

*This short form prospectus is a base shelf prospectus. This short form base shelf prospectus has been filed under legislation in each of the provinces of Canada that permit certain information about these securities to be determined after the short form base shelf prospectus has become final and that permit the omission of that information from this prospectus. The legislation requires the delivery to purchasers of a prospectus supplement containing the omitted information within a specified period of time after agreeing to purchase any of these securities, except in cases where an exemption from such delivery requirements has been obtained.*

*No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise. This short form base shelf prospectus constitutes a public offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell such securities.*

*These securities have not been and will not be registered under the United States Securities Act of 1933, as amended (the “U.S. Securities Act”). They may not be offered or sold in the United States of America or to or for the account or benefit of a “U.S. person” as defined in Regulation S under the U.S. Securities Act. This short form prospectus does not constitute an offer to sell or a solicitation of an offer to buy these securities in the United States or to any “U.S. person”.*

*Information has been incorporated by reference in this short form base shelf prospectus from documents filed with securities commissions or similar authorities in Canada. Copies of the documents incorporated herein by reference may be obtained on request without charge from the Corporate Secretary of Algernon Pharmaceuticals Inc., Suite 915 – 700 West Pender Street, Vancouver, BC, V6C 1G8, Telephone: 604-646-1553, and are also available electronically at [www.sedar.com](http://www.sedar.com).*

## SHORT FORM BASE SHELF PROSPECTUS

New Issue

May 5, 2021



### ALGERNON PHARMACEUTICALS INC.

**\$50,000,000**

**Common Shares  
Warrants  
Subscription Receipts  
Units**

This short form base shelf prospectus (this “**Prospectus**”) relates to the offering for sale of class A common shares (the “**Common Shares**”), warrants (the “**Warrants**”) and subscription receipts (the “**Subscription Receipts**”) or any combination of such securities (the “**Units**”) (all of the foregoing, collectively, the “**Securities**”) by Algernon Pharmaceuticals Inc. (“**Algernon**” or the “**Company**”) from time to time, during the 25-month period that the Prospectus, including any amendments hereto, remains effective, in one or more series or issuances, with a total offering price of the Securities in the aggregate, of up to \$50,000,000. The Securities may be offered for sale separately or in combination with one or more other Securities and may be sold from time to time in one or more transactions at a fixed price or prices (which may be changed) or at market prices prevailing at the time of sale, at prices determined by reference to such prevailing market prices or at negotiated prices.

The specific terms of any Securities offered will be described in one or more shelf prospectus supplements (collectively or individually, as the case may be, a “**Prospectus Supplement**”), including, where applicable: (i) in the case of Common Shares, the number of Common Shares offered, the offering price and any other specific terms; (ii) in the case of Warrants, the number of Warrants offered, the offering price, the designation, number and terms of the Common Shares issuable upon exercise of the Warrants, any procedures that will result in the adjustment of these numbers, the exercise price, dates and periods of exercise, the currency in which the Warrants are issued and any other specific terms; (iii) in the case of Subscription Receipts, the number of Subscription Receipts being offered, the offering price, the procedures for the exchange of the Subscription Receipts for Common Shares or Warrants, as the case may be, and any other specific terms; and (iv) in the case of Units, the designation, number and terms of the Common Shares, Warrants or Subscription Receipts comprising the Units. Where required by statute, regulation or policy, and where Securities are offered in currencies other than Canadian dollars, appropriate disclosure of foreign exchange rates applicable to the Securities will be included in the Prospectus Supplement describing the Securities. A Prospectus Supplement may include specific variable terms pertaining to the Securities that are not within the alternatives and parameters described in this Prospectus.

All shelf information permitted under applicable laws to be omitted from this Prospectus will be contained in one or more Prospectus Supplements that will be delivered to purchasers together with this Prospectus. Each Prospectus Supplement will be incorporated by reference to this Prospectus for the purposes of securities legislation as of the date of the Prospectus Supplement and only for the purposes of the distribution of the Securities to which the Prospectus Supplement pertains. Investors should read the Prospectus and any applicable Prospectus Supplement carefully before investing in the Securities.

The Company and/or any selling securityholders may sell the Securities to or through underwriters or dealers purchasing as principals, and may also sell the Securities directly to one or more purchasers pursuant to applicable statutory exemptions or through agents. See “Plan of Distribution”. This Prospectus may qualify an “at-the-market” distribution (as such term is defined in National Instrument 44-102 – *Shelf Distributions* (“**NI 44-102**”). The Prospectus Supplement relating to a particular offering of Securities will identify each underwriter, dealer or agent, as the case may be, engaged by the Company and/or the selling securityholder in connection with such offering and sale of the Securities, and will set forth the terms of the offering of such Securities, including, to the extent applicable, any fees, discounts or any other compensation payable to underwriters, dealers or agents in connection with the offering, the method of distribution of the Securities, the initial issue price (in the event that the offering is a fixed price distribution), the proceeds that the Company and/or selling securityholder will receive and any other material terms of the plan of distribution. The Securities may be sold from time to time in one or more transactions at a fixed price or prices or at non-fixed prices. If offered on a non-fixed price basis, Securities may be offered at market prices prevailing at the time of sale, at prices determined by reference to such prevailing market prices or at negotiated prices, which prices may vary as between purchasers and during the period of distribution of the Securities.

In connection with any offering of the Securities, other than an at-the-market offering, the underwriters, dealers or agents, as the case may be, may over allot or effect transactions which stabilize or maintain the market price of the Securities at a level above that which otherwise might prevail on the open market. Such transactions, if commenced, may be discontinued at any time. See “Plan of Distribution”.

The Company’s outstanding Common Shares are listed and posted for trading on the Canadian Securities Exchange (the “**CSE**”) under the symbol “AGN”, on the QTCQB under the symbol “AGNPF” and on the Frankfurt Stock Exchange under the symbol “AGW”. The Company’s head office is located at Suite 915 – 700 West Pender Street, Vancouver, BC, V6C 1G8. The Company’s registered office is located at Suite 1500-1055 West Georgia Street, Vancouver, British Columbia, V6E 4N7.

The Company has a negative operating cash flow for the year ended August 31, 2020 and for the three and six months ended February 28, 2021. To the extent that the Company has negative operating cash flow in future periods, it may need to allocate a portion of its cash reserves to fund such negative cash flow. The Company may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that the Company will be able to generate a positive cash flow from its operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to the Company.

**No underwriter has been involved in the preparation of the Prospectus or performed any review of the contents of the Prospectus.**

**Unless otherwise disclosed in any applicable Prospectus Supplement, the Warrants, Subscription Receipts and the Units will not be listed on any securities exchange. Unless the Securities are disclosed to be listed, there will be no market through which these Securities may be sold and purchasers may not be able to resell these Securities purchaser under this Prospectus. This may affect the pricing of such Securities in the secondary market, the transparency and availability of trading prices, the liquidity of such Securities, and the extent of issuer regulation. See “Risk Factors”.**

**The Canadian and United States federal governments regulate drugs through the *Controlled Drugs and Substances Act* (Canada) (the “CDSA”) and the Controlled Substances Act (21 U.S.C. § 811) (the “CSA”), respectively, which place controlled substances in a schedule. Under the CDSA, N,N-Dimethyltryptamine (“DMT”) is currently a Schedule III drug. The CDSA generally prohibits all uses of controlled substances unless an exemption is granted under section 56 of the CDSA or the regulations allow otherwise. The Minister of Health can grant exemptions under section 56 of the CDSA to use controlled substances if it is deemed to be necessary for a medical or scientific purpose or is otherwise in the public interest. Under the CSA, DMT is currently a Schedule I drug. Health Canada and the United States Food and Drug Administration (the “FDA”) have not approved DMT as a drug for any indication. If the Company is found to be in violation of the CSA or any of the requirements of the United States Drug Enforcement Administration (the “DEA”), the DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke any registrations once granted, which could have a material adverse effect on the Company’s business, operations and financial condition. Certain states of the United States also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on the Company’s business, operations and financial condition.**

**In the United States, DMT is classified as Schedule I drug under the CSA and the Controlled Substances Import and Export Act (the “CSIEA”) and as such, medical and recreational use is illegal under the United States federal laws. The Company’s program involving a Schedule I drug is conducted in strict compliance with the laws and regulations regarding the production, storage and use of Schedule I drugs. 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. The Company does not advocate for the legalization of psychedelic substances and does not deal with psychedelic substances except within laboratory or clinical trial settings conducted within approved regulatory frameworks. The Company currently sponsors and works with licensed third parties in the United States to conduct any clinical trials and research relating to psychedelics and currently does not handle controlled or restricted substances under the CDSA or CSA. If the Company were to conduct this work without reliance on third parties, it would**

**need to obtain the required licenses, approvals and authorizations from Health Canada, the FDA or other applicable regulatory bodies. 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. It is a criminal offence to possess substances under the CDSA and the CSA without a prescription.**

**In the United States, the Company's activities are potentially subject to additional regulation by various federal, state, and local authorities in addition to the FDA, including, among others, the Centers for Medicare and Medicaid Services, other divisions of Health and Human Services, or HHS, (for example, the Office of Inspector General), the Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. In addition, all psychedelic research being conducted must have authorization by the DEA. In Canada, the Company's activities are potentially subject to additional regulation by various federal and provincial authorities, including, among others, Health Canada.**

**Although the Company is in compliance with all applicable laws (and intends to continue to comply), there can be no assurance that new laws, regulations, and guidelines will not be enacted, or that existing or future laws and regulations will not be changed. Any introduction of new (or changes to existing) laws, regulations, and guidelines, or other unanticipated events could, among other things, (a) require the Company to implement extensive changes to its operations (which could, among other things increase compliance costs, and give rise to material liabilities), and (b) subject the Company to heightened scrutiny by regulators, stock exchanges, clearing agencies and other authorities.**

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## GENERAL MATTERS

In this Prospectus, references to “Algernon”, the “Company”, “we”, “us” and “our” refers, collectively, to Algernon Pharmaceuticals Inc. and our subsidiaries.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This Prospectus contains forward-looking information and forward-looking statements (collectively, “**forward-looking statements**”) that relate to the Company’s current expectations and views of future events. In some cases, these forward-looking statements can be identified by words or phrases such as “may”, “might”, “will”, “expect”, “anticipate”, “estimate”, “intend”, “plan”, “indicate”, “seek”, “believe”, “predict” or “likely”, or the negative or grammatical variations of these terms, or other similar expressions intended to identify forward-looking statements, although not all forward-looking statements include such words. The Company has based these forward-looking statements on its current expectations and projections about future events and financial trends that it believes might affect its financial condition, results of operations, business, prospects and financial needs. These forward-looking statements include, among other things, statements relating to:

- uncertainties with respect to the effects of the novel coronavirus known as COVID-19 (“**COVID-19**”) will directly and indirectly have on the Company;
- the Company’s expectations regarding its revenue, expenses and research and development operations;
- the Company’s anticipated cash needs and its needs for additional financing;
- the ability of the Company to successfully complete its research in a timely fashion;
- the Company’s intention to grow its business and operations;
- expectations with respect to future production costs and capacity;
- expectations regarding the Company’s growth rates and growth plans and strategies;
- expectations with respect to the approval of the Company’s license applications;
- the Company’s competitive position and the regulatory environment in which the Company operates;
- the Company’s business objectives for the next twelve months;
- the Company’s plans with respect to the payment of dividends;
- the Company’s ability to obtain additional funds through the sale of equity or debt instruments;
- the ability of the Company’s products to access markets;
- the Company’s ability to expand into international markets;
- the timing of the Company’s pre-clinical and clinical studies; and
- the Company’s relationship with its distribution partners.

