

**Algernon Pharmaceuticals Inc.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS  
For the nine months ended May 31, 2021 and 2020**

**Dated July 30, 2021**

# ALGERNON PHARMACEUTICALS INC.

## Management's Discussion and Analysis

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This Management's Discussion and Analysis ("MD&A") is intended to help the reader understand Algernon Pharmaceuticals Inc., ("Algernon" or the "Company"), its operations, financial performance, current and future business environment and opportunities and risks. This MD&A is intended to supplement and complement the condensed interim consolidated financial statements and notes thereto, prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") for the nine months ended May 31, 2021 (the "financial statements").

This MD&A is prepared as of July 30, 2021. 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.

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

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

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

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

#### **CONFLICTS OF INTEREST**

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

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### **OVERVIEW**

Algernon Pharmaceuticals Inc. 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 is carried out by both the Company and its 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 May 31, 2021, the Company has an accumulated deficit of \$23,332,766 (August 31, 2020 - \$17,463,488) and for the period then ended incurred a net loss of \$7,493,813 (May 31, 2020 - \$5,550,537). The Company will need to raise sufficient working capital to maintain operations. Without additional financing, the Company may not be able to fund its ongoing operations and complete development activities. Management anticipates that the Company will continue to raise adequate funding through equity or debt financings, although there is no assurance that the Company will be able to obtain adequate funding on favorable terms. These uncertainties may cast significant doubt on the Company's ability to continue as a going concern. The accompanying 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. The accompanying 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 well-tolerated, 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.

The Company has investigated a number of repurposed generic drugs in the global disease areas of non-alcoholic steatohepatitis ("NASH"), a type of liver disease, chronic kidney disease ("CKD"), inflammatory bowel disease ("IBD"), idiopathic pulmonary fibrosis ("IPF") and chronic cough. The compounds being advanced by the Company have all performed equal to or better than controls used in widely accepted pre-clinical in vivo animal research studies.

Algernon's business strategy is to fast track its lead compounds into phase 2 clinical trials as quickly and as inexpensively as possible by using a variety of strategies. One of the key strategies is to conduct off label phase 2 trials in Australia where non-locally approved drugs are more easily accepted for clinical trials. This often means not having to repeat all of the preclinical toxicology work originally completed in the drug's country of origin. This additional work would in comparison, add significant time and costs to the Company's development timeline and budget. The next step post positive phase 2 results would be to begin the U.S. Food and Drug Administration approval process.

At present, the Company does not plan to develop a sales team to advance the marketing sales and distribution of any of its lead compounds if such compounds achieve regulatory approval in any given market. The Company's strategy is to look for moments of inflection where the potential exists to be able to consummate the best possible licensing or partnering deal or acquisition transaction.

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### **Research and Development**

Key Research Milestone Summary:

1. On April 26, 2021, the Company filed an end of Phase 2 (EOP2) meeting request with the U.S. Food and Drug Administration ("US FDA"), based on the completion of the Phase 2b part of its Phase 2b/3 COVID-19 trial of NP-120 (Ifenprodil).
2. On May 11, 2021, (the Company announced that it had reached 50% of its enrollment target for its Phase 2 IPF and chronic cough clinical study of its re-purposed drug NP-120 (Ifenprodil).
3. On May 12, 2021, the Company announces that NP-120 (Ifenprodil) reduced interleukin 6 (IL-6) with statistical significance in its recent Ifenprodil Phase 2b/3 COVID-19 trial, which may be informative for the Company's ongoing Phase 2 trial of Ifenprodil for IPF and chronic cough.
4. On May 17, 2021, the Company announced it received positive feedback from the US FDA regarding its plans to investigate AP-188 ("N,N-Dimethyltryptamine" or "DMT"), a known psychedelic compound that is part of the tryptamine family, as an adjunct to physical therapy in the rehabilitation of stroke.
5. 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.
6. On June 17, 2021, the Company announced that all of the required permits and licenses for the manufacture of its cGMP supply of DMT have been received and as a result, is targeting its Phase 1 human study to be conducted at Hammersmith Medicines Research UK in Q4, 2021.
7. On July 6, 2021, the Company announced that it will not be advancing Ifenprodil into a Phase 3 clinical study for COVID-19.
8. On July 7, 2021, the Company announced that it has reached 70% of its enrollment target for its Phase 2 clinical study of its re-purposed drug Ifenprodil for IPF and chronic cough.

### **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.

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 October 13, 2020, that it has reached 25% 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.

The Company announced on March 6, 2020, that it was going to explore Ifenprodil as a possible treatment for COVID-19 when it discovered an independent research study that showed the drug was active in an

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animal model for H5N1, the world's most lethal avian flu, with an approximately 60% mortality rate in humans. In the study, Ifenprodil reduced mortality by 40% and reduced acute lung injury and inflammation in the lung tissue.

The Company has announced its topline data from the Phase 2b part of its multinational Phase 2b/3 human study of Ifenprodil for the treatment of COVID-19. The Company also filed an EOP2 meeting request with the US FDA, based on the completion of the Phase 2b part of its Phase 2b/3 COVID-19 trial of Ifenprodil.

