. Mark Williams, was appointed as a Director of the Company.

On October 21, 2021, the Company announced that it had received a \$2,000,000 cash payment from a refundable tax credit program from its clinical research work in Australia.

On October 21, 2021, the Company announced that it has submitted an application to have its common shares listed on the Nasdaq Capital Market. The listing of the Company's common shares on the Nasdaq Capital Market remains subject to Nasdaq approval and the satisfaction of all applicable listing, governance and regulatory requirements. While the Company intends and believes it will be able to satisfy all of the applicable requirements, there is no assurance that it will be successful in satisfying the listing requirements or its application will be approved.

On November 23, 2021, the Company announced that it had completed a consolidation of its common shares on one-hundred (100) to one (1) basis. The post-consolidation common shares began trading on the CSE on November 24, 2021. The total issued and outstanding number of common shares post-consolidation totalled 1,674,868.

On November 30, 2021, the Company announced that it has appointed Mr. James Kinley as the Company's Chief Financial Officer ("CFO"), effective December 1, 2021 replacing the departing CFO, Mike Sadhra.

On January 4, 2022, the Company announced that has granted 96,000 stock options exercisable at \$4.10 for five years from date of grant, for officers and directors, employees and a consultant and are subject to approval by regulatory authorities.

Effective February 28, 2022, former Ambassador (rtd) Howard Gutman was appointed as a Director of the Company and David Levine, whom did not stand for re-election at the Company's Annual General Meeting was no longer a member of the Company's Board of Directors.

On August 23, 2022, the Company has engaged GRA Enterprises LLC (the "Consultant") to provide investor relations services pursuant to a consulting agreement dated August 22, 2022. Services will include the production and publication of investor bulletins, distribution of investor bulletins to the Consultant's email list, and posts via the Consultant's blogs and social media accounts. In consideration of these services, the Company will pay the Consultant a fee of US\$100,000 for a 12-month contract. The Consultant is an arm's length party to the Company and does not currently own any securities of the Company as at the date hereof but may purchase securities in the Company from time to time for investment purposes. The consulting agreement with the Consultant is subject to acceptance by the Canadian Securities Exchange.

On August 31, 2022, the Company granted 221,000 restricted share units pursuant to its RSU Plan (each, an "RSU") to executives, directors, employees and consultants of the Company. Each RSU entitles the recipient to receive one common share of the Company or a cash payment equal to the equivalent for one common share of the Company on vesting. The RSUs vest one-third on January 1, 2023, one-third on June 1, 2023, and one-third on January 1, 2024.

Management's Discussion and Analysis

The Company also granted 92,000 stock options exercisable at \$5.39 for five years from date of grant, to officers, directors, employees and consultants of the Company. The stock options vest 50% on the grant date and 50% on February 28, 2023.

On September 8, 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 will be held in Miami from November 3-5th, 2022 at the Mana Wynwood Convention Centre and deliver 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 provides an opportunity to discover the world of psychedelic medicine, and is 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.

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. 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.

Intended Use of Proceeds of Of	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	\$ 62,383	\$ 1,187,617	Trial in progress, offerings completed in Q4 2022
General and Administrative Expenses and Working Capital	\$ 805,123	\$ 1,992,740	(\$ 1,187,617)	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 as a result the funds raised in the Prior Offerings primarily remain in working capital at August 31, 2022. Funds will be used to further the DMT Phase 1 stroke trial into fiscal 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.

Management's Discussion and Analysis

RESULTS OF OPERATIONS

Year ended August 31, 2022 and 2021

The Company had a net loss of \$6,054,356 for the year ended August 31, 2022 compared to a net loss of \$7,734,080 for the year ended August 31, 2021. The Company's significant operating expenses for the year ended August 31, 2022 included the following:

- Research and development expenses of \$2,329,927 (2021 \$4,797,012)
- Salaries and benefits of \$1,065,739 (2021 \$656,829)
- Marketing expenses of \$729,798 (2021 \$794,324)
- Professional fees of \$924,464 (2021 \$607,672)
- General and administrative expenses of \$243,916 (2021 \$194,573)
- Shareholder communications expenses of \$231,755 (2021 \$173,312)
- Share-based payment expenses of \$530,835 (2021 \$827,402)