Forward-looking statements are based on certain assumptions and analyses made by the Company in light of the experience and perception of historical trends, current conditions and expected future developments and other factors it believes are appropriate and are subject to risks and uncertainties. In

making the forward-looking statements included in this Prospectus, the Company has made various material assumptions, including but not limited to , the following: (i) the Company obtaining the necessary regulatory approvals; (ii) that regulatory requirements will be maintained; (iii) general business and economic conditions; (iv) the Company's ability to successfully execute its plans and intentions; (v) the availability of financing on reasonable terms; (vi) the Company's ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company's competitors; (ix) the maintenance of the Company's current good relationships with its suppliers, service providers and other third parties; (x) financial results, future financial position and expected growth of cash flows; (xi) business strategy, including budgets, projected costs, projected capital expenditures, taxes, plans, objectives, potential synergies and industry trends; (xii) research and development; (xiii) expectations concerning the size and growth of the global medical technology market; and (xiv) the effectiveness of the Company's products compared to its competitors' products. Although the Company believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect, and the Company cannot assure that actual results will be consistent with these forward-looking statements. Given these risks, uncertainties and assumptions, investors should not place undue reliance on these forward-looking statements. Whether actual results, performance or achievements will conform to the Company's expectations and predictions is subject to a number of known and unknown risks, uncertainties, assumptions and other factors, including those listed under "Risk Factors", which include:

- the Company is a development stage company with little operating history, a history of losses and the Company cannot assure profitability;
- the Company is subject to changes in Canadian laws regulations and guidelines which could adversely affect the Company's future business and financial performance;
- the Company may not be able to effectively manage its growth and operations, which could materially and adversely affect its business;
- the ability of the Company and its third party contractors to obtain the necessary licenses to conduct research;
- the Company's ability to obtain Health Canada, FDA or EMA (as defined below) approval, within the time frame or at all;
- changes in regulations and legislation regarding psychedelic therapy;
- changes in the psychedelic therapy market;
- the Company may be unable to obtain additional financing on acceptable terms or not at all;
- the effectiveness Company's technology and the Company's ability to bring its technology into commercial production cannot be assured;
- the effect of COVID-19 outbreak on the ability of the Company to carry on business, including the ability to conduct clinical trials;
- the continued growth of the global medical technology market cannot be assured;
- the Company may become subject to litigation, including for possible product liability claims, which may have a material adverse effect on the Company's reputation, business, results from operations and financial condition;
- the Company faces competition from other companies where it will conduct business and those companies may have a higher capitalization, more experienced management or may be more mature as a business;

- the Company is reliant on management and if the Company is unable to attract and retain key personnel, it may not be able to compete effectively;
- the Company's industry is experiencing rapid growth and consolidation that may cause the Company to lose key relationships and intensify competition;
- the Company expects to sell additional equity securities or secure debt facilities to fund operations, for capital expansion, and for mergers and acquisitions, which would have the effect of diluting the ownership positions of the Company's current shareholders;
- the Company's officers and directors may be engaged in a range of business activities resulting in conflicts of interest;
- regulatory scrutiny of the Company's industry may negatively impact its ability to raise additional capital;
- the Company cannot assure you that a market will continue to develop or exist for the Common Shares and, if such market continues to develop, what the market price of the Common Shares will be;
- the market price for Common Shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond our control;
- the Company does not anticipate paying cash dividends; and
- future sales of Common Shares by existing shareholders could reduce the market price of the Common Shares.

The above list is not exhaustive of the factors that may affect any of the forward-looking statements of the Company. If any of these risks or uncertainties materialize, or if assumptions underlying the forward-looking statements prove incorrect, actual results might materially vary from those anticipated in those forward-looking statements. The assumptions referred to above and described in greater detail under "Risk Factors" should be considered carefully by readers.

Certain of the forward-looking statements and other information contained herein concerning the pharmaceutical industry and the general expectations of the Company concerning the pharmaceutical industry and concerning the Company are based on estimates prepared by the Company using data from publicly available governmental sources as well as from market research and industry analysis and on assumptions based on data and knowledge of this industry which the Company believes to be reasonable. While the Company is not aware of any misstatement regarding any industry or government data presented herein, the pharmaceutical industry involves risks and uncertainties that are subject to change based on various factors and the Company has not independently verified such third-party information.

The Company's forward-looking statements are based on the reasonable beliefs, expectations and opinions of management on the date of this Prospectus (or as of the date they are otherwise stated to be made). Although the Company has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. There is no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements.

Further, any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by applicable law, the Company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made



or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for management of the Company to predict all such factors and to assess in advance the impact of each such factor on the business of the Company or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. See “Risk Factors”.

*All of the forward-looking statements contained in this Prospectus are expressly qualified by the foregoing cautionary statements. Investors should read this entire Prospectus and consult their own professional advisors to assess the income tax, legal, and other risk factors, and other aspects, of their investment*

## CURRENCY PRESENTATION

Unless stated otherwise or as the context otherwise requires, all references to dollar amounts in this Prospectus, any Prospectus Supplement, and any other document that are incorporated by reference into this Prospectus are references to Canadian dollars, unless otherwise indicated.

## DOCUMENTS INCORPORATED BY REFERENCE

**Information has been incorporated by reference in this Prospectus from documents filed with the securities commissions in each of the Provinces of Canada (the “Securities Commissions”) or any similar authorities in the provinces and territories of Canada.** Copies of the documents incorporated herein by reference may also be obtained on request without charge from the Corporate Secretary of Algernon Pharmaceuticals Inc., Suite 915 – 700 West Pender Street, Vancouver, BC V6C 1G8, Telephone: (604) 646-1553. In addition, copies of the documents incorporated by reference herein may be obtained from the Securities Commissions electronically on SEDAR, at [www.sedar.com](http://www.sedar.com).

The following documents or portions of documents filed with the Securities Commissions are specifically incorporated by reference into, and form an integral part of, this Prospectus:

- the annual information form of the Company for the year ended August 31, 2020, dated February 4, 2021 (the “AIF”);
- the audited consolidated financial statements of the Company, for the years ended August 31, 2020 and 2019, together with the auditors’ report thereon and the notes thereto;
- the management’s discussion and analysis of financial condition and results of operations of the Company for the year ended August 31, 2020;
- the unaudited condensed interim consolidated financial statements for the three and six months ended February 28, 2021 and February 29, 2020, together with the notes thereto;
- the management’s discussion and analysis of financial condition and results of operations of the Company for the three and six months ended February 28, 2021;
- the management information circular dated July 3, 2020 with respect to the Company’s annual general meeting held on August 18, 2020; and
- the statement of executive compensation for the Company as at August 31, 2020 as filed on SEDAR on March 1, 2021.

Any documents of the type referred to above or in Section 11.1 of Form 44-101F1, including any material change reports (excluding confidential reports), annual and interim financial statements (including management's discussion and analysis filed in connection with such annual and interim financial statements), updated disclosure of earnings interest coverage ratios, and information circulars or annual filings that are filed by the Company with the Securities Commissions or any similar authorities in the provinces and territories of Canada after the date of this Prospectus and prior to the termination of the offering under any Prospectus Supplement shall be deemed to be incorporated by reference into this Prospectus.

**Any statement contained in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for the purposes of this Prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is, or is deemed to be, incorporated by reference herein modifies or supersedes such statement. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement shall not be deemed an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that was required to be stated or that was necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Prospectus.**

Upon a new annual information form and the related annual financial statements being filed by the Company with, and, where required, accepted by the Securities Commissions and similar authorities in the provinces and territories of Canada during the currency of this Prospectus, the previous annual information form, the previous annual financial statements and all interim financial statements, material change reports and annual filings or information circulars filed before the commencement of the Company's fiscal year in which the new annual information form is filed will be deemed no longer to be incorporated by reference into this Prospectus for purposes of future offers and sales of Securities under this Prospectus.

A Prospectus Supplement containing the specific terms in respect of any Securities, updated disclosure of earnings interest coverage ratios (if applicable) and any additional or updated information that the Company may elect to include (provided that such information does not describe a material change that has not already been the subject of a material change report or a prospectus amendment) will be delivered to purchasers of such Securities, together with this Prospectus, and will be deemed to be incorporated into this Prospectus as of the date of such Prospectus Supplement, but only for the purposes of the offering of such Securities.

Any template version of any "marketing materials" (as such terms are defined in National Instrument 41-101 – *General Prospectus Requirements* of the Canadian Securities Administrators) filed after the date of a Prospectus Supplement and before the termination of the distribution of the Securities offered pursuant to such Prospectus Supplement (together with this Prospectus) is deemed to be incorporated by reference in such Prospectus Supplement.

## THE COMPANY

The Company is a clinical stage pharmaceutical development company focused on advancing its lead compounds for of non-alcoholic steatohepatitis ("NASH"), chronic kidney disease ("CKD"), inflammatory bowel disease ("IBD"), idiopathic pulmonary fibrosis ("IPF"), chronic cough, and COVID-19.

The Company's outstanding Common Shares are listed and posted for trading on the CSE under the symbol "AGN", on the QTCQB under the symbol "AGNPF" and on the Frankfurt Stock Exchange under the symbol "AGW". The Company's head office is located at Suite 915 - 700 West Pender Street, Vancouver, BC, V6C 1G8. The Company's registered office is located at Suite 1500 - 1055 West Georgia Street, Vancouver, British Columbia, V6E 4N7.