On July 6, 2021, the Company announced that it would not be advancing Ifenprodil into a Phase 3 clinical study for COVID-19. The Company's decision was based on several factors including the overall findings of the Phase 2b COVID-19 study final data set, the global rate of vaccinations to date, other COVID-19 drug treatment programs under development, and the projected trial size, costs and timelines needed to successfully complete a Phase 3 trial. Feedback recently received from the US FDA regarding the Company's end of Phase 2 meeting request was also informative.

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 May 17, 2021, the Company announced it received positive feedback from the US FDA regarding its plans to investigate DMT as an adjunct to physical therapy in the rehabilitation of stroke. Another pre-IND meeting request for the use of DMT as a treatment for acute stroke will be filed once the Company completes additional preclinical work. Regardless of where the Company's DMT clinical trials will be conducted, only the various parties that manufacture, ship, receive and handle DMT will be required to have all required licenses and permits. The Company will be undertaking to ensure that these are all in order. DMT is a controlled substance in most countries globally and the import and export of it is closely scrutinized and monitored.

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.

#### Upcoming Milestones

##### Calendar Year 2021

Q4: Phase 1 DMT clinical trial

Q4: Final data from IPF/cough study

##### Calendar Year 2022

Q2: Phase 2 DMT Clinical Trial

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#### **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."

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 US FDA, the National Institute on Drug Abuse, and the DEA –involved in the scheduling of controlled substances, including both narcotic drugs and psychotropic substances. Controlled substances are categorized by the DEA according to five schedules, based upon eight factors, including: 1) actual or relative potential for abuse; 2) scientific evidence of pharmacological effect, if known; 3) state of current scientific knowledge about the drug; 4) history and current pattern of abuse; 5) scope/duration/significance of abuse; 6) what, if any, risk to public health; 7) psychic or physiological dependence liability; and 8) whether the substance is an immediate precursor of an already controlled substance.

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

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

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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 US FDA prior to registration with the DEA. All practitioners who participate in a clinical trial as a principal investigator or sub-investigator must also be authorized by the state in which they practice prescribing, dispense, administer, and conduct research with controlled substances. In most cases, these activities are authorized when a license is granted to the practitioner by the local Institutional Review Board. However, some states require a separate, state-issued controlled substance license and other states have a separate state-controlled substances authority that requires practitioners to obtain a separate registration, in addition to their board license.

#### Europe

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

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

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- (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. 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.

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#### Europe

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

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

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

#### Canada –Health Canada

##### Clinical Study Regulatory Process

In Canada, a CTA is composed of three modules:

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

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

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

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

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

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

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

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

United States –US FDA

#### **Clinical Study Regulatory Process**

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

The IND application must contain information in three broad areas:

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

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

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

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

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

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

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

In some cases, the approval of a new drug is expedited. Accelerated approval can be applied to promising therapies that treat a serious or life-threatening condition and provide therapeutic benefit over available therapies. The US FDA also employs several approaches to encourage the development of certain drugs,

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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

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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").

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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.

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#### **Financing**

On March 5, 2021, the Company closed a private placement offering of 11,260,040 units at the price of \$0.25 per unit for gross proceeds of \$2,815,010 (the "Offering").

Each unit is comprised of one common share and one share purchase warrant. Each warrant will entitle the holder to acquire one additional common share at a price of \$0.40 per share until March 5, 2023.

In connection with the Offering, the Company paid cash commissions in the aggregate amount of \$161,400, being 8% of the aggregate proceeds raised from the sale of units to purchasers introduced by eligible finders. In addition, the Company has issued 645,600 finders' warrants ("Finders' Warrants"), being 8% of the number of units sold under the Offering to purchasers introduced by such finders. Each Finders' Warrant entitles the holder to purchase one additional common share at a price of \$0.40 per share until March 5, 2023.

The net proceeds of the Offering will be used to fund the Company's general corporate purposes.

#### **Corporate**

Dr. Mark Williams resigned from his role as Chief Science Officer ("CSO") effective March 1, 2021, in order to take on the role of President/CSO of a new company.

Dr. Christopher Bryan was appointed as Vice President, Research & Operations ("VPRO") effective March 1, 2021.

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#### Use of Proceeds of Prior Offerings

The Company received gross proceeds totalling \$10,491,880 collectively from the November 2019 Offering, the February 2020 Offering, and the May 2020 Special Warrants Offering (collectively the "Prior Offerings"). After deducting Agent's Fees and expenses in connection with the Prior Offerings the Company received net proceeds from the Prior Offerings of \$9,259,075. The following table sets out a comparison of how the Company intended to use the net proceeds from the Prior Offerings and its actual use of proceeds from the Prior Offerings as at May 31, 2021, an explanation of variances and the impact of variances on the ability of the Company to achieve its business objectives and milestones.

