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**ARCH BIOPARTNERS INC.**

**MANAGEMENT DISCUSSION AND ANALYSIS:**

**FOR THE YEAR ENDED SEPTEMBER 30, 2022**

**DATED JANUARY 30, 2023**

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## Management's Discussion and Analysis

The following Management Discussion and Analysis (“MD&A”) should be read in conjunction with Arch Biopartners Inc’s (the “Company”) audited consolidated Financial Statements and related notes for the year ended September 30, 2022, which were prepared in accordance with International Financial Reporting Standards (“IFRS”) and comparative periods have been restated in accordance with IFRS where applicable.

The audited consolidated financial statements have been prepared in accordance with IFRS applicable to a going concern that contemplates the realization of assets and the payment of liabilities in the ordinary course of business. Accordingly, they do not give effect to adjustments that would be necessary should the Company be unable to continue as a going concern. In other than the normal course of business, the Company may be required to realize its assets and liquidate its liabilities and commitments at amounts different from those in the accompanying consolidated financial statements. The Company's viability as a going concern is dependent upon its ability to obtain adequate financing, the on-going support of its shareholders, affiliates, and creditors, and to achieve profitable levels of operation. It is not possible to predict whether financing efforts shall be successful or if the Company will attain profitable levels of operations.

These financial statements, along with additional information relating to the Company, is available by accessing the Canadian Securities Administrators’ System for Electronic Document Analysis and Retrieval (“SEDAR”) at [www.sedar.com](http://www.sedar.com).

## Forward-Looking Statements

This Management Discussion and Analysis contains forward-looking statements within the meaning of applicable Canadian securities laws regarding expectations of our future performance, liquidity and capital resources, as well as the ongoing clinical development of our drug candidates targeting the dipeptidase-1 (DPEP-1) pathway, including the outcome of our clinical trials relating to LSALT Peptide (Metablok), the successful commercialization and marketing of our drug candidates, whether we will receive, and the timing and costs of obtaining, regulatory approvals in Canada, the United States, Europe and other countries, our ability to raise capital to fund our business plans, the efficacy of our drug candidates compared to the drug candidates developed by our competitors, our ability to retain and attract key management personnel, and the breadth of, and our ability to protect, our intellectual property portfolio. These statements are based on management’s current expectations and beliefs, including certain factors and assumptions, as described in our most recent annual audited financial statements and related management discussion and analysis under the heading “Business Risks and Uncertainties”. As a result of these risks and uncertainties, or other unknown risks and uncertainties, our actual results may differ materially from those contained in any forward-looking statements. The words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We undertake no obligation to update forward-looking statements, except as required by law. Additional information relating to Arch Biopartners Inc., including our most recent annual audited financial statements, is available by SEDAR at [www.sedar.com](http://www.sedar.com).

## Corporate Structure Overview

Arch Biopartners Inc. (“Arch” or the “Company”) is incorporated under the Business Corporation Act (Ontario) with continuance under the Canadian Business Corporations Act.

On May 7, 2010, the Company was restructured into a biotechnology firm following a reverse takeover transaction involving three private Canadian biotechnology firms, all formed in 2009: Arch Biotech Inc. (Ontario), Arch Biophysics Ltd. (Alberta), and Arch Cancer Therapeutics Ltd (Alberta). The Company formed Arch Bio Ohio Inc. (Delaware) in 2014, Arch Bio Ireland Ltd. in 2016 and Arch Clinical Pty Ltd (Australia) in 2018 to facilitate future activity in the United States, Europe, and Australia respectively. Each of the six subsidiaries continue to operate as separate entities, though 100% owned, and consolidated for financial purposes. The status of each subsidiary is as follows:

**Arch Clinical Pty Ltd.** (Australia) was used in the past as a vehicle to conduct a Phase I human trial in Australia. This trial is complete, and this entity is dormant at present.

**Arch Bio Ohio Inc.** (Delaware) is an entity available to the Company for any US operations. Currently a dormant entity with no active operations.

**Arch Bio Ireland Ltd.** is a dormant subsidiary and was formed as a holding company to act as the holder of an orphan drug designation from the European Medicines Authority. This subsidiary has no active operations.

**Arch Cancer Therapeutics Ltd.** (Alberta) is a holding company for IP assignments. Currently no active operations.

**Arch Biophysics Ltd.** (Alberta) is a holding company for IP assignments. Currently no active operations.

**Arch Biotech Inc.** (Ontario) – IP holding company and no active operations.

The Company’s common shares are listed on the TSX Venture Exchange (“TSXV”) and trade under the ticker “ARCH”. The Company’s common shares trade in the U.S. on the OTCQB Venture Market under the ticker “ACHFF”.

The Company had 47,360,179 Common Shares outstanding as of May 7, 2010. As of the date hereinabove, the Company has 62,398,815 common shares outstanding. Please see ***Outstanding Share Data*** below for more information on the Company’s outstanding shares, warrants and options.

## Business Overview

Arch Biopartners Inc. is a portfolio-based biotechnology company focused on the development of innovative technologies that have the potential to make a significant medical or commercial impact. Arch works closely with the scientific community, universities, and research institutions to advance and build the value of select preclinical technologies, develop the most promising intellectual property, and create value for its investors.

At present, the Company is focused on the clinical development of its novel drug platform targeting dipeptidase-1 (DPEP-1) mediated organ inflammation in the lungs, liver and kidneys. Organ inflammation often results in organ damage or failure, including in the cases of sepsis and COVID-19. The Company's lead drug candidate is Metablok™ (also known as "LSALT Peptide").

LSALT Peptide completed an international Phase II trial targeting organ inflammation often experienced in hospitalized COVID-19 patients. Following this trial, LSALT Peptide entered the Canadian Treatments for COVID-19 Phase III trial (CATCO) in the first quarter of 2022. CATCO is a nationwide trial and is mainly funded by the Canadian Institutes of Health Research. CATCO is managed and sponsored by the Sunnybrook Research Institute and not Arch Biopartners management.

The Company continues to pursue the therapeutic development of LSALT Peptide and other DPEP-1 targeting drug candidates for non-COVID-19 indications where inflammation of the lungs, liver and kidneys is an unmet problem.

The goal of pre-clinical studies and all human trials testing LSALT Peptide is to produce data demonstrating safety and therapeutic efficacy in humans to support new drug approval by health authorities, such as the U.S. FDA, European Medicines Agency, and Health Canada ("Health Authorities"). Such drug approval is necessary to enable commercialization and future sales of LSALT Peptide.

