# ALGERNON PHARMACEUTICALS INC.

# ANNUAL INFORMATION FORM

For The Financial Year Ended August 31, 2019

June 1, 2020

Suite 915 - 700 West Pender Street Vancouver, B.C. V6C 1G8

# PAGE

# CONTENTS

TERMS OF REFERENCE1
MARKET DATA1
CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS1
GLOSSARY OF TERMS
CORPORATE STRUCTURE
GENERAL DEVELOPMENT OF THE BUSINESS
OVERVIEW OF BUSINESS 10
RISK FACTORS
DIVIDENDS AND DISTRIBUTIONS
DESCRIPTION OF CAPITAL STRUCTURE
MARKET FOR SECURITIES
ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER 50
DIRECTORS AND OFFICERS
CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS
CONFLICTS OF INTEREST
PROMOTORS
LEGAL PROCEEDINGS AND REGULATORY ACTIONS
INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS
TRANSFER AGENTS AND REGISTRARS53
MATERIAL CONTRACTS
INTERESTS OF EXPERTS
ADDITIONAL INFORMATION

#### **TERMS OF REFERENCE**

In this Annual Information Form (the "**AIF**"), unless the context otherwise dictates, references to the "Company", "Algernon", "we" and "our" refer to Algernon Pharmaceuticals, Inc. (formerly Breathtec Biomedical Inc.)

The information contained in this AIF is current as of August 31, 2019 with subsequent events disclosed to May 29, 2020.

All references to dollars (\$) in this AIF are expressed in Canadian dollars, unless otherwise indicated. Defined terms used herein have the respective meanings given to such terms under the heading "Glossary of Terms"

# MARKET DATA

Unless otherwise indicated, information contained in this AIF concerning the industry and markets in which the Company operates, including its general expectations and market position, market opportunity and market share is based on information from independent industry organizations, and other third-party sources (including industry publications, surveys and forecasts), and management estimates.

The management estimates in this AIF are derived from publicly available information released by independent industry analysts and third party sources, as well as data from the Company's internal research, and are based on assumptions made by the Company based on such data and its knowledge of such industry and markets, which the Company believes to be reasonable. The Company's internal research has not been verified by any independent source, and it has not independently verified any third-party information. While the Company is not aware of any misstatement regarding any industry or market data included in this AIF, such information is inherently imprecise. In addition, projections, assumptions and estimates of the Company's future performance and the future performance of the industry in which the Company operates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described under the "Risk Factors".

# CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

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

- the Company's plans to develop, obtain regulatory approval for and commercialize its lead product candidates;
- the Company's ability to conduct successful clinical trials for its product candidates;
- the perceived benefits of the Company's product candidates over other treatments for NASH, IBS and CKD;

- 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 Company's intention to grow the business and its operations;
- the potential size of markets for the Company's product candidates;
- the Company's ability to partner with other pharmaceutical companies to develop, obtain regulatory approval and commercialize its products candidates;
- expectations regarding regulatory requirements and developments for its product candidates;
- the Company's competitive position and the regulatory environment in which the Company operates;
- the Company's expected 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 commitments; and
- the ability of the Company's products to access markets.

Forward-looking statements are based on certain assumptions and analyses made by the Company in light of the Company's 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 AIF, the Company has made various material assumptions, including but not limited to, the following: (i) 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) that the Company's current good relationships with its suppliers, service providers and other third parties will be maintained; and (x) the efficacy of its products candidates and the success of clinical trials. 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 expects to have negative cash flow for the foreseeable future;
- whether the Company can continue as a going concern;
- the Company is a research and development stage company with little operating history, a history of losses and the Company cannot assure profitability;
- the Company may not be successful in its efforts to identify, license or discover additional product candidates;
- none of the Company's current product candidates has to date received regulatory approval for their intended commercial sale;
- failure to follow regulatory requirements;
- additional financing needs;
- risk related to Intellectual property rights;
- pre-clinical and clinical trials, including reliance on third parties to conduct same;

- pre-clinical and clinical trials will be lengthy and expensive;
- the Company may not be able to effectively manage its growth and operations, which could materially and adversely affect its business;
- the Company faces product liability exposure, which, if not covered by insurance, could result in significant financial liability;
- the Company may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of its drug candidates;
- in light of the Company's current resources and limited experience, it may need to establish successful third-party relationships to successfully commercialize its future product candidates;
- rapid technological change;
- the Company's ability to protect and enforce intellectual property rights;
- 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, prospects results from operations and financial condition;
- there may be larger, better financed companies which may become competition for the Company;
- the Company's officers and directors may be engaged in a range of business activities resulting in conflicts of interest;
- the Company does not anticipate paying cash dividends;
- the Company cannot assure you that a market will continue to develop or exist for the Common Shares and or what the market price of the Common Shares will be;
- the ability of the Company to obtain any necessary permits and licenses;
- the Company may be unable to obtain insurance;
- the market price of the Company's common shares may be subject to wide price fluctuations;
- the lack of product for commercialization;
- the lack of experience of the Company/management in marketing, selling, and distribution products;
- risks associated with future acquisitions;
- difficulty to forecast product demand;
- management conflicts of interest; and
- global economy risk.

If any of these risks or uncertainties materialize, or if assumptions underlying the forward-looking statements prove incorrect, actual results might vary materially 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 forward-looking information and other information contained herein concerning the medical cannabis industry and the general expectations of the Company concerning the medical cannabis 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 medical cannabis 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 AIF (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. We do not undertake to update or revise any forward-looking statements, except as, and to the extent required by, applicable securities laws in Canada.

All of the forward-looking statements contained in this AIF are expressly qualified by the foregoing cautionary statements.

#### **GLOSSARY OF TERMS**

The following is a glossary of certain terms used in this AIF:

"5-ASA" means 5-amino salicylic acid;

"AIF" or "Annual Information Form" means this annual information form of the Company in respect of the fiscal year ended August 31, 2019;

"Algernon Parent" means Petro Basin Energy Corp.;

"ALI" means acute lung injury;

"AST" means AST Trust Company (Canada);

"CAGR" means compound annual growth rate;

"BCBCA" the Business Corporations Act (British Columbia);

"Breathtec" means Breathtec Biomedicals, Inc.;

"Breathtec Acquisition" has the meaning ascribed thereto on page 7 of this AIF;

"Board" or "Directors" means the directors of the Company as at the date of this document;

"CKD" means chronic kidney disease;

"CSE" means the Canadian Securities Exchange;

"Common Shares" means the Class A common shares without par value in the capital of the Company;

"Company" or "Algernon" means Algernon Pharmaceuticals Inc.;

"COVID-19" means a disease caused by a new strain of coronavirus;

"FAIMS" means field asymmetric ion mobility sensor;

"February 2020 Offering" has the meaning ascribed thereto on page 9 of this AIF;

"FDA" United States Food and Drug Administration;

"IBD" means inflammatory bowel disease;

"IFRS" means International Financial Reporting Standards;

"IPF" means idiopathic pulmonary fibrosis;

"NAFLD" means non-alcoholic fatty liver disease;

"NASH" means non-alcoholic steatohepatitis;

"Nash Pharma" means Nash Pharmaceuticals Inc.;

"NCE" means new chemical entity;

"NI 52-110" means National Instrument 52-110 Audit Committees;

"November 2019 Offering" has the meaning ascribed thereto on page 8 of this AIF;

"NP-120" means Ifenprodil, the Company's lead compound in its IPF research program;

"Options" means stock options of the Company;

"person" means a company or individual;

"POC" means point of care;

"QID" means four times per day;

"Qualification Date" has the meaning ascribed thereto on page 9 of this AIF;

"RSUs" means restricted share units of the Company;

"RUO" means research use only;

"SEDAR" means the System for Electronic Document Analysis and Retrieval filing system, available on the Internet at <a href="http://www.sedar.com">http://www.sedar.com</a>;

"Share Exchange Agreement" has the meaning ascribed thereto on page 8 of this AIF;

"Special Warrants" has the meaning ascribed thereto on page 9 of this AIF;

"Special Warrant Financing" has the meaning ascribed thereto on page 9 of this AIF;

"Special Warrant Unit" has the meaning ascribed thereto on page 9 of this AIF;

"United States" or "U.S." means the United States of America;

"UC" mean ulcerative colitis;

"UFRF" means the University of Florida Research Foundation; and

"UUO" means unilateral urinary obstruction.

# CORPORATE STRUCTURE

## Name, Address And Incorporation

The Company was incorporated under the *Business Corporations Act* (British Columbia) (the "**BCBCA**") on April 10, 2015 as "PBA Acquisitions Corp.", a wholly-owned subsidiary of Petro Basin Energy Corp. ("**Breathtec**"). On July 23, 2015, the Company changed its name to "Breathtec Biomedical, Inc." The Company entered into an arrangement agreement with Algernon Parent. The arrangement agreement and associated plan of arrangement were approved by Algernon Parent's shareholders on July 30, 2015, and approved by the Ontario Superior Court of Justice (Commercial List) on August 5, 2015. The plan of arrangement was completed on September 23, 2015. On February 19, 2019, the Company changed its name to "Algernon Pharmaceuticals Inc."

The Company's head office is located at Suite 915 - 700 West Pender Street, Vancouver, BC, V6C 1G8 and its registered and records office is located at Suite 1500 – 1055 West Georgia St., Vancouver, BC V6E 4N7.

The Class A common shares of the Company (the "**Common Shares**") are listed on the Canadian Securities Exchange (the "**CSE**") under the trading symbol "AGN". The Company is a reporting issuer in Canada in the provinces of British Columbia, Alberta, and Ontario.

## Inter-corporate Relationships

As at the date of this AIF, the Company has the following wholly-owned subsidiaries:

- Nash Pharmaceuticals Inc. ("Nash Pharma"), a British Columbia corporation; and
- Algernon Research PTY Ltd ("**AGN Research**"), an Australian proprietary company established on January 6, 2020.

# GENERAL DEVELOPMENT OF THE BUSINESS

#### Summary

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**") and chronic cough.

# **Three Year History**

# Acquisition of Nash Pharmaceuticals Inc.

On October 19, 2018, the Company acquired all of the issued and outstanding shares of Nash Pharma, a clinical stage pharmaceutical development company focused on drug repurposing in the areas of NASH, CKD and IBD. Through its ongoing research programs, Nash Pharma has developed data that supports the advancement of up to seven drug candidates into phase II trials.

Pursuant to the terms of a share exchange agreement (the "**Share Exchange Agreement**") dated October 5, 2018 among the Company, Nash Pharma and the securityholders of Nash Pharma, the Company issued 15,800,000 Common Shares to the shareholders of Nash Pharma at an issue price of

\$0.22 per Common Share. Existing warrants to purchase common shares of Nash Pharma were cancelled and were replaced with 14,800,000 Common Share purchase warrants of the Company, each having an exercise at a price equal to the exercise price of the Nash Pharma warrants.

## Share Consolidation

On October 16, 2018, the Company consolidated its Common Shares on a two for one basis and began trading on the CSE on a post-consolidated basis effective October 17, 2018.

## Private Placement of Units

On October 23, 2018, the Company completed a non-brokered private placement of 2,083,334 units at a price of \$0.24 per unit for gross proceeds of \$500,000. Each unit was comprised of one Common Share and one Common Share purchase warrant. Each Common Share purchase warrant entitles the holder to purchase one additional Common Share until October 23, 2020 at a purchase price of \$0.50 per Common Share.

In connection with the private placement, the Company paid a cash commission in the aggregate amount of \$1,263, being 8% of the aggregate proceeds raised from the sale of units to purchasers introduced by eligible finders. In addition, the Company issued finder's warrants to acquire a total of 5,266 Common Shares, being 8% of the number of units sold under the private placement to purchasers introduced by such finders. Each finders' warrant entitles the holder to purchase one Common Share at a price of \$0.50 per Common Share until October 23, 2020.