Intended Use of Proceeds of Prior Offerings		Actual Use of Proceeds from Prior Offerings <sup>(1)</sup>	Variance – (Over)/Under Expenditure	Explanation of Variance and Impact on business objectives
Phase 2 Clinical Trial				
NP-178 IBD Trial/or NP-120 IPF Trial	\$ 1,200,000	\$ 1,233,616	(\$ 33,616)	Trial in progress
Additional Phase 2 Study Planning	\$ 400,000	Nil	\$ 400,000	Not commenced
Research and Development	\$ 146,000	\$ 146,000	-	In progress
First portion of the Phase 2b multinational COVID-19 Study	\$ 4,000,000	\$ 3,983,828	(\$ 16,172)	Trial in progress
Phase 2 COVID-19 South Korean Trial	\$ 1,000,000	\$ 982,531	\$ 17,469	Suspended <sup>(2)</sup>
Synthesis of cGMP material of NP-120 (Ifenprodil)	\$ 450,000	\$ 465,737	(\$ 15,737)	Work in progress
<b>Sub Total</b>	<b>\$ 7,196,000</b>	<b>6,811,712</b>	<b>\$ 384,288</b>	
Working Capital and general purposes	\$ 2,063,075	\$ 2,447,363		
<b>TOTAL</b>	<b>\$ 9,259,075</b>	<b>\$ 9,259,075</b>		

(1) The Australian research and development ("R&D") incentive tax credit allows qualifying companies to receive a cash refund of 43.5% of the eligible R&D expenditures connected to R&D activities undertaken at Australia. As at May 31, 2021, the Company was eligible for a cumulative total of \$3,167,962 tax credits from the Australian tax authority; \$929,301 from the year ended August 31, 2020 and \$2,238,661 for the nine months from September 1, 2020 to May 31, 2021. For the portion of qualified R&D expenditures incurred up to June 30, 2020, a total of AUD \$607,910 or \$551,815 at the CAD Equivalent of R&D incentive tax credit was received on November 4, 2020.

The cumulative actual expenses shown above have been offset by the cumulative total of \$3,167,962 Australian tax credits.

(2) The trial was suspended due to lack of patients.

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

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## Management's Discussion and Analysis

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### RESULTS OF OPERATIONS

#### Nine months ended May 31, 2021 and May 31, 2020

For the nine months ended May 31, 2021, the Company recorded a net loss of \$7,493,813 compared to a net loss of \$5,550,537 for the nine months ended May 31, 2020. Some of the major items comprising the net loss for the nine months ended May 31, 2021 included increases in research and development expenses and salaries and benefits that were partially offset by decreases in share-based payment, marketing expenses and professional fees.

Research and development expenses for the nine months ended May 31, 2021 were \$5,004,253 (May 31, 2020 - \$1,638,819) after partially offset by the Australia R&D incentive cash tax credit of \$2,238,661 (May 31, 2020 - \$162,608 and the contribution of \$66,012 (May 31, 2020 - \$nil) from the NRC – Industrial Research Assistance Program for its COVID-19 Therapeutic Development project. The increase was mainly due to increased activities in connection with the Company's various research studies and clinical trial programs that have been supported by the Company's CRO partner in Australia and run through the Company's foreign subsidiary in Australia. Eligible research and development expenditures incurred by the Company in Australia are refundable at 43.5%.

Salaries and benefits for the nine months ended May 31, 2021 were \$492,410 (May 31, 2020 - \$nil) which included salaries paid to officers, independent directors and two employees. For the period ended May 31, 2021, officers and director fees were remunerated as salaries whereas over the same period in the prior year, they were remunerated as consultants.

Share-based payment for the nine months ended May 31, 2021 was \$770,000 (May 31, 2020 - \$2,303,881). It was mainly consisted of share-based payment recognized, under the graded vesting method, for the remaining unvested restricted share units ("RSU") that were granted to certain directors, officers and consultants of the Company on July 23, 2020. The decrease for the nine-month period ended May 31, 2021 was mainly attributed to no issuance of stock options grant by the Company whereas a total of 8,925,000 stock options with a weighted average exercise price of \$0.20 were granted to directors, officers and consultants of the Company over the same period in the prior year.

Marketing expenses for the nine months ended May 31, 2021 were \$559,414 (May 31, 2020 - \$850,118). The decrease was a result of reduced activities in marketing communication over the same period in the prior year. For the nine months ended May 31, 2020, the Company invested in new and additional marketing communications campaigns and investor communications initiatives to improve the Company's visibility and to reach out to more potential investors and capital markets.

Professional fees, which included legal, accounting and consulting fees, incurred in the operation of the business, were \$387,089 for the nine months ended May 31, 2021 (May 31, 2020 - \$608,086). The decrease was mainly due to a reclassification of remuneration for officers and directors from consulting fees to salaries.

#### Three months ended May 31, 2021 and May 31, 2020

In the third quarter ended May 31, 2021 ("Q3 2021"), the Company recorded a net loss of \$1,676,265 compared to a net loss of \$4,604,805 in the second quarter ended May 31, 2020 ("Q3 2020"). The decrease in net loss was mainly due to decreases in share-based payment, research and development expenses, marketing expenses, professional fees and shareholder communication expenses. These decreases were partially offset by an increase in salaries and benefits.

Share-based payment for Q3 2021 was \$101,556 (Q3 2020 - \$2,006,990). Share-based payment in Q3 2021 decreased over the same quarter in prior year because there were no stock options granted in Q3

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2021. In Q3 2020, a total of 4,550,000 stock options with a weighted average exercise price of \$0.29 were granted to directors, officers and consultants of the Company.