The Company has additional technology platforms in its portfolio, currently not under active clinical or commercial development, namely: (i) AB569: an anti-infective candidate for treating or preventing antibiotic resistant bacterial infections, primarily as a topical treatment for wounds (ii) Borg: Peptide-Solid Surface Interface: a binding of proprietary peptides to solid metal and plastic surfaces to inhibit biofilm formation and to reduce corrosion; and (iii) MetaMx™: proprietary synthetic molecules that target brain tumor initiating cells and invasive glioma cells.

For more information on these programs not under commercial development at this time, please visit the Company's website at [www.archbiopartners.com](http://www.archbiopartners.com) or visit the Company's past disclosures at [www.sedar.com](http://www.sedar.com).

The Company owns, or has exclusive licensing rights on, the intellectual property ("IP") emanating from the programs listed above.

## Technology Overview

### I. Metablok™ (LSALT Peptide) - Lead DPEP-1 Inhibitor Drug Candidate

Metablok is a new peptide drug candidate and has emerged to be the lead opportunity among the Company's growing pipeline of DPEP-1 inhibitor drug candidates. Metablok is also referred to as "LSALT Peptide" or "LSALT" in Company communications, academic publications and with health authorities such as the U.S. FDA or Health Canada.

The Company is currently focused on executing the human trials required by the Health Authorities to produce sufficient human data to support new drug approval and future drug sales.

#### Scientific Background of LSALT Peptide

LSALT has the potential to be a breakthrough in the treatment of diseases where inflammation plays a major role. The inventors of LSALT published the details of the mechanism of action and efficacy of LSALT. The publication, titled "Dipeptidase-1 is an adhesion receptor for neutrophil recruitment in lungs and liver" by Choudhry et. al. was published by the journal *Cell* in August 2019 and can be found at the following link:

["Dipeptidase-1 is an adhesion receptor for neutrophil recruitment in lungs and liver"](#)

In February 2022, Arch scientists and their collaborators published a paper in the journal *Science Advances* describing the mechanism of action for dipeptidase-1 (DPEP-1) in acute kidney injury (AKI) in a pre-clinical study. Importantly, the study also confirmed the mechanism of action of two DPEP-1 inhibitors (the LSALT peptide and cilastatin) that effectively protected the kidney during ischemia reperfusion injury. These findings provide Arch with the scientific rationale to pursue a Phase II trial for LSALT and/or cilastatin targeting the prevention of cardiac surgery-associated AKI. The publication, entitled "Dipeptidase-1 governs renal inflammation during ischemia reperfusion injury" by Lau et al. can be found at:

["Dipeptidase-1 governs renal inflammation during ischemia reperfusion injury"](#)

LSALT was invented by Arch scientists led by Dr. Stephen Robbins and Dr. Donna Senger. The inventors have assigned the intellectual property related to Metablok to the Company. All the DPEP-1 inhibitors invented by the Arch team, including LSALT, are protected by composition patents held by Arch.

Cilastatin, for treatment of kidney inflammation, is protected by methods of use patents also held by Arch, or exclusively licensed to Arch.

#### Inflammation Based Disease

Inflammation is a localized physical condition that involves the activation of the immune system in response to infection, tissue injury, or autoimmunity. Inflammation is involved in the

pathogenesis of many diseases and contributes to organ dysfunction and failure, such as certain types of acute injury in the lungs, liver and kidneys.

## **Sepsis**

Sepsis is caused by the body's immune response to an infection. If the immune system activates too many white blood cells, or leukocytes, to fight an infection or defend against toxins, there is a risk of widespread, life-threatening inflammation termed "Sepsis".

Sepsis is known to cause inflammation and cause damage in organs. Blood clotting during Sepsis inhibits blood flow to organs, reducing their intake of nutrients and oxygen. In severe cases of Sepsis, one or more organs can fail. In the worst cases, infection leads to a dangerous drop in blood pressure, called septic shock, which can quickly lead to the failure of several organs such as lungs, kidneys, and liver, causing death.

Metablok has the potential to treat or prevent organ inflammation due to Sepsis.

## **COVID-19**

COVID-19 is the disease caused by the novel coronavirus SARS-CoV-2 that emerged in China in late 2019. Severe complications from COVID-19 are in large part due to excessive host immune responses to the virus that result in progressive lung inflammation and acute respiratory distress syndrome that often requires mechanical ventilation and critical care. Patients with severe COVID-19 also experience multiple organ dysfunction including acute kidney injury, liver dysfunction, cardiac failure, and blood abnormalities. Treatment of severe COVID-19 has been primarily supportive, relying heavily on respiratory, infectious diseases, and critical care medicine.

Survival rates and health care system capacity could both be improved with ongoing vaccination and new treatments that prevent the severe inflammation complications related to coronavirus variants and to a greater extent, in organ inflammation indications not related to the recent global pandemic.

## **Human Trial Development for LSALT Peptide**

New drug candidates such as LSALT Peptide must follow Health Authority regulations which dictate the general requirements for producing sufficient human safety and efficacy data to support new drug approval. In general, a new drug must show safety during in vivo non-human studies before safety and tolerability can be tested in humans in a clinical trial, commonly known as a Phase I trial.

Following a successful and safe Phase I trial, a Phase II trial is typically a human trial where the new drug candidate is tested to treat a specific disease in humans. Phase II trials typically involve a smaller number of sick patients, often less than one hundred. The goal of a Phase II trial is to

show a signal that the new drug is showing enough therapeutic efficacy to support a subsequent Phase III trial.

The Phase III trial usually involves a greater number of patients than the Phase II trial to confirm, with a high degree of statistical confidence, that the new drug shows therapeutic efficacy and safety in humans to warrant new drug approval from the Health Authorities.

The size of Phase III trials depends on the strength of the new drug's performance in the Phase II trial. Generally, drugs that show strong performance versus a placebo will require fewer patients in a Phase III trial, and those new drugs that show minimal benefit in a Phase II trial will generally require many more patients in a Phase III trial to confirm therapeutic efficacy and safety to support drug approval.

### *Phase I*

In pre-clinical studies, Arch scientists have demonstrated LSALT's ability to prevent acute kidney injury by blocking the inflammatory response triggered by ischemia/reperfusion and other insults to the kidney. The Arch team has similarly shown LSALT's ability to prevent acute inflammation injury to the lungs and liver in preclinical in vivo models. Currently, there are no specific or effective treatments to prevent acute organ injury caused by inflammation.

The Company completed initial toxicology, including a maximum tolerable dose and pharmacokinetic studies for LSALT, to support a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) in April 2018. The FDA members addressed questions from the Arch team and confirmed key components of a future IND application for Metablok.

Arch received approval during March 2019 from the Alfred Health Human Research Ethics Committee (HREC) in Melbourne, Australia to conduct a Phase I human trial for LSALT.