Research and development expenses totaled \$2,329,927 for the year ended August 31, 2022 (2021 – \$4,797,012) and pertained primarily to the on-going costs of the Company's IPF/chronic cough Phase 2 clinical trial for which results were announced during the fourth quarter of fiscal 2022. Additionally costs associated with the Company's DMT program including the manufacturing and preclinical development of the product as well as the planning stages of the Phase 1 clinical trial and manufacturing and preclinical work associated with the Company's CKD program using Ripirinast. The decrease was mainly due to activities during the year ended August 31, 2021 in connection with the Company's multinational Phase 2b/3 study of Ifenprodil as a potential therapeutic treatment for patients with COVID-19 and costs associated with the IPF/chronic cough Phase 2 clinical trial. The Company was also supporting an investigator led Phase 2 human trial for Ifenprodil and COVID-19 in South Korea during the year ended August 31, 2021.

Salaries and benefits for the year ended August 31, 2022 were \$1,065,739 (2021 – \$656,829) which included salaries paid to officers, independent directors and employees, bonuses accrued for executives and employees as well as severance costs associated with a change in CFO which occurred on December 1, 2021. The increase from the year ended August 31, 2021 resulted from accrued bonuses as well as the severance costs for the year ended August 31, 2022.

Marketing expenses, consisted of expenses in relation to promotional activities to create and expand market presence of the Company, were \$729,798 for the year ended August 31, 2022 (2021 – \$794,324). The decrease from the year ended August 31, 2021 resulted from more marketing activities being performed during the year ended August 31, 2021 as a result of the on-going COVID-19 clinical trial the Company was involved in during fiscal 2021.

Professional fees, which included legal, accounting and consulting fees, incurred in the operation of the business, were \$924,464 for the year ended August 31, 2022 (2021 – \$607,672). The increase from the year ended August 31, 2021 resulted from increasing in legal and accounting fees experienced by the Company during the year ended August 31, 2022 as a result of the Company's potential Nasdaq listing.

General and administrative expenses which included expenses incurred to support Company's day-to-day operational activities were \$243,916 for the year ended August 31, 2022 (2021 – \$194,573). The increase from the years ended August 31, 2021 primarily resulted from expenses relating to updating the Company's website incurred during the year ended August 31, 2022.

Management's Discussion and Analysis

Shareholder communications expenses, which included newswire subscription fees, communication advisory fees, transfer agent and filing expenses, were \$231,755 for the year ended August 31, 2022 (2021 – \$173,312). The increase from the year ended August 31, 2021 resulted from increasing expenses experienced by the Company during the year ended May 31, 2022 as a result of the Company's potential Nasdaq listing.

Share-based payment expenses were \$530,835 for the year ended August 31, 2022 (2021 – \$827,402) including share-based payment expenses in relation to the stock options granted by the Company on January 1, 2022 and August 31, 2022. This compares to share-based payments for the year ended August 31, 2021 of \$827,402 which related to higher share-based payments recognized related to restricted share units ("RSUs") that were previously granted to certain directors, officers and consultants of the Company.

Selected Annual Information

		ended ist 31, 2022	_	ear ended August 31, 2021		r ended gust 31, 2020
Total revenue	\$	nil	\$	nil	\$	nil
Loss before other items	(6,056,434)		(8,051,124)		(8,661,055)	
Net loss	(6,504,356)		(7,734,080)		(8,538,207)	
Net loss per common share, basic and diluted	(3.48)			(4.97)	(9.71)	
Working capital / (deficit)	\$ 3 ⁻	10,999	\$	3,886,947	\$ 7,	131,172
Total assets	8,140,757		10,137,632		12,823,968	

Three months ended August 31, 2022 and 2021

The Company had a net loss of \$2,217,641 for the three months ended August 31, 2022 (Q4 2022) compared to a net loss of \$240,267 for the three months ended August 31, 2021 (Q4 2021). The Company's significant operating expenses for the three months ended August 31, 2022 included the following:

