Algernon Pharmaceuticals Inc.

MANAGEMENT'S DISCUSSION AND ANALYSIS
For the three months ended November 30, 2021 and 2020

Dated January 27, 2022

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 condensed interim consolidated financial statements and notes thereto, prepared in accordance with International Accounting Standard 34, Interim Financial Reporting ("IAS 34") using policies consistent with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

This MD&A is prepared as of January 27, 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;
- 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.

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.algernonpharmaceuticals.com.

CONFLICTS OF INTEREST

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

OVERVIEW

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

As at November 30, 2021, the Company has an accumulated deficit of $24,746,905 (August 31, 2021 - $23,546,345) and for the period ended incurred a net loss of $1,200,560 (November 30, 2020 - $3,434,448). 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. These condensed interim consolidated financial statements have been prepared on a going concern basis, which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business. These condensed interim consolidated financial statements do not reflect adjustments, which could be material, to the carrying value of assets and liabilities, which may be required should the Company be unable to continue as a going concern.

BUSINESS MODEL

Algernon is a drug re-purposing company that investigates safe, already approved drugs, including naturally occurring compounds, for new disease applications, moving them efficiently and safely into new human trials, developing new formulations and seeking new regulatory approvals in global markets. Algernon specifically investigates compounds that have never been approved in the 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.

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 is 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 it was announced that the trial achieved 70 % enrollment on July 7, 2021. Costs related to the IPF and Chronic Cough study in Australia and New Zealand, estimated to cost approximately $1.2 million, will paid for by the Company with cash on hand.

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-IND application with the 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 September 7, 2021, the Company announced that it had confirmed in its own preclinical study, that AP-188 (N,N-Dimethyltryptamine or "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 September 20, 2021 the Company announced that it planned to file a pre-investigational new drug ("pre-IND") meeting request with the United States Food and Drug Administration ("FDA") for an NP-120 (Ifenprodil) Phase 2 chronic cough study.

On September 22, 2021, the Company announced that it had filed a pre-IND meeting request with the US FDA for its investigation of NP-120 (Ifenprodil) for the treatment of SCLC.

On October 8, 2021, the Company announced that it had filed a pre-IND meeting request with the FDA for its investigation of Ifenprodil for a planned Phase 2 study for the treatment of refractory chronic cough. Ifenprodil, is an NMDA GluN2B subunit inhibitor and may represent a potential novel "first-in-class" treatment for chronic cough.

On October 13, 2021, the Company announced that it had filed a scientific advice meeting request with the United Kingdom ("UK") Medicines and Healthcare Products Regulatory Agency ("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 MHRA. The scientific advice meeting was related to the Company's planned Phase 1/2a stroke study with DMT.

On November 24, 2021, the Company announce that it has received positive feedback from the FDA at its pre-Investigational New Drug (pre-IND) meeting for its investigation of Ifenprodil for the treatment of small cell lung cancer (SCLC). Ifenprodil is an NMDA receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B).

On December 2, 2021, the Company announced that it has added a clinical trial site in Australia for its ongoing Phase 2 Ifenprodil idiopathic pulmonary fibrosis ("IPF') and chronic cough study. Corresponding with the recent opening up of the country from its COVID-19 lockdown policies, the Company projected full enrollment of the trial by the end of December 2021, with a data readout in calendar Q2, 2022.

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.

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

On January 19, 2022, the Company announced that it has filed a combined Clinical Trials of Investigational Medicinal Products 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.

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.

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 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.

The Company announced on July 7, 2021, that it has reached 70% of its enrollment target for its Phase 2 IPF and chronic cough clinical study. The Company has undertaken a number of initiatives to help improve the enrollment velocity of the study which has been affected negatively by COVID-19.

On September 20, 2021, the Company announced that it planned to file a pre-IND meeting request with the FDA for an Ifenprodil Phase 2 chronic cough study.

On December 2, 2021, the Company announced that it has added a clinical trial site in Australia for its ongoing Phase 2 Ifenprodil IPF and chronic cough study. Corresponding with the recent opening up of the country from its COVID-19 lockdown policies, the Company is now projecting full enrollment of the trial by the middle of January 2022, with a data readout in calendar Q2, 2022.

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.

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 March 1, 2021, the Company awarded the contract for its Phase 1 stroke program study of DMT, to the renowned contract research organization ("CRO"), Hammersmith Medicines Research Ltd ("HMR") located in London, UK.

On May 17, 2021, the Company announced it received positive feedback from the FDA regarding its plans to investigate DMT as an adjunct to physical therapy in the rehabilitation of stroke.

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.