The Phase I human trial was a double-blind, placebo-controlled, randomized, single and multiple ascending dose study to evaluate the safety and pharmacokinetic profile of LSALT in 52 healthy, normal participants. The drug was well tolerated by all volunteers and no significant drug related adverse effects were observed.

The cost of this Phase I trial was very capital efficient at approximately \$1.0 million CAD, net of Australian Government research investment incentives.

### *Phase II*

In May 2020, Health Canada granted a *No Objection Letter* to Arch to conduct a Phase II trial to investigate LSALT's efficacy to prevent organ damage caused by inflammation in patients with COVID-19.



In June 2020, U.S. Food and Drug Administration (FDA) granted permission to the Company to proceed with a Phase II trial in the U.S. and an Investigational New Drug application was activated. The trial began October 2020, at a hospital site in Florida, which was followed by clinical trial sites elsewhere in the U.S., Canada, and Turkey. A total of 7 sites were activated into the trial, with two each in Canada and Turkey and three sites in the U.S.

In December 2020, the Company entered into a Contribution Agreement (CA) with the Canadian government. As part of the CA, the Company received a commitment to contribute up to \$6.7 million CAD to complete the Phase II trial and related activities to support drug approval. This funding represented up to approximately 75-80% of the Company's budget for the Phase II trial and came from Innovation Science and Economic Development (ISED) Canada's Strategic Innovation Fund (SIF), which is part of the Canadian Government's [Plan to Mobilize Science to Fight COVID-19](#).

The Phase II trial was an international, multicenter, randomized, double-blind, placebo-controlled, proof of concept study of LSALT Peptide as prevention of organ inflammation known to trigger acute respiratory distress syndrome (ARDS) and acute kidney injury (AKI) in patients infected with SARS-CoV-2 (COVID-19).

The composite primary endpoint reflected early global pandemic data from COVID-19 patients that showed the SARS-CoV-2 virus resulted in damage to organs besides the lungs and LSALT's potential to prevent inflammation injury in multiple organs. Studies have shown that COVID-19 results in mortality with AKI (Hirsch, *Kidney Int.* 2020) and mortality with cardiomyopathy (Akhmerov, *Circ Res.* 2020). Further, acute liver injury (Lee, *J Chin Med Assoc.* 2020) and thrombotic disease (Llitjos, *J Thromb Haemost* 2020) have resulted in poor outcomes in COVID-19 patients.

Secondary endpoints to measure the performance of LSALT included continuous measurements of respiratory, renal, hepatic, cardiac, and blood-clotting function throughout treatment and end of study, hospital stays (floor, ICU, and overall), 28-day mortality, and viral infection (clearance rate, SARS-CoV-2-specific immunoglobulins) compared between the active treatment arm and the placebo group. Exploratory endpoints included changes in cytokines between treatment arms and description of the pharmacokinetics of LSALT peptide.

Patient recruitment into the Phase II trial was completed at the end of April 2021 and the dosing of the final patients occurred in May 2021. A total of 65 patients were randomized into the trial with 61 patients receiving at least one dose of treatment.

## **Overview of Top-Line Phase II Results**

Sixty-one patients were enrolled in the study and randomized 1:1 to receive LSALT or placebo. Despite having older patients and having greater co-morbidities in the LSALT group, the unadjusted analysis of all patients in the trial demonstrated 22.8 ventilation-free days for the LSALT group compared to 20.9 days in the placebo group during the 28-day evaluation period. "Ventilation" was defined as a need for high flow oxygen therapy ( $\geq 6\text{L}/\text{min}$ ), non-invasive



ventilation, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Adjusting for age, body mass index (BMI), and PaO<sub>2</sub>/FiO<sub>2</sub> ratio (a measure of lung disease severity), the average number of ventilation-free days was 6.7 days less in the LSALT group of patients than the placebo group.

There were no unexpected differences in adverse events between LSALT and placebo treated patients. LSALT was well tolerated with no safety issues related to the drug. The exploratory study was designed to detect a clinical signal of efficacy and was not powered for statistical significance. Based on the promising clinical signal observed in the patients who received LSALT in the Phase II trial, 320 patients are scheduled to be dosed in the CATCO trial in order to detect a statistically significant difference.

The patients enrolled in both the placebo and drug groups of the Phase II trial, for the most part, did not experience AKI. This was consistent between all clinical sites in Canada, United States and Turkey.

Full details of the Phase II study are currently under consideration at a peer-reviewed scientific journal and will be released as soon as they are published.

*Phase II results also provide a first-ever signal towards validating Dipeptidase-1's role in the mechanism of action of organ inflammation in humans*

These Phase II results provide key human data which, in conjunction with extensive preclinical studies, further support DPEP-1 as a relevant therapeutic target for diseases of the lung, liver and kidney where inflammation plays a major role. In addition to evaluating LSALT as a treatment of inflammation complications experienced by hospitalized COVID-19 patients, Arch Biopartners intends to pursue its strategy to develop new DPEP-1 targeting drugs and clinical indications outside of COVID-19.

### **Entry into the Phase III Canadian Treatments for Covid-19 Trial**

In December 2021, the Company announced that LSALT Peptide would enter the Canadian Treatments for COVID-19 (CATCO) human trial, a multi-centre adaptive, randomized, open-label, controlled study being conducted in fifty-five hospitals across Canada as of the date hereinabove. The CATCO trial is taking place in conjunction with the World Health Organization's (WHO) SOLIDARITY trial, in collaboration with countries around the world and with support from the Canadian Institutes of Health Research (CIHR) funded COVID-19 Network of Clinical Trials Networks.

Usually, Phase III trials in the biotech and pharmaceutical industry can cost the sponsor of the trial millions upon millions of dollars. The Company did not pursue a financing to support the participation of LSALT Peptide in the CATCO trial due to the national funding sources already in place to complete the Phase III trial. This is highly unusual among biotech companies and represents a financial de-risking for the Company as LSALT participates in the Phase III CATCO trial.

Based on results of the Phase II study, the primary endpoint of the confirmatory Phase III clinical trial will be the difference in the number of respiratory support free days between study groups during the 28-day study period. The control group will receive standard of care and the drug group will receive standard of care plus LSALT. Based on the Phase II results, a total of 320 patients will be required in each study group to detect an unadjusted treatment difference of 3.35 days requiring ventilation with 90% statistical power.

Secondary endpoints include mortality, differences in outcomes involving other organs affected by COVID-19, such as kidney, liver, and heart function, time of hospitalization and intensive care stay, healthcare resource utilization, and late follow-up at 12 months post hospitalization.

Sunnybrook Research Institute (SRI) is the manager and sponsor of the CATCO trial. SRI has entered into a collaboration agreement with Arch Biopartners to use LSALT in a new arm of the CATCO trial. SRI and CATCO leadership have received ethics committee approval and Health Canada approval to commence the dosing of LSALT in the CATCO trial.