- Research and development expenses of \$851,171 (Q4 2021 (\$207,241))
- Salaries and benefits of \$482,499 (Q4 2021 \$164,419)
- Marketing expenses of \$339,782 (Q4 2021 \$234,910)
- Professional fees of \$235,862 (Q4 2021 \$220,583)
- General and administrative expenses of \$41,493 (Q4 2021 \$58,894)
- Shareholder communications expenses of \$37,979 (Q4 2021 \$17,069)
- Share-based payment expenses of \$228,855 (Q4 2021 \$57,402)

Research and development expenses totaled \$851,171 for the three months ended August 31, 2022 (Q4 2021 – (\$207,241)) and pertained primarily to the Company's DMT program including the manufacturing and preclinical development of the product as well as the planning stages of the Phase 1 clinical trial. The increase was mainly due to higher costs during the three months ended August 31, 2022 in connection with the DMT program as well as a recovery during the three months ended August 31, 2021 from Australian tax incentives.

Salaries and benefits for the three months ended August 31, 2022 were \$482,499 (Q4 2021 – \$164,419). The increase in salaries and benefits for the three months ended August 31, 2022 related to faccrued bonuses during the period.

Management's Discussion and Analysis

Marketing expenses were \$339,782 for the three months ended August 31, 2022 (Q4 2021 – \$234,910). The increase from the three months ended August 31, 2021 resulted from additional marketing activities being performed during the three months ended August 31, 2022.

Professional fees were \$235,862 for the three months ended August 31, 2022 (Q4 2021 – \$220,583) and remained consistent with expenses for the three months ended August 31, 2021.

General and administrative expenses were \$41,493 for the three months ended August 31, 2022 (Q4 2021 – \$58,894) and were consistent with the three months ended August 31, 2021.

Shareholder communications expenses were \$37,979 for the three months ended August 31, 2022 (Q4 2021 – \$17,069). The increase from the three months ended August 31, 2021 resulted from increasing expenses experienced by the Company during the three months ended August 31, 2022 as a result of the additional communications surrounding the results of the Company's IPF/chronic cough Phase 2 clinical trial and the Company's DMT program.

Share-based payment expenses were \$228,855 for the three months ended August 31, 2022 (Q4 2021 – \$57,402) including share-based payment expenses in relation to the stock options granted by the Company on January 1, 2022 and August 31, 2022. This compares to share-based payments for the three months ended August 31, 2021 of \$57,402 which related to higher share-based payments recognized related to restricted share units ("RSUs") that were previously granted to certain directors, officers and consultants of the Company.

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.

	2022	2022	2022	2021
Quarter Ended	Aug. 31 ⁽¹⁾	May 31 ⁽²⁾	Feb. 28 ⁽³⁾	Nov. 30 ⁽⁴⁾
		\$		
Total revenue	\$ nil	nil	\$ nil	\$ nil
Loss before other items	2,217,642	801,166	1,836,591	1,201,025
Net loss	2,217,643	800,161	1,835,992	1,200,560
Net loss per share, basic and diluted	1.28	0.48	1.10	0.72

		2021		2021		2020		2020
Quarter Ended	Aug. 31 ⁽⁵⁾		Ма	ay 31 ⁽⁶⁾	Feb 28 ⁽⁷⁾		⁷⁾ Nov. 30 ⁽⁸⁾	
Total revenue	\$	nil	\$	nil	\$	nil	\$	nil
Loss before other items	5	46,036	1,6	76,265	2,3	88,068	3,44	40,755
Net loss	2	40,267	1,6	73,993	2,3	85,372	3,43	34,448
Net loss per share, basic and diluted		0.14		1.00		1.65		2.46

Management's Discussion and Analysis

- (1) 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.
- ⁽²⁾ 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.
- (3) 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.
- (4) 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.
- (5) 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.
- ⁽⁶⁾ The Company had a net loss of \$1,673,993 for the quarter ended May 31, 2021 as compared to a net loss of \$2,385,372 for the prior quarter ended February 28, 2021. The decrease in net loss was primarily due to decreases in research and development expenses and share-based payment.
- ⁽⁷⁾ The Company had a net loss of \$2,385,372 for the quarter ended February 28, 2021 as compared to a net loss of \$3,434,448 for the prior quarter ended November 30, 2020. The decrease in net loss was primarily due to a decrease in research and development expenses.
- ⁽⁸⁾ The Company had a net loss of \$3,434,448 for the quarter ended November 30, 2020 as compared to a net loss of \$2,987,670 for the prior quarter ended August 31, 2020. The increase in net loss was primarily due to an increase in research and development expenses.