## SUMMARY DESCRIPTION OF THE BUSINESS

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

The Company's early research identified a number of drug candidates that had already been approved for other diseases. Only drugs that were approved in Russia, Ukraine, South Korea and Japan were chosen to avoid off-label prescription writing in the United States and Europe. Eleven drug candidates were initially screened in globally accepted *in vivo* animal models for three new disease areas: NASH, CKD, IBD and chronic cough. The Company has also screened a number of candidates for IPF and chronic cough in an *in vivo* animal model study. In addition, the Company is also investigating one of its drug candidates for COVID-19.

The Company's lead candidate is NP-120 (Ifenprodil) ("**NP-120**"), which is the key compound for multiple research studies and disease indications. NP-120 is an N-methyl-D-aspartate ("**NMDA**") receptor antagonist specifically targeting the NMDA-type subunit 2B (Glu2NB). NP-120 (Ifenprodil) prevents glutamate signalling. The NMDA receptor is found on many tissues including lung cells and T-cells, neutrophils. NP-120 (brand name Cerocal) was initially developed by Sanofi in the 1990s in the French and Japanese markets for the treatment of circulatory disorders. Although no longer available in France, the drug is highly genericized and sold in Japan and South Korea.

The Company is investigating NP-120 for IPF and chronic cough and is conducting a Phase 2 study in Australia and New Zealand. The purpose of this proof-of-concept trial is to determine the efficacy of NP-120 in the preservation of lung function in IPF patients (including biomarkers of fibrosis) and its associated cough. On May 6, 2020, the Company received ethics approval from the Royal Brisbane & Women's Hospital, Human Research Ethics Committee. The Phase 2 IPF and chronic cough trial began on August 5, 2020 and it was announced that the trial achieved 25% enrollment on October 13, 2020. Costs related to the IPF and chronic cough study in Australia and New Zealand, estimated to cost approximately \$1.2 million, will be paid for by the Company with cash on hand.

The Company is also investigating NP-120 for COVID-19. An independent study, published by the American Society of Microbiology in *mSystems*, found that NP-120 significantly reduced ALI and improved survivability in an animal study with H5N1 infected mice. H5N1 is the most lethal form of influenza known to date with an over 50% mortality rate.<sup>1</sup> In light of these findings, the Company believes that NP-120 has the potential to be a therapeutic treatment for the most severe cases of COVID-19, and may also reduce morbidity in patients.

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

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<sup>1</sup> American Society of Microbiology, December 2019 issue of *mSystems*

South Korea trial. Instead, the Company will remain focussed on its Phase 2b/3 multinational NP-120 COVID-19 study.

In addition, on April 29, 2020, the Company received a “No Objection” letter from Health Canada to proceed with a NP-120 COVID-19 Phase 2b/3 multinational clinical trial. The study is an adaptive pilot to pivotal trial design based on guidance documents from the World Health Organization to determine if NP-120 can improve clinical symptoms of COVID-19 by reducing the number of COVID-19 diagnosed patients from progressing to mechanical ventilation with intubation and death. The trial will begin as a Phase 2b study and after an interim analysis is performed on the first 150 patients, the data will determine the number of expected patients needed to reach statistical significance in a Phase 3 trial. With positive preliminary data, the clinical trial will be able to move directly from a Phase 2b into a Phase 3. As of the date of this Prospectus, the Company does not have enough funds to commence a Phase 3 clinical trial. The Company intends to seek additional funding in order to commence the Phase 3 clinical trial should the results of the Phase 2b trial prove positive as well as based on feedback received from the FDA for an end of Phase 2 meeting submission. No assurance can be given that the Company will be able to raise additional funding to move forward with the Phase 3 clinical trial.

As part of the planned multinational Phase 2 COVID-19 trial, the Company has also filed for ethics approval in Australia and has also filed an investigational new drug (“IND”) application with the FDA. On June 3, 2020, the Company received clearance from the FDA for the IND application for the planned multinational Phase 2b/3 study of NP-120 as a potential therapeutic treatment for patients with COVID-19. The clinical study for Ifenprodil is entitled, “A Randomized Open Label Phase 2b/3 Study of the Safety and Efficacy of NP-120 (Ifenprodil) for the Treatment of Confirmed COVID-19 Infected Hospitalized Patients”.

On December 15, 2020, the Company announced positive trending interim data from its COVID-19 Phase 2b/3 study of NP-120<sup>2</sup>.

On December 24, 2020, the Company announced that the last patient from the Phase 2b part of its multinational Phase 2b/3 human study of NP-120 for the treatment of COVID-19, completed treatment as well as the required two-week follow up<sup>3</sup>.

On February 20, 2021, the Company provided an update on its COVID-19 study reporting that due to a fire at the Romanian Hospital site, there was a delay in completing the site audit as planned<sup>4</sup>. The Company reported that the source data audit from all sites and for all patients is now complete. The database was locked for analysis on March 5, 2021 and on March 31, 2021, the Company announced topline data from the Phase 2b part of its Phase 2b/3 COVID-19 trial of NP-120.

Key topline findings include:

*All Cause Mortality:* At Day 15 of the study (the last day of treatment) there was 0% mortality in the 20 mg dose Ifenprodil treatment arm compared to a 3.3% mortality rate in the untreated control arm,  $p=0.18$ . For a Phase 3 trial to be sufficiently powered to confirm this endpoint, it is projected that 1,900 patients would need to be enrolled to reach a statistically significant result.

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<sup>2</sup> <https://www.globenewswire.com/news-release/2020/12/15/2145345/0/en/Algernon-Pharmaceuticals-Announces-Positive-Trending-Interim-Data-for-its-Phase-2b-3-Ifenprodil-COVID-Study.html>.

<sup>3</sup> <https://www.globenewswire.com/news-release/2020/12/24/2150551/0/en/Algernon-Pharmaceuticals-Announces-Last-Patient-Out-in-Multinational-Phase-2b-3-Human-Study-of-Ifenprodil-for-COVID-19.html>.

<sup>4</sup> <https://www.globenewswire.com/news-release/2021/02/17/2177029/0/en/Algernon-Pharmaceuticals-Provides-Update-on-COVID-19-Phase-2b-Final-Study-Data.html>.

*Oxygenation (SpO2):* Of patients with a low blood oxygen level (SpO2 <94%), 100% of patients in the 20 mg dose treatment arm returned to normal levels of oxygen at day four compared to day nine for patients in the untreated arm (adjusted hazard ratio 1.91, 95% CI 0.97-3.77, p=0.061). Power calculations project that 450 patients would be required to confirm a statistically significant result with this endpoint in a Phase 3 trial.

*Time in Intensive Care Unit:* Topline results for this endpoint indicate that there was also a strong trend to less time spent in the intensive care unit in the overall study by patients in the 20 mg dose arm, as compared to patients in the untreated arm (adjusted hazard ratio 10.45, CI 1.23-88.61, p=0.0315). However, the Company cautions that additional, confounding variables were detected, and these numbers need to be confirmed with additional analysis, as well as power calculations conducted to project the required size for a Phase 3 study.

*WHO Score and Other Endpoints:* The World Health Organization (WHO) Clinical Progression score, the primary default endpoint for the study, showed a similar mean in all patients in all study arms. No significant changes were seen in other secondary endpoints, namely the time to hospital discharge, rates and duration of mechanical ventilation, or the New Early Warning (NEWS) score. The Company investigated a 20 mg and 40 mg dose of Ifenprodil. Based on the initial data review, no significant changes were observed in the 40 mg dose group.

On April 26, 2021, the Company filed an end of Phase 2 meeting request with the FDA based on the completion of the Phase 2b part of its Phase 2b/3 COVID-19 trial of NP-120.

The size and cost of the Phase 3 study cannot be determined until the final data is available from the Phase 2b part of the trial. The phase 2b part of the trial if positive, and the statistical significance achieved for its various stated endpoints and feedback from the FDA will determine how many patients is required for the Phase 3 portion.

The Company has also retained Organic Consultants, Inc. (dba Cascade Chemistry) to produce the active pharmaceutical ingredient (“API”) of NP-120. Algernon made the decision to scale-up cGMP manufacturing of NP-120 to support its quickly evolving clinical programs for its clinical focus on COVID-19 as well as its IPF and chronic cough clinical program. The Company has manufactured its first multi-kilogram batch of cGMP material produced. Stability testing of the API is on-going. The Company filed a pre-IND application with the FDA to seek guidance on the use of Algernon’s planned new proprietary injectable and slow release formulation. The FDA advised that for the toxicology program of a new intravenous NP-120 formulation, a single animal 30-day study would be acceptable. The Company estimates that if it moves forward with its NP-120 the toxicology studies will cost approximately \$500,000, which will be funded by the Company with cash on hand.

The Company advises that it is not making any express or implied claims that NP-120 has the ability to eliminate, cure or contain COVID-19 (or the SARS-2 Coronavirus) at this time.

The Company had previously disclosed in its AIF that it was currently engaged in conducting research to confirm the mechanism of action for each of the lead compounds. Since all of Algernon’s lead compounds are genericized, there is historical data available on each compound’s mechanism of action as it relates to the disease it was originally developed to treat. The Company has decided not to pursue independent confirmation as to whether these known pathways are involved in the specific biochemical interaction that produced the pharmacological effect seen in the Company’s animal model research.

## Clinical Research on DMT

On February 1, 2021, Algenon 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.). Algenon 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.

The Company’s decision to investigate DMT and move it into human trials for stroke is based on multiple independent, positive pre-clinical studies demonstrating that DMT helps promote neurogenesis as well as structural and functional neural plasticity<sup>5</sup>. These are key factors involved in the brain’s ability to form and reorganize synaptic connections, which are needed following a brain injury.

A recently published pre-clinical study<sup>6</sup> in an animal model for stroke, showed that rats treated with DMT recovered motor function more quickly and to a greater extent and also exhibited lower lesion volumes when compared to control group animals that did not receive DMT. Key data from the study achieved statistical significance. Data from a study published in *Experimental Neurology*, in May 2020 showed that in a rat model of cerebral ischemia-reperfusion injury, DMT reduced the infarct (dead cells) volume and improved functional recovery. The key findings in this study were:

- animals treated with DMT displayed lower lesion volumes than control animals measured by MRI 24 hours following the occlusion. ( $p = 0.0373$ );
- animals in the DMT group improved motor function more quickly and to a greater extent than the control group; The differences became significant on the 4th day ( $p = 0.0325$ ) and persisted throughout a 30-day follow-up; and
- mRNA expression of brain-derived neurotrophic factor (BDNF) was upregulated in both the peri-infarct cortex ( $p = 0.0273$ ) and contralateral cortex ( $p = 0.0048$ ) as well as in serum ( $p < 0.0001$ ). BDNF is a key facilitator of neuroplasticity.