The Company's responsibilities during the trial include supplying LSALT drug vials to support the trial until completion. Arch completed the manufacturing of a new supply of vials during the summer and autumn of 2021 and has enough drug supply on hand for the 320 patients scheduled to be dosed in the CATCO trial. Arch is also responsible for a nominal fee payable to SRI for each patient recruited and dosed with LSALT Peptide. These costs are expected to be paid out of the Company's existing working capital as they arise.

As the CATCO Phase III trial is being run independently by Sunnybrook Research Institute, Arch is not in control of recruitment and trial progress. Further, the progress of the trial depends on the incidence of patients with severe complications from COVID treated in hospitals at any given time.

The past year saw a decrease in patients with severe complications of COVID-19 and very few patients on ventilators during 2022, not only in Canada, but around the world.

### **LSALT Peptide and a Potential Path to Drug Registration (Drug Approval)**

The path to drug approval for LSALT Peptide will depend on additional human data showing efficacy in preventing or treating organ inflammation. Such additional data may result from the CATCO trial, but likely will not, as recruitment depends on a waning pandemic in Canada at present and in the future.

As a result, Arch Biopartners is currently exploring opportunities to generate additional human safety and efficacy data for LSALT Peptide to support future drug approval from Health Authorities outside of the CATCO trial and the COVID-19 indication. One opportunity Arch management is exploring at present is to test LSALT peptide in a Phase II trial targeting the prevention of inflammation of the kidney and acute kidney injury in high-risk cardiac surgery patients.

At the present time, management of the Company believes it is not possible to responsibly forecast a budget for such a trial that has not yet been officially designed and confirmed. As a result, financing requirements and sources of financing cannot be accurately predicted at this time.

In the past, the Company has demonstrated and disclosed a consistent track record of keeping costs under control and maintaining a low burn rate of cash compared with many of its peers in the biotech industry. Cost control and capital efficiencies can only be disclosed once realized.

Future disclosure regarding the initiation, budgeting, and financing of a non-Covid-19 trial to generate sufficient human data to support future drug approval will be made only after such a trial is organized and approved to proceed by any of the Health Authorities.

### **Manufacturing of LSALT Peptide**

While LSALT peptide was part of the CATCO trial in 2022, Arch management was working to prepare new LSALT Peptide drug supply to enable future non-Covid related human trials.

During the calendar year 2022, including subsequent to the September 30, 2022 year end, the Company has been actively developing the manufacturing capability to produce LSALT Peptide at the standard required to enable phase II and III trials as well as future drug approval and commercial scale production.

In 2019, the Company produced LSALT Peptide with the US FDA and Health Canada standards required to support a Phase I trial. Once the COVID-19 pandemic ensued, the Health Authorities allowed the Company, on an urgent basis, to use the Phase I supply of LSALT Peptide to support the international Phase II trial to treat patients in hospital suffering from severe organ complications from Covid-19. Health Canada subsequently allowed the Company and the CATCO Phase III trial to also use the Phase I supply of LSALT peptide, again on an urgent basis.

Outside of the COVID-19 indication, the Company and its manufacturers, are required to abide by pre-pandemic regulations to produce LSALT Peptide drug substance and drug product with the necessary chemistry, manufacturing and control standards. These milestones are necessary to enable phase II and Phase III clinical trials, regulatory drug approval and commercial scale manufacturing for non-Covid indications.

In the past 12 months, the Company has successfully worked with a new U.S. contract manufacturing organization to produce Phase II/III drug substance. The Company continues to work with Dalton Pharma to increase LSALT Peptide drug product manufacturing capacity that will eventually support commercial scale production.

The most recent LSALT Peptide drug substance lot will be used in March 2023 to manufacture drug product for the planned Phase II clinical trial for cardiac surgery associated-AKI.

## Discussion Regarding Key Milestones

The Company is focused on the approval of its lead drug candidate, LSALT Peptide. Key milestones to achieve drug approval with the Health Authorities and pursue drug sale revenues will be determined by the performance of LSALT Peptide in a Phase III trial. If there is not enough patient volunteers for the CATCO trial due to dwindling hospitalizations of patients with severe lung complications from COVID-19, the Company intends to pursue a non-Covid indication to demonstrate sufficient safety and efficacy data to support drug approval.

Since there are no treatments to prevent cardiac surgery associated acute kidney injury caused by ischemia reperfusion injury, a potential milestone for the Company would be to demonstrate sufficient efficacy and safety of LSALT Peptide in preventing or treating AKI to warrant any of the Health Authorities to grant a faster regulatory path toward drug approval and drug sales. The actual path can only be determined by the specific health authority after such a trial is completed.

Contrarily, if LSALT Peptide does not show therapeutic effect in treating or preventing AKI, then the drug will likely not be approved by any of the Health Authorities. Please see **Risk Factors** of this management discussion and analysis for various risk factors that may inhibit LSALT Peptide from achieving drug approval and future drug sales.

## II. AB569: Treatment for Drug Resistant Bacterial Infections

AB569 is a novel drug candidate for treating antibiotic resistant bacterial infections. The first formulation of AB569 was designed for inhalation use to target infections in the lungs. It also has potential to be modified for use as a topical cream for preventing bacterial skin infections, including in wounds and burns.

AB569 has a mechanism of action that involves breaking down the defenses of the drug resistant bacteria. AB569 has patent protection on composition of matter. Arch has orphan drug status in the U.S. and Europe for the treatment of *Pseudomonas aeruginosa* infections in the respiratory tracts of patients with cystic fibrosis. Arch management has decided not to pursue this orphan drug indication.

As mentioned above, this program is not currently under commercial development by the Company as it focuses on supporting the development of LSALT Peptide and other DPEP-1 inhibitors.

## Financial and Operating Performance

The Company has not yet generated commercial revenue. During the year ended September 30, 2021, the Government of Canada awarded a contribution of up to \$6.7 million from the department of Innovation, Science and Economic Development (ISED) to support the Phase II development of LSALT (Metablok). This funding from the Strategic Innovation Fund (SIF) was part of the Canadian Government's [\*Plan to Mobilize Science to Fight COVID-19\*](#). The funding helped Arch

advance Metablok through the Phase II trial targeting the prevention of acute lung inflammation and other complications in hospitalized patients with moderate to severe cases of COVID-19.

The Company spent \$1,272,097 during the year related to clinical research which included the Company's share of CATCO trial expenses and supporting work to prepare non-Covid Phase II and III trials. This is a decrease from research expenses of \$3,777,744 (net of \$467,450 relating to Australian research and development credits) in the prior year when the company was incurring all of the costs of the Phase II trial for LSALT as a treatment for complications relating to Covid. Not including research and non-cash expenses, the Company spent approximately \$62,000 per month on patents, professional fees, operations and governance.