## Name Change

Effective February 19, 2019, the Company changed its name to "Algernon Pharmaceuticals Inc.".

# November 2019 Offering of Units

On November 1, 2019, the Company completed a public offering of units by way of short form prospectus in Canada (the "**November 2019 Offering**"). Pursuant to the November 2019 Offering, the Company issued 24,401,300 units at the issue price of \$0.085 per unit for total gross proceeds of \$2,074,110. Each unit was comprised of one Common Share and one Common Share purchase warrant. Each Common Share purchase warrant entitles the holder to purchase one additional Common Share until May 1, 2022 at a purchase price of \$0.12 per Common Share. These Common Share purchase warrants are listed and posted for trading on the CSE under the symbol AGN.WT.

As compensation, the Company issued 1,801,080 compensation options to the agents under the November 2019 Offering. Each compensation option entitles the holder to purchase one unit of the Company at a price of \$0.085 per unit until May 1, 2022. Each unit consists of one Common Share and one Common Share purchase warrant entitling the holder to acquire an additional Common Share at a purchase price of \$0.12 per Common Share. The Company also paid a cash commission in the aggregate amount of \$153,092 to a syndicate of agents.

## Algernon Research Pty Ltd

On January 6, 2020, Nash Pharma established AGN Research, its wholly-owned subsidiary, in Australia. AGN Research is a proprietary company formed with the aim to provide supporting scientific research activities to Nash Pharma.

## February 2020 Offering of Units

On February 20, 2020, the Company completed a non-brokered private placement of 18,304,939 units at a price of \$0.085 per unit for gross proceeds of \$1,555,920 (the "**February 2020 Offering**"). Each unit was comprised of one Common Share and one unlisted Common Share purchase warrant. Each Common Share purchase warrant entitles the holder to purchase one additional Common Share until August 20, 2022 at a purchase price of \$0.12 per Common Share.

As compensation, the Company issued a total of 969,571 finder's warrants, being 8% of the number of units sold under the February 2020 Offering to purchasers introduced by such finders. Each finder warrant entitles the holder to purchase one unit of the Company at a price of \$0.085 per unit until August 20, 2022. Each unit consists of one Common Share and one unlisted Common Share purchase warrant entitling the holder to acquire an additional Common Share at the price of \$0.12 per Common Share. The Company also paid a cash commission to certain finders in the aggregate amount of \$82,413, being 8% of the aggregate proceeds raised under the February 2020 Offering.

## Private Placement of Special Warrants

On May 13, 2020, the Company completed a private placement of 19,605,285 special warrants of the Company (the "**Special Warrants**") at a price of \$0.35 per Special Warrant for gross proceeds of \$6,861,849 (the "**Special Warrant Financing**"). Each Special Warrant is exercisable, for no additional consideration at the option of the holder, into one unit of the Company (a "**Special Warrant Unit**"). Each Special Warrant Unit is comprised of one Common Share and one Common Share purchase warrant. Each whole Common Share purchase warrant will entitle the holder to purchase one Common Share at an exercise price of \$0.55 per Common Share until May 13, 2022. If, at any time after the Qualification Date (as defined below) and prior to the expiry date of the Common Share purchase warrants, the volume weighted average trading price of the Common Shares on the CSE, or other principal exchange on which the Common Shares are listed, is greater than \$1.00 for 10 consecutive trading days, the Company may, within 15 days of the occurrence of such event, deliver a notice to the holders of Common Share purchase warrants accelerating the Expiry Date to the date that is 30 days following the date of such notice.

All unexercised Special Warrants will be automatically exercised, without payment of additional consideration, on the date (the "**Qualification Date**") that is the earlier of: (i) four months and a day following May 13, 2020; and (ii) three business days following the date on which receipt is issued by the British Columbia Securities Commission for a final short form prospectus qualifying the distribution of the underlying the Special Warrants Units. In the event the Qualification Date has not occurred prior to 5:00 p.m. on the date that is 35 days from May 13, 2020, each unexercised Special Warrant will thereafter entitle holders thereof to receive upon the exercise or deemed exercise thereof, for no additional consideration, 1.10 Units in lieu of one (1) Unit and thereafter at the end of each additional 30 day period prior to the Qualification Date, each Special Warrant will be exercisable for an additional 0.02 of a Unit.

In connection with the Special Warrant Financing, the Company paid Mackie Research Capital Corporation, the sole agent and bookrunner, and a syndicate of sub-agents, a cash fee of \$526,853, equal to 8% of the gross proceeds from the sale of the Special Warrants, subject to a reduced fee of 4% for Special Warrants issued to President's list purchasers. As additional compensation, the Company also issued an aggregate of 1,505,293 non-transferable compensation options, entitling the holder to acquire one Special Warrant Unit at an exercise price of \$0.35 per Special Warrant Unit until May 13, 2022.

## **OVERVIEW OF BUSINESS**

Algernon is a clinical stage drug development company focused on the areas of NASH, CKD, IBD, IPF, chronic cough and ALI (specifically in relation to COVID-19). Algernon's business model is to move its lead compounds into human trials in both a time sensitive and capital efficient manner.

Algernon's drug discovery program was based on the concept of drug repurposing. Drug repurposing is the process of discovering new therapeutic uses for existing drugs. Repurposing offers several benefits over traditional drug development including a reduction in investment and risk, shorter research periods and as a result, a longer active patent life.

The Company's early research program identified a number of genericized drug candidates as possible compounds for the management and treatment of new diseases. However, only drugs that were approved in Russia, Korea, Ukraine and Japan were chosen for screening. This was to avoid off-label prescription writing in the U.S. in the event one of the compounds achieved FDA approval. Off-label prescription writing can interfere with the normal economic pricing models and revenue potential of newly approved drug treatments and may make them less attractive targets for licensing or acquisition by a large pharmaceutical company.

The Company screened 11 drug candidates in well-accepted *in vivo* animal research models. Initial studies showed that a number of the drug candidates screened either performed equal to or better than the positive controls in each of the animal studies. The positive controls in the studies were widely accepted current standard of care treatments for each disease except for NASH where there is currently no approved treatment.

Subsequent *in vivo* studies have supported the efficacy of these candidates and as a result, Algernon is now in the planning stages to move a number of its lead compounds into Phase II clinical trials. The Company believes that these compounds have the potential to be the first-in-class with unique structures.

Since all of the lead compounds are older than 20 years, and are genericized, all of the original composition of matter patents have expired. In order to build an intellectual property position around its discoveries, Algernon has filed new method of use patents for each of its lead compounds in the above stated disease areas. Where Algernon deemed it necessary, and based on intellectual property searches for new chemical entity ("**NCE**"), the Company has also filed Markush structure patents in respect of certain of its lead compounds. The Company believes this approach will minimize the risk of a third party trying to make small structural changes to Algernon's lead compounds and filing new composition of matter patents.

# Pre-Clinical Results

Algernon has announced the following preclinical results from the Company's main disease areas:

# 1. NASH *In Vivo* Study #1

Data from this study demonstrated statistically significant improvements in several key measures relevant to the development and progression of NASH including:

- A 2.0% reduction in the NAFLD/NAS score vs controls (p<0.05);
- A 42.0% reduction in fibrosis as measured by Sirius red staining (p<0.01); and
- No negative side effects were observed.

In the same study, Telmisartan (a well-accepted control in NASH studies) significantly reduced the NAS score by 2.0 points (p<0.05) and reduced fibrosis by 19.7% (not statistically significant).

# 2. NASH *In Vivo* Study # 2

Data from this study demonstrated statistically significant improvements in several key measures relevant to the development and progression of NASH including:

- Cenicriviroc (40 mg/kg, QID) both a positive control and comparator arm in the study showed a 1.5 point drop in the NAFLD/NAS score versus controls (p<0.01) and 54.1% (p<0.0001) reduction in fibrosis area compared to controls as measured by Sirius Red staining;
- NP-160 (40 mg/kg, QID) showed a 1.25 point drop in the NAFLD/NAS score versus controls (p<0.05) and a 59.9% reduction (p<0.0001) in fibrosis area;
- NP-135 (200 mg/kg, QID) showed a 1.1 point drop in the NAFLD/NAS score versus controls (p>0.05) and a 84.4% reduction (p<0.0001) in fibrosis area;
- As previously reported, both NP-160 and NP-135 at the same doses recently showed significant anti-fibrotic activity in a unilateral urinary obstruction ("**UUO**") model of CKD, reducing fibrosis by 57.6% (p <0.000001) and 52.1% (p<0.000001) respectively. Cenicriviroc reduced fibrosis in the same study by only 31.9% (p=0.00032);
- Neither NP-135 or Cenicriviroc showed any significant negative effect on any important metabolic markers including glucose, lipids and cholesterol;
- NP-135 (200 mg/kg, QID) showed a 34.6% (p<0.001) reduction in liver hydroxyproline compared to negative controls; and
- Cenicriviroc (40 mg/kg, QID) showed a 29.0% (p<0.01) reduction in liver hydroxyproline when compared to negative controls.

# 3. CKD *In Vivo* Study # 1

Data from this study demonstrated statistically significant improvements in multiple measurements over untreated controls relevant to chronic kidney disease including:

- A 43.1% (p=0.003) reduction in fibrosis as measured by Sirius red staining;
- A reduction of blood urea nitrogen, a marker of kidney function (p=0.000047);
- Telmisartan, a positive control in the study and a current standard of care for CKD, reduced fibrosis by 42.2% (p=0.004);

- Telmisartan also reduced blood urea nitrogen but was not statistically significant; and
- NP-135 is a repurposed, orally delivered drug with no known anti-hypertensive effect.

# 4. CKD *In Vivo* Study # 2

Data from this study demonstrated that clinically relevant doses resulted in statistically significant improvements in the reduction in fibrosis in the UUO model as measured by Sirius Red staining over untreated controls:

- Telmisartan (3mg/kg), a positive control, reduced fibrosis by 32.6% (p<0.001);
- Cenicriviroc (40 mg/kg) a CCR2/5 chemokine receptor antagonist with reported antifibrotic activity, reduced fibrosis by 31.9% (p=0.00032);
- NP-135 (200 mg/kg) reduced fibrosis by 52.1% (p<0.000001). In addition, the mass of the fibrotic kidney was lower than the negative control (i.e. closer to normal, p=0.016);
- NP-160 (40 mg/kg) reduced fibrosis by 57.6% (p <0.000001). NP-160 was also previously reported to be anti-fibrotic in a mouse model of NASH; and
- NP-251 (90 mg/kg) reduced fibrosis by 50.6% (p<0.000001) with evidence of slight synergy (54.2% reduction in fibrosis, p<0.000001) when a low dose (30 mg/kg, 20.8% reduction in fibrosis, p>0.05) was combined with the same dose of Telmisartan (3mg/kg). In addition, the mass of the fibrotic kidney was lower than the negative control (p<0.001).
- 5. IBD *In Vivo* Study # 1

Data from this study demonstrated statistically significant improvements in multiple measurements over multiple time points relevant to ulcerative colitis including:

- Body weight, stool consistency, colon length and weight ratios and occult positivity (p<0.001 to p<0.05);
- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD;
- No negative side effects were observed; and
- NP-178 is a repurposed, orally delivered neurological drug.
- 6. IBD *In Vivo* Study # 2

Data from this study demonstrated statistically significant improvements in multiple measurements over multiple time points relevant to CD including:

NP-178

- Body weight (p<0.001), occult positivity (p<0.05), colon weight (p<0.05), colon length (p<0.001) and the colon weight/length ratio (p<0.001);
- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD;
- No negative side effects were observed; and
- NP-178 is a repurposed, orally delivered neurological drug.