Research and development expenses for Q3 2021 were \$1,037,673 (Q3 2020 - \$1,406,593) after partially offset by the Australia R&D incentive cash tax credit of \$458,687 (Q3 2020 - \$162,608) and the contribution of \$7,060 (Q3 2020 - \$nil) from the NRC – Industrial Research Assistance Program for its COVID-19 Therapeutic Development project. The decrease in Q3 2021 could be attributed to more expenditures were eligible for R&D incentive cash tax credit than over the same quarter in the prior year.

Marketing expenses for Q3 2021 were \$180,646 (Q3 2020 - \$659,216). The expenses were lower in Q3 2021 because more costs related to additional marketing and social media campaigns to improve the Company's visibility and to reach out to more potential investors and capital markets were incurred in Q3 2020.

Professional fees, which included legal, accounting and consulting fees, incurred in the operation of the business, were \$130,903 for Q3 2021 (Q3 2020 - \$364,200). The decrease was mainly due to a decrease in consulting fees resulting from a reclassification of remuneration for officers and directors from a consulting fees to salaries over the same quarter in the prior year.

Shareholder communications expenses for Q3 2021 were \$32,003 (Q3 2020 - \$106,456). The decrease in Q3 2021 could be attributed to additional costs related to additional transfer agent and filing fees in connection with the private placement of special warrants of the Company in Q3 2020.

#### 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	2021	2020	2020
	May 31 <sup>(1)</sup>	Feb. 28 <sup>(2)</sup>	Nov. 30	Aug. 31 <sup>(3)</sup>
Total revenue	\$ nil	\$ nil	\$ nil	\$ nil
Loss before other items	1,676,265	2,388,068	3,440,755	3,201,304
Net loss	1,673,993	2,385,372	3,434,448	2,987,670
Net loss per share, basic and diluted	0.01	0.02	0.02	0.02

Quarter Ended	2020	2020	2019	2019
	May 31 <sup>(4)</sup>	Feb. 29 <sup>(5)</sup>	Nov. 30 <sup>(6)</sup>	Aug. 31
Total revenue	\$ nil	\$ nil	\$ nil	\$ nil
Loss before other items	4,604,805	793,777	257,217	425,690
Net loss	4,594,055	790,145	166,337	425,066
Net loss per share, basic and diluted	0.04	0.01	0.01	0.01

(1) 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.

(2) 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.

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- (3) 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.
- (4) 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.
- (5) 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, a contract research organization chose to conduct the Company's first phase 2 clinical trial. 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.
- (6) The Company had a net loss of \$166,337 for the quarter ended November 30, 2019 as compared to a net loss of \$425,066 for the prior quarter ended August 31, 2019. The decrease in net loss was mainly due to decrease in research and development expenses incurred by Nash Pharma and decrease in professional fees as costs associated with a fully marketed public offering of units of the Company were capitalized as share issuance costs. The decrease in net loss could also be attributed to a gain on debt forgiveness related to the quarterly payments 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 May 31, 2021, the Company had a working capital of \$4,504,763 compared to working capital at August 31, 2020 of \$7,131,172. This included cash and cash equivalents of \$3,288,008 (August 31, 2020 - \$6,121,424) available to meet short-term business requirements and current liabilities of \$1,900,106 (August 31, 2020 - \$607,053).

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

#### *Non-GAAP Financial Measure*

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

- (1) Working capital is calculated as current assets (May 31, 2021 - \$6,404,869; August 31, 2020 - \$7,738,225), less current liabilities (May 31, 2021 - \$1,900,106; August 31, 2020 - \$607,053).

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#### OUTSTANDING SHARE DATA

As at May 31, 2021 and the date of this report, the Company has:

As at	May 31, 2021 & July 30, 2021
Issued and outstanding common shares	167,486,769
Warrants outstanding	35,667,010
Agent Warrant Units outstanding	1,543,342
Stock options outstanding	8,425,000
Restricted Share Units	1,139,000

#### OFF-BALANCE SHEET ARRANGEMENTS

There are no off-balance sheet arrangements.

#### CONTRACTUAL COMMITMENTS

N/A

#### INTANGIBLE ASSETS

	Acquisition of Nash Pharma <sup>(1)(2)</sup>	Trademark Application Costs <sup>(3)</sup>	Patent Application Costs <sup>(2)</sup>	Total
<b>Cost</b>				
Balance, August 31, 2019	\$ 4,862,756	\$ 5,403	\$ 83,521	\$ 4,951,680
Additions	-	7,825	68,738	76,563
Balance, August 31, 2020	\$ 4,862,756	\$ 13,228	\$ 152,259	\$ 5,028,243
Additions	-	467	113,597	114,064
Balance, May 31, 2021	\$ 4,862,756	\$ 13,695	\$ 265,856	\$ 5,142,307

(1) On October 19, 2018, the Company completed the acquisition transaction of Nash Pharma. There were four programs acquired from Nash Pharma at date of acquisition. No amortization was taken on the intangibles acquired as the assets with finite life are not available for use. On an annual basis, the intangibles with finite life are reviewed for impairment. The Company will impair or write-off when it abandons a drug or determine an amortization policy when a compound is approved.