The total spending by the Company on research and clinical development during 2022 has decreased from the prior year. This is due to LSALT participating in the CATCO trial which is funded by third parties.

The current operations of the Company do not show a buildup of capital expenditures as any facilities used for continuing research and development to date have been owned by third parties.

Cash flow from operating activities totaled \$479,476 and the Company reported a net loss of \$1,407,857 for the year ending September 30, 2022.

## Results from Operations

	Sept 30 2022	Sept 30 2021	Sept 30 2020
Revenue	\$964,681	\$3,886,620	\$67,886
Expenses			
Research & development	1,272,097	3,777,744	1,958,513
Interest	309,333	273,307	175,962
General & administrative	747,640	890,810	840,301
Stock based compensation	24,976	109,604	1,727,194
	<u>2,354,046</u>	<u>5,051,465</u>	<u>4,701,970</u>
Income (loss) from Operations	(1,389,365)	(1,164,845)	(4,634,084)
Foreign Exchange Gain (Loss)	<u>(18,492)</u>	<u>(4,863)</u>	<u>5,426</u>
Income (Loss)	(1,407,857)	(1,169,708)	(4,628,658)
per share (basic)	(0.023)	(0.019)	(0.077)

The Company reported a *loss from operations* of \$1,389,365 for the year ended September 30, 2022 versus a *loss from operations* of \$1,164,845 for the year ending September 30, 2021.

The increase in operational loss year-over-year is mostly explained by the decrease in revenue due to the Canadian government contribution for the Covid-19 Phase II trial for LSALT described above. Total industry grant revenue decreased from \$3,886,620 during 2021 compared with \$964,681 during the year ended September 30, 2022.

Research expense decreased to \$1,272,097 from \$3,777,744 (net of \$467,450 relating to Australian research and development credits) a year earlier, as a result of the Company incurring the majority of the costs related to the Phase II human trial for Metablok in the 2021 fiscal year. The difference in research expense year over year reflects the lower costs associated with the passive participation in the CATCO trial which includes such things as supplying investigational drug supply of LSALT and clinical site setup. These items collectively are far less costly than incurring all of the costs associated with completing the Phase II trial to treat hospitalized Covid patients during the height of the pandemic.

Included in the research expense total for the year ending September 30, 2022, are some of the costs associated with manufacturing new drug supply and improving manufacturing standards. Manufacturing costs relating to LSALT Peptide for the year totaled approximately \$516,000, as the Company began to prepare the ability to commercially scale up manufacturing for future drug sales as well as meet the Health Authorities drug manufacturing requirements to conduct Phase II and Phase III trials outside of the Covid-19 indication.

The non-cash expense of stock-based compensation dropped to \$24,976 from \$109,604 a year earlier as the Company did not issue any new options to directors, officers, and other employees during the year due to various blackout periods in effect inside the Company throughout the year.

Interest on the Promissory Note was \$101,699 compared with \$100,164 a year earlier as the Company maintained the same short-term borrowing facility in 2021 it arranged with an arm's length party to help fund payment of research expenses related to clinical operations. Please see Note 15 of the 2022 Financial Statements for more details.

Interest on long-term debt increased to \$205,188 in 2022 compared with \$171,733 in 2021. The difference of interest year over year is the result of a timing difference in the interest accrued and amount paid to the lender. The Deferred Convertible Debt issued by the Company, remains at \$3,100,000, unchanged year over year. The Deferred Convertible Debt notes outstanding are accruing interest that is scheduled to be paid in common shares priced at the market at the time of settling the interest outstanding. Please see Notes 7 and 8 of the 2022 Financial Statements for more detail.

Patent expense decreased to \$195,463 versus \$258,666 in 2021 due to the decreased amount of patent work performed by the Company's U.S. patent lawyers during the year. There is no trend or seasonality associated with this decrease from the prior year. Management of the Company has increasingly allocated patent work to Canadian and European lawyers and decreased work with U.S. law firms, which may account for the decrease in patent expense in light of the US dollar strength during the past year.

Professional fees decreased to \$200,818 in 2022 from \$271,634 during 2021 due to decreased clinical development costs of Metablok during the CATCO trial. As well, new consulting contracts executed by the Company decreased with the reduction in clinical activities managed directly by Arch Biopartners during the 2022 fiscal year.



The remaining expenses associated with managing the Company, including regulatory and exchange fees, wages, and employee benefits, general and administrative expenses, and marketing, were similar to the prior year as the company maintained stable operating costs. The Company's net loss was \$1,407,857 for the year ended September 30, 2022, compared with a net loss of \$1,169,708 a year earlier.

Management of the Company expects to maintain a controlled cost environment for progressing the technology development projects. Management expects an increased pace of expenditures during the remainder of 2023 in order to advance certain proprietary technologies through additional clinical trials and toward viable commercial opportunities.

If deemed necessary, management of the Company will access capital markets to raise more funds to complement existing resources. Please see *Liquidity, Capital Resources and Cash Flows* below.

#### *Comment Regarding Operating Segments*

The annual consolidated Financial Statements for the year ending September 30, 2022, include the accounts of the Company and its subsidiaries. Each subsidiary is considered an operating segment for consolidation purposes. The Company and its subsidiaries represent one reporting segment as all activity is effectively in the same line of business.

#### **Selected Annual Information**

The following information is derived from, and should be read in conjunction with, the Company's Financial Statements and related notes, and has been prepared in accordance with IFRS. The Company's fiscal year end is September 30 and all values herein are in Canadian dollars.

	<b>Sept 30 2022</b>	<b>Sept 30 2021</b>	<b>Sept 30 2020</b>
Revenue	\$964,681	\$3,886,620	\$67,886
Income (Loss)	(1,407,857)	(1,169,708)	(4,628,658)
<i>per share (basic)</i>	<i>(0.023)</i>	<i>(0.019)</i>	<i>(0.077)</i>
Total Assets	621,641	2,668,255	741,301
Total Liabilities	5,092,233	6,550,663	4,609,405
Shares Outstanding (basic)	62,330,292	61,962,302	60,782,302

The Company currently is developing technology and commercial products. Until these products are sold or licensed, the Company is primarily incurring expenses.

The Company reported a net loss for the fiscal year ended September 30, 2022 of \$1,407,857 or \$0.023 loss per share based on 62,158,611 weighted average shares outstanding, versus a net loss of \$1,169,708 or \$0.019 a year earlier on 61,323,206 weighted average shares outstanding.

The Company has not yet paid any dividends.