NP-120

• Body weight (p<0.01), colon length (p<0.001) and colon weight/length ratios (p<0.01);

- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD in both the Crohn's Disease and an earlier Ulcerative Colitis study;
- No negative side effects were observed; and
- NP-120 is a repurposed, orally delivered neurological drug.

# 7. IPF In Vivo Study #1

The Company announced positive preliminary data from its first IPF study. Out of the eight compounds screened by the Company during the early research phase, NP - 251 showed the most promise. Based on the data, the Company decided to conduct further research.

# 8. IPF *In Vivo* Study #2

Data from this study demonstrated a statistically significant improvement in established fibrosis in a 21day bleomycin mouse model (treatment began on Day 7):

# NP-120

- Pirfenidone (100 mg/kg, BID), both a positive control and comparator arm in the study, showed a 44% reduction in fibrosis versus untreated controls (not statistically significant) as measured by Trichrome staining and modified Ashcroft scoring.
- Nintedanib (40 mg/kg, QD), a second positive control and comparator arm, and NP-251 (30 mg/kg, TID) both showed a 51% reduction in fibrosis versus untreated controls (p<0.05).
- NP-120 (20 mg/kg, TID) showed a 56.0% reduction in fibrosis versus untreated controls (p=0.015).
- In an earlier experiment, NP-121, which shares the same target and similar pharmacology as NP-120, also reduced fibrosis to a similar level as NP-120 at the same dose, suggesting a class effect of the pharmacophore.
- NP-120 is a drug currently used for neurological indications in Japan, and was originally developed by a global top 10 pharmaceutical company. NP-121 is a repositioned drug that has undergone extensive Phase II and III testing.

# 9. Chronic Cough

Data from this study demonstrated that at clinically relevant doses:

# NP-120

- NP-120 (1.5 mg/kg) showed a reduction of 42% in mean cough frequency versus untreated control (p <0.01);</li>
- Gefapixant (3.5 mg/kg) showed a 20% reduction in mean cough frequency versus untreated control (p <0.05); and
- NP-120 (59.8 seconds) and Gefapixant (49.7 seconds) both showed a non-statistically significant delay in the onset of the first cough when compared to control (34.2 seconds).
- 10. ALI Associated with COVID-19

A recent independent study, published by the American Society of Microbiology in the December 2019 issue of 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. Based on the findings of this study, the Company believes that NP-120 has the potential to be a front-line treatment for the most severe cases of coronavirus, and may also reduce morbidity in patients.

# NP-120 H5N1 Animal Study Data:

A genome wide RNAi interference approach to identify genes that aid in the recovery of cell viability after H5N1 infection, lead to the identification of the NMDA receptor antagonist NP-120 which when tested in an animal model of H5N1 infection showed:

- Markedly decreased leukocyte infiltration and lung injury scores in effected lungs
- Significantly ameliorated edema infected mouse lung tissue
- Significantly improved the survival of H5N1 infected mice by 40%

# Update on FAIMS Breathalyzer Development Program

On November 13, 2019, the Company terminated the research and development agreement with the University of Florida relating to the FAIMS V3 prototype.

On January 7, 2020, the Company made a formal request to University of Florida Research Foundation ("**UFRF**") to terminate the license agreement with respect to an exclusive royalty-bearing license to certain UFRF patent rights and a non-exclusive royalty-bearing license to certain UFRF know-how to enable commercial advancements in the infections detections. Pursuant to the terms of the license agreement, the license agreement was terminated effectively on March 7, 2020, and all development on the breathalyzer ceased.

# Development of a Therapy for Non Alcoholic Steatohepatitis (NASH)

Algernon's two lead compounds for the treatment and management of NASH are NP-135 and NP-160. Both compounds are orally administered small molecules. Non-alcoholic fatty liver disease ("NAFLD") is the most common cause of chronic liver disease in developed countries. NASH occurs in these patients when inflammation and hepatocyte injury occurs, increasing the risk of further development into liver fibrosis, cirrhosis, and potential liver failure. The Company believes that there is an unmet clinical need for treatment for NASH, as, to the Company's knowledge, there are currently no effective standards of care treatments available.

The Company conducted two *in vivo* studies using the STAM<sup>™</sup> mouse model from SMC Laboratories. NP-135, and notably NP-160, showed repeated positive results in the reduction of fibrosis when compared to the positive controls in each study. Fibrosis is the thickening and scarring of connective tissue, usually as a result of injury and is a very serious complication of NASH.

Key milestones for Algernon's NASH program include:

November 1, 2018 – NP-160 data from this study demonstrated statistically significant improvements in several key measures relevant to the development and progression of NASH including:

- A 2.0% reduction in the NAFLD/NAS score versus controls (p<0.05);
- A 42.0% reduction in fibrosis as measured by Sirius red staining (p<0.01); and
- No negative side effects were observed.

In the same study, Telmisartan (a well-accepted control in NASH studies) significantly reduced the NAS score by 2.0 points (p<0.05) and reduced fibrosis by 19.7% (not statistically significant).

January 21, 2018 – NP-160 and NP-135 data from this study demonstrated statistically significant improvements in several key measures relevant to the development and progression of NASH including:

- NP-160 (40 mg/kg, QID) showed a 1.25 point drop in the NAFLD/NAS score versus controls (p<0.05) and a 59.9% reduction (p<0.0001) in fibrosis area;
- NP-135 (200 mg/kg, QID) showed a 1.1 point drop in the NAFLD/NAS score versus controls (p>0.05) and a 84.4% reduction (p<0.0001) in fibrosis area; and
- Cenicriviroc (40 mg/kg, QID) both a positive control and comparator arm in the study showed a 1.5 point drop in the NAFLD/NAS score versus controls (p<0.01) and 54.1% (p<0.0001) reduction in fibrosis area compared to controls as measured by Sirius Red staining.

April 1, 2019 – NP-135 data from the biochemical analysis from the most recent NASH pre-clinical research study showed :

- Neither NP-135 or Cenicriviroc, both a positive control and comparator arm in the study, and currently in Phase III trials for NASH, showed any significant negative effect on any important metabolic markers including glucose, lipids and cholesterol;
- NP-135 (200 mg/kg, QID) showed a 34.6% (p<0.001) reduction in liver hydroxyproline compared to negative controls; and
- Cenicriviroc (40 mg/kg, QID) showed a 29.0% (p<0.01) reduction in liver hydroxyproline when compared to negative controls.

# Development of A Therapy for Chronic Kidney Disease (CKD)

Algernon's lead compounds for the treatment and management of CKD are NP-135, NP-160, NP-178 and NP-251. All of the compounds are orally administered small molecules. CKD involves the gradual loss of kidney function leading to kidney failure. Advanced stage CKD leads to dangerous accumulation of fluid, electrolytes and waste in the body. CKD can progress to end-stage kidney failure, which is fatal without artificial filtering (dialysis) or a kidney transplant. Treatment for chronic kidney disease focuses on slowing the progression of the kidney damage, usually by controlling the underlying cause.

The Company conducted two separate animal *in vivo* mouse studies using a UUO mouse model of kidney fibrosis.

Key milestones for Algernon's CKD program include:

November 19, 2018 - Data from this study demonstrated that NP-135 showed statistically significant improvement in multiple measurements over untreated controls relevant to chronic kidney disease including:

- A 43.1% (p=0.003) reduction in fibrosis as measured by Sirius red staining;
- A reduction of blood urea nitrogen, a marker of kidney function (p=0.000047);
- Telmisartan, a positive control in the study and a current standard of care for CKD, reduced fibrosis by 42.2% (p=0.004); and
- Telmisartan also reduced blood urea nitrogen but was not statistically significant

January 14, 2019 - Data from this study demonstrated that clinically relevant doses of NP-135 and NP-160 and NP-251 resulted in statistically significant improvements in the reduction in fibrosis in the UUO model as measured by Sirius Red staining over untreated controls:

- NP-135 (200 mg/kg) reduced fibrosis by 52.1% (p<0.000001). In addition, the mass of the fibrotic kidney was lower than the negative control (i.e. closer to normal, p=0.016);
- NP-160 (40 mg/kg) reduced fibrosis by 57.6% (p <0.000001). NP-160 was also previously reported to be anti-fibrotic in a mouse model of NASH;
- NP-251 (90 mg/kg) reduced fibrosis by 50.6% (p<0.000001) with evidence of slight synergy (54.2% reduction in fibrosis, p<0.000001) when a low dose (30 mg/kg, 20.8% reduction in fibrosis, p>0.05) was combined with the same dose of Telmisartan (3mg/kg). In addition, the mass of the fibrotic kidney was lower than the negative control (p<0.001);</li>
- Telmisartan (3mg/kg), a positive control, reduced fibrosis by 32.6% (p<0.001); and
- Cenicriviroc (40 mg/kg) a CCR2/5 chemokine receptor antagonist with reported anti-fibrotic activity, reduced fibrosis by 31.9% (p=0.00032).

# Development of a Therapy for Inflammatory Bowel Disease (IBD)

Algernon's lead compounds for the treatment and management of IBD, specifically ulcerative colitis ("**UC**") and Crohn's Disease, are NP-120 and NP-178. Both of the compounds are orally administered small molecules. IBD is an umbrella term used to describe disorders that involve chronic inflammation of the digestive tract. This condition causes long-lasting inflammation and sores (ulcers) in the innermost lining of the large intestine (colon) and rectum. Despite successful treatment of IBD with salicylates, especially for UC patients, up to 50% of patients still fail therapy, and the Company believes that there is still a major unmet medical need for patients with moderate or severe IBD.

The Company conducted two separate animal *in vivo* studies including a UC mouse model and a model for Crohn's disease.

Key milestones for Algernon's IBD program include:

November 13, 2018 - Data from this study demonstrated that NP-178 showed statistically significant improvements in multiple measurements over multiple time points relevant to UC including:

- Body weight, stool consistency, colon length and weight ratios and occult positivity (p<0.001 to p<0.05);</li>
- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD; and
- No negative side effects were observed.

December 3, 2018 - Data from this 2,4,6-trinitrobenzene sulfonic acid (TNBS) induced *in vivo* animal study showed NP-178 and NP-120 demonstrated statistically significant improvements in multiple measurements over multiple time points relevant to Crohn's Disease including:

NP-178

- Body weight (p<0.001), occult positivity (p<0.05), colon weight (p<0.05), colon length (p<0.001) and the colon weight/length ratio (p<0.001);
- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD; and
- No negative side effects were observed.

NP-120

- Body weight (p<0.01), colon length (p<0.001) and colon weight/length ratios (p<0.01);
- The drug compared very favourably to the control, 5-ASA, the current standard of care for IBD in both the Crohn's Disease and an earlier Ulcerative Colitis study; and
- No negative side effects were observed.

# The Development of a Therapy for IPF

IPF is a type of chronic lung disease characterized by a progressive and irreversible decline in lung function and scarring (fibrosis) of the lungs. There is no cure for IPF and there are currently no procedures or medications that can remove the scarring from the lungs.

Key milestones for Algernon's IPF and Chronic Cough program include:

Feb 25, 2019 - the Company announced that, based on positive preliminary data from its first IPF research study, the Company has elected to conduct further research on compounds NP-251 and NP-120. Both compounds are orally administered small molecules.

July 3, 2019 - the Company announced that in a second *in vivo* study, NP-120, its repurposed lead candidate for treatment of IPF, showed superiority in reducing fibrosis over two globally approved therapies for IPF, Pirfenidone and Nintedanib, in an *in vivo* animal model study of IPF.

December 5, 2019 - the Company announced that NP-120, its repurposed lead candidate for the treatment of IPF, showed superiority over Gefapixant, Merck's lead phase 3 trial drug, in an acute cough *in-vivo* animal study.

March 23, 2020 - the Company announced that it had awarded the contract to manufacture the active pharmaceutical ingredient for NP-120 to U.S. based Cascade Chemistry. Algernon made the decision to scale-up cGMP manufacturing of NP-120 to support its quickly evolving clinical program for ALI, its urgent clinical focus on COVID-19, as well as its IPF clinical program.