Unlike other companies recently researching psychedelic drugs, such as Mind Medicine Inc. and Numinus Wellness Inc., Algenon will be focusing on a sub-hallucinogenic, or microdose of DMT provided by continuous intravenous administration. By pursuing a continuous active microdose, the goal will be to provide patients with the therapeutic benefits of DMT, without having a psychedelic experience. This is an important element when considering treating a patient who has just suffered a stroke, wherein the Company believes that medications that cause a hallucinogenic response would not be preferred.

Based on historical data showing that several DMT Phase 1 studies have already been conducted, the Company believes that it will be able to use this data to seek approval to begin its own Phase 1 study without having to complete certain toxicology work.

The Company has engaged GVI Clinical Development Solutions (“GVI”), a contract research organization (“CRO”) that is on retainer with the Company, to assist the Company with certain aspects of the preclinical and clinical trials. This includes the preparation an investigational brochure on DMT, which

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<sup>5</sup> Olsen in vitro study: *Cell Reports* (2018) 23:3170-28 and *ACS Chem Neurosci* (2019) 10:3261-70; Rat stroke study (Nardai): *Experimental Neurology* (2020) 327-113245.

<sup>6</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0014488620300765?via%3Dihub>

can be used to communicate with regulatory authorities, and the preparation of the protocol for a Phase 1 clinical study at an estimated cost of approximately \$20,000.

The Company intends to file a Clinical Trial Application (“CTA”) and meeting request with Health Canada in order to obtain additional insight and options for the Company’s planned clinical research program. The CTA filing and meeting are not a prerequisite for the Company to commence its planned clinical trials.

Algenron has also filed a pre-IND (Investigational New Drug) application with the FDA in order to receive feedback from the FDA on the Company’s planned clinical program for DMT and stroke. This filing is not a regulatory requirement as the Company’s currently planned clinical trials do not fall under the jurisdiction of the FDA as they are not being conducted in the United States. The Company believes it can benefit from early FDA guidance in the event the Company’s presently planned clinical trials are promising and FDA approval is sought in the future for latter stage research. The actual meetings with each of Health Canada and the FDA are expected to take place within 30 to 45 days of the meeting request and does not require any direct fees to be paid by the Company.

On January 29, 2021, the Company filed a provisional patent with the U.S. Patent Office for new forms of DMT, in addition to formulation, dosage and method of use claims for ischemic stroke. The Company has also filed claims for combination therapy of DMT and Constraint Induced Movement Therapy. A provisional patent filed in the U.S. means a priority date has been established which can then be used for global patent filings at a later date as the patent enters the Patent Cooperation Treaty (or international) phase.

#### *Pre-Clinical Research*

On February 8, 2021, the Company appointed Charles River Laboratories (“**Charles River**”) to conduct its preclinical (non-human testing) research work, which will be conducted in Finland. The pre-clinical research will include:

- 1) conducting a cortical neurite outgrowth study, which is a study that looks at the neuronal effects of DMT over various time periods and durations. This research is being conducted *in-vitro*. This research will be required before the start of the Phase 1 clinical study;
- 2) investigating DMT and its effects in an animal model of hemorrhagic stroke. This research will be required before the start of the Phase 2 clinical study; and
- 3) investigating DMT in an animal ischemic stroke model to validate and extend the scope of the data that was developed in a similar study last year by Dr. Nardai of Department Section of Vascular Neurology, Heart and Vascular Center, Semmelweis University, Budapest, Hungary. This research will be required before the start of the Phase 2 clinical study.

The Company anticipates the pre-clinical research will cost approximately \$750,000 and take six to eight months. The contract with Charles River can be cancelled at any time by the Company, subject to the payment of charges for any outstanding work orders. The Company will own the rights to all results of the pre-clinical research conducted by Charles River.

Charles River requires the following three permits to conduct this research in Finland:

- 1) DMT Handling permit: This permit has already been granted by the Finnish Medicines Agency (“**FIMEA**”); and

- 2) DMT Import permit: This permit has already been granted by FIMEA; Charles River is waiting on a paper copy to send to the exporter (Toronto Research Chemicals Inc. (“TRC”)); and
- 3) DMT Export permit: Once TRC receives the paper copy of the import permit, Charles River will apply to Health Canada for the export permit, which is expected to take 30-35 business days.

#### *Research-Grade DMT Manufacturing*

As part of the Company’s work order with Charles River, Charles River is required to obtain its own supply of research grade DMT. Charles River has chosen to obtain this DMT from TRC, the cost of which is included in the Company’s work order. TRC manufactures and supply researchers in the biomedical fields with specialized complex organic small molecules not otherwise commercially available. TRC will ship the DMT directly to Charles River’s facility in Finland. The Company understands the TRC holds a Health Canada dealer’s license, but will require an amendment to that license to produce the research grade DMT. Please refer to the discussion of dealer’s license amendment under the following paragraph “Clinical-Grade DMT Manufacturing”. The Company understands that the TRC’s license amendment is pending.

#### *Clinical-Grade DMT Manufacturing*

The Company recently awarded the contract to manufacture its cGMP (clinical grade (for human use) material) DMT to Dalton Pharma Services (“**Dalton**”). The DMT produced by Dalton is intended for use by Hammersmith (as defined below) in the Company’s Phase 1 clinical trials. Dalton is a Health Canada approved GMP contract provider of integrated chemistry, drug development and manufacturing services to the pharmaceutical and biotechnology industries. Dalton holds a dealer’s licence with Health Canada under the CDSA that allows Dalton to possess, produce, assemble, sell, send, transport and deliver controlled substances. In order to produce DMT for the Company, Dalton must obtain an amendment to its dealer license that will add DMT to the list of substances that Dalton can produce and deal with in accordance with its dealer license. Dalton submitted a request for this amendment to Health Canada on February 18, 2021 and expects to receive the amendment by early May 2021. Once this amendment is received, Dalton will commence synthesis of DMT for the Company. Dalton is also required to submit an annual request to Health Canada for pre-approval of the specific quantity of DMT it intends to produce. Any quantities beyond this requires a further licence amendment to be added within that calendar year. In order to export, Dalton will need to file for an export permit once they receive the import permit from the receiving country (UK). Dalton expects to receive this permit approximately 45 days after the application is made. The estimated cost of Dalton’s services to the Company is \$352,000 and this contract can be cancelled at any time by the Company, subject to the payment of charges for any outstanding work orders.

#### *Phase 1 Clinical Research*

The Phase 1 clinical trial on DMT involves the study of safety and dosing of DMT in healthy individuals. The Company anticipates commencing the Phase 1 clinical trial by the end of 2021 after the Company completes the Phase 1 study protocol. The Company has engaged Hammersmith Medicines Research in the United Kingdom (“**Hammersmith**”) to conduct the Company’s Phase 1 clinical trials for DMT. Under U.K. law, Hammersmith requires a Schedule 1 license and a “Manufacture/Import Authorisation” (known as an MIA(IMP)) in order to handle DMT and conduct the Phase 1 trials. Hammersmith presently has both the required licence and authorisation, but Hammersmith will need to apply for a study-specific Schedule 1 license as well. The Phase 1 trial must also be approved by the Medicines and Healthcare Products Regulatory Agency (the “**MHPR Agency**”) and its research ethics committee, which is expected to take approximately five weeks. The MHPR Agency regulates medicines,



medical devices and blood components for transfusion in the U.K. Upon receipt of approval from the MHPR Agency, Hammersmith will make an application to the Home Office of U.K. for a study-specific Schedule 1 licence, which is expected to take approximately one month from the date the application is made. There can be no assurance that the Schedule 1 study-specific license will be granted by the Home Office of the U.K. In addition, Hammersmith requires an import permit in order to import the DMT manufactured in Canada by Dalton. To import DMT, Hammersmith will require a certificate of analysis with the material, which is a standard document for a drug manufacturing company and which Dalton will provide as part of its contractual obligations. Obtaining the import permit can be done in parallel with the other approvals, and precedes the export permit required to be obtained by Dalton. The Company estimates the cost of its Phase 1 trial will to be approximately \$1 million and is anticipated to be completed by the end of 2021. The contract with Hammersmith can be cancelled at any time by the Company, subject to the payment of charges for any outstanding work orders. The Company will own the rights to all results of the Phase 1 clinical trial conducted by Hammersmith.

After completion of the Phase 1 clinical trial, the Company will review the data and consider conducting a Phase 2 clinical trial. A Phase 2 clinical trial is the first time a drug can be tested in the patient population that the drug has been identified to treat. The Company's initial focus will be the acute treatment of ischemic stroke patients as well as combination therapy of DMT and Constraint Induced Movement Therapy.

The Company will need to engage a contract research organization in order to conduct Phase 2 clinical trial, which could be Hammersmith should the Company wish to continue the clinical trials with them.

#### *Breakthrough Therapy Designation*

At present, the Company's business activities surrounding DMT are strictly based on either pre-clinical research or clinical trials being conducted by third parties. The regulatory steps required to gain approval for DMT are the same as any other drug or compound being studied. While each global jurisdiction has their own approval process (which often defaults to FDA approval) the FDA rules and guidelines are considered the gold standard. The drug approval process includes successfully navigating through Phase 1, 2 and 3 clinical studies and based on the strength of the data, applying for marketing approval. Since DMT is currently a Schedule 1 drug, for DMT to be approved in the U.S. for sale, there will need to be some form of communication and agreement between the FDA and the DEA to allow for its sale for a clinical purpose in the U.S.

The Company also believes that a microdosing approach to developing a DMT treatment may enable a much wider review and acceptance of its data, including garnering the early interest of research investigators, the interest of clinical trial patients and ultimately clinical acceptance. Algernon's approach may also allow for a quicker pathway to regulatory approval, including a Breakthrough Therapy designation from the FDA should the Company seek FDA approval in the future. The FDA Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). If the results of the Company's Phase 1 and Phase 2 clinical trials are promising, which are expected to be completed before the end of 2022, the Company may consider making an application to the FDA for a Breakthrough Therapy designation. Generally, the FDA reviews the application and considers all data presented before it makes its determination. If the Breakthrough Therapy designation is not approved by the FDA, the Company intends to continue with its planned Phase 3 clinical trials and follow the standard pathway for drug approval, which does not require any special designation. There are no additional costs associated with pursuing a Breakthrough Therapy Designation.

Regardless of where the Company's clinical trial will be conducted, only the various parties that manufacture, ship, receive and handle DMT will be required to have all required licenses and permits and 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.