**Fourth Quarter ending September 30, 2022**

	<b>Sept 30 2022</b>	<b>Sept 30 2021</b>
Revenue	\$(593,700)	\$1,868,457
Expenses		
Research & development	513,803	(868,267)
Interest	(104,149)	(92,060)
General & administrative	(271,844)	(229,412)
Stock based compensation	-	(12,488)
	<hr/> 137,810	<hr/> (1,202,227)
Income (loss) from operations	(455,890)	666,230
Foreign Exchange Gain (Loss)	(42,115)	(13,150)
Income (Loss)	<hr/> (498,005)	<hr/> 653,080
<i>per share (basic)</i>	<i>(0.008)</i>	<i>0.011</i>

The Company recorded a *loss from operations* of \$455,890 for the quarter ended September 30, 2022, versus a *gain from operations* of \$666,230 for the same quarter in 2021. The loss in the quarter is mainly the result of government contract reimbursements decreasing to \$(593,700) in the fourth quarter of 2022 from \$1,851,776 in the fourth quarter last year. The negative revenue amount of \$(593,700) reflects a fourth quarter adjustment to remove the final reimbursement from SIF in the same amount due to the related third party contractors, including contract manufacturers who completed their deliverables later than expected and subsequent to September 30, 2022. At the same time, the expenses for the final deliverables which are offset by the SIF receivable of \$593,700 have been removed as well, which explains the fourth quarter adjustment to research expense of positive \$513,803 for the quarter ending September 30, 2022. Subsequent to year end, the final deliverables have been completed and Arch management expects to book the final SIF reimbursement as a receivable when confirmed by SIF.

Research expenses for the fourth quarter of 2022 were \$(513,801) compared with \$868,267 a year earlier. The additional decrease independent of the adjustments explained above were the result of lower clinical trial costs (LSALT Peptide) incurred by the Company during the year as a result of third-party funding and management supporting the CATCO Phase III trial.

Patent expenses increased to \$143,168 during the quarter compared with \$121,496 in the same quarter last year. The decrease is attributable to timing differences of patent expenses and not a new trend in patent costs. On the entire year, patent expenses decreased by about 25% and on the whole is consistent with the activity level of the patent portfolio protecting the Company's new drug candidates.

The remainder of the expenses for the fourth quarter were otherwise similar year-over-year with no other significant differences to report.

The variations in revenue and income (loss) from quarter to quarter do not reflect any seasonality nor any pattern. The differences in loss are the result of increased or decreased research expenses

and/or non-dilutive funding events in any given quarter, depending on the level of clinical trial activity underway at the time.

### Selected Quarterly Information

The following table sets forth, for each quarter ended on the date indicated, information relating to the Company's revenue, net income (loss) per common share as prepared under IFRS.

All values in CAD

Quarter Ending:	Sept 30 2022 Q4	June 30 2022 Q3	Mar 31 2022 Q2	Dec 31 2021 Q1	Sept 30 2021 Q4	June 30 2021 Q3	Mar 31 2021 Q2	Dec 31 2020 Q1
Revenue	(593,700)	-	1,123,478	434,903	1,868,457	1,997,078	21,085	16,681
Income (loss)	(498,005)	(247,394)	(487,706)	(174,751)	653,080	881,969	(1,052,513)	(1,652,475)
Per share	(0.008)	(0.004)	(0.008)	(0.003)	0.011	0.014	(0.017)	(0.027)

*Based on weighted average shares outstanding as at quarter end*

### Liquidity, Capital Resources and Cash Flows

The Company's adjusted working capital surplus as at September 30, 2022 was \$132,207, adjusted to exclude the Deferred Convertible Debt notes maturing within the next 12 months and interest expense on the Deferred Convertible Debt, both converting into, and payable in common shares, respectively. This adjusted working capital surplus is a calculated number and does not have a formal definition according to IFRS but management feels it provides useful information to the user of the Financial Statements. Calculations of adjusted working capital are as follows:

	Year Ended		
	Sept 30 2022	Sept 30 2021	Sept 30 2020
Current assets	621,641	2,668,255	741,301
Current liabilities	2,779,434	3,189,019	1,218,994
Working capital surplus (deficit)	(2,157,793)	(520,764)	(477,693)
Adj. for: convertible debt	2,100,000	-	-
Adj. for: interest on convertible debt	190,000	424,767	269,767
Adjusted working capital surplus (deficit)	132,207	(95,997)	(207,926)

The Company's primary source of cash flow in the last two years has been from the contribution agreement with the Canadian Government department of Innovation Science and Economic Development (ISED) to support the Phase II development of LSALT (Metablok). This funding from ISED's Strategic Innovation Fund was part of the Canadian Government's [Plan to Mobilize Science to Fight COVID-19](#).

	<b>Year Ended</b>		
	<b>Sept 30 2022</b>	<b>Sept 30 2021</b>	<b>Sept 30 2020</b>
Cash from (used in) operating activities	479,476	(2,980,743)	(1,904,783)
Cash from (used in) investing activities	-	-	-
Cash from (used in) financing activities	(421,370)	2,775,300	2,158,100
Increase (decrease) in cash	58,106	(205,443)	253,317
Cash, beginning of period	448,242	653,685	400,368
Cash, end of period	506,348	448,242	653,685

In addition, the Company relies on the issuance of its own securities to fund much of its activities, as the Company has not generated positive cash flow from operations. Raising capital through the issuance of its own securities can be difficult or uncertain, depending on the state of the economy, the health of the stock market, restrictions on capital and liquidity due to crises, such as the global financial crisis of 2008-09 or the impact of the global COVID-19 pandemic.

In the next 6 to 12 months, management of the Company will consider accessing capital markets to raise more funds to complement existing resources and improve its cash position.

The Company has taken the following steps to improve liquidity and working capital since 2021 and subsequent to the year ending September 30, 2022:

- In December 2022, the Company issued 68,523 common shares at a price of \$2.94 to settle \$201,459 in total annual interest that accrued up to September 30, 2022, on all of the outstanding convertible notes. In February 2022, the Company issued 117,990 common shares at a price of \$3.60 to settle \$424,767.07 in total interest that accrued up to September 30, 2021, on all of the outstanding convertible notes. These notes originally were structured to have the interest paid by the issuance of common shares instead of cash payments and the issuance of such shares to settle the accrued interest was subject to TSXV approval.
- During the second and third quarters of 2022, a non-insider consultant exercised a total of 250,000 stock options for cash proceeds of approximately \$370,000 to the Company.
- During August and September 2021, three directors, one former director and two strategic advisors of the Company exercised a total of 500,000 stock options to purchase 500,000 common shares for proceeds of \$278,000 to the Company.
- During the third quarter ending June 30, 2021, the Company entered into a short-term financing agreement with an arm's length party. The note was in the amount of \$2.2 million and carries interest at 10% per annum for a term of up to 90 days. The purpose of the note was to reduce accounts payable until amounts were reimbursed from the government contract with SIF. (As described in note 14 of the Financial Statements.) In August 2021, the Company paid the lender a partial repayment and replaced the note with a new one of \$1.775 million, as described in Note 15 of the 2022 annual financial statements. In October 2021, this note was replaced with a new note for \$1 million following the repayment of 775,000 plus interest to the lender.