# The Development of a Therapy for ALI associated with COVID-19

On March 6, 2020 the Company identified a recently published independent study that found that NP-120 significantly reduced ALI and improved survivability in an animal study with H5N1 infected mice. Based on the data, the Company began a process to review the potential of NP-120 as a novel treatment option for coronavirus.

On April 23, 2020 the Company received approval from the Ministry of Food and Drug Safety in South Korea, as well as ethics approval, for an investigator-led, Phase 2 COVID-19 clinical study of its repurposed drug NP-120, an NMDA receptor antagonist. The study is expected to begin in mid June 2020.

On April 29, 2020 Algernon received a "No Objection" letter from Health Canada to proceed with a NP-120 COVID-19 Phase 2b/3 multinational clinical trial. The same study protocol was filed on May 22<sup>nd</sup> as part of an investigational New Drug (IND) application for the same NP-120 COVID 19 Phase 2b/3 multinational clinical trial with the U.S. FDA.

On May 15, 2020 Algernon submitted for ethics approval in Australia for its planned multinational Phase 2b/3 study of its re-purposed drug NP-120 for COVID-19. The ethics submission was made at Princess Alexandra Hospital located in Brisbane, Queensland.

## Safety History of Lead Compounds

## NP-120

NP-120 was developed in France and introduced into the Japanese market in 1987 by a global pharmaceutical company. NP-120 was withdrawn from the French market in 2014 owing to a lack of risk/benefit analysis but is still available in Japan as a generic drug. Since its origin, there have been a number of clinical trials investigating its use in other diseases, as summarized below:

- 1. Circulatory System Related Disorders (4,821 Patients over one 1 Year);
- 2. Circulatory Issues (94 Patients over six months); and
- 3. Alcohol Dependence (46 Patients over three months).

# NP-135

NP-135 was developed in Russia in 1970. NP-135 is currently prescribed for neurological conditions in Russia, where it is genericized, and as a supplement in the Ukraine. Since its origin, there have been a number of clinical trials investigating its use in other diseases, as summarized below:

- 1. Viral Hepatitis A (148 Patients);
- 2. Chronic Non-specific Respiratory Diseases (36 Patients);
- 3. Radiation Sickness (9 Patients);
- 4. Ischemic Heart Disease (75 Patients);
- 5. Coronary Artery Bypass Surgery (29 Patients);
- 6. Prevention Of Hearing Loss (148 Patients);
- 7. Neuromuscular Diseases (145 Patients);
- 8. Ischemic Stroke (2 Studies: 53 And 28 Patients);
- 9. Fetal Hypoxia During Gestosis (157 Patients); and
- 10. Treatment Of Recurrent Erysipelas (66 Patients)

**Note**: No significant adverse side effects in any of the above noted studies were identified by the Company.

# NP-160

NP-160 was developed in Russia in the 1980's. NP-160 was approved in Russia for the treatment of neurologically related diseases. The Company believes that it was withdrawn from the market in the fourth quarter of 2018 due to declining sales. Since its origin, there have been a number of clinical trials investigating its use in other diseases, as summarized below:

- 1. Pilot trial (30 patients);
- 2. Multicenter trial (795 patients);
- 3. Phase II trial (30 patients, randomized, blinded, placebo-controlled);
- 4. Non-motor symptoms of Parkinson's Disease (70 patients, open label); and
- 5. Irritable Bowel Syndrome (30 patients, open label w/ control group)

**Note**: No significant adverse side effects in any of the above noted studies were identified by the Company.

# NP-178

NP-178 was developed in Russia and was first approved in 1986. NP-178 is available in Russia and the Ukraine as a highly genericized prescription medicine. In Russia, NP-178 is one of the top selling drugs and is on the state registry of essential drugs. Since its origin, there have been a number of clinical trials investigating its use in other diseases, as summarized below:

- 1. Cerebral Ischemia (26 Trials, 6337 patients);
- 2. Cardiology (12 trials, 2531 patients);
- 3. Psychiatry (10 trials, 733 Patients);
- 4. Ophthalmology (11 trials, 1163 patients);
- 5. Pancreatitis (6 trials, 505 patients);
- 6. Epilepsy, Encephalopathy, Pain, Eczema, Dentistry and others; and
- 7. Phase III registered trial for stroke on going.

**Note**: No significant adverse effects in any of the above noted studies were identified by the Company.

# NP-251

NP-251 was developed in Japan and approved in 1987. NP-251 is no longer available in Japan where it was initially approved as an anti-allergy medication. It was withdrawn from the market in 2014 for sales reasons. Little reported clinical Information exists for NP-251.

**Note**: The Company did not identify any publically available significant adverse side effect issues related to this compound.

# Current Pre-Clinical Drug Research Program

The Company is 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. However, the Company is working to independently confirm whether these known pathways are involved in the specific biochemical interaction that produced the pharmacological effect seen in the Company's animal model research.

## About Company Research Programs

All of the Company's research programs and statistical analysis are being conducted by third party contract research organizations. All of the Company's drug development research programs are directly managed by Dr. Mark Williams, the Company's Chief Science Officer. Some independent laboratories are also being utilized for mechanism of action research. The Company is not planning to hire any full-time employees related to research activities other than for management purposes.

## Medical and Scientific Advisory Board

# Dr. Arun Sanyal

On March 21, 2019, the Company announced the appointment of Dr. Arun Sanyal, MD, a leading global expert and clinician in the area of chronic liver disease. Dr. Sanyal has developed, mediated and encouraged global liver research as a physician-scientist for 25 years. Currently, Dr. Sanyal is the Vlahcevic Chair of Medicine in the department of Internal Medicine at Virginia Commonwealth University (VCU) and Director of the KL2 program in the Center for Clinical and Translational Research at VCU.

Dr. Sanyal's medical career has spanned the spectrum of translational science in liver cirrhosis, NASH and NAFLD, with a particular focus on obesity and cardiovascular affects related to liver disease. Dr. Sanyal is a Past President of the American Association for the Study of Liver Diseases, and has chaired committees at the National Institute of Diabetes and Digestive Kidney Diseases' NASH clinical research network and the United States National Institute of Health's hepatobiliary study section. He recently received the 2018 Distinguished Achievement Award from the American Association for the Study of Liver Diseases. The award signifies 30 years of research including 17 continuous years of National Institutes of Health funding, the development of therapeutics reducing liver disease across the globe, and countless international leadership roles and awards.

# Dr. Walter Reinisch

On April 4, 2019, the Company announced that Dr. Walter Reinisch, MD, a leading global scientific expert and clinician in the area of IBD has joined the Algernon Medical and Scientific Advisory Board. Dr. Reinisch is a founding member of the European Crohn's & Colitis Organization and was assigned as honorary member after having contributed in various positions. He was active in the Scientific and Public Affairs Committee of the United European Gastroenterology and headed the Austrian IBD Study Group. Dr. Reinisch is member of the International Organization For the Study of Inflammatory Bowel Disease.

Dr. Reinisch is an expert in designing, conducting and interpreting the results of clinical trials in IBD. He envisions a customized management of IBD utilizing the innovations of translational medicine. He advocates the implementation of a "common language of inflammatory bowel disease" to improve the communication with patients and between physicians for a better care and more robust research outcomes. Dr. Reinisch has also either written or made contributions to over 250 publications on IBD and remains active in all aspects of IBD research.

## Dr. Martin Kolb

Dr. Kolb is the Moran Campbell Chair and Professor in Respiratory Medicine and Director of the Division of Respirology, McMaster University, Hamilton, Ontario, Canada. He is lead of the interstitial lung disease program, located at St. Joseph's Healthcare Hamilton, where more than 1,500 patients with different types of fibrotic interstitial lung disorders are seen annually. His major research interests are the mechanisms of lung fibrosis, with a particular interest in the role of growth factors, matrix abnormalities and pulmonary vessel remodelling in disease progression.

He leads activities in biomarker development for lung fibrosis, and is a Principal Investigator and steering committee member in numerous clinical trials. Dr. Kolb has authored over 150 peer-reviewed publications on different basic science and clinical topics. He is the Chief-Editor of the European Respiratory Journal, the flagship publication of the European Respiratory Society. He is also an editorial board member of American Journal of Respiratory and Critical Care Medicine, American Journal of Respiratory Cell and Molecular Biology, the European Respiratory Review and Respirology and serves on the Lung Injury & Repair Study Section for the National Institute of Health.

# Dr. Jacky Smith

Dr. Smith is a Professor of Respiratory Medicine at the University of Manchester and an Honorary Consultant at Manchester University NHS Foundation Trust. She runs a multi-disciplinary research team whose focus is on understanding mechanisms underlying pathological cough and a regional clinical service seeing patients with refractory chronic cough. She is also the Director of the NIHR Manchester Clinical Research Facility and Leads the Rapid Translational Incubator Theme of the NIHR Manchester Biomedical Research Centre.

In collaboration with Mr. Kevin McGuinness (clinical engineer), she has developed a novel method for semi-automated cough detection that was licensed to Vitalograph Ltd., a medical device company with whom she collaborates. The subsequent commercialization of this cough monitoring system has changed the standards by which novel cough therapies are evaluated in regulatory clinical trials. Moreover, the use of this system to quantify coughing in a study of patients attending her chronic cough clinic facilitated the discovery of a new class of efficacious anti-tussive therapy, P2X3 antagonists

#### **Business Advisory Board**

# Howard Guttman

Ambassador (Rtd) Gutman acted, during his distinguished career over the past three decades, as a an international lawyer, served in a number of high-profile appointments for the government of the United States, including Ambassador to Belgium, and served as Special Assistant to the Director of the FBI for Counter-Intelligence and Counter-Terrorism. During his legal career he served as a United States Supreme Court and federal appellate court law clerk prior to entering private practice in Washington, DC., where in addition to legal practice, he served as advisor to candidates for President, Governor and the U.S. Senate.

# **Business Strategy**

The Company is engaged in advancing a number of repurposed genericized drugs into phase II clinical trials for the global disease areas of NASH, CKD and IBD, IPF, Chronic Cough and ALI associated with COVID-19.

The compounds being advanced by the Company have all performed equal to or better than the positive controls used in the Company's widely accepted pre-clinical *in vivo* animal research studies.

Algernon's business strategy is to fast track a number of its lead compounds into phase II clinical trials as quickly and as inexpensively as possible by leveraging the currently existing regulatory approval and finished product supply in the country of origin where the drugs were originally approved. Conducting off label phase II trials in the drugs' currently approved market would save the company from having to synthesize the compounds and conduct all of the preclinical toxicology work. This additional work would in comparison, add significant time and costs to the Company's development timeline and budget.

Based on the results of some of the feasibility studies in progress, the Company believes that conditions exist that could allow the Company to conduct up to four off-label phase II trials without having to do any compound manufacturing or additional pre-clinical work. This would include conducting multiple trials for different diseases with the same lead compound. A final decision will be made on which compounds, diseases and locations will be included in the phase II trials once all of the feasibility studies are completed.

The Company is planning to conduct a minimum of two phase II clinical trials simultaneously in order to improve the Company's potential of success. Ensuring the Company is not conducting and relying on a single phase II clinical trial is key part of the current strategy.

Subject to the success of the phase II trials, the Company plans to engage in licensing, partnership and or acquisition (as the target) discussions with a number of larger pharmaceutical partners. If for whatever reason, a partnership, license or acquisition opportunities do not materialize, the Company will explore moving all successful phase II compounds forward into phase III clinical trials.

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

# Phase II Clinical Trials - Feasibility Studies

The Company has initiated a number of feasibility studies in order to determine the best geographical location to run its planned phase II trials based on a number of factors including availability of finished product and the suitability of the country where the drug is registered. Some of the compounds have been approved in multiple jurisdictions.