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 August 31, 2022, the Company had a working capital of \$310,999 compared to working capital at August 31, 2021 of \$3,886,947. This included cash and cash equivalents of \$1,408,509 (August 31, 2021 - \$2,411,163) available to meet short-term business requirements and current liabilities of \$2,516,099 (August 31, 2021 - \$1,022,314). 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.

Management's Discussion and Analysis

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⁽¹⁾. 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 (August 31, 2022 - \$2,827,098; August 31, 2021 - \$4,909,261), less current liabilities (August 31, 2022 - \$2,516,099; August 31, 2021 - \$1,022,314).

Cash Used in Operating Activities

Operating activities used \$5,497,227 in cash for the year ended August 31, 2022 compared to \$7,224,743 for the year ended August 31, 2021. The decrease in cash used in operating activities was primarily due to the reduction in the Company's net loss combined with the receipt of amounts pertaining to the Australian research and development tax credit from August 31, 2021, which were received during the year ended August 31, 2022.

Cash Used in Investing Activities

The cash used in investing activities for the year ended August 31, 2022 was \$126,428 consistent with \$124,448 in cash used in investing activities for the year ended August 31, 2021 and relates entirely to additions in intangible assets.

Cash flows from Financing Activities

The Company generated \$2,055,123 cash flows from financing activities for the year ended August 31, 2022 compared to \$4,245,207 for the year ended August 31, 2021. The cash flows from financing activities for the year ended August 31, 2022 are as a result of the gross proceeds from the issuances of shares in financings closed on July 4, 2022 and August 22, 2022. For the year ended August 31, 2021, the Company received proceeds from an issuance of shares as well as the exercise of warrants, compensation options and stock options, net of withholdings paid on the settlement of RSUs.

OUTSTANDING SHARE DATA

On November 23, 2021, the Company announced that it had completed a consolidation of its common shares on one-hundred (100) to one (1) basis. The post-consolidation common shares began trading on the CSE on November 24, 2021. The total issued and outstanding number of common shares post-consolidation totalled 1,674,868.

As at August 31, 2022 and the date of this report, the Company has:

As at	August 31, 2022	November 21, 2022
Issued and outstanding common shares	2,357,885	2,385,332
Warrants outstanding	802,073	780,173
Agent warrant units outstanding	31,325	31,325
Stock options outstanding	235,750	235,750
Restricted share units	221,000	221,000

Management's Discussion and Analysis

OFF-BALANCE SHEET ARRANGEMENTS

There are no off-balance sheet arrangements.

CONTRACTUAL COMMITMENTS

There are no contractual commitments to disclose.

INTANGIBLE ASSETS

	Ad	equisition of Nash Pharma ⁽¹⁾	Trademark Application Costs ⁽²⁾	licensed atents ⁽³⁾	Patent Application Costs ⁽⁴⁾	Total
Cost Balance, August 31, 2020 Additions	\$	4,862,756	\$ 13,228 1,204	\$ - -	\$ 152,259 141,424	\$ 5,028,243 142,628
Balance, August 31, 2021	\$	4,862,756	\$ 14,432	\$ -	\$ 293,683	\$ 5,170,871
Additions Write-downs			1,291 -	50,292 -	105,120 (36,479)	156,703 (36,479)
Balance, August 31, 2022	\$	4,862,756	\$ 15,723	\$ 50,292	\$ 362,324	\$ 5,291,095

	isition of Nash Pharma ⁽¹⁾	Trademark Application Costs ⁽²⁾	licensed Patents ⁽³⁾	Patent Application Costs ⁽⁴⁾	Total
Accumulated Amortization					
Balance, August 31, 2021and 2020	\$ -	\$ -	\$ -	\$ -	\$ _
Amortization	-	(1,572)	(9,598)	(23,766)	(34,936)
Balance, August 31, 2022	\$ -	\$ (1,572)	\$ (9,598)	\$ (23,766)	\$ (34,936)