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

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

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

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

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

### Europe

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

- (a) prohibit all use except for scientific and very limited medical purposes by duly authorized persons, in medical or scientific establishments which are directly under the control of their Governments or specifically approved by them;
- (b) require that manufacture, trade, distribution and possession be under a special licence or prior authorization;
- (c) provide for close supervision of the activities and acts mentioned in paragraphs a) and b);

(d) restrict the amount supplied to a duly authorized person to the quantity required for his authorized purpose;

(e) require that persons performing medical or scientific functions keep records concerning the acquisition of the substances and the details of their use, such records to be preserved for at least two years after the last use recorded therein; and

(f) prohibit export and import except when both the exporter and importer are the competent authorities or agencies of the exporting and importing country or region, respectively, or other persons or enterprises which are specifically authorized by the competent authorities of their country or region for the purpose.

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

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

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

#### *Canada*

##### CDSA

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

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

##### Canada FDR

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

#### *United States*

The DEA has a streamlined application process for researchers who wish to conduct clinical trials using a Schedule I substance not currently approved for medical use (such as DMT). Schedule I substances

are defined as drugs, substances, or chemicals with no accepted medical use and a high potential for abuse. Applicants must provide information about their qualifications, research protocol, and institution where the research will take place; complete requirements are outlined in the United States Code of Federal Regulations Title 21 –Food and Drugs 21 Part 1301.18.

### *Europe*

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

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

The Company’s goal is to ultimately get market authorization from Health Canada, the FDA and the 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)***

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 –FDA*

#### Clinical Study Regulatory Process

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

The IND application must contain information in three broad areas:

- Animal Pharmacology and Toxicology Studies, consisting of preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use);

- Manufacturing Information, pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This is equivalent to the CMC data referenced above for Health Canada applications, and is assessed to ensure that the company can adequately produce and supply consistent batches of the drug; and
- Clinical Protocols and Investigator Information, including detailed protocols for proposed clinical studies to assess whether the initial trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an Institutional Review Board, and to adhere to the investigational new drug regulations.

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

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

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

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical products in the United States to ensure that such medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical products manufactured in the United States to international markets and the importation of medical products manufactured abroad. Unless an exemption applies, each new or significantly modified medical product a company seeks to commercially distribute in the United States will require FDA approval. The FDA approval process is conducted through the submission of a New Drug Application (“NDA”). The process can be expensive, and lengthy (6-12 months), and require payment of significant user fees, unless an exemption is available. Significant reductions in fees are available through the Small Business Fee Waiver/Reduction program. Drug companies seeking to sell a drug in the United States must first test it. The company then sends the Centre for Drug Evaluation and Research (“CDER”) at the FDA the evidence from these tests to prove the drug is safe and effective for its intended use, using the NDA. A team of CDER physicians, statisticians, chemists, pharmacologists, and other scientists reviews the company’s data and proposed labeling. If this independent and unbiased review establishes that a drug’s health benefits outweigh its known risks, the drug is approved for sale. The center does not actually test drugs itself, although it does conduct limited research in the areas of drug quality, safety, and effectiveness standards. The FDA drug approval process takes place within a structured framework that includes: (i) analysis of the target condition and available treatments; (ii) assessment of benefits and risks from clinical data; and (iii) strategies for managing risks.

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

### Clinical Study Regulatory Process

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

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

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

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

### ***Market Authorization Regulatory Process***

Under the centralized authorization procedure, pharmaceutical companies submit a single marketing-authorization application to the EMA, which provides the basis of a legally binding recommendation that will be provided by the EMA to the European Commission, the authorizing body for all centrally authorized products. This allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the European Union on the basis of a single marketing authorization. EMA’s Committee for Medicinal products for Human Use or Committee for Medicinal Products for Veterinary Use carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not, under any particular dosing regime. Although, under European Union law, the EMA has no authority to permit marketing in the



different European Union countries, the European Commission is the authorizing body for all centrally authorized products, who takes a legally binding decision based on EMA's recommendation. This decision is issued within 67 days of receipt of EMA's recommendation. Once granted by the European Commission, the centralized marketing authorization is valid in all European Union Member States as well as in the European Economic Area countries Iceland, Liechtenstein and Norway. European Commission decisions are published in the Community Register of medicinal products for human use. Once a medicine has been authorized for use in the European Union, the EMA and the European Union Member States constantly monitor its safety and take action if new information indicates that the medicine is no longer as safe and effective as previously thought. The safety monitoring of medicines involves a number of routine activities ranging from: assessing the way risks associated with a medicine will be managed and monitored once it is authorized; continuously monitoring suspected side effects reported by patients and healthcare professionals, identified in new clinical studies or reported in scientific publications; regularly assessing reports submitted by the Company holding the marketing authorization on the benefit-risk balance of a medicine in real life; and assessing the design and results of post-authorization safety studies which were required at the time of authorization. The EMA can also carry out a review of a medicine or a class of medicines upon request of a Member State or the European Commission. These are called European Union referral procedures; they are usually triggered by concerns in relation to a medicine's safety, the effectiveness of risk minimization measures or the benefit-risk balance of the medicine. The EMA has a dedicated committee responsible for assessing and monitoring the safety of medicines, the Pharmacovigilance Risk Assessment Committee. This ensures that EMA and the European Union Member States can move very quickly once an issue is detected and take any necessary action, such as amending the information available to patients and healthcare professionals, restricting use or suspending a medicine, in a timely manner in order to protect patients.

### ***Legislation on controlled substances United Kingdom***

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

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

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

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

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

The amended Misuse of Drugs Act 1971, sets out the penalties for unlawful production, possession and supply of controlled drugs based on three classes of risk (A, B and C). The MDR sets out the permitted uses of controlled drugs based on which Schedule (1 to 5) they fall within. In the United Kingdom, Class A drugs are deemed to be the most dangerous, and so carry the harshest punishments for unlawful manufacture, production, possession and supply. Schedule 1 drugs can only be lawfully manufactured,

produced, possessed and supplied under a Home Office licence. While exemptions do exist, none are applicable to the API.

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

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

#### Licensing Requirements

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

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

### **CONSOLIDATED CAPITALIZATION**

There have been no material changes in the Company’s share and loan capitalization, on a consolidated basis, since February 28, 2021, being the date of the Company’s most recently filed unaudited condensed interim consolidated financial statements incorporated by reference in this Prospectus other than:

- the issuance of an aggregate of 14,000 Common Shares pursuant to the exercise of common share purchase warrants at the exercise price of \$0.12 per Common Share for proceeds to the Company of \$1,680;
- the issuance of an aggregate of 11,260,040 units upon the closing of a private placement offering of units (the “**March Private Placement**”) at the price of \$0.25 per unit for gross proceeds to the Company of \$2,815,010. Each unit consists of one Common Share and one Common Share purchase warrant with each Common Share purchase warrant being exercisable into one Common Share at the exercise price of \$0.40 until March 5, 2023; and
- the issuance of 645,600 finders’ warrants in connection with the March Private Placement. Each finders’ warrant is exercisable into one Common Share at an exercise price of \$0.40 per Common Share until March 5, 2023.

## USE OF PROCEEDS

The use of proceeds from the sale of Securities will be described in a Prospectus Supplement relating to a specific issuance of Securities. This information will include the net proceeds to the Company from the sale of the Securities, the use of those proceeds and the specific business objectives that the Company expects to accomplish with those proceeds. As of the date of this Prospectus, the Company expects net proceeds from the sale of Securities to be used towards general and administrative expenses (estimated to be up to \$2 million over the next 12 months), the clinical research program for strokes involving DMT for 2021 and into 2022 (estimated to be approximately \$3 million), the completion of the Ifenprodil Phase 2 IPF/chronic cough program and the Ifenprodil COVID-19 study.

All expenses relating to an offering of Securities and any compensation paid to underwriters, dealers or agents, as the case may be, will be paid out of our general funds, unless otherwise stated in the applicable Prospectus Supplement.

The Company has a negative operating cash flow for the year ended August 31, 2020. To the extent that the Company has negative operating cash flow in future periods, it may need to allocate a portion of its cash reserves to fund such negative cash flow. The Company may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that the Company will be able to generate a positive cash flow from its operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to the Company.

Certain COVID-19 related risks would delay or slow the implementation of the planned objectives resulting in additional costs for the Company to achieve its business objectives. The extent to which COVID-19 may impact the Company's business activities will depend on future developments, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in Canada, the United States and other countries to contain and treat the disease. As these events are highly uncertain and the Company cannot determine their potential impact on operations at this time. The COVID-19 pandemic may negatively impact the Company's business as a result of government regulations that impact the Company's ability to conduct its studies and clinic trials, including further lock-downs which could prevent access to test subjects, which would influence the amount and timing of planned expenditures, which may adversely impact the Company's business. See "Risk Factors".

## DESCRIPTION OF SECURITIES

The following is a summary of the material attributes and characteristics of the Securities as at the date of this Prospectus. This summary does not purport to be complete. A Prospectus Supplement may include specific variable terms pertaining to the Securities that are not within the alternatives and parameters described in this Prospectus.

### Common Shares

The Company is authorized to issue an unlimited number of Common Shares without par value. As of the date of this Prospectus 166,986,769 Common Shares are issued and outstanding.

Each Common Share carries the right to attend and vote at all general meetings of shareholders. Holders of Common Shares are entitled to receive on a pro rata basis such dividends, if any, as and when declared by the Company's board of directors at its discretion from funds legally available for the payment of dividends and upon the liquidation, dissolution or winding up of the Company are entitled to receive on a pro rata basis the net assets of the Company after payment of debts and other liabilities, in

each case subject to the rights, privileges, restrictions and conditions attaching to any other series or class of shares ranking senior in priority to or on a pro rata basis with the holders of Common Shares with respect to dividends or liquidation. The Common Shares do not carry any pre-emptive, subscription, redemption or conversion rights, nor do they contain any sinking or purchase fund provisions.

## **Warrants**

This section describes the general terms that will apply to any Warrants that may be offered by the Company pursuant to this Prospectus. Warrants may be offered separately or together with other Securities.

The specific terms of the Warrants, and the extent to which the general terms described in this section apply to those Warrants, will be set forth in the applicable Prospectus Supplement. The Warrants may be issued under a warrant indenture. The applicable Prospectus Supplement will include the details of the warrant indenture governing the Warrants being offered.