As part of its feasibility study process the Company has developed an investigational brochure for three of its lead compounds. These investigational brochures include a protocol synopsis of the planned study as well as the historical safety data for the compounds.

Since the size of the planned phase II trial (i.e. number of patients) is dependent on the strength of the data achieved from the pre-clinical research, the Company has received initial cost estimates for 2 phase II trials as part of the feasibility process.

On April 23, 2020 Algernon received approval from the Ministry of Food and Drug Safety in South Korea, as well as ethics approval, for an investigator-led, Phase 2 COVID-19 clinical study of its re-purposed drug NP-120, an NMDA receptor antagonist.

On May 6, 2020 Algernon received ethics approval from the Royal Brisbane & Women's Hospital, Human Research Ethics Committee for the Company's planned Phase 2 Idiopathic Pulmonary fibrosis (IPF) and chronic cough clinical study of its re-purposed drug NP-120, an NMDA receptor antagonist.

## Drug Development Programs

Through the Company's preclinical screening programs, a number of lead compounds have been identified for the following major global disease areas.

- NP-135 and NP-160 are Algernon's lead compounds for the treatment and management of NASH. According to a report published by Allied Market Research titled, "Global Opportunity Analysis and Industry Forecast, 2021-2025," the global NASH market was valued at \$1.17 billion in 2017, and is expected to reach \$21.4 billion by 2025, growing at a compound annual growth rate of 58.4% from 2021 to 2025. Currently, there are no FDA approved treatments for NAFLD or NASH.<sup>1</sup>
- 2. NP-135, NP-160, NP-178 and NP-251 are Algernon's lead compounds for the treatment and management of CKD. The global market for CKD drugs continues to proliferate at a significant pace, driven by the increasing number of CKD patients and the growing need of novel treatments to improve patients' quality of life. According to Research and Markets, the global CKD drugs market was valued at US\$12.4 billion in 2016, and is expected to reach US\$17.4 billion by 2025, expanding at a compound annual growth rate of 3.9% from 2017 to 2025.<sup>2</sup>
- **3.** NP-120 and NP-178 are Algernon's lead compounds for the treatment and management of IBD. According to Transparency Market Research, the global IBD treatment market was valued at US\$10.52 billion in 2016. Rising at a steady 2.6% compound annual growth rate between 2017 and 2025, the market is likely to be valued at US\$14.8 billion by the end of 2025. In 2016, North America led the global IBD market, which is attributable to the rising incidence of the disease witnessed among men and women alike in the region. The incidence of ulcerative colitis and Crohn's disease is high in US and Canada, which fuels the demand for IBD treatment in North America.
- 4. NP-120 is Algernon's lead compound for IPF and Chronic cough. According to a report from research and consulting firm, GlobalData's, the IPF market is projected to rise from just over US \$900 million in 2015 to US \$3.2 billion by 2025, assuming a compound annual growth rate ("CAGR") of 13.6%. Such growth is expected to occur across the seven major markets of the USA, France, Germany, Italy, Spain, the UK and Japan, and primarily be driven by the increased

<sup>&</sup>lt;sup>1</sup> Pallavi Jaiswal & Sayali Shinde, "Non-Alcoholic Steatohepatitis (NASH) Market by Drug Type (Vitamin E & Pioglitazone, Ocaliva, Elafibranor, and Selonsertib & Cenicriviroc), and Sales Channel (Hospital Pharmacy, Online Provider, and Retail Pharmacy) - Global Opportunity Analysis and Industry Forecast, 2021-2025", *Allied Market Research*, June 2018.

<sup>&</sup>lt;sup>2</sup> Infoholic Research LLP, "Chronic Kidney Disease Drugs Market – Global Forecast to 2025", Research and Markets, March 2019.

use of expensive therapies, the anticipated launches of two novel therapies, FibroGen's FG-3019 and Promedior's PRM-151, and a rise in diagnosed prevalent cases of the disease.<sup>3</sup>

According to a research report from IndustryARC, the cough remedies market size was estimated to be US \$11.40 billion in 2018, and is projected to grow at a CAGR of 6.64% during 2019-2024.<sup>4</sup> Pleasant taste and easy intake of oral syrups are among the key factors driving the global cough remedies market. Some traditional cough remedies include drinking honey, bromelain and bacterial microbes. Further, some new generation cough remedies include corticosteroids, bronchodilators and antibiotics. Currently there is no approved treatment for this condition.

5. NP-120 Is Algernon's lead compound for COVID-19 related ALI. The virus responsible for the disease is also known as severe acute respiratory syndrome coronavirus 2 and abbreviated as SARS-CoV-2. The disease started in China on December 29, 2019, and by March 2020 it was reported that it had spread to several countries across the world. From early-stage studies, it appears that mesenchymal stem cell treatments may exert beneficial effects, potentially by improving the lung microenvironment, inhibiting immune system over-activation, promoting tissue repair, protecting lung alveoli epithelial cells, preventing pulmonary fibrosis, or improving lung function. In recent months, there has been increased activity in the clinical trial sector in using stem cells against COVID-19.<sup>5</sup>

## Regulatory – Drug Development

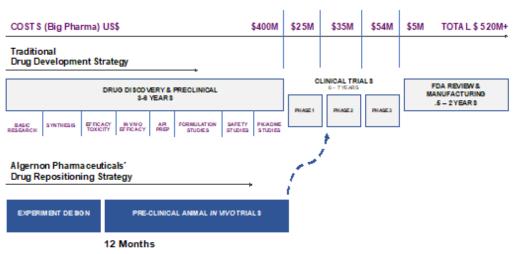
The regulatory pathway for drug development is well established in most major world markets. The most familiar in terms of stages and timing is the FDA pathway which has been estimated for discussion purposes and illustrated in the below diagram. The various stages are well known and documented in terms of timing, cost and the rate of success in each stage.

Drug discovery and pre-clinical describes all of the work and stages prior to testing the compound in human beings. A phase I study is the first point in which the compound begins testing in human beings. All new chemical entities must successfully follow the below pathway in order to achieve regulatory approval and to begin sales to the public.

<sup>&</sup>lt;sup>3</sup> PBR Staff Writer, "GlobalData expects IPF market to more than treble to \$3.2bn by 2025", *Pharmaceutical Business Review*, June 2016, https://www.pharmaceutical-business-review.com/news/globaldata-expects-ipf-market-to-more-than-treble-to-32bn-by-2025-220616-4930247/; Globaldata, "*Idiopathic Pulmonary Fibrosis – Opportunity Analysis and Forecast to 2025*", published June 2016.

<sup>&</sup>lt;sup>4</sup> IndustryARC, "Cough Remedies Market - Forecast(2020 - 2025)", 2019.

<sup>&</sup>lt;sup>5</sup> Golchin, Ali et al. "Mesenchymal Stem Cell Therapy for COVID-19: Present or Future." *Stem cell reviews and reports* vol. 16,3 (2020): 427-433. doi:10.1007/s12015-020-09973-w.



# **REGULATORY PATHWAY**

Algernon's drug discovery program is based on repurposing drugs that have already been approved. Successful drug repurposing is based on finding new uses for known and safe drugs in order to treat and manage new diseases. Since Algernon's lead compounds already have a well-established safety history and have already under gone pre-clinical testing when they were originally developed, the compounds are eligible in the market(s) where they were first approved, to be moved directly into off label phase II clinical studies.

Typically, in order for the Company to be able to move its lead compounds into phase II clinical trials, the finished drug product needs to be available for purchase and the drug needs have an active registration in a market where clinical testing can be successfully executed. The next step is for the Company to conduct what is known as an off-label phase II clinical study confirming that the drug shows efficacy in human beings for the new disease.

Since Algernon only screened compounds that were from Russia, Korea, Ukraine and Japan, none of the currently identified finished product manufacturers meet the 'current good manufacturing practice' ("**cGMP**") standard of production for entry into an FDA study. As a result it is unlikely that the data from the phase II study would be able to be used in a future phase III trial application. However, if any of the Company's lead compounds are successful in their respective phase II studies, the Company would then begin the process of synthesizing and conducting all of the toxicology and safety studies under cGMP and 'good laboratory practice' conditions in order to move forward to phase III study in the U.S.

Prior to a decision to begin synthesizing any compounds, the Company intends to seek out a favourable licensing, partnership or acquisition transaction (as the target) after a successful phase II trial.

# **Competitive Conditions**

# NASH

With rising global rates of obesity and diabetes, NASH, a chronic inflammatory liver disease, is becoming an increasingly prevalent medical concern. To the Company's knowledge there are currently no approved treatments for the disease.

Due to the complexity of the disease, key drug developers are seeking to develop combination therapies to target multiple stages of NASH progression to produce a successful treatment. For example, on October 29, 2018, Pfizer Inc. and Novartis International AG collaborated to develop a therapy combining their NASH pipelines, including Novartis' Emricasan.

As the field matures and positive data is generated from clinical trials, the levels of later-stage partnering activities are expected to rise. According to a 2018 report by GlobalData, approximately 127 drugs are currently in preclinical trials, 40 in phase 2 and just seven in phase 3. This suggests the industry is still in a pioneering phase of growth. A representative list of later stage trials is given below.

# NASH Phase 2/3 Anti-fibrotics and Anti-Inflammatories

3	Cencriviroc	Allergan	CCR2/5 Inhibitor
2	BI-1467335	Pharmaxis	SSAO Inhibitor
2	GR-MD-02	Galectin	Galectin-3 inhibitor
2	Tipelukast	Medicinova	PDE3/4 inhibitor
2	SMG-0109	Second Genome	Inflammasome Inhibitor

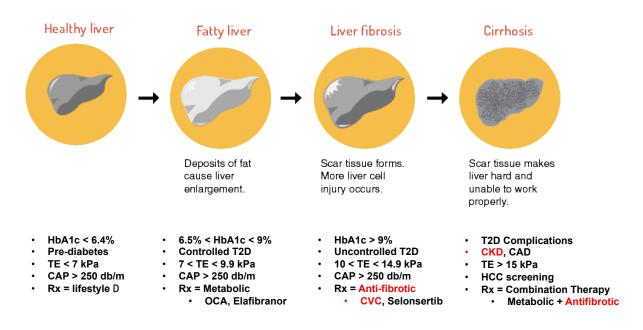
# Legend: 2 = Phase 2 Trial 3 = Phase 3 Trial

# Product Positioning

Algernon believes its products NP-135 and NP-160, being primarily anti-fibrotic, are likely to be used in the later stages of the disease where patients are at risk for developing cirrhosis and ultimately liver cancer. Interestingly, both compounds exhibited anti-fibrotic effects in a pre-clinical animal model of kidney fibrosis as well.

According to a study reported in the Journal of Clinical Endocrinology & Metalobolism, approximately 50% of NASH patients have type 2 diabetes, and kidney disease is a common complication of diabetes.<sup>6</sup> As a result, NP-135 and NP-160 may be useful to treat both NASH and its diabetes associated complications. Furthermore, Algernon's lead compounds both outperformed a lead drug called Cenicriviroc in both its NASH and CKD pre-clinical studies. Cenicriviroc is a lead candidate in later stage trials being developed primarily on the basis of its anti-fibrotic activity. The product placement for Algernon's compounds is noted in the diagram below.

<sup>&</sup>lt;sup>6</sup> Portillo-Sanchez P, Bril F, Maximos M, et al., "High Prevalence of Nonalcoholic Fatty Liver Disease in Patients With Type 2 Diabetes Mellitus and Normal Plasma Aminotransferase Levels." *The Journal of Clinical Endocrinology & Metabolism*, (2015): 100(6):2231-2238.



Additional benefits may arise from combining Algernon's compounds with other agents such as the peroxisome proliferator-activated receptor agonists or thyroid-stimulating hormone agonists.