Intangibles Acquired	Status of Programs	Dates Patent Applications were Filed	% of Total Value of Nash Pharma	Acquisition Costs
CKD program	Clinical results	June 27, 2018	30%	\$ 1,458,827
IBD program	Clinical results	July 6, 2018	30%	\$ 1,458,827
NASH program	Clinical results	July 6, 2018	30%	\$ 1,458,827
IPF program	Anticipated results	February 14, 2019	10%	\$ 486,275
TOTAL			100%	\$ 4,862,756

(2) The Company has filed new method of use patents for lead compounds for treatment of three new disease areas: NASH, CKD and IBD. Patents, once approved, will have a finite life based on their expiry dates and will be amortized on a straight-line basis over their economic or legal life. No amortization was taken as these assets are not available for use.

(3) The Company has filed trademark applications for the name "ALGERNON". Trademarks are assets with an indefinite life that cannot be amortized in the same way as assets with a finite life. Instead, every year, a test for impairment is conducted on indefinite life assets. If the asset is found to be impaired, then its life is estimated, and it is amortized over the remainder of its useful life in the same way for a finite life intangible.

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#### RELATED PARTY TRANSACTIONS AND KEY MANAGEMENT COMPENSATION

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

##### Short-term benefits

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2021	Nine months ended May 31, 2020
Christopher Moreau <sup>(1)</sup>	CEO / Director	CEO remuneration	\$ 165,000	\$ nil
Michael Sadhra <sup>(2)</sup>	CFO / Director	CFO remuneration	\$ 90,000	\$ nil
Mark Williams <sup>(3)</sup>	CSO	CSO remuneration	\$ 100,000	\$ nil
Christopher Bryan <sup>(4)</sup>	VPRO	VPRO remuneration	\$ 32,500	\$ nil
David Levine	Director	Director fees	\$ 4,500	\$ nil
Raj Attariwala	Director	Director fees	\$ 4,500	\$ nil
Short-term benefits paid to key management personnel			\$ 396,500	\$ nil

(1) No director fees paid.

(2) No director fees paid.

(3) Resigned effectively March 1, 2021.

(4) Assumed position of VPRO effectively March 1, 2021.

##### Consulting fees – other

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2021	Nine months ended May 31, 2020
7360232 Manitoba Ltd.	Company owned by Christopher Moreau, CEO / Director	Management Consulting fees	\$ nil	\$ 107,000
Michael Sadhra Ltd.	Company owned by Michael Sadhra, CFO / Director	Management Consulting fees	\$ nil	\$ 36,000
Mark Williams	CSO	Management Consulting fees	\$ nil	\$ 119,995
Sadhra & Chow LLP	Company where Michael Sadhra, CFO / Director is a partner	Tax services	\$ 11,750	\$ 3,000
Consulting fees - other			\$ 11,750	\$ 265,995

##### Share-based payments

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2021	Nine months ended May 31, 2020
Christopher Moreau	CFO / Director	RSU grant	\$ 226,954	\$ nil
Michael Sadhra	CFO / Director	RSU grant	\$ 181,563	\$ nil
Mark Williams	CSO	RSU grant	\$ 151,247	\$ nil
David Levine	Director	RSU grant	\$ 45,391	\$ nil
Raj Attariwala	Director	RSU grant	\$ 45,391	\$ nil
Share-based compensation paid to key management personnel			\$ 650,546	\$ nil

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

Name	Relationship	Purpose of Transaction	Nine months ended May 31, 2021	Nine months ended May 31, 2020
Pacific Urban Advisory Group Inc.	Company with Michael Sadhra, CEO / Director as a principal	Office rent	\$ 27,000	\$ 23,000

As at May 31, 2021 and August 31, 2020 there are no amounts payable to related parties.

#### RESEARCH AND DEVELOPMENT PROGRAM

Since the acquisition of Nash Pharma, the Company has used the data and provisional patents to advance the Company's lead compound, NP-120 ("NP 120" or "Ifenprodil") in areas related to the treatment of NASH, CKD, IBD and chronic cough.

In March 2020, the Company announced that it has begun a process to review the potential of using NP-120 (Ifenprodil) as a novel treatment for COVID-19 based on studies that it could reduce both the severity and duration of a COVID-19 infection. The Company retained Novotech, a leading Asia-Pacific clinical research organization ("CRO") to conduct a feasibility study in South Korea. This led to identification of physicians in South Korea who have agreed to conduct an investigator initiated Phase 2 clinical trial of Ifenprodil for coronavirus patents. In addition, the Company contracted with a U.S. based company specializing on developing and scaling synthetic chemical processes to manufacture the active pharmaceutical ingredient for NP-120 (Ifenprodil) to support its various clinical programs.

In April 2020, the protocol for a planned physician initiated Phase 2 clinical study of NP-120 (Ifenprodil) for COVID-19 infected patients in South Korea was finalized. The Company also announced that it has retained Novotech to conduct an additional Ifenprodil Phase 2 COVID-19 human trial in Australia sponsored by the Company.

In August 2020, the Company announced that the first patient has been dosed in its Phase 2 IPF and chronic cough clinical study of its re-purposed drug NP-120 (Ifenprodil).