The particular terms of each issue of Warrants will be described in the related Prospectus Supplement. Such description will include, where applicable:

- a) the number of Warrants being offered and, if offered as a unit with another Security, the number of Warrants or a fraction of a Warrant being offered with such other Security;
- b) the Securities which are underlying the Warrants;
- c) the exercise price of the Warrants;
- d) the expiry date of the Warrants;
- e) the procedure for exercising Warrants into underlying Securities;
- f) the indenture trustee of the Warrants under the warrant indenture pursuant to which the Warrants are to be issued, if applicable;
- g) the material tax consequences of owning the Warrants (if any); and
- h) any other material terms and conditions of the Warrants.

## **Subscription Receipts**

This section describes the general terms that will apply to any Subscription Receipts that may be offered by the Company pursuant to the Prospectus. Subscription Receipts may be offered separately or together with Common Shares or Warrants, as the case may be. The Subscription Receipts will be issued under a Subscription Receipt agreement.

In the event the Company issues Subscription Receipts, the Company will provide the original purchasers of Subscription Receipts a contractual right of rescission exercisable following the issuance of Common Shares to such purchasers.

The applicable Prospectus Supplement will include details of the Subscription Receipt agreement covering the Subscription Receipts being offered. A copy of the Subscription Receipt agreement relating to an offering of Subscription Receipts will be filed by the Company with the applicable securities regulatory authorities after it has been entered into. The specific terms of the Subscription Receipts, and the extent to which the general terms described in this section apply to those Subscription Receipts, will be set forth in the applicable Prospectus Supplement. This description will include, where applicable:

- a) the number of Subscription Receipts;
- b) the price at which the Subscription Receipts will be offered;
- c) the procedures for the exchange of the Subscription Receipts into Common Shares or Warrants;
- d) the number of Common Shares or Warrants that may be exchanged upon exercise of each Subscription Receipt;
- e) the designation and terms of any other securities with which the Subscription Receipts will be offered, if any, and the number of Subscription Receipts that will be offered with each security;
- f) terms applicable to the gross or net proceeds from the sale of the Subscription Receipts plus any interest earned thereon;
- g) material Canadian federal income tax consequences of owning the Subscription Receipts; and
- h) any other material terms and conditions of the Subscription Receipts.

## **Units**

This section describes the general terms that will apply to any Units that may be offered by the Company pursuant to this Prospectus.

The following sets forth certain general terms and provisions of the Units under this Prospectus. The following sets forth certain general terms and provisions of the Units offered pursuant to an accompanying Prospectus Supplement, and the extent to which the general terms described in this section apply to those Units, will be set forth in the applicable Prospectus Supplement.

The Units may be comprised of one or more of the other Securities described in the Prospectus in any combination. Each Unit will be issued so that the holder of the Unit is also the holder of each of the Securities included in the Unit. Thus, the holder of a Unit will have the rights and obligations of a holder of each included Security. The unit agreement, if any, under which a Unit is issued may provide that the Securities included in the Unit may not be held or transferred separately, at any time or at any time before a specified date.

The particular terms of each issue of Units will be described in the related Prospectus Supplement. Such description will include, where applicable:

- a) the number of Units offered;

- b) the price or prices, if any, at which the Units will be issued;
- c) the currency at which the Units will be offered;
- d) the Securities comprising the Units;
- e) whether the Units will be issued with any other Securities and, if so, the amount and terms of these Securities;
- f) any minimum or maximum subscription amount;
- g) whether the Units and the Securities comprising the Units are to be issued in registered form, “book-entry only” form, non-certificated inventory system form, bearer form or in the form of temporary or permanent global securities and the basis of exchange, transfer and ownership thereof;
- h) any material risk factors relating to such Units or the Securities comprising the Units;
- i) any other rights, privileges, restrictions and conditions attaching to the Units or the Securities comprising the Units; and
- j) any other material terms or conditions of the Units or the Securities comprising the Units, including whether and under what circumstances the Securities comprising the Units may be held or transferred separately.

#### **PLAN OF DISTRIBUTION**

The Company and/or any selling securityholders may from time to time during the 25-month period that this Prospectus, including any amendments hereto, remains valid, offer for sale and issue Common Shares, Warrants, Subscription Receipts and Units. During such period, the Company may sell up to \$50,000,000 in the aggregate, of initial offering price of Securities (or the equivalent amount if any Securities are denominated in a currency other than Canadian dollars).

The Company and/or any selling securityholders will sell the Securities to or through underwriters or dealers or purchasers directly or through agents. The Securities may be sold from time to time in one or more transactions at a fixed price or prices, which may be changed or at market prices prevailing at the time of sale, at prices related to such prevailing market prices or at negotiated prices, including sales in transactions that are deemed to be “at-the-market distributions” (as defined in NI 44-102).

A Prospectus Supplement will set forth the terms of the offering, including the name(s) of any underwriters, dealers or agents, the purchase price(s) of the Securities, the proceeds to the Company and/or any selling securityholders from the sale of Securities, any initial public offering price (or the manner of determination thereof if offered on a non-fixed price basis), any underwriting discount or commission and any discounts, concessions or commissions allowed or paid by any underwriter to other dealers. Any initial public offering price and any discounts, concessions or omissions allowed or paid to dealers may be changed from time to time.

Underwriters, dealers and agents who participate in the distribution of the Securities may be entitled under certain agreements to be entered into with the Company and/or any selling securityholders to indemnification by the Company and/or any selling securityholders against certain liabilities, including liabilities under securities legislation or to contribution with respect to payments that they may be required

to make in respect thereof. Such underwriters, dealers and agents may be customers of, engage in transactions with, or perform services for the Company and/or any selling securityholders in the ordinary course of business.

In connection with any offering of Securities other than an “at-the-market distribution”, unless otherwise specified in a Prospectus Supplement, underwriters or agents may over-allot or effect transactions which stabilize, maintain or otherwise affect the market price of Securities offered at levels other than those which might otherwise prevail on the open market. Such transactions may be commenced, interrupted or discontinued at any time. No underwriter or dealer involved in an “at-the-market distribution” under this Prospectus, no affiliate of such an underwriter or dealer and no person or company acting jointly or in concert with such underwriter or dealer will over-allot Securities in connection with such distribution or effect any other transactions that are intended to stabilize or maintain the market price of the Securities.

The Securities have not been and will not be registered under the U.S. Securities Act or any state securities laws. Accordingly, the Securities may not be offered, sold or delivered within the United States, and each underwriter or agent for any offering of Securities will agree that it will not offer, sell or deliver the Securities within the United States, except pursuant to the exemption from the registration requirements of the U.S. Securities Act provided by Rule 144A thereunder (“**Rule 144A**”) and in compliance with applicable state securities laws. In addition, until 40 days after the commencement of the offering of Securities, any offer or sale of such Securities within the United States by a dealer (whether or not participating in the offering) may violate the registration requirements of the U.S. Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A.

This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy the Securities in the United States or to, or for the account or benefit of, U.S. persons.

## RECENT DEVELOPMENTS

There have been no material developments in the Company’s business since February 4, 2021, the date of the Company’s AIF, which have not been disclosed in this Prospectus or the documents incorporated by reference therein.

## PRIOR SALES

For the 12-month period before the date of this Prospectus, the Company issued the following Common Shares and securities exercisable or convertible into Common Shares:

Date of Issuance	Issuance of Common Shares Upon:	Number of securities issued	Issue/exercise price per security
May 6, 2020	Exercise of Warrants – November 2019 Offering	7,160	\$0.12
May 7, 2020	Exercise of Warrants – November 2019 Offering	150,000	\$0.12
May 8, 2020	Exercise of Warrants – November 2019 Offering	135,500	\$0.12
May 11, 2020	Exercise of Compensation Options – November 2019 Offering	14,883	\$0.085
June 15, 2020	Exercise of Stock Options	50,000	\$0.10
June 17, 2020	Conversion of Special Warrants	19,605,285 <sup>(1)</sup>	\$0.35
June 21, 2020	Exercise of Compensation Options – February 2020 Offering	200,000	\$0.085

June 24, 2020	Exercise of Compensation Options – February 2020 Offering	30,240	\$0.085
July 10, 2020	Exercise of Compensation Options – February 2020 Offering	66,400	\$0.085
July 10, 2020	Exercise of Warrants – February 2020 Offering	830,000	\$0.12
July 16, 2020	Exercise of Compensation Options – February 2020 Offering	54,560	\$0.085
July 16, 2020	Exercise of Compensation Options – November 2019 Offering	13,750	\$0.085
July 22, 2020	Exercise of Warrants – February 2020 Offering	100,000	\$0.12
July 22, 2020	Exercise of Compensation Options – February 2020 Offering	30,240	\$0.085
July 22, 2020	Exercise of Warrants – February 2020 Offering	4,370,000	\$0.12
July 22, 2020	Exercise of Warrants – November 2019 Offering	158,900	\$0.12
July 30, 2020	Exercise of Warrants – February 2020 Offering	116,000	\$0.12
July 30, 2020	Exercise of Warrants – February 2020 Offering	50,000	\$0.12
August 7, 2020	Exercise of Compensation Options – February 2020 Offering	349,600	\$0.085
August 14, 2020	Exercise of Warrants – February 2020 Offering	66,400	\$0.12
August 21, 2020	Exercise of Warrants – November 2019 Offering	11,500	\$0.12
August 21, 2020	Exercise of Compensation Options – November 2019 Offering	8,250	\$0.085
August 21, 2020	Exercise of Warrants – February 2020 Offering	30,240	\$0.12
August 21, 2020	Exercise of Warrants – February 2020 Offering	650,000	\$0.12
August 21, 2020	Exercise of Compensation Options – February 2020 Offering	11,200	\$0.085
August 21, 2020	Exercise of Warrants – February 2020 Offering	100,000	\$0.12
August 26, 2020	Exercise of Warrants – February 2020 Offering	1,000,000	\$0.12
August 26, 2020	Exercise of Warrants – November 2019 Offering	20,500	\$0.12
August 26, 2020	Exercise of Warrants – February 2020 Offering	115,294	\$0.12
August 27, 2020	Exercise of Warrants – November 2019 Offering	147,500	\$0.12
August 28, 2020	Exercise of Warrants – February 2020 Offering	88,000	\$0.12
August 28, 2020	Exercise of Compensation Options – February 2020 Offering	7,040	\$0.085
September 1, 2020	Exercise of Warrants – November 2019 Offering	44,000	\$0.12
September 10, 2020	Exercise of Warrants – February 2020 Offering	50,000	\$0.12