As a result of the meeting, the Company plans to file a Clinical Trial Authorisation ("CTA") application for the study as soon as possible. In addition, and based on the feedback received, the Company is also considering focussing on DMT as a possible treatment for acute stroke for the Phase 2a part of the study, in addition to investigating DMT as an adjunctive treatment for stroke rehabilitation therapy. The Company is planning to conduct the Phase 1 part of the study at Hammersmith Medicines Research in London, UK and is now targeting to begin the study in January 2022.

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

The Company 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 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.

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.

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 announce 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.

Chronic Cough

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 is planning the following milestones:

<u>Calendar Year 2022</u>

Q1
- Begin Phase 1 Study DMT/Stroke

Q2
- Final Data From IPF/Cough Study

Q3
- Begin Phase 1 Ifenprodil Pancreatic Cancer
- Begin Phase 1 Ifenprodil Small Cell Lung Cancer

Q4
- Begin Phase 2 DMT Acute Stroke Study

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 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, the EU and the U.S.) – Canada".*

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 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 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.

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 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 to prescribe, 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. 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 states 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.

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. In order 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.

Europe

Refer to the discussion above under the heading "*Drug Scheduling Regulations - 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 FDA and 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.

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

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 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. 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.

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 FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

The 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 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 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 FDA approval. The 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 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.

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 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 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 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.

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.

Legislation on controlled substances United Kingdom

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.

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

The Company did not complete any financings or issue any securities during the three months ended November 30, 2021.

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 Class A 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.

RESULTS OF OPERATIONS

Three months ended November 30, 2021 and 2020

The Company had a net loss of $1,200,560 for the three months ended November 30, 2021 ("Q1 2022") compared to a net loss of $3,434,448 for the three months ended November 30, 2020 ("Q1 2021"). The Company's significant operating expenses for the three months ended November 30, 2021 included the following:

- Research and development expenses of $626,718 (Q1 2021 – $2,505,231)
- Salaries and benefits of $222,152 (Q1 2021 - $171,892)
- Marketing expenses of $142,698 (Q1 2021 – $155,443)
- Professional fees of $103,327 (Q1 2021 – $112,190)
- General and administrative expenses of $48,573 (Q1 2021 - $45,095)
- Shareholder communications expenses of $57,557 (Q1 2021 - $58,129)
- No share-based payment expenses (Q1 2021 - $392,775)

Research and development expenses totaled $626,718 for the three months ended November 30, 2021 (Q1 2021 – $2,505,231) and pertained primarily to the Company's DMT manufacturing and development. The decrease was mainly due to activities during the three months ended November 30, 2020 in connection with the Company's multinational Phase 2b/3 study of Ifenprodil as a potential therapeutic treatment for patients with COVID-19. The Company was also supporting an investigator led Phase 2 human trial for Ifenprodil and COVID-19 in South Korea during the three months ended November 30, 2020.

Salaries and benefits for the three months ended November 30, 2021 were $222,152 (Q1 2021 - $171,892) which included salaries paid to officers, independent directors and two employees as well as severance costs associated with a change in CFO which occurred on December 1, 2021. The increase from the three months ended November 30, 2020 resulted from severance costs which totaled $56,000 for the three months ended November 30, 2021.

Marketing expenses, consisted of expenses in relation to promotional activities to create and expand market presence of the Company, were $142,698 for the three months ended November 30, 2021 (Q1 2021 - $155,443) and were consistent with marketing expenses for the three months ended November 30, 2020.

Professional fees, which included legal, accounting and consulting fees, incurred in the operation of the business, were $103,327 for the three months ended November 30, 2021 (Q1 2021 - $112,190) and were consistent with professional fees for the three months ended November 30, 2020.

General and administrative expenses which included expenses incurred to support Company's day-to-day operational activities were $48,573 for the three months ended November 30, 2021 (Q1 2021 - $45,095) and were consistent with general and administrative expenses for the three months ended November 30, 2020.

Shareholder communications expenses, which included newswire subscription fees, communication advisory fees, transfer agent and filing expenses, were $57,557 for the three months ended November 30, 2021 (Q1 2021 - $58,129) and were consistent with shareholder communications expenses for the three months ended November 30, 2020.

There were no share-based payment expenses for the three months ended November 30, 2021 compared to share-based payments for the three months ended November 30, 2021 of $392,775 which related to 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.