In October 2020, the Company announced that its multinational Phase 2b/3 human study of NP-120 (Ifenprodil) for COVID-19 was being conducted in U.S., Australia, the Philippines and Romania. Enrollment of the program's last patient was announced in December 2020.

On October 9, 2020, due to lack of sufficiently ill patients, which is a direct result of a successful government-initiated pandemic mitigation strategy, the Company decided to close the investigator-led South Korea trial. Instead, the Company will remain focussed on its Phase 2b/3 multinational NP-120 COVID-19 study.

In January 2021, after the external Data and Safety Monitoring Board ("DSMB") has completed its latest review of the Phase 2b part of the Company's Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19, the Company was given approval to continue with the Phase 3 part of the study.

On February 1, 2021, Algernon has launched a clinical research program for stroke focused on N,N-Dimethyltryptamine, ("DMT") a known psychedelic compound that is part of the tryptamine family (other drugs in the tryptamine family include psilocybin and psilocin.). Algernon plans to be the first company globally to pursue DMT for ischemic stroke in humans. The Company intends to undertake pre-clinical research and a Phase 1 clinical trial on DMT during 2021. If the results of the Phase 1 clinical trial are promising, the Company will move forward with a Phase 2 trial and possibly a Phase 3 clinical trial in the future.

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

Nine months ended	May 31, 2021	May 31, 2020
Clinical Trials:		
Phase 2 for IPF and chronic cough	\$ 826,691	\$ 622,880
Investigator-led COVID study in South Korea	344,517	407,290
Phase 2b/3 multinational COVID study	5,645,153	256,448
	\$ 6,816,361	\$ 1,286,618
Preclinical:		
Ifenprodil preclinical and manufacture	\$ 91,555	\$ 324,761
Oncology preclinical	49,535	-
NASH preclinical	12,468	-
	\$ 153,558	\$ 324,761
DMT	\$ 182,437	\$ -
QA Consulting	\$ 1,927	\$ 2,787
Management and Ad Hoc scientific support	\$ 154,643	\$ 187,261
Total	\$ 7,308,926	\$ 1,801,427
Less: Australian R&D Tax Credit	(\$ 2,238,661)	(\$ 162,608)
Less: Canadian NRC Research Grant	(\$ 66,012)	\$ -
Total Net Expenses	\$ 5,004,253	\$ 1,638,819

Subsequent to the period ended May 31, 2021, the Company announced that it would not be advancing Ifenprodil into a Phase 3 clinical study for COVID-19. The Company's decision was based on several factors including the overall findings of the Phase 2b COVID-19 study final data set, the global rate of vaccinations to date, other COVID-19 drug treatment programs under development, and the projected trial size, costs and timelines needed to successfully complete a Phase 3 trial. Feedback recently received from the US FDA regarding the Company's end of Phase 2 meeting request was also informative.

#### 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 May 31, 2021, the Company's long-term assets are located as follows:

	Canada	Australia	Total
Restricted cash equivalents	\$ 57,500	\$ -	\$ 57,500
Deposits – Long-term	22,487	-	22,487
Intangible asset	5,142,307	-	5,142,307
	\$ 5,222,294	\$ -	\$ 5,222,294

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### Management's Discussion and Analysis

As at August 31, 2020, the Company's long-term assets were located as follows:

	Canada	Australia	Total
Restricted cash equivalents	\$ 57,500	\$ -	\$ 57,500
Intangible asset	5,028,243	-	5,028,243
	\$ 5,085,743	\$ -	\$ 5,085,743

### 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, 2020.

#### Significant Accounting Judgments, Estimates and Assumptions

The preparation of consolidated 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 May 31, 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, 2020.

### FINANCIAL INSTRUMENTS AND RISK MANAGEMENT

The Company's financial instruments as at May 31, 2021 included cash and cash equivalents, accounts receivable 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 fair value through profit or loss;
- accounts receivable is classified as loans and receivables; and
- accounts payable and accrued liabilities are classified as other financial liabilities, which are measured at amortized cost.

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Financial instruments are measured at fair value by level using a fair value hierarchy that reflects the relative reliability of the inputs used in making the measurements.

- 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 carrying values of receivables and accounts payable and accrued liabilities approximate their fair values due to the short-term maturity of these financial instruments.

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

	<b>Financial Assets</b>	<b>Loans and Receivables</b>	<b>Financial Liabilities</b>
	Fair Value Through Profit	Measured at Amortized Cost	Measured at Amortized Cost
<b>May 31, 2021</b>			
Cash and cash equivalents	\$ 3,288,008	\$ -	\$ -
Accounts receivable	-	31,533	-
Accounts payable and accrued liabilities	\$ -	\$ -	\$ (1,900,106)

	<b>Financial Assets</b>	<b>Loans and Receivables</b>	<b>Financial Liabilities</b>
	Fair Value Through Profit	Measured at Amortized Cost	Measured at Amortized Cost
<b>August 31, 2020</b>			
Cash and cash equivalents	\$ 6,121,424	\$ -	\$ -
Accounts receivable	-	37,408	-
Accounts payable and accrued liabilities	\$ -	\$ -	\$ (607,053)

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.