	Acquisition of Nash	Trademark Application	ln-	licensed	Patent Application	
	Pharma ⁽¹⁾	Costs ⁽²⁾	F	atents ⁽³⁾	Costs ⁽⁴⁾	Total
Net Book Value						
Balance, August 31, 2021	\$ 4,862,756	\$ 14,432	\$	-	\$ 293,683	\$ 5,170,871
Balance, August 31, 2022	\$ 4,862,756	\$ 14,151	\$	40,694	\$ 338,558	\$ 5,256,159

⁽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 are reviewed for impairment. The Company will impair or write-off the intangible assets related to the acquisition of Nash Pharma when indicators of impairment exist and the recoverable value is less than the carrying value.

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 of ten years. The Company recorded \$1,572 of amortization within general and administrative expenses on the consolidated statement of loss and comprehensive loss for the year ended August 31, 2022 (2021 - \$nil).

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 \$9,598 of amortization within research and development expenses on the consolidated statement of loss and comprehensive loss for the year ended August 31, 2022 (2021 - \$nil).

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 representing the remaining months to expiration of the associated patent. The Company recorded \$23,766 of amortization within research and development expenses on the consolidated statement of loss and comprehensive loss for the year ended August 31, 2022 (2021 - \$nil). Additionally, during the year ended August 31, 2022, the Company wrote-off patents application costs that were previously capitalized for patents that are no longer being pursued by the Company. The Company recorded \$36,479 of write-downs within research and development expenses on the consolidated statement of loss and comprehensive loss for the year ended August 31, 2022 (2021 - \$nil). Management determined the value in use of these patents in accordance with level 3 of the fair value hierarchy was \$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	Year ended August 31, 2022		Year ended August 31, 2021	
Christopher Moreau ⁽¹⁾	CEO / Director	CEO remuneration	\$	418,000	\$	256,079
Michael Sadhra ^{(2) (3)}	CFO / Director	CFO remuneration	\$	75,000	\$	148,864
James Kinley ⁽⁴⁾	CFO	CFO remuneration	\$	107,500	\$	nil
Mark Williams ⁽⁵⁾	CSO	CSO remuneration	\$	nil	\$	100,000
Christopher Bryan ⁽⁶⁾	VPRO	VPRO	\$	195,000	\$	65,000
		remuneration				
Harry Bloomfield KC ⁽⁷⁾	Chairman/Director	Director fees	\$	36,100	\$	nil
Mark Williams ⁽⁸⁾	Director	Director fees	\$	19,500	\$	nil
Howard Gutman ⁽⁹⁾	Director	Director fees	\$	14,116	\$	nil
David Levine ⁽¹⁰⁾	Director	Director fees	\$	3,000	\$	13,216
Raj Attariwala	Director	Director fees	\$	17,000	\$	13,216
Short-term benefits paid t	Short-term benefits paid to key management personnel		\$	885,216	\$	596,375

- (1) No director fees paid.
- (2) No director fees paid.
- (3) Resigned as a director effective September 16, 2021 and resigned as CFO effective November 30, 2021.
- (4) Appointed CFO effective December 1, 2021.
- (5) Resigned as CSO effectively March 1, 2021.
- (6) Assumed position of VPRO effectively March 1, 2021.
- (7) Appointed to the Board of Directors and as Chairman effective September 7, 2021.
- (8) Appointed as a member of the Board of Directors effective September 16, 2021.
- (9) Appointed to the Board of Directors effective February 28, 2022.
- (10) Did not stand for reelection and ceased to be a member of the Board of Directors on February 28, 2022.