- On March 1, 2021, a consultant of the Company exercised a total of 100,000 stock options to purchase 100,000 common shares for proceeds of \$60,000 to the Company.
- On January 28, 2021, three directors of the Company exercised a total of 150,000 stock options to purchase 150,000 common shares for proceeds of \$67,500 to the Company.
- Company management has secured loans from Richard Muruve, the CEO, a director and a shareholder of the Company since January 2015. Proceeds of the loan were used to settle payables and ongoing expenses of the Company's operations when the Company had insufficient working capital. The Company agreed to pay 6% per annum paid semi-annually on the outstanding loan amount. As at September 30, 2022, the outstanding amount is \$260,532.

The Company's short- and long-term requirements to fund working capital have decreased significantly since the end of the Phase II trial of LSALT Peptide for the treatment of complications related to Covid-19. This Phase II trial was mostly funded by a contribution from Innovation Science and Economic Development Strategic Innovation Fund and as the trial came to an end, expenses for this Phase II trial ceased to be incurred. The claims reimbursed under the contribution agreement with the government matched the clinical expenses contained in the contracted budget for the Phase II trial plus related research and development work necessary to help support future drug approval. The funds from the contribution agreement with ISED were intended for these specific project tasks, and not for general working capital.

Working Capital funding requirements did not change as the Company's lead drug LSALT Peptide entered the national Phase III Canadian Treatments for Covid-19 trial (CATCO). This Phase III trial is funded mostly by the Canadian Institutes of Health Research (CIHR) and is sponsored and managed by the Sunnybrook Research Institute. As a result, the inclusion of LSALT Peptide in the CATCO trial does not significantly draw on the Company's working capital.

As of the date hereinabove, there are no new development activities that have been confirmed or approved that need to be funded at the present time. The Company continues to evaluate new non-pandemic clinical opportunities to produce additional human data showing efficacy and safety of LSALT Peptide to support future drug approval.

Management expects during the next 12 months to make additional expenditures of at least \$150,000 to protect intellectual property emanating from its R&D efforts. Management views this as vital to maintaining the Company's competitive position in developing new technologies for commercial use and to be able to fund development activities in the future. Exact amounts of future patent expense will depend on future success of technology development within the Company's subsidiaries.

Presently, the Company does not have significant sources of capital other than issuing new equity or receiving government contracts or research grants.

## Off-Balance Sheet Arrangement

### *Intellectual Property Transfer Agreements*

The university scientists in Arch contractually assigned ownership of current and future intellectual property relating to the Arch Biotech, Arch Biophysics and Arch Cancer Therapeutics' research projects to the Company. These IP assignments are irrevocable.

The Company has an exclusive licensing contract with the University of Calgary on potential future revenue emanating from the intellectual property produced at the University of Calgary relating to the dipeptidase-1 inhibition program. This exclusive license is legally binding and governs a future revenue sharing arrangement with the University of Calgary if the Company succeeds in obtaining drug approval from Health Authorities and begins to sell a drug such as LSALT peptide. The royalty contained in the exclusive licensing contract is within the expected range determined by industry standard. There are no other milestone payments in the exclusive licensing contract with the University of Calgary.

The Company has entered an exclusive licensing contract with the University of Cincinnati on the intellectual property relating to AB569. This exclusive license is legally binding and governs a future revenue sharing arrangement with the University of Cincinnati if the Company succeeds in obtaining drug approval from Health Authorities and begins to sell AB569. The royalty contained in the exclusive licensing contract is within the expected range determined by industry standard. There are no other milestone payments in the exclusive licensing contract with the University of Cincinnati.

Both licensing contracts with the Universities of Calgary and Cincinnati cannot be terminated unilaterally without cause and the Company is not aware of any event or uncertainty that may affect the availability of the benefits of the licensing arrangements.

This intellectual property and related licenses represent key assets of the Company.

## Transactions with Related Parties

The following were transactions with Related Parties during the last two years from the date hereinabove:

- In December 2022, the board of directors granted a total of 735,000 stock options to directors, officers, and certain consultants pursuant to the Company's stock option plan and the requirements of the TSX Venture Exchange (TSXV). The total grant of 500,000 options to the directors and officers (the related parties) represents remuneration for serving on the board and managing the Company's affairs for the annual periods ending April 1, 2022 and April 1, 2023. Each of the director and officer stock options is exercisable into one common share of the Company for a period of ten years. All the stock options issued to the related parties are exercisable at \$3.00 per share and will be subject to all necessary regulatory approvals.

- During August and September 2021, three directors, one former director and two strategic advisors of the Company exercised a total of 500,000 stock options to purchase 500,000 common shares for proceeds of \$278,000 to the Company.
- On January 28, 2021, three directors of the Company exercised a total of 150,000 stock options to purchase 150,000 common shares for proceeds of \$67,500 to the Company.
- Company management has secured a loan from a director, shareholder and CEO of the Company, Richard Muruve. The outstanding amount is approximately \$260,532 as at September 30, 2022. During January 2015 the Company agreed to extend this loan and to pay 6% per annum, paid semi-annually. These funds were used when the Company had insufficient working capital at various times to settle payables and ongoing expenses of the Company's operations. During the year ended September 30, 2022, \$16,300 was repaid and \$45,500 the prior year. Subsequent to the year ended 2022, a further \$50,000 was repaid in October 2022.

### Proposed Transactions

The Company does not have any proposed transactions as at the date of this MD&A.

For more information regarding past transactions, please consult *Corporate Structure Overview* above and the Company's public filings at [www.sedar.com](http://www.sedar.com).

### Outstanding Share Data

The table below sets out the outstanding share capital of the Company as at September 30, 2022 and as of the date of this MD&A:

Class of Security	As of the date of this MD&A	As of September 30, 2022
Common Shares	62,398,815	62,330,292
Convertible Debentures (underlying Common Shares)	3,781,945	3,781,945
Stock Options	5,335,000	4,600,000
Warrants	Nil	Nil

The Company is authorized to issue an unlimited number of common shares, where each common share provides the holder to one vote. At of the date of this Management Discussion and Analysis there were 62,398,815 common shares issued and outstanding.