September 16, 2020	Exercise of Warrants – November 2019 Offering	12,000	\$0.12
September 17, 2020	Exercise of Warrants – February 2020 Offering	7,040	\$0.12
September 21, 2020	Exercise of Warrants – November 2019 Offering	19,000	\$0.12
September 23, 2020	Exercise of Warrants – November 2019 Offering	64,000	\$0.12
September 24, 2020	Exercise of Warrants – February 2020 Offering	100,000	\$0.12
September 25, 2020	Exercise of Warrants – November 2019 Offering	34,800	\$0.12
September 28, 2020	Exercise of Warrants – November 2019 Offering	200	\$0.12
September 29, 2020	Settlement of Restricted Share Units - July 2020 Offering	1,068,521 <sup>(2)</sup>	\$0.35
October 19, 2020	Exercise of Warrants – November 2019 Offering	52,500	\$0.12
October 22, 2020	Exercise of Warrants – February 2020 Offering	100,000	\$0.12
October 22, 2020	Exercise of Compensation Options – February 2020 Offering	205,251	\$0.085
October 27, 2020	Exercise of Warrants – November 2019 Offering	36,500	\$0.12
November 6, 2020	Exercise of Warrants – February 2020 Offering	50,000	\$0.12
November 23, 2020	Exercise of Compensation Options – November 2019 Offering	1,375	\$0.085
December 2, 2020	Exercise of Warrants – February 2020 Offering	349,600	\$0.12
December 3, 2020	Exercise of Warrants – November 2019 Offering	33,000	\$0.12
December 7, 2020	Exercise of Warrants – November 2019 Offering	57,500	\$0.12
December 7, 2020	Exercise of Compensation Options – November 2019 Offering	4,040	\$0.085
December 7, 2020	Exercise of Warrants – February 2020 Offering	600,000	\$0.12
December 10, 2020	Exercise of Warrants – February 2020 Offering	1,000,000	\$0.12
December 10, 2020	Exercise of Warrants – February 2020 Offering	328,000	\$0.12
December 10, 2020	Exercise of Warrants – February 2020 Offering	11,200	\$0.12
December 14, 2020	Exercise of Warrants – November 2019 Offering	8,000	\$0.12
December 16, 2020	Exercise of Compensation Options – February 2020 Offering	15,040	\$0.085
December 18, 2020	Exercise of Warrants – February 2020 Offering	55,251	\$0.12
December 18, 2020	Exercise of Warrants – February 2020 Offering	176,470	\$0.12
December 18, 2020	Exercise of Warrants – February 2020 Offering	200,000	\$0.12

December 18, 2020	Exercise of Warrants – February 2020 Offering	400,000	\$0.12
December 29, 2020	Exercise of Warrants – November 2019 Offering	200,000	\$0.12
December 29, 2020	Exercise of Warrants – February 2020 Offering	350,000	\$0.12
December 30, 2020	Exercise of Warrants – February 2020 Offering	1,750,000	\$0.12
December 31, 2020	Exercise of Warrants – November 2019 Offering	79,500	\$0.12
January 7, 2021	Exercise of Warrants – November 2019 Offering	134,000	\$0.12
January 7, 2021	Exercise of Warrants – February 2020 Offering	50,000	\$0.12
January 8, 2021	Exercise of Warrants – November 2019 Offering	89,500	\$0.12
January 12, 2021	Exercise of Warrants – November 2019 Offering	221,500	\$0.12
January 13, 2021	Exercise of Warrants – November 2019 Offering	3,909,000	\$0.12
January 14, 2021	Exercise of Warrants – November 2019 Offering	43,000	\$0.12
January 15, 2021	Exercise of Warrants – November 2019 Offering	314,368	\$0.12
January 18, 2021	Exercise of Warrants – November 2019 Offering	90,000	\$0.12
January 19, 2021	Exercise of Warrants – November 2019 Offering	83,000	\$0.12
January 20, 2020	Exercise of Warrants – November 2019 Offering	183,000	\$0.12
January 20, 2021	Exercise of Compensation Options – November 2019 Offering	3,000	\$0.085
January 21, 2021	Exercise of Compensation Options – November 2019 Offering	38,280	\$0.085
January 21, 2021	Exercise of Warrants – November 2019 Offering	696,383	\$0.12
January 21, 2021	Exercise of Compensation Options – November 2019 Offering	38,500	\$0.12
January 21, 2021	Exercise of Warrants – February 2020 Offering	50,000	\$0.12
January 21, 2021	Exercise of Warrants – November 2019 Offering	175,000	\$0.12
January 21, 2021	Exercise of Warrants – November 2019 Offering	462,100	\$0.12
January 22, 2021	Exercise of Warrants – November 2019 Offering	38,500	\$0.085
February 2, 2021	Exercise of Compensation Options – November 2019 Offering	4,125	\$0.085
February 2, 2021	Exercise of Compensation Options – February 2020 Offering	50,000	\$0.12
February 2, 2021	Exercise of Warrants – February 2020 Offering	82,352	\$0.12
February 2, 2021	Exercise of Warrants – February 2020 Offering	50,000	\$0.12

February 2, 2021	Settlement of Restricted Share Units- July 2020 Offering	1,114,001 <sup>(2)</sup>	\$0.35 (deemed)
February 8, 2021	Exercise of Warrants – February 2020 Offering	200,000	\$0.12
February 10, 2021	Exercise of Warrants – November 2019 Offering	114,600	\$0.12
February 10, 2021	Exercise of Warrants – November 2019 Offering	20,000	\$0.12
February 10, 2021	Exercise of Compensation Options – November 2019 Offering	4,125	\$0.085
February 11, 2021	Exercise of Warrants – February 2020 Offering	30,240	\$0.12
February 11, 2021	Exercise of Warrants – November 2019 Offering	27,500	\$0.12
February 18, 2021	Exercise of Stock Options	25,000	\$0.10
February 22, 2021	Exercise of Warrants – February 2020 Offering	470,588	\$0.12
February 22, 2021	Exercise of Warrants – February 2020 Offering	100,000	\$0.12
March 3, 2021	Exercise of Warrants – November 2019 Offering	14,000	\$0.12
March 5, 2021	March Private Placement	11,260,040 <sup>(3)</sup>	\$0.25

### *Warrants*

Date of Issuance	Issuance of Warrants upon	Number of securities issued	Issue/exercise price per security
May 11, 2020	Exercise of Compensation Options– November 2019 Offering	14,883	\$0.12
June 17, 2020	Conversion of Special Warrants	19,605,285 <sup>(1)</sup>	\$0.55
June 22, 2020	Exercise of Compensation Options – February 2020 Offering	200,000	\$0.12
June 24, 2020	Exercise of Compensation Options – February 2020 Offering	30,240	\$0.12
July 10, 2020	Exercise of Compensation Options – February 2020 Offering	66,400	\$0.12
July 16, 2020	Exercise of Compensation Options – November 2019 Offering	13,750	\$0.12
July 16, 2020	Exercise of Compensation Options – February 2020 Offering	54,560	\$0.12
July 22, 2020	Exercise of Compensation Options – February 2020 Offering	30,240	\$0.12
August 7, 2020	Exercise of Compensation Options– February 2020 Offering	349,600	\$0.12
August 21, 2020	Exercise of Compensation Options– February 2020 Offering	11,200	\$0.12
August 21, 2020	Exercise of Compensation Options– November 2019 Offering	8,250	\$0.12

Date of Issuance	Issuance of Warrants upon	Number of securities issued	Issue/exercise price per security
August 28, 2020	Exercise of Compensation Options– February 2020 Offering	7,040	\$0.12
October 22, 2020	Exercise of Compensation Options– February 2020 Offering	205,251	\$0.12
November 23, 2020	Exercise of Compensation Options– November 2019 Offering	1,375	\$0.12
December 7, 2020	Exercise of Compensation Options– November 2019 Offering	4,040	\$0.12
December 14, 2020	Exercise of Compensation Options– February 2020 Offering	15,040	\$0.12
January 20, 2021	Exercise of Compensation Options– November 2019 Offering	3,000	\$0.12
January 21, 2021	Exercise of Compensation Options– November 2019 Offering	38,280	\$0.12
January 21, 2021	Exercise of Compensation Options– November 2019 Offering	38,500	\$0.12
February 2, 2021	Exercise of Compensation Options– November 2019 Offering	4,125	\$0.12
February 10, 2021	Exercise of Compensation Options– November 2019 Offering	4,125	\$0.12
March 5, 2021	March Private Placement	11,260,040 <sup>(3)</sup>	\$0.40
March 5, 2021	March Private Placement – Finders Warrants	645,600 <sup>(3)</sup>	\$0.40

***Special Warrants***

Date of Issuance	Issuance of Special Warrants pursuant to:	Number of securities issued	Issue/exercise price per security
May 13, 2020	Special Warrant Offering	19,605,285 <sup>(1)</sup>	\$0.35

***Compensation Options***

Date of Issuance	Issuance of Compensation Options pursuant to:	Number of securities issued	Issue/exercise price per security
May 13, 2020	Special Warrant Offering	1,505,293	\$0.35

***Stock Options***

Date of Issuance	Issuance of Stock Options upon:	Number of securities issued	Issue/exercise price per security
August 17, 2020	Stock Options Grant	600,000	\$0.35

### Restricted Share Units

Date of Issuance	Issuance of Restricted Share Units upon:	Number of securities issued	
July 23, 2020	Restricted Share Units Grant	4,350,000 <sup>(2)</sup>	N/A

**Note:**

- (1) On May 13, 2020, the Company closed a private placement offering of 19,605,285 special warrants at a price of \$0.35 per special warrant (the “**Special Warrant Offering**”). Each special warrant is exercisable, for no additional consideration at the option of the holder, into one unit of the Company. Each unit consists of one Common Share and one warrant. Each warrant entitles to holder to purchase one Common Share until May 13, 2022 at an exercise price of \$0.55 per Common Share. In addition, a total of 1,505,293 compensation options were issued, each compensation option entitling the holder to purchase one unit of the Company at a price of \$0.35 per unit until May 13, 2022. Each unit consists of one Common Share and one warrant entitling the holder to purchase one Common Share until May 13, 2022 at an exercise price of \$0.35 per Common Share. On June 17, 2020, in accordance with the terms of a special warrant indenture dated May 13, 2020, each special warrant was automatically converted into one common share of the Company and one warrant. Each warrant is exercisable for one Common Share on or before May 13, 2022 at an exercise price of \$0.55 per Common Share.
- (2) On July 23, 2020, the Company granted a total of 4,350,000 RSUs to certain directors, officers and consultants of the Company with a fair value of \$0.35 per RSU. One-third was vested on the grant date. One-third vested on January 22, 2021 and the remaining one-third to be vested on July 22, 2021. On September 29, 2020, 1,068,521 of Common Shares were issued net of withholding taxes in settlement of the 1,435,500 RSUs that were vested. On February 2, 2021, 1,114,001 of Common Shares were issued net of withholding taxes in settlement of the 1,435,500 RSUs that were vested on January 22, 2021.
- (3) Issued in connection with the March Private Placement.