Management's Discussion and Analysis

Share-based payments

Name	Relationship	Purpose of Transaction	 ear ended ugust 31, 2022	Year ended August 31, 2021		
Christopher Moreau	CEO / Director	Stock Option Grant	\$ 158,449	\$	nil	
James Kinley	CFO	Stock Option Grant	\$ 62,541	\$	nil	
Christopher Bryan	VPRO	Stock Option Grant	\$ 62,541	\$	nil	
Harry Bloomfield KC	Chairman/Director	Stock Option Grant	\$ 69,920	\$	nil	
Mark Williams	Director	Stock Option Grant	\$ 34,371	\$	nil	
David Levine	Director	Stock Option Grant	\$ 22,711	\$	nil	
Raj Attariwala	Director	Stock Option Grant	\$ 34,371	\$	nil	
Howard Gutman	Director	Stock Option Grant	\$ 23,320	\$	nil	
Christopher Moreau	CEO / Director	RSU grant	\$ nil	\$	248,372	
Michael Sadhra	CFO / Director	RSU grant	\$ nil	\$	198,698	
Mark Williams	CSO	RSU grant	\$ nil	\$	151,247	
David Levine	Director	RSU grant	\$ nil	\$	49,675	
Raj Attariwala	Director	RSU grant	\$ nil	\$	49,675	
Share-based compens	\$ 468,224	\$	697,667			

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

Name	Relationship	Purpose of Transaction		r ended gust 31, 2022	Year ended August 31, 2021		
Bloomfield & Advocats	Company with Harry Bloomfied Chairman / Director as principal (1)	Corporate secretarial services	()	2,500	\$	1	
Pacific Urban Advisory Group Inc.	Company with Michael Sadhra, CFO / Director as a principal (2)	Office rent	()	9,000	\$	36,000	
Sadhra & Chow LLP	Company with Michael Sadhra, CFO / Director as a partner (2)	Tax services	\$	nil	\$	11,750	

⁽¹⁾ Harry Bloomfield KC was appointed to the Board of Directors and as Chairman effective September 7, 2021.

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

As at	Augu	ıst 31, 2022	August 31, 2021		
Key management personnel – bonuses	\$	268,000	\$	-	
Key management personnel – directors fee		5,244		-	
Key management personnel – consulting fees		788		-	
Key management personnel – expense reimbursements		-		111	
Total	\$	274,032	\$	111	

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

As at August 31, 2022, there was \$32,133 (2021 - \$nil) pertaining to prepaid board of directors fees.

⁽²⁾ 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

Management's Discussion and Analysis

RESEARCH AND DEVELOPMENT PROGRAM

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 U.S. or Europe 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 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, stroke, and pancreatic and small cell lung cancer. 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. On January 6, 2020, Nash Pharma established a 100% owned Australian subsidiary, AGN Research".

The breakdown of the major components of the research and development programs for the year ended August 31, 2022.

	August 31,			August 31	
Year ended		2022		2021	
Clinical Trials:					
Phase 2 for IPF and chronic cough	\$	1,168,908	\$	1,203,109	
Phase 1 DMT		150,325		-	
Investigator-led COVID study in South Korea		<u>-</u>		148,182	
Phase 2b/3 multinational COVID study		3,120		4,617,199	
		1,322,353		5,968,490	
Preclinical:					
Ifenprodil preclinical and manufacture		46,286		116,802	
DMT preclinical and manufacture		776,355		398,501	
Repirinast preclinical and manufacture		341,516		-	
Oncology preclinical		39,277		49,535	
NASH preclinical		<u>-</u>		12,468	
		1,203,434		577,306	
Management and Ad Hoc scientific support		108,728		214,247	
Amortization and write-downs of intangible assets		69,843		<u> </u>	
Total		2 704 259		6 760 042	
Total		2,704,358		6,760,043	
Less: Australian R&D Tax Credit		(374,431)		(1,897,019)	
Less: Canadian NRC Research Grant				(66,012)	
Total Net Expense	\$	2,329,927	\$	4,797,012	

Management's Discussion and Analysis

SEGMENTED DISCLOSURES

The Company is a Canadian clinical stage pharmaceutical development company that operates in two reportable operating segments being 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 August 31, 2022, the Company's long-term assets are located as follows:

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

As at August 31, 2021, the Company's long-term assets were located as follows:

	Canada		Australia			Total
Restricted cash equivalents	\$	57,500	\$	-	\$	57,500
Intangible assets		5,170,871		-	;	5,170,871
	\$	5,228,371	\$	-	\$:	5,228,371

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 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.