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## Management's Discussion and Analysis

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### 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.

### 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.

#### a) 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 its short-term investment nature. The Company's financial asset exposed to interest rate risk consists of cash and cash equivalents and restricted cash equivalents. The Company's cash equivalents hold interest rates ranging from 0.15% to 1.8%.

#### b) 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.

#### c) 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\$") and other operating expenses that are mainly in Canadian dollars ("CAD\$"). The Company funds cash calls to its foreign subsidiary in Australia in AUD\$. The Company's exposure to foreign currency risk arises primarily on fluctuations in the exchange rate of the CAD\$ relative to the US\$ and the AUD\$.

As at May 31, 2021, the Company had monetary assets of US\$7,748 or \$9,353 (August 31, 2020 - US\$21,499 or \$28,040) at the CAD equivalent and monetary liabilities of US\$50,039 or \$60,407 (August 31, 2020 - US\$84,285 or \$109,924) 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 \$5,105 (August 31, 2020 - \$8,188).

As at May 31, 2021, the Company had monetary assets of AUD\$3,238,538 or \$3,025,118 (August 31, 2020 - AUD\$1,187,241 or \$1,142,720) at the CAD equivalent and monetary liabilities of AUD\$1,802,826 or \$1,684,020 (August 31, 2020 - AUD\$262,018 or \$252,192) 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 \$134,110 (August 31, 2020 - \$89,053).

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.

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

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#### **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. However, as a result of the outbreak of COVID-19 and the company's focus on developing repurposed therapeutic drugs, the Company announced on March 6, 2020 that it was going to explore NP-120 (Ifenprodil) as a possible treatment for COVID-19 when it discovered an independent research study that showed the drug was active in an animal model for H5N1, the world's most lethal avian flu, with an approximately 60% mortality rate in humans. In the study, Ifenprodil reduced mortality by 40% and reduced acute lung injury and inflammation in the lung tissue.

After review of the full data set from the Phase 2b part of its Phase 2b/3 human study of NP-120 (Ifenprodil) for the treatment of COVID-19, the Company announced that it would not proceed with the phase 3 portion of the trial. The Company's decision was based on several factors including the overall findings of the Phase 2b COVID-19 study final data set, the global rate of vaccinations to date, other COVID-19 drug treatment programs under development, and the projected trial size, costs and timelines needed to successfully complete a Phase 3 trial. Feedback recently received from the U.S. Food and Drug Administration regarding the Company's end of Phase 2 meeting request was also informative.

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

## **RISKS RELATED TO THE BUSINESS**

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

The Company has no present prospect of generating revenue from the sale of products. The Company is therefore subject to many of the risks common to early-stage 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 success must be considered in light of the 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, certain of the net proceeds from any offering the company undertakes may be used to fund such negative cash flow from operating activities, if any.

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

While the Company provides information regarding the planned use of proceeds from sales of the Securities, the Company will have broad discretion over the use of the net proceeds from an offering of Securities. Because of the number and variability of factors that will determine the use of such proceeds, the Company's ultimate use might vary substantially from its planned use. Purchasers of Securities may not agree with how the Company allocates or spends the proceeds from an offering of Securities. The Company may pursue acquisitions, collaborations or other opportunities that do not result in an increase in the market value of our securities, including the market value of the Common Shares, and that may increase our losses.

### ***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 agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on the Company's business, operating results or financial condition.

### ***Reliance on Successful Development of Repurposed Drugs for New Disease Applications***

The Company's ability to generate future revenue or achieve profitable operations is largely dependent on the ability to attract the experienced management and scientific know-how to develop new repurposed drugs and to partner with larger, more established companies in the industry to successfully commercialize products. Successfully developing a new repurposed drug into a marketable product may take several years and significant financial resources, and the Company may not achieve those objectives.

In order to commercialize any products, the Company will need to conduct clinical trials, which may not succeed, and to obtain regulatory approvals which it may fail to do. The Company does not know and is unable to predict what type and how many clinical trials the U.S. Food and Drug Administration (the "FDA") will require the Company to conduct before granting approval for it to market its drug products. The development programs may not lead to a commercial product, either because failure to demonstrate that product candidates are safe and effective in clinical trials and cannot obtain necessary approvals from the

## **ALGERNON PHARMACEUTICALS INC.**

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

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FDA and/or similar foreign regulatory agencies or because of inadequate financial or other resources to advance product candidates through the clinical trial process for successful commercialization.

#### ***Future Sales May Affect the Market Price of the Company Shares.***

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 future profitability.

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 the Company 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. Even if additional financing is obtained, there is no guarantee that it could be completed on terms favourable to the Company.

The Company cannot predict the size of future issuances of Common Shares or the issuance of debt instruments or other securities convertible into Common Shares or the dilutive effect, if any, that future issuances and sales of the Company's securities will have on the market price of the Common Shares. These sales may have an adverse impact on the market price of the Common Shares.

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

The operations of the Company may require the Company and its third party contractors to obtain the necessary licenses and permits from various governmental authorities to conduct research. There can be no assurance that such licenses and permits will be granted.