### PRICE RANGE AND TRADING VOLUME

The Common Shares are listed on the CSE under the trading symbol “AGN”. The following tables set forth information relating to the trading of the Common Shares on the CSE for the months indicated. On May 4, 2021, the last trading day prior to the date of this Prospectus, the closing price of the Common Shares on the CSE was \$0.17.

Month	CSE Price Range (\$)		Total Volume
	High	Low	
May, 2020	0.45	0.285	21,100,454
June, 2020	0.425	0.18	28,551,448
July, 2020	0.43	0.195	24,276,702
August, 2020	0.395	0.29	16,449,663
September, 2020	0.335	0.245	11,814,852
October, 2020	0.335	0.245	6,235,601
November, 2020	0.31	0.19	9,843,037
December, 2020	0.54	0.185	37,429,976
January 2021	0.315	0.225	14,963,660
February 2021	0.41	0.25	25,668,256
March 2021	0.40	0.22	12,489,762
April 2021	0.26	0.145	10,287,710
May 3 - 4, 2021	0.19	0.17	275,547

## RISK FACTORS

An investment in the securities of the Company is speculative and subject to risks and uncertainties. The occurrence of any one or more of these risks or uncertainties could have a material adverse effect on the value of any investment in the Company and the business, prospects, financial position, financial condition or operating results of the Company. Additional risks and uncertainties not presently known to the Company or that the Company currently deems immaterial may also impair the Company's business operations.

Prospective investors should carefully consider all information contained in this Prospectus, including all documents incorporated by reference, and in particular should give special consideration to the risk factors under the section titled "Risk Factors" in the AIF, which is incorporated by reference in this Prospectus and which may be accessed on the Company's SEDAR profile at [www.sedar.com](http://www.sedar.com), and the information contained in the section entitled "Cautionary Statement Regarding Forward-Looking Information". Additionally, purchasers should consider the risk factors set forth below.

The risks and uncertainties described or incorporated by reference in this Prospectus are not the only ones the Company may face. Additional risks and uncertainties that the Company is unaware of, or that the Company currently deems not to be material, may also become important factors that affect the Company. If any such risks actually occur, the Company's business, financial condition or results of operations could be materially adversely affected, with the result that the trading price of the Common Shares could decline and investors could lose all or part of their investment.

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

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

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

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

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

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

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

Algenron's and its contract research organization's research and development activities and are and will be significantly regulated by a number of governmental entities, including Health Canada, the EMA, the Home Office in the U.K. and the FDA. Regulatory approvals are required prior to each clinical trial and Company and its contract research organizations may fail to obtain the necessary approvals to commence or continue clinical testing in one or more jurisdictions. The time required to obtain approval by regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials. Any analysis of data from clinical activities Algenron 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 Algenron'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 Algenron's interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a submission to obtain regulatory approval;

- deficiencies in the manufacturing processes or the failure of facilities of collaborators with whom Algernon contracts for clinical supplies to pass a pre-approval inspection;
- changes in the approval policies or regulations that render Algernon’s preclinical and clinical data insufficient for approval.

***Psychedelic regulatory risks***

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

***Decriminalisation of psychedelics***

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

***Enforcing Contracts***

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

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



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

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

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

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

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

While information regarding the use of proceeds from the sale the Securities will be described in the applicable Prospectus Supplement, 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.

### ***Return on Investment is not Guaranteed***

There is no guarantee that an investment in the securities described herein will provide any positive return in the short term or long term. An investment in the securities of the Company is speculative and involves a high degree of risk and should be undertaken only by investors whose financial resources are sufficient to enable them to assume such risks and who have no need for immediate liquidity in their investment. An investment in the securities of the Company described herein is appropriate only for holders who have the capacity to absorb a loss of some or all of their investment.

### ***Negative Cash Flow from Operations***

During the year ended August 31, 2020, the Company had negative cash flow from operating activities, reported a net comprehensive loss of \$8,554,912 and net loss per common share of \$0.10. For the three and six months ended February 28, 2021 the Company had a negative cash flow of operating activities, reported a net comprehensive loss of \$5,805,117 and net loss per share of \$0.04. The Company anticipates it will have negative cash flow from operating activities in future periods. To the extent that the Company has negative cash flow in any future period, 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.

### ***No Existing Trading Market (other than for Common Shares)***

There is currently no market through which the Securities (other than Common Shares) may be sold and purchasers of such Securities may not be able to resell such Securities purchased under this Prospectus. There can be no assurance that an active trading market will develop for such Securities after an offering or, if developed, that such market will be sustained. This may affect the pricing of such Securities in the secondary market, the transparency and availability of trading prices, the liquidity of such Securities and the extent of issuer regulation. The public offering prices of the Securities may be determined by negotiation between the Company and underwriters based on several factors and may bear no relationship to the prices at which the Securities will trade in the public market subsequent to such offering. See “Plan of Distribution”.

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

In order to finance future operations, the Company may determine to raise funds through the issuance of additional Common Shares or the issuance of debt instruments or other securities convertible into Common Shares. 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.

### ***Ongoing Impact of COVID-19***

Since December 31, 2019, governments worldwide have been enacting emergency measures to combat the spread of COVID-19. 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 development and operation of the Company’s business plan is dependent on labour inputs and governmental approvals, which could be adversely disrupted by the ongoing impact of COVID-19. While it is difficult to predict the impact of the coronavirus outbreak on the Company’s business, measures taken by the Canadian government and voluntary measures undertaken by the Company with a view to the safety of the Company’s employees, may adversely impact the Company’s business. While the pandemic has not materially affected the Company’s clinical trials and research, its continued disruption may delay the Company’s timeline with respect to planned clinical trials. The ultimate extent of the impact of the pandemic on the Company’s business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the pandemic and actions taken to contain or prevent the further spread of COVID-19, among others. Thus, the current pandemic could therefore materially and adversely affect the Company’s business, financial condition and results of operations

## **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Other than disclosed in this Prospectus, there are no material interest, direct or indirect, of the directors or officers of the Company, any shareholder that beneficially owns more than 10% of the Common Shares or any associate or affiliate of any the foregoing persons in any transaction within the last three years or any proposed transaction that has materially affected or would materially affect the Company or any of its subsidiaries.

## **CERTAIN INCOME TAX CONSIDERATIONS**

The applicable Prospectus Supplement may describe certain Canadian federal income tax consequences generally applicable to investors described therein of acquiring Securities, including, in the case of an investor who is not a resident of Canada, Canadian non-resident withholding tax consideration.

## **LEGAL MATTERS AND INTEREST OF EXPERTS**

Certain legal matters relating to an offering of the Securities will be passed upon by McMillan LLP, on behalf of the Company. As at the date hereof, the partners and associates of McMillan LLP, as a group beneficially own, directly or indirectly, less than one percent of the outstanding Common Shares of the Company. In addition, certain legal matters in connection with any offering of Securities will be passed upon for any underwriters, dealers or agents by counsel to be designated at the time of the offering by such underwriters, dealers or agents with respect to matters of Canadian and, if applicable, United States or other foreign law.

## **AUDITORS, TRANSFER AGENT AND REGISTRAR**

The auditors of the Company are Smythe LLP, Chartered Professional Accountants, Vancouver, British Columbia.

The Company's Registrar and Transfer Agent is AST Trust Company (Canada), located in Vancouver, British Columbia.

## **EXEMPTIONS**

Pursuant to a decision of the *Autorité des marchés financiers* dated January 20, 2021, the Company was granted a permanent exemption from the requirement to translate into French this Prospectus as well as the documents incorporated by reference therein and any Prospectus Supplement to be filed in relation to an "at-the-market distribution". This exemption is granted on the condition that this Prospectus and any Prospectus Supplement (other than in relation to an "at-the-market distribution") be translated into French if the Company offers Securities to Québec purchasers in connection with an offering other than in relation to an "at-the-market distribution".

## **PURCHASERS' CONTRACTUAL RIGHTS**

Original purchasers of Warrants which are convertible into other securities of the Company will have a contractual right of rescission against the Company in respect of the conversion, exchange or exercise of such Warrants. The contractual right of rescission will entitle such original purchasers to receive, in addition to the amount paid on original purchase of the Warrant or Subscription Receipt, as the case may be, the amount paid upon conversion, exchange or exercise, upon surrender of the underlying securities gained thereby, in the event that this Prospectus (as supplemented or amended) contains a misrepresentation, provided that: (i) the conversion, exchange or exercise takes place within 180 days of

the date of the purchase of the convertible, exchangeable or exercisable security under this Prospectus; and (ii) the right of rescission is exercised within 180 days of the date of the purchase of the convertible, exchangeable or exercisable security under this Prospectus. This contractual right of rescission will be consistent with the statutory right of rescission described under section 130 of the *Securities Act* (British Columbia), and is in addition to any other right or remedy available to original purchasers under section 130 of the *Securities Act* (British Columbia) or otherwise at law.

Original purchasers are further advised that in certain provinces or territories the statutory right of action for damages in connection with a prospectus misrepresentation is limited to the amount paid for the convertible, exchangeable or exercisable security that was purchased under a prospectus, and therefore a further payment at the time of conversion, exchange or exercise may not be recoverable in a statutory action for damages. The purchaser should refer to any applicable provisions of the securities legislation of the province in which the purchaser resides for the particulars of these rights, or consult with a legal advisor.

### **PURCHASERS' STATUTORY RIGHTS**

Securities legislation in certain of the provinces of Canada provides purchasers with the right to withdraw from an agreement to purchase securities. This right may be exercised within two business days after receipt or deemed receipt of a prospectus and any amendment. In several of the provinces, securities legislation further provides a purchaser with remedies for rescission or, in some jurisdictions, revisions of the price or damages if the prospectus and any amendment contains a misrepresentation or is not delivered to the purchaser, provided that the remedies for rescission, revision or the price or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal advisor.

## CERTIFICATE OF THE COMPANY

Dated: May 5, 2021

This short form prospectus, together with the documents incorporated in this prospectus by reference, will, as of the date of the last supplement to this prospectus relating to the securities offered by this prospectus and the supplement(s), constitute full, true and plain disclosure of all material facts relating to the securities offered by this prospectus and the supplement(s) as required by the securities legislation of each of the Provinces of Canada.

*(signed) Christopher Moreau*  
Chief Executive Officer

*(signed) Michael Sadhra*  
Chief Financial Officer

On Behalf of the Board of Directors

*(signed) Raj Attariwala*  
Director

*(signed) David Levine*  
Director