As at the date of this MD&A, there were 5,335,000 stock options are outstanding, as follows:

<b>Stock Options</b>	<b>Quantity</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
	1,950,000	\$0.50	April 18, 2024
	100,000	\$1.36	June 1, 2024
	250,000	\$0.60	March 27, 2025
	200,000	\$1.48	June 11, 2025
	1,100,000	\$0.78	May 8, 2028
	20,000	\$1.25	May 16, 2029
	980,000	\$1.48	June 11, 2030
	735,000	\$3.00	December 15, 2032
	<b>5,335,000</b>		

On December 15, 2022, the Board of Directors authorized and disclosed in a December 15, 2022 press release the approval of 785,000 stock options and subsequently granted only 735,000 stock options as compensation to the Board, Management and several consultants and advisors for the years 2021 and 2022. 50,000 of the 785,000 approved stock options were cancelled. Please see *Transactions with Related Parties* for details on stock option transactions.

In addition, the Company had the convertible securities outstanding as detailed in Note 7 of the Financial Statements for the year ending September 30, 2022, which can be converted into 3,781,945 common shares, as follows:

<b>Convertible Series</b>	<b>Par Value</b>	<b>Exercise Price</b>	<b>Common Shares</b>
Note A	\$500,000	\$0.50	1,000,000
Note B	\$600,000	\$0.60	1,000,000
Note C	\$500,000	\$1.27	393,701
Note D	\$1,000,000	\$1.21	826,446
Note E	\$500,000	\$0.89	561,798
	<b>\$3,100,000</b>		<b>3,781,945</b>

### Share based payments

The fair value of share-based compensation expenses is estimated using the Black-Scholes option pricing model and rely on a number of estimates, such as the expected life of the option, the volatility of the underlying share price, the risk-free rate of return, and the estimated rate of forfeiture of options or warrants granted.

### Critical Accounting Estimates

This section is not required as the Company is a Venture Issuer, as the term is defined in National Instrument 51-102. Comments on accounting estimates are disclosed in the notes to the annual financial statements.



## Financial Instruments and Other Instruments

Please refer to Note 3 “**Summary of Significant Accounting Policies - *Financial Instruments***” and Note 5 “**Financial Instruments**” in the Company’s audited annual Financial Statements for the year ending September 30, 2022.

## Summary of Significant Accounting Policies

Please refer to Note 3 of the Company’s audited annual Financial Statements for the year ending September 30, 2022, for a **Summary of Significant Accounting Policies** and future accounting changes.

## Disclosure and Internal Controls

**As a venture issuer, Arch Biopartners management is not required to certify or include representations about the design and maintenance of Disclosure Controls & Procedures or Internal Control over Financial Reporting and none of the following comments should be so interpreted; however, in the interest of full disclosure, management wishes to include the following comments on Internal Control over Financial Reporting and Disclosure Controls & Procedures.**

In assessing Disclosure Controls and Procedures and Internal Control over Financial Reporting, readers are cautioned that a control system can only provide reasonable, not absolute, assurance that the objectives of the control system are achieved. Due to the inherent limitations in all control systems, an evaluation of controls cannot provide absolute assurance that all control issues, including instances of fraud, if any, have been detected. Inherent limitations include the possibility that the assumptions and judgments of management could ultimately prove to be incorrect under varying conditions and circumstances; or that isolated errors could prove to have a significant impact on the reliability of information.

Additionally, controls may be circumvented by the unauthorized acts of individuals, by collusion of two or more people, or by management override. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and it is not possible to provide complete assurance that a control system will succeed in achieving its stated goals under all potential future conditions.

## Risk Factors

An investment in the Common Shares of the Company should be considered highly speculative due to the nature of the business of the Company, consisting of research, development, and commercialization of patents for industrial products, pharmaceuticals or therapies for the treatment related of human diseases, as well the Company’s present stage of its development and its lack of operating history. In evaluating the business of the Company, readers should carefully consider the following risk factors; and additional risks not currently known to the Company as of the date

hereof may also impair future business operations of Company. The list below is not a definitive list of all risk factors associated with the business of the Company.

#### *Current Global Financial and Economic Conditions*

Current global financial and economic conditions remain uncertain and at times volatile due to the effects of the global pandemic, high global debt levels, inflation risks and political risks. Such factors may impact the Company's ability to obtain financing in the future on favourable terms or obtain any financing at all. Additionally, global economic conditions may cause a long-term decrease in asset values. If such global volatility, market turmoil and a global recession emerges, the Company's operations and financial condition could be adversely impacted.

#### *Risks Related to Clinical Stage Development*

The Company is currently at a clinical stage of development and subject to human trial risks, including among other things, the potential for its lead drug candidate to not show efficacy or safety in human patients, unforeseen cost increases, the potential emergence of superior new drugs from competitors and the unavailability of patients to recruit into a particular human trial. There is no guarantee that a successful human trial will result in future revenue.

#### *Risks Associated with Biomedical Research, Development and Product Commercialization*

The Company's growth and future success will be substantially dependent on its ability to develop, license or otherwise acquire new commercially viable patents and products and obtain related governmental approvals. Any failure in respect of the commercial viability of the Company's patents or failure to obtain related governmental approvals could result in a material adverse effect on the business, financial condition, and results of operations of the Company. The business of the Company is subject to significant and material risks that cannot be eliminated or adequately mitigated, even with careful and prudent planning and evaluation, experience, knowledge, and managerial and operational know-how. The Company will face a number of uncertainties. Development of intellectual property into commercially viable patents can oftentimes completely fail or be terminated at any stage in the research and development process, oftentimes after the expenditure of considerable financial resources.

Health Canada's Pharmaceutical Drugs Directorate (the "**PDD**") is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. The United States Food and Drug Administration (the "**FDA**") performs a similar function at the federal level in the United States. Prior to being given market authorization to sell products sold in the U.S. and Canada, respectively, the PDD and FDA must be presented with substantive scientific evidence of a product's safety, efficacy, and quality. Member states of the European Union and other nations may impose similar regulatory pre-approvals before products can be brought to market. Obtaining FDA, PDD and other regulatory and governmental approvals is extremely time consuming, requires a material amount of capital and subjects' products to thorough testing. The outcome of such regulatory applications can be unpredictable and yield unanticipated outcomes. The time involved, and the potential failure to obtain, FDA, PDD and other similar regulatory approvals

could adversely affect the Company's business plan, product pipeline, financial condition, and results of operations.

The Company may rely on the acquisition or licensing of other patents, products or technologies sourced from third parties. The use of such a strategy will draw down the Company's resources in connection with due diligence and expenses in identifying, evaluating, and negotiating joint venture or acquisition agreements. In addition, the licensing of patents, products, or technologies from third parties can involve significant counterparty contractual risk.

#### *Risks Related to Pre-Clinical and Clinical Trials