#### ***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.

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#### ***Low Barriers to Entry and Competition***

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 manufacturing and marketing experience 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 the Company has certain direct competition from Menssana Research Inc. ("Menssana") and Owlstone Nanotech Inc. ("Owlstone"). Menssana is based in New Jersey and Owlstone 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, results of operations and financial condition.

The Company's industry is experiencing rapid growth and consolidation that may cause the Company to lose key relationships and intensify competition. 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.

#### ***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 business, results of operations and financial condition of the Company.

#### ***Litigation***

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, it cannot guarantee that it has identified every patent or patent application that may be relevant to the research, development, or commercialization of its products. Moreover, it cannot assure that third parties will not assert valid, erroneous, or frivolous patent infringement claims.

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#### ***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.

#### ***Dividends***

The Company has no earnings or dividend record, and does not anticipate paying any dividends on the common shares in the foreseeable future.

#### ***Regulatory Changes and Approval Risks***

The Company and its contract research organization's research and development activities are and will be significantly regulated by a number of governmental entities, including Health Canada, the European Medicines Agency ("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 the Company'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.

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

## **ALGERNON PHARMACEUTICALS INC.**

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

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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 regulatory requirements will have a detrimental impact on the business. Changes in legislation cannot be predicted and could irreparably harm the business.

#### ***Risks Associated with 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 the Company. In addition, if such third parties fail to perform their obligations in compliance with regulatory requirements and the Company's protocols, the Company'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 the Company's dependence on third parties, the Company may face delays or failures outside of its direct control in its efforts to develop product candidates.

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

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

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#### ***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 governmental 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 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 the Company to achieve regulatory approval. The legalization of psilocybin, and potentially other psychedelic compounds (including DMT) in the future may also impact commercial sales for the Company due to a reduced barrier to entry leading to a risk of increasing competition.

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

Due to the nature of the business of the Company 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, the Company 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, the Company will ensure that such contractors are appropriately licensed. Were such contractors to operate outside the terms of these licenses, the Company 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

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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 the Company and, few, if any, established companies whose business model the Company can follow or upon whose success the Company can build. Accordingly, investors will have to rely on their own estimates in deciding about whether to invest in the Company. There can be no assurance that the Company'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.

#### ***Risks Associated with Brand Development***

The Company believes that continuing to strengthen its brand is critical to achieving widespread acceptance of the Company, particularly in light of the competitive nature of the Company's market. Promoting and positioning its brand will depend largely on the success of the Company's marketing efforts and the ability of the Company to provide high quality services. In order to promote its brand, the Company will need to increase its marketing budget and otherwise increase its financial commitment to creating and maintaining brand loyalty among users. There can be no assurance that brand promotion activities will yield increased revenues or that any such revenues would offset the expenses incurred by the Company in building its brand. If the Company fails to promote and maintain its brand or incurs substantial expenses in an attempt to promote and maintain its brand or if the Company's existing or future strategic relationships fail to promote the Company's brand or increase brand awareness, the Company's business, results of operations and financial condition would be materially adversely affected.

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

The business of the Company is subject to rapid technological changes. Failure to keep up with such changes may adversely affect the business of the Company. The Company is subject to the risks of companies operating in the medical and healthcare business.

The market in which the Company 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 stocks 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.

#### ***Risks Associated with 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

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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.

#### ***Risks Associated with International Operations***

A component of the Company's strategy is to expand internationally. Expansion into the international markets will require management attention and resources. The Company has limited experience in localizing its service, and the Company believes that many of its competitors are also undertaking expansion into foreign markets. There can be no assurance that the Company will be successful in expanding into international markets. In addition to the uncertainty regarding the Company's ability to generate revenues from foreign operations and expand its international presence, there are certain risks inherent in doing business on an international basis, including, among others, regulatory requirements, legal uncertainty regarding liability, tariffs, and other trade barriers, difficulties in staffing and managing foreign operations, longer payment cycles, different accounting practices, problems in collecting accounts receivable, political instability, seasonal reductions in business activity and potentially adverse tax consequences, any of which could adversely affect the success of the Company's international operations. To the extent the Company expands its international operations and has additional portions of its international revenues denominated in foreign currencies, the Company could become subject to increased risks relating to foreign currency exchange rate fluctuations. There can be no assurance that one or more of the factors discussed above will not have a material adverse effect on the Company's future international operations and, consequently, on the Company's business, results of operations and financial condition.

#### ***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 employees 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, results of operations and financial condition.

#### ***Economic Environment***

The Company's operations could be affected by the economic context should the unemployment level, interest rates or inflation reach levels that influence consumer trends and consequently, impact the Company's future sales and profitability.

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#### ***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 its 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.

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

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.

#### ***Financial Risk Exposures***

The Company may have financial risk exposure to varying degrees relating to the currency of each of the countries where it operates and has financial risk exposure towards digital currencies. The level of the financial risk exposure related to a currency and exchange rate fluctuations will depend on the Company's ability to hedge such risk or use another protection mechanism.

#### ***Attracting and keeping senior management and key scientific personnel***

The success of the Company depends on the continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel and to develop and maintain important relationships with leading academic institutions, companies, and thought leaders.

### **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.

July 31, 2021

On behalf of Management and the Board of Directors,

*"Michael Sadhra"*

Chief Financial Officer and Director