## СКД

Currently, there is no known cure for CKD; however, according to the Mayo clinic, depending on the underlying cause, some types of kidney disease can be treated.

Treatment usually consists of measures to help control symptoms, reduce complications, and slow progression of the disease. If the kidneys become too severely damaged through fibrosis and progress to end-stage kidney disease, dialysis or a kidney transplant are the only interventions available.

The majority of drugs are used to treat the often associated high blood pressure (e.g. angiotensin converting enzyme inhibitors, ACE inhibitors: angiotensin receptor blockers, ARBs) in patients at risk of, or are developing CKD. The CKD market is growing, owing to an increasingly older population who are more susceptible to age related diseases such as diabetes and cardiovascular disorders. With respect to the latter complication, patients with chronic CKD often experience high levels of bad cholesterol, which can increase the risk of heart disease, thus cholesterol lowering agents are often prescribed to patients. Anemia is also a common complication of CKD and therapies such as erythropoietin is often prescribed.

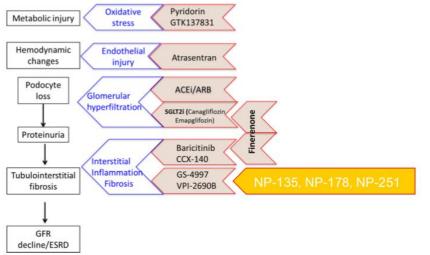
Algernon believes that its compounds NP-135, NP-160, NP-178 and NP-251, which all demonstrated anti-fibrotic activity in a commonly used model of CKD, are attractive candidates for development. None of the compounds appear to possess anti-hypertensive activity which is important to nephrologists who already have many effective, genericized blood pressure lowering agents available to them. The lead compounds discovered by Algernon were as effective or better than a moderate dose of Telmisartan, a prototypic angiotensin receptor blockers.

т	Pyridorin	Nephrogenyx	AGE inhibitor (bankruptcy)
2	GTK831	Genkyotex	NOX1/4 inhibitor
Т	Atrasentan	Abbvie	ET-1 inhibitor
3	Canagliflozine	181	SGLT1 inhibitor
3	Finerenone	Bayer	non-steroidal selective mineral corticoid receptor
2	Baricitinib	Incyte	JAK1/2 inhibitor (approved for RA)
2	CCX140	Chemocentryx	CCR2 inhibitor (on hold)
2	CTP-499	Concert	PDE inhibitor (out-licensed unknown status)
2	Seloncertib	Gilead	ASK-1 inhibitor (note Phase 3 NASH failure)
2	VPI-2690B	Janssen	alpha-5-beta-3 integrin-IGF-1 mAb
2	SER150	Serodus	TXA2-synthase and TX receptor antagonist
Legend: 2 = Phase 2 Trial 3 = Phase 3 Trial		ial 3 = Phase 3 Trial	T = Trial Terminated

CKD Phase 2/3 Compounds in Development (not Targeting CKD Complications, e.g. anemia)

# Product Positioning

Based on the data from the pre-clinical animal research models, the Company believes the product placement of its compounds are likely to be used in the later stages of the disease (post development of glomerulonephritis) where there are currently no approved therapies.



Semin Nephrol. 2016 Nov;36(6):436-447

#### IBD

The common symptoms of IBD include chronic pain and cramps in the abdomen, persistent diarrhea, occasional rectal bleeding, and fever. The exact cause of inflammatory bowel disease is not well understood and there is high prevalence and incidence rates of these diseases have been observed in developed countries.

Moderate cases of both UC and Crohn's are well served by 5-amino salicylic acid ("**5-ASA**") where remission can occur quickly. However, up to 50% of patients can eventually fail therapy. In the case of patients with moderate disease, next in-line treatment options include immunosuppressants and corticosteroids or TNF-alpha inhibitors. Both steroids and IMs can have an unfavourable safety profile, and in the latter case can take time to reduce disease severity. TNF-alpha inhibitors and other biological drugs (anti-a4b7 and IL-12/23) can be effective for severe cases, but patients can still fail biological therapy. In addition, the cost of biological drugs can be very high.

Interestingly, up to half of all Crohn's disease patients will develop disease complications, one which is development of fibrotic strictures (fibrostenosis), leading to GI tract obstruction and severe clinical consequences. Fibrostenosis is also a serious problem for UC with approximately 8% incidence over the lifetime.<sup>7</sup>

Currently, to the Company's knowledge, there is no clinical solution for preventing or treating fibrostenosis in patients with IBD, except for surgical intervention. Therefore, the Company believes, there is a great unmet need to understand fibrotic complications in IBD and how to prevent and treat them. Given the anti-fibrotic potential of NP-178, this is Algernon's lead compound for this disease

IBD Phase 2/3 Recent Approvals and Compounds in Development

#### **Ulcerative** Colitis

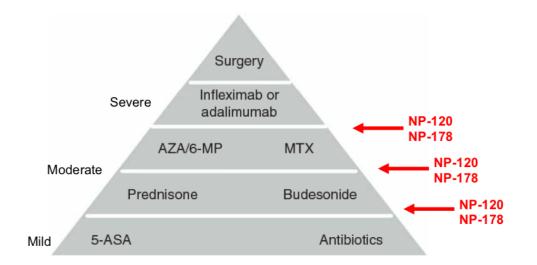
Μ	Tofactinib	Pfizer	JAK1 inhibitor mAb
3	Usteniumab	Janssen	IL-12/23 inhibitor mAb
3	AJM 300	Eisai	alpha-4-beta-7-integrin
3	Etrolizumab	Roche	alpha-4-beta-7-integrin mAb
3	Ozanimod	Celgene	S1PR1/5 inhibitor
3	Mirikizumab	Eli Lilly	IL-23 mAb
3	Risenkizumab	Abbvie	IL-23 mAb
3	Filgotinib	Galapagous	JAK1 inhibitor
3	Upadacitinib	Abbvie	JAK1 inhibitor

<sup>&</sup>lt;sup>7</sup> Mak JWY, Siew Chien N., "Epidemiology of fibrostenosing IBD" [published online ahead of print, 2020 Feb 27]. *Journal of digestive diseases*. 2020, 10.1111/1751-2980.12853.

3	TD-1473	Theravance	JAK1/2/3 inhibitor
2	Apremilast	Celgene	PDE4 inhibitor (approved for RA, Otezla <sup>®</sup> )
2	Etrasimod	Arena	S1PR1/4/5 inhibitor
2	Brazikumab	Allergan	IL-23 mAb
Legen	d: 2 = Phase 2 Tr	ial 3 = Phase 3 Trial	M = Approved & Marketed
Crohn	's		
М	Usteniumab	Jannsen	IL-12/23 mAb (Stelara®)
3	Etrolizumab	Roche	alpha-4-beta-7-integrin mAb
3	Ozanimod	Celgene	S1PR1/5 inhibitor
2	Guselkumab	Jannsen	IL-23 mAb
2	Risenkizumab	Abbvie	IL-23 mAb
Legend: 2 = Phase 2 Trial 3 = Phase 3 Trial M = Approved & Marketed			M = Approved & Marketed

## Product Positioning

Algernon has identified two orally available compounds, NP-178 and NP-120, that have shown activity in both UC and Crohn's preclinical models, with an efficacy profile similar (and in some end points better) than 5-ASA. NP-178 demonstrated anti-fibrotic effects in an animal model of CKD, which the Company believes could make it a clinically attractive candidate, should it demonstrate additional anti-fibrotic activity in clinical testing for IBD. Until clinical testing is completed and the efficacy of the product is known, the Company expects the product to be used in advance of steroids and immunosuppressants.



## **IPF & Chronic Cough**

IPF

IPF is a fatal disease involving scarring of the lungs. When diagnosed, patients typically have a 3-5 year life expectancy. The condition is rare and is considered an orphan disease. There are two approved treatments for IPF, Ninetdanib and Pirfenidione, although there are multiple drugs in clinical trials for IPF.

IPF is a type of interstitial lung disease in which the lung tissues are damaged, thereby reducing its oxygen delivering capacity. Increase in incidence of fibrotic diseases poses a high risk factor for IPF.

In addition, the Company believes that a rise in the geriatric population or a surge in the cigarette smoking population could boost the market growth, as could lung injury following COVID-19 infection.

One of the clinical problems with a subset of IPF patients is a persistent cough. To the Company's knowledge, no reliable data on the prevalence of cough in IPF exist. Some studies report that up to 80% of patients experience chronic cough; however, lower numbers are also reported.<sup>8</sup> The Company believed this may be attributed to the method of reporting and the definition of cough used (any cough *versus* disabling cough). When cough is present in IPF, it is severe and difficult to treat.

## *IPF Phase 2/3 Compounds in Development<sup>9</sup>*

Phase	Compound
3	Anticmicrobial Therapy
2	Autoantibody Reductive therapy
2	BLD-2660
2	CC-90001
2	Danazol
2	GB0139
2	GKT137831
3	GLPG1690
2	HEC 68498
2	IDL-2965
2	iNO
2	KD025
2	MN-001
2	ND-L02-s0201
3	Pamrevlumab
2	PLN-74809
2	PRM-151
2	Rituximab
2	RVT-1601
2	VAY736

<sup>&</sup>lt;sup>8</sup> Mirjam J.G. van Manen, et. al., "Cough in idiopathic pulmonary fibrosis", *European Respiratory Review*, Sep 2016, 25 (141) 278-286. <sup>9</sup> "Drug Development Pipeline - PF & IPF", *Pulmonary Fibrosis Foundation*, April, 2020, https://www.pulmonaryfibrosis.org/life-with-pf/clinical-trials/pipeline.

## Chronic Cough

Chronic cough is defined as a cough lasting for at least 8 weeks. In the general population it has a prevalence of 9% to 33% in the United States and Europe.<sup>10</sup> It is a frequent reason for seeking medical advice, with a high number of medical consultations.

Although at present, to the Company's knowledge, there are no approved treatments, Gefapixant recently reported positive Phase 3 data, but the drug causes issues of taste disturbance with a large fraction of patients.<sup>11</sup>

# Chronic Cough Phase 2/3 Compounds in Development

There are a number of drugs in development for chronic cough including TRP modulators, NK1 Antagonists, and P2X3 antagonists ranging from early pre-clinical to phase 3.

## Product Positioning

Algernon believes its NP-120 has an attractive profile in the treatment paradigm of IPF owing its ability to reduce fibrosis and cough frequency. The compound also has minimal known issues with respect to taste disturbance and diarrhea which affects up to 60% of patients taking Nintedanib.<sup>12</sup> Owing to the multi-year regulatory exclusivity afforded to orphan diseases, the preferred indication is IPF.

## COVID-19 as a Subset of ALI Patients

The initial ALI target of Algernon is COVID-19 related ALI. The recent outbreak of the COVID-19 pandemic has dramatically affected economies and strained health care systems. It is difficult to estimate the value of an effective therapy or vaccine based on the paucity of data.

Respiratory viruses, such as COVID-19, influenza and coronavirus can be highly infectious, and the subsequent lung injury can result in death or pulmonary fibrosis. Improvements with mechanical ventilation have improved ALI outcomes, but, to the Company's knowledge, there is currently no known approved therapy.

#### COVID-19 Phase 2/3 Compounds in Development<sup>13</sup>

Compound
Aviptadil
Azithromycin
Baricitinib
BMS-986253
CD24Fc
Clazakizumab

<sup>&</sup>lt;sup>10</sup> Van Manen MJG, Birring SS, Vancheri C, Cottin V, Renzoni EA, Russell AM, et al. "Cough in idiopathic pulmonary fibrosis." *Eur Respir Rev.*, 2016;25:278–86.