Management's Discussion and Analysis

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.

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.

Management's Discussion and Analysis

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.

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 August 31, 2022 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.

Management's Discussion and Analysis

- 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).

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

	 Financial Assets	Financial Assets	Financial Liabilities
	Fair Value Through Profit	Measured at Amortized Cost	Measured at Amortized Cost
August 31, 2022			
Cash and cash equivalents	\$ 1,408,509	\$ -	\$ -
Accounts receivable	-	481	-
Restricted cash equivalents	57,500	-	-
Accounts payable and accrued liabilities	\$ -	\$ -	\$ (2,516,099)

	Financial Assets	Financial Assets	Financial Liabilities
	Fair Value Through	Measured at Amortized	Measured at Amortized
	Profit	Cost	Cost
August 31, 2021			
Cash and cash equivalents	\$ 2,411,163	\$ -	\$ -
Accounts receivable	-	484	-
Restricted cash equivalents	57,500	-	-
Accounts payable and accrued liabilities	\$ -	\$ -	\$ (1,022,314)

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.

Management's Discussion and Analysis

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.

At August 31, 2022, the Company had a working capital of \$310,999 compared to working capital at August 31, 2021 of \$3,886,947. This included cash and cash equivalents of \$1,408,509 (2021 - \$2,411,163) available to meet short-term business requirements and current liabilities of \$2,516,099 (2021 - \$1,022,314).

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 2.65% 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 and other operating expenses that are mainly in Canadian dollars ("CAD\$").

The Company holds funds in its Australian subsidiary in AUS\$ 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 August 31, 2022, the Company had monetary assets of US\$29,841 or \$39,125 (2021 - US\$19,796 or \$24,976) at the CAD\$ equivalent and monetary liabilities of US\$508,797 or \$667,084 (2021 - US\$78,289 or \$98,777) 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 other comprehensive loss by approximately \$62,796 (2021 - \$7,380).

Management's Discussion and Analysis

As at August 31, 2022, the Company had monetary assets of AUD\$698,522 or \$627,832 (2021 - AUD\$2,685,541 or \$2,478,217) at the CAD equivalent and monetary liabilities of AUD\$668,260 or \$600,632 (2021 - AUD\$638,313 or \$589,035) 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 other comprehensive loss by approximately \$2,720 (2021 - \$188,918).

As at August 31, 2022, the Company had monetary liabilities of \$161,764 Euros or \$212,898 (August 31, 2021 - \$nil Euros or \$nil) 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 other comprehensive loss by approximately \$21,290 (August 31, 2021 - \$nil).

As at August 31, 2022, the Company had monetary liabilities of GBP\$120,000 or \$182,892 (August 31, 2021 – GBP\$nil or \$nil) 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 other comprehensive loss by approximately \$18,289 (August 31, 2021 - \$nil).

As at August 31, 2022 and 2021, the Company did not have any significant monetary assets or liabilities denominated in Swedish Krona.

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 include the implementation of travel bans, self-imposed quarantine periods and physical distancing, have caused material disruption to business globally resulting in an economic slowdown. Global equity markets have experienced 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 have led to temporary site closures and delays in patient screening/enrolment. With recent widespread adoption of vaccination, these restrictions have been lifted.

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.

Management's Discussion and Analysis

APPENDIX 1

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;

Management's Discussion and Analysis

- 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.

Management's Discussion and Analysis

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 fillings, 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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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 thirdparty 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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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 materials 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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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 ever 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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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.

Management's Discussion and Analysis

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 the Company's ability conduct operations and may result 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 judgements and have been properly reflected in the accompanying financial statements.

November 21, 2022

On behalf of Management and the Board of Directors,

"Chris Moreau"

Director and Chief Executive Officer