Quarter Ended	2021 Nov. 30[1]	2021 Aug. 31[2]	2021 May 31[3]	2021 Feb. 28[4]
Total revenue	$ nil	$ nil	$ nil	$ nil
Loss before other items	1,200,560	546,036	1,676,265	2,388,068
Net loss	1,200,560	240,267	1,673,993	2,385,372
Net loss per share, basic and diluted	0.72	0.14	1.00	1.53

Quarter Ended	2020 Nov. 30[5]	2020 Aug. 31[6]	2020 May 31[7]	2020 Feb. 29[8]
Total revenue	$ nil	$ nil	$ nil	$ nil
Loss before other items	3,440,755	3,005,256	4,604,805	793,777
Net loss	3,434,448	2,987,670	4,594,055	790,145
Net loss per share, basic and diluted	2.45	2.16	4.17	0.00

[1] 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.

[2] 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.

[3] 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.

[4] 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.

[5] 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.

[6] The Company had a net loss of $2,987,670 for the quarter ended August 31, 2020 as compared to a net loss of $4,594,055 for the prior quarter ended May 31, 2020. The decrease in net loss was primarily due to a decrease in share-based payment and marketing expenses.

[7] The Company had a net loss of $4,594,055 for the quarter ended May 31, 2020 as compared to a net loss of $790,145 for the prior quarter ended February 29, 2020. The increase in net loss was mainly due to additional share-based payment of $1,710,099 as a result of an option grant; additional research and development expenses of $1,355,347 incurred by Nash Pharma and its Australian subsidiary; additional marketing expenses of $536,088 as well as additional professional fees of $242,918 associated with consulting fees incurred by Nash Pharma and business advisory activities.

[8] The Company had a net of loss of $790,145 for the quarter ended February 29, 2020 as compared to a net loss of $166,337 for the prior quarter ended November 30, 2019. The increase in net loss was primarily due to the share-based payment of $296,891 as a result of an option grant as well as additional research and development expenses of $196,027 incurred by Novotech. The increase in net loss was also attributable to a gain on debt forgiveness recognized in the prior quarter in connection with the research and development agreement that the Company was no longer required to pay to the University of Florida as a result of the mutual termination of the research and development agreement on November 13, 2019.

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 November 30, 2021, the Company had a working capital of $2,619,066 compared to working capital at August 31, 2021 of $3,886,947. This included cash and cash equivalents of $2,697,056 (August 31, 2021 - $2,411,163) available to meet short-term business requirements and current liabilities of $624,938 (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.

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 (November 30, 2021 - $3,244,005; August 31, 2021 - $4,909,261), less current liabilities (November 30, 2021 - $624,938; August 31, 2021 - $1,022,314).

OUTSTANDING SHARE DATA

On November 23, 2021, the Company announced that it had completed a consolidation of its Class A 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 November 30, 2021 and the date of this report, the Company has:

As at	November 30, 2021	January 27, 2022
Issued and outstanding common shares	1,674,868	1,674,868
Warrants outstanding[(1)]	356,587	356,587
Agent Warrant Units outstanding[(2)]	15,433	15,433
Stock options outstanding	83,500	155,750

Subsequent to November 30, 2021, on January 1, 2022, the Company granted a total of 96,000 incentive stock options to certain directors, officers, employees and consultants of the Company with an exercise price of $4.10 per share. The options expire on January 1, 2027.

Additionally, a total of 23,750 unexercised incentive stock options were forfeited, 11,000 with exercise prices of $10, 10.500 with exercise prices of $29, 500 with exercise prices of $30 and 1,750 with exercise prices of 48.

OFF-BALANCE SHEET ARRANGEMENTS

There are no off-balance sheet arrangements.

CONTRACTUAL COMMITMENTS

There are no contractual commitments to disclose.

INTANGIBLE ASSETS

	Acquisition of Nash Pharma[1]	Trademark Application Costs[3]	Patent Application Costs[2]	Total
Cost				
Balance, August 31, 2020	$ 4,862,756	$ 13,228	$ 152,259	$ 5,028,243
Additions	-	1,204	141,424	142,628
Balance, August 31, 2021	$ 4,862,756	$ 14,432	$ 293,683	$ 5,170,871
Additions	-	-	45,554	45,554
Balance, November 30, 2021	$ 4,862,756	$ 14,432	$ 339,237	$ 5,216,425

1. No amortization was taken on the intangibles acquired from the acquisition of Nash Pharma as the assets are not available for use.

2. 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. No amortization was taken as the assets are not available for use.