<sup>&</sup>lt;sup>11</sup> Nick Paul Taylor, "Merck hits goal in cough phase 3 but yet to quash tolerability concern", Fierce Biotech, March 17, 2020

https://www.fiercebiotech.com/biotech/merck-hits-goal-cough-phase-3-but-yet-to-quash-tolerability-concern.

<sup>&</sup>lt;sup>12</sup> Proesmans, V L J et al. "Self-reported Gastrointestinal Side Effects of Antifibrotic Drugs in Dutch Idiopathic Pulmonary Fibrosis patients." Lung vol. 197,5 (2019): 551-558. doi:10.1007/s00408-019-00260-1

<sup>&</sup>lt;sup>13</sup> "Drug Development Pipeline - PF & IPF", *Pulmonary Fibrosis Foundation*, April 17, 2020, https://www.pulmonaryfibrosis.org/life-with-pf/clinical-trials/pipeline.

2	CM4620
3	Colchicine
2	Convalescent Plasma
3	Dapagliflozin
3	DAS181
2	Favipiravir
2	Fluvoxamine
2	HAZCpaC
2	HELPCOVID-19
2	Hydroxychloroquine
2	Leonlimab
3	Lopinavir/Ritonavir/Hydroxychloroquine/Losartan
2	Losartan
2	Mavrilimumab
2	Nitric Oxide
2	PEginterferon Lambda
2	Povidone-Iodine
2	PUL-042
3	Remdesivir
2	Sarilumab
2	TJ003234
3	Tocilizumab
2	Tranexamic acid

#### Product Positioning

Algernon believes that NP-120 as it targets the NMDA receptor, a host target, may find broad use against many sources of ALI, including COVID-19. Its protective effect on host cells could in principal be applicable to future respiratory virus outbreaks, and complement anti-viral treatments, or be used while anti-viral treatments are being tested.

Algernon believes that NP-120 may find broad use against many sources of ALI, including COVID-19, as it targets the NMDA receptor, a host target. The Company believes that NP-120's protective effect on host cells could be applicable to future respiratory virus outbreaks, and complement anti-viral treatments, or be used while anti-viral treatments are being tested.

#### Intellectual Property – Drug Program

The Company's major assets revolve around a number of provisional patents that have been filed protecting its key scientific discoveries. Since all of Algernon's lead compounds are already genericized, all of the original composition of matter patents have expired. Prior to the selection of the initial 11 drug compounds that were selected for screening, an initial intellectual property search was conducted in order to gain insight on the intellectual property landscape for these compounds. Once the initial *in vivo* animal research studies were concluded for each disease, searches were conducted by two independent leading Canadian trade mark law firms confirming the suitability for filing new method of use patents. Once the searches were completed, method of use provisional patents were filed for all of the active compounds from each of the research studies

Where Algernon deemed it necessary, and based on intellectual property searches for NCEs, the Company has also taken each lead compound and has additionally filed a markush structure patent. This approach will minimize the risk of a third party trying to make small structural changes to Algernon's lead compounds and filing new composition of matter patents. This strategy was designed to help convince potential competitors that exploring a partnership or licensing agreement with the Company would be more productive that trying to compete by developing a new NCE program for derivatives developed around the core structure of the Company's lead compounds.

If the Company begins to synthesize any of its lead compounds for a phase III trial, some modifications to the drugs current formula may be made which could provide an opportunity to file additional formulation patents.

## Key Research Milestone Summary

- 1. November 1, 2018 Company Announces Positive Pre-Clinical Results Showing Lead Compound NP-160 Significantly Reduces NALFD Score and Fibrosis in Non-Alcoholic Fatty Liver Disease.
- 2. November 13, 2018 Company Announces Positive Pre-Clinical Results For Its Lead Compound NP-178 in Inflammatory Bowel Disease.
- 3. November 19, 2018 Company Announces Positive Pre-Clinical Results For Its Lead Compound NP-135 in Chronic Kidney Disease.
- 4. December 3, 2018 Company Announces Positive Pre-Clinical Results For Its Lead Compound NP-178 in a New Study for Crohn's Disease.
- 5. January 14, 2019 Company Announces Positive Pre-Clinical Results From a Second Study for Chronic Kidney Disease as well as two Additional Lead Targets.
- 6. January 21, 2019 Company Announces 84% Reduction of Fibrosis by Additional Lead Compound In Second Pre-Clinical Study For Non-Alcoholic Fatty Liver Disease.
- 7. February 25, 2019 Company Expands Its Research Program to Include Idiopathic Pulmonary Fibrosis.
- 8. April 1, 2019 Company announces NP-135 further demonstrated a 34.6% reduction of a key secondary marker of fibrosis, liver hydroxyproline.
- July 3, 2019 Company announced that NP-120, showed superiority in reducing fibrosis over two globally approved therapies for IPF, Pirfenidone and Nintedanib, in a well-established in vivo animal model study of IPF.
- 10. December 5, 2019 Company announced that NP-120 showed superiority over Gefapixant, Merck's lead phase 3 trial drug, in a well accepted acute cough in-vivo animal study.

## **Risk Assessment and Contingency Plan**

Circumstances may occur where the Company is not able to access currently available and approved finished product for any of its lead compounds, and or may not able to gain approval to conduct any phase II trials in markets where the current drug is approved. Should this occur, the Company will proceed to synthesize its lead compounds through a global cGMP contract manufacturer. The Company will conduct all of the pre-clinical toxicological testing required of a new NCE program, which could take up to 18 months. In addition, before a phase II study can begin with the new material, a phase I dosing study will need to be completed, which could take approximately six months to complete.

While this contingency approach is expected to add an additional 24 months to the product development timeline before a phase I trial can be conducted, the Company will have considerable flexibility to conduct a phase I trial in a number of geographical regulatory jurisdictions including in the U.S.

## **Employees**

As at the end of the Company's most recently completed financial year, August 31, 2019, the Company had no employees, other than the Company's executive officers. As at the date of this AIF, the Company has no employees, other than the Company's executive officers. The Company uses consultants for the provision of all management and other services.

## **RISK FACTORS**

The following are certain factors relating to the Company's business which prospective investors should carefully consider before deciding whether to purchase Common Shares in the Company's authorized capital. The following information is a summary only of certain risk factors and is qualified in its entirety by reference to, and must be read in conjunction with, the detailed information appearing elsewhere in this AIF. These risks and uncertainties are not the only ones the Company is facing. Additional risk and uncertainties not presently known to us, or that we currently deem immaterial, may also impair our operations. If any such risks actually occur, the business, financial condition, liquidity and results of our operations could be materially adversely affected.

## Limited Operating History

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

# Negative Cash Flow for the Foreseeable Future

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

#### Going-Concern Risk

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

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

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

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

- the Company's research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- the Company may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- the Company's product candidates may not succeed in pre-clinical or clinical testing;
- the Company's product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render the Company's product candidates obsolete or less attractive;
- product candidates the Company develops may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during the Company's program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

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

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

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

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

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

## Failure to follow regulatory requirements

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

## Additional financing needs

The Company will require equity and/or debt financing to support on-going operations, to undertake capital expenditures or to undertake acquisitions or other business combination transactions. There can

be no assurance that additional financing will be available to the Company when needed or on terms which are acceptable. The Company's inability to raise financing to fund capital expenditures or acquisitions could limit its growth and may have a material adverse effect upon its business, prospects, results of operations and financial condition.

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

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

## Intellectual Property Rights

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

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

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

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

The Company's clinical trials for each product candidate may fail to adequately demonstrate the safety and efficacy of that candidate, which could force the Company to abandon its product development plans for that product candidate. Before obtaining regulatory approval for the commercial sale of any of its product candidates, the Company must demonstrate, through lengthy, complex and expensive preclinical testing and clinical trials, that each product is both safe and effective for use in each target indication. Clinical trial results are inherently difficult to predict, and the results the Company has obtained or may obtain from third-party trials or from its own trials may not be indicative of results from future trials. The Company may also suffer significant setbacks in advanced clinical trials even after obtaining promising results in earlier studies.

Although the Company intend to modify any of its protocols in ongoing studies or trials to address any setbacks, there can be no assurance that these modifications will be adequate or that these or other factors will not have a negative effect on the results of its clinical trials. This could significantly disrupt the Company's efforts to obtain regulatory approvals and commercialize its product candidates. Furthermore, the Company may voluntarily suspend or terminate its clinical trials if at any time it believes that they present an unacceptable safety risk to patients, either in the form of undesirable side effects or otherwise. If the Company cannot show that its product candidates are both safe and effective in clinical trials, it may be forced to abandon its business plan.

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

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

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

- delays in obtaining regulatory approval to commence a trial;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- imposition of a clinical hold because of safety or efficacy concerns by the FDA, a data safety monitoring board or committee or by the Company;

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

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

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

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

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

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

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

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

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

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

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

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

- the Company may not have the ability to control the activities of its partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of drug candidates, in a timely manner or at all;
- such partners may not devote sufficient resources to the Company's drug candidates or properly maintain or defend our intellectual property rights;
- relationships with collaborators could also be subject to certain fraud and abuse laws if not structured properly to comply with such laws;
- any failure on the part of the Company's partners to perform or satisfy their obligations to the Company could lead to delays in the development or commercialization of drug candidates and affect the Company's ability to realize product revenue; and

 disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time-consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

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

## Rapid Technological Change

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

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

## Protection and Enforcement of Intellectual Property Rights

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

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

#### Litigation Risks

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

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

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

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

There is high potential that the Company will face intense competition from other companies, some of which can be expected to have longer operating histories and more financial resources and research and manufacturing than the Company. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Company.

At present, management believes that there are a number of drug development companies, on a global scale, that are advancing compounds for the treatment of NASH, IBD and CKD and are in various stages of development from pre-clinical up to and including Phase 3 human trials.

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

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

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

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

#### Reliance on Management

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

#### Dividends

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

#### Limited Market for Securities

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

#### Permits and Licenses

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

#### Uninsurable Risks

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

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

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

#### The lack of product for commercialization

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

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

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

## Risks Associated with Future Acquisitions

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

## Difficulty to Forecast

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

## Conflicts of Interest

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

## Global Economy Risk

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

## Public Health Crises, including COVID-19

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

## **DIVIDENDS AND DISTRIBUTIONS**

The Company has not paid dividends or made distributions on its Common Shares during the past three financial years and through the date of this AIF. The Company has no present intention of paying dividends in the near future. It will pay dividends when, as and if declared by the Board. The Company expects to pay dividends only out of retained earnings in the event that it does not require its retained earnings for operations and reserves. There are no restrictions in the Company's articles of incorporation or bylaws that prevent it from declaring dividends. The Company has no shares with preferential dividend and distribution rights authorized or outstanding.

## DESCRIPTION OF CAPITAL STRUCTURE

The Company's authorized share capital consists of an unlimited number of Common Shares without par value. As of the date of this AIF, there are 110,057,080 Common Shares issued and outstanding. Holders of Common Shares:

- have one vote per share on election of each director and other matters submitted to a vote of stockholders;
- do not have cumulative voting rights;
- have equal rights with all holders of issued and outstanding Common Shares to receive dividends from funds legally available therefore, if any, when, as and if declared from time to time by the Board; and
- are entitled to share equally with all holders of issued and outstanding Common Shares in all of our assets remaining after payment of liabilities, upon liquidation, dissolution or winding up of the Company's affairs.