3. The Company has filed trademark applications for the name "ALGERNON". No amortization was taken.

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	Three months ended November 30, 2021	Three months ended November 30, 2020
Christopher Moreau[1]	CEO / Director	CEO remuneration	$ 55,000	$ 55,000
Michael Sadhra[2] [3]	CFO / Director	CFO remuneration	$ 30,000	$ 30,000
Mark Williams[4] [5]	CSO	CSO remuneration	$ nil	$ 50,000
Christopher Bryan[6]	VPRO	VPRO remuneration	$ 32,500	$ nil
Harry Bloomfield	Chairman/Director	Director fees	$ 5,600	$ nil
David Levine	Director	Director fees	$ 1,500	$ 1,500
Raj Attariwala	Director	Director fees	$ 1,500	$ 1,500
Short-term benefits paid to key management personnel			$ 126,100	$ 138,000

(1) No director fees paid.
(2) No director fees paid.
(3) Resigned as a director effective September 16, 2021and resigned as CFO effective November 30, 2021.
(4) Resigned as CSO effectively March 1, 2021 and appointed as a member of the Board of Directors effective September 16, 2021.
(5) No director fees paid.
(6) Assumed position of VPRO effectively March 1, 2021.
(7) Appointed to the Board of Directors and as Chairman effective September 7, 2021.

Share-based payments

Name	Relationship	Purpose of Transaction	Three months ended November 30, 2021	Three months ended November 30, 2020
Christopher Moreau	CFO / Director	RSU grant	$ nil	$ 109,845
Michael Sadhra	CFO / Director	RSU grant	$ nil	$ 87,875
Mark Williams	CSO	RSU grant	$ nil	$ 87,875
David Levine	Director	RSU grant	$ nil	$ 21,969
Raj Attariwala	Director	RSU grant	$ nil	$ 21,969
Share-based compensation paid to key management personnel			$ nil	$ 329,533

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

Name	Relationship	Purpose of Transaction	Three months ended November 30, 2021	Three months ended November 30, 2020
Pacific Urban Advisory Group Inc.	Company with Michael Sadhra, CFO / Director as a principal [1]	Office rent	$ 9,000	$ 9,000

(1) Michael Sadhra resigned as a director effective September 16, 2021and resigned as CFO effective November 30, 2021.

The were no amounts due to related parties as at November 30, 2021 or August 31, 2021.

RESEARCH AND DEVELOPMENT PROGRAM

Algernon is a clinical stage pharmaceutical development company focused on developing repurposed therapeutic drugs in the areas of non-alcoholic steatohepatitis ("NASH"), a type of liver disease, chronic kidney disease ("CKD"), inflammatory bowel disease ("IBD"), IPF, chronic cough and stroke. Drug re-purposing (also known as re-profiling, re-tasking or therapeutic switching) is the application of approved drugs and compounds to treat a different disease than what it originally developed for. All the research and development ("R&D") work are carried out by the Company's 100% owned Canadian subsidiary, Nash Pharmaceuticals Inc. ("Nash Pharma"). On January 6, 2020, Nash Pharma established a 100% owned Australian subsidiary, Algernon Research Pty Ltd. ("AGN Research"). Through its ongoing research programs, Nash Pharma is seeking to minimize investment and drug development risk by taking advantage of regulatory approved drugs and discovering alternative clinical uses by accelerating entry into phase II clinical trials (human).

On September 7, 2021, the Company announced that it had confirmed in its own preclinical study, that AP-188 (N,N-Dimethyltryptamine or "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 September 20, 2021 the Company announced that it planned to file a pre-investigational new drug ("pre-IND") meeting request with the United States Food and Drug Administration ("FDA") for an NP-120 (Ifenprodil) Phase 2 chronic cough study.

On September 22, 2021, the Company announced that it had filed a pre-IND meeting request with the US FDA for its investigation of NP-120 (Ifenprodil) for the treatment of SCLC.

On October 8, 2021, the Company announced that it had filed a pre-IND meeting request with the FDA for its investigation of Ifenprodil for a planned Phase 2 study for the treatment of refractory chronic cough. Ifenprodil, is an NMDA GluN2B subunit inhibitor and may represent a potential novel "first-in-class" treatment for chronic cough.

On October 13, 2021, the Company announced that it had filed a scientific advice meeting request with the United Kingdom ("UK") Medicines and Healthcare Products Regulatory Agency ("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 MHRA. The scientific advice meeting was related to the Company's planned Phase 1/2a stroke study with DMT.

On November 24, 2021, the Company announce that it has received positive feedback from the FDA at its pre-Investigational New Drug (pre-IND) meeting for its investigation of Ifenprodil for the treatment of small cell lung cancer (SCLC). Ifenprodil is an NMDA receptor antagonist specifically targeting the NMDA-type subunit 2B (GluN2B).

The breakdown of the major components of the research and development programs

Three month period ended	November 30 2021	August 31, 2021
Clinical Trials:		
Phase 2 for IPF and chronic cough	$ 388,701	$ 376,418
Investigator-led COVID study in South Korea	-	(196,335)
Phase 2b/3 multinational COVID study	2,676	(1,027,954)
	391,377	(847,871)
Preclinical:		
Ifenprodil preclinical and manufacture	37,726	25,247
Oncology preclinical	36,993	-
	74,719	25,247
DMT	224,548	216,064
Management and Ad Hoc scientific support	47,199	57,677
Total	737,843	(548,883)
Less: Australian R&D Tax Credit	(111,125)	341,642
Total Net Expenses	$ 626,718	$ (207,241)

Subsequent to November 30, 2021, on December 2, 2021, the Company announced that it has added a clinical trial site in Australia for its ongoing Phase 2 Ifenprodil idiopathic pulmonary fibrosis ("IPF') and chronic cough study. Corresponding with the recent opening up of the country from its COVID-19 lockdown policies, the Company projected full enrollment of the trial by the end of December 2021, with a data readout in calendar Q2, 2022.

Additionally, 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.

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

On January 19, 2022, the Company announced that it has filed a combined Clinical Trials of Investigational Medicinal Products 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.

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.

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 November 30, 2021, the Company's long-term assets are located as follows:

	Canada	Australia	Total
Restricted cash equivalents	$ 57,500	$ -	$ 57,500
Intangible asset	5,216,425	-	5,216,425
	$ 5,273,925	$ -	$ 5,273,925

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 asset	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, 2021.

Significant Accounting Judgments, Estimates and Assumptions

The preparation of unaudited condensed consolidated interim 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.

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. The estimates are reviewed at least annually and are updated if expectations change as a result of the technical obsolescence or legal and other limits to use. A change in the useful life or residual value will impact the reported carrying value of the intangible assets resulting in a change in related amortization expense. As at November 30, 2021, the Company has not amortized the intangible assets as the Company will only make adjustments (impair / write-off) when it abandons a drug or determines an amortization policy when a compound is approved.

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, 2021.

FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

The Company's financial instruments as at November 30, 2021 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 is classified as loans and receivables;
- restricted cash equivalents are classified as financial assets at FVTPL;
- accounts payable and accrued liabilities are classified as other 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.

> Level 1 – fair values are based on quoted prices (unadjusted) in active markets for identical assets or liabilities;
> 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
> 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 Fair Value Through Profit	Financial Assets Measured at Amortized Cost	Financial Liabilities Measured at Amortized Cost
November 30, 2021			
Cash and cash equivalents	$ 2,697,056	$ -	$ -
Accounts receivable	-	949	-
Restricted cash equivalents	57,500	-	-
Accounts payable and accrued liabilities	$ -	$ -	$ (624,938)

	Financial Assets Fair Value Through Profit	Financial Assets Measured at Amortized Cost	Financial Liabilities Measured at Amortized 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. Management believes that the credit risk with respect to receivables is minimal.

Liquidity risk

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

At November 30, 2021, the Company had a working capital of $2,619,066 compared to working capital at August 31, 2021 of $3,886,947. This included cash and cash equivalents of $2,697,056 (August 31, 2021 - $2,411,163) available to meet short-term business requirements and current liabilities of $624,938 (August 31, 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. Cash equivalents, totaling $1,000,000, consists of a GIC held at banking institutions that bears interest at 0.2% and matures on June 14, 2022. Restricted cash equivalents consist of GICs held at banking institutions that bear interest at prime less 2.2% and matures o April 13, 2022.

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

  The Company holds funds in 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 November 30, 2021, the Company had monetary assets of US$13,378 or $17,113 (August 31, 2021 - US$19,796 or $24,976) at the CAD equivalent and monetary liabilities of US$19,774 or $25,295 (August 31, 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 $818 (August 31, 2021 - $7,380).

  As at November 30, 2021, the Company had monetary assets of AUD$1,466,460 or $1,336,092 (August 31, 2021 – AUD$2,685,541 or $2,478,217) at the CAD equivalent and monetary liabilities of AUD$377,200 or $343,667 (August 31, 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 $99,242 (August 31, 2021 - $188,918).

  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.

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 unaudited condensed consolidated interim 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;

- 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 the 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.

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

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

Reliance on Third Parties for Research

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

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

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

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.

Decriminalisation of psychedelics

Despite the current status of DMT as a controlled substance in the 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.

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.

Intellectual Property Rights

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

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

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

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

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

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

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.

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.

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.

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.

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.

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.

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.

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.

January 27, 2022

On behalf of Management and the Board of Directors,

"Chris Moreau"

Director and Chief Executive Officer