## MARKET FOR SECURITIES

## Trading Price And Volume

On February 1, 2016, the Common Shares began trading on the CSE under the trading symbol "BTH". On February 19, 2019, the Common Shares commenced trading under the symbol "AGN" on the CSE. The table below sets forth the reported high and low closing prices and the aggregate volume of trading of the Company's Common Shares on the for each of the months (or, if applicable, partial months) indicated :

	CSE Price Range (\$)			
Month	High	Low	Total Volume	
September 2018	0.13	0.10	2,066,785	
October 2018	0.35	0.20	1,731,370	
November 2018	0.28	0.155	1,056,393	
December 2018	0.17	0.10	934,197	
January 2019	0.45	0.125	4,598,865	
February 2019	0.55	0.24	6,025,455	
March 2019	0.36	0.225	1,883,552	
April 2019	0.33	0.225	1,833,657	
May 2019	0.28	0.195	730,795	
June 2019	0.25	0.20	766,474	
July 2019	0.225	0.185	910,028	
August 2019	0.19	0.195	499,195	
September 2019	0.16	0.105	1,254,896	
October 2019	0.20	0.075	6,402,868	
November 2019	0.08	0.04	5,594,500	

	CSE Price Range (\$)		
Month	High	Low	Total Volume
December 2019	0.085	0.045	11,211,467
January 2020	0.09	0.055	6,157,129
February 2020	0.11	0.07	7,459,261
March 2020	0.35	0.085	71,222,746
April 2020	0.58	0.22	55,720,977
May, 2020	0.45	0.285	21,100,454

#### **Prior Sales**

During the financial year ended August 31, 2019, the Company issued the following securities exercisable into Common Shares.

		Number of securities	Exercise price per
Date of Grant	Class of security	issued	security
October 19, 2018	Warrants <sup>(1)</sup>	14,800,000	\$0.24
October 23, 2018	Warrants <sup>(2)</sup>	2,083,334	\$0.50
October 23, 2018	Finder's Warrants <sup>(3)</sup>	5,266	\$0.50

Notes:

- (1) Issued in connection with the Share Exchange Agreement to the security holders of Nash Pharma whereby existing warrants to purchase common shares of Nash Pharma ("Nash Pharma Warrants") were cancelled and were replaced with 14,800,000 Common Share purchase warrants ("Replacement Warrants") of the Company. The exercise price under each Replacement Warrant was equal to the exercise price under the particular Nash Pharma Warrant that was cancelled in consideration for such Replacement Warrant. The weighted average exercise price of these Replacement Warrants was \$0.24. Subsequent to the financial year ended August 31, 2019, 10,800,000 of these Replacement Warrants expired with a weighted average exercise price of \$0.21.
- (2) Issued in connection with the closing of a non-brokered private placement of 2,083,334 units at a price of \$0.24 per unit. Each unit consists of one Common Share and one warrant. Each warrant entitles the holder to purchase one Common Share until October 23, 2020 at the exercise price of \$0.50 per Common Share.
- (3) Issued in connection with the closing of a non-brokered private placement of 2,083,334 units at a price of \$0.24 per unit. Each finders' warrant entitles the holder to acquire one Common Share until October 23, 2020 at the exercise price of \$0.50 per Common Share.

Subsequent to the financial year ended August 31, 2019, the Company issued the following securities exercisable into Common Shares.

Date of Grant	Class of security	Number of securities issued	Exercise price per security
November 1, 2019	Warrants <sup>(1)</sup>	24,401,300	\$0.12
November 1, 2019	Compensation Options <sup>(1)</sup>	1,801,080	\$0.12
February 13, 2020	Incentive Stock Options <sup>(2)</sup>	4,375,000	\$0.10

February 20, 2020	Warrants <sup>(3)</sup>	18,304,939	\$0.12
February 20, 2020	Finder Warrants <sup>(3)</sup>	969,571	\$0.12
April 13, 2020	Incentive Stock Options <sup>(4)</sup>	4,550,000	\$0.29
May 13, 2020	Special Warrants <sup>(5)</sup>	19,605,285	\$0.35
May 13, 2020	Compensation Options <sup>(5)</sup>	1,505,293	\$0.35

Notes:

- (1) Issued in connection with the November 2019 Offering. See "General Development of Business Three Year History November 2019 Offering of Units".
- (2) Granted to directors, officers and consultants pursuant to the Company's stock option plan expiring on February 13, 2025.
- (3) Issued in connection with the February 2020 Offering. See "General Development of Business Three Year History February 2020 Offering of Units".
- (4) Granted to directors, officers and consultants pursuant to the Company's stock option plan expiring on April 13, 2025.
- (5) Issued in connection with the Special Warrant Financing. See "General Development of Business Three Year History Private Placement of Special Warrants".

## ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER

As at August 31, 2019, to the Company's knowledge, none of the Company's securities were in escrow or subject to a contractual restriction on transfer.

## DIRECTORS AND OFFICERS

#### Name, Occupation and Security Holding

The following table sets forth information regarding the Company's directors and executive officers. The term of office for the Directors expires at the Company's next Annual General Meeting.

Name, Province or State, and Country of Residence	Positions with the Company	Date of Appointment	Principal Occupation within the past five years	Common Shares Beneficially Owned or Controlled
Christopher J. Moreau Manitoba, Canada	Chief Executive Officer	March 1, 2018	CEO & Director of Miraculins from 2007 – 2016 CEO of Algernon 2018 to Present	750,000
Mark Williams Manitoba, Canada	Chief Science Officer	October 19, 2018	VP Research Diamedica 2011 – 2016 VP Research & Clinical Affairs Cerebra 2016 – 2018; Chief Science Officer of Algernon since October 2018	4,000,000 <sup>(2)</sup>

Name, Province or State, and Country of Residence	Positions with the Company	Date of Appointment	Principal Occupation within the past five years	Common Shares Beneficially Owned or Controlled
Raj Attariwala <sup>(1)</sup> British Columbia, Canada	Director	October 26, 2015	Radiologist at Aim Medical Imaging Inc. since 2009.	1,000,000
Michael Sadhra <sup>(1)</sup> British Columbia, Canada	Chief Financial Officer and Director	October 26, 2015	Chief Financial Officer of Micron Waste Technologies Inc. since 2016; Director of Gromax Resources Corp. since March 2019; Partner with Sadhra & Chow LLP since April 2009. CFO and Director of Algernon since October 2015	263,907
David Levine <sup>(1)</sup> British Columbia, Canada	Director	October 26, 2015	CEO of R1 Ventures since October, 2015; CEO of North America, Gaxys GmbH since July 2010. Vice President, Corum Group Since December 2015.	Nil

Notes:

- (1) Member of Audit Committee.
- (2) Shares held by a company for which Mr. Mark Williams is a director and officer.

As of the date of this AIF, the Company's directors and executive officers, as a group, beneficially owned, directly or indirectly, or exercised control of direction over 6,013,907 Common Shares, representing approximately 5.46% of the issued and outstanding Common Shares.

# CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

Other than set out below, no director or executive officer of the Company is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer of any company (including the Company), that:

- a) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer, or
- b) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days, that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and

which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

No director or executive officer of the Company, nor a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company:

- a) is, as at the date of this AIF, or has been within 10 years before the date of this AIF, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or
- b) has, within 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the proposed director.

No director or executive officer of the Company has been subject to:

- any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable security holder in deciding whether to vote for a proposed director.

## CONFLICTS OF INTEREST

The Company's directors and officers may serve as directors or officers, or may be associated with, other reporting companies, or have significant shareholdings in other public companies. To the extent that such other companies may participate in business or asset acquisitions, dispositions, or ventures in which the Company may participate, the directors and officers of the Company may have a conflict of interest in negotiating and concluding terms respecting the transaction. If a conflict of interest arises, the Company will follow the provisions of the BCBCA dealing with conflict of interest. These provisions state that where a director has such a conflict, that director must, at a meeting of the Company's directors, disclose his or her interest and refrain from voting on the matter unless otherwise permitted by the BCBCA. In accordance with the laws of the Province of British Columbia, the directors and officers of the Company are required to act honestly, in good faith, and the best interest of the Company.

To the best of the Company's knowledge, and other than disclosed herein, there are no known existing or potential conflicts of interest among the Company, its promoters, directors and officers or other members of management of the Company or of any proposed promoter, director, officer or other member of management as a result of their outside business interests except that certain of the directors and officers serve as directors and officers of other companies, and therefore it is possible that a conflict may arise between their duties to the Company and their duties as a director or officer of such other companies. If a conflict of interest arises at a meeting of the Board, any director in a conflict will disclose his interest and abstain from voting on such matter.

#### PROMOTORS

A "Promoter" is defined in the *Securities Act* (British Columbia) as a "person who (a) alone or in concert with other persons directly or indirectly takes the initiative of founding, organizing or substantially reorganizing the business of the issuer; or (b) in connection with the founding, organization or substantial reorganization of the business of the Company, directly or indirectly receives, in consideration of services or property or both, 10% or more of a class of the Company's own securities or 10% or more of the proceeds from the sale of a class of the Company's own securities of a particular issue.

No person or company has been, within the two most recently completed financial years or during the current financial year, a promoter of the Company or of a subsidiary of the Company.

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

#### Legal Proceedings

The Company is not, and was not during the most recently completed financial year, engaged in any legal proceedings and none of its property is or was during that period the subject of any legal proceedings. The Company does not know of any such legal proceedings which are contemplated.

#### **Regulatory Proceedings**

During the most recently completed financial year and during the current financial year, the Company is not and has not been the subject of any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority, any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor, or entered into any settlement agreements before a court relating to securities legislation or with a securities regulatory authority.

## INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as described elsewhere in this AIF, none of our directors, executive officers or shareholders, owning or exercising control or direction over more 10% of the Common Shares, or any associate or affiliate of the foregoing, has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year prior to the date of this AIF that has materially affected us or is reasonably expected to materially affect the Company.

## TRANSFER AGENTS AND REGISTRARS

The Company's Registrar and Transfer Agent is AST Trust Company (Canada), located at 1066, West Hastings Street, Suite 1600, Vancouver, British Columbia, V6E 2X1.

## **MATERIAL CONTRACTS**

Except for contracts entered into in the ordinary course of business, as of the date of this AIF, the only material contracts which the Company entered into within the most recently completed financial year, subsequent to the most recently completed financial year to the date of this AIF, or prior to the most recently completed financial year still in effect are set out below:

- Share Exchange Agreement. See "General Development of Business Three Year History Acquisition of Nash Pharmaceuticals Inc."
- Warrant Indenture dated November 1, 2019 between the Company and AST with respect to the November Offering. See "General Development of Business Three Year History Public Offering of Units".
- Agency Agreement dated May 13, 2020 between the Company and the Agent with respect to the Special Warrant Financing. See "General Development of Business Three Year History Private Placement of Special Warrants".
- Warrant Indenture dated May 13, 2020 between the Company and the Agent with respect to the Special Warrant Financing. See "General Development of Business Three Year History Private Placement of Special Warrants".
- Special Warrant Indenture dated May 13, 2020 between the Company and the Agent with respect to the Special Warrant Financing. See "General Development of Business Three Year History Private Placement of Special Warrants".

## **INTERESTS OF EXPERTS**

#### Names of Experts

The following are persons or companies whose profession or business gives authority to a statement made in this AIF as having prepared or certified a part of that document or report described in this AIF:

Smythe LLP is the external auditor of the Company and reported on the Company's audited consolidated financial statements for the years ended August 31, 2019 and 2018, which are filed on SEDAR.

To the knowledge of management, as of the date hereof, no expert, nor any associate or affiliate of such person has any beneficial interest, direct or indirect, in the securities or property of the Company or of an associate or affiliate of any of them, and no such person is or is expected to be elected, appointed or employed as a director, officer or employee of the Company or of an associate or affiliate thereof.

#### Interests of Experts

Smythe LLP, auditors of the Company, have confirmed that they are independent of the Company within the meaning of the 'CPABC Code of Professional Conduct' of the Chartered Professional Accountants of British Columbia.

#### ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com. Additional information, including directors' and officers' remuneration and indebtedness, the Company's principal shareholders, and securities authorized for issuance under equity compensation plans, if applicable, is contained in the Company's most recently filed management information circular available on SEDAR at www.sedar.com. Additional financial information is provided in our consolidated financial statements and management's discussion and analysis for the financial year ended August 31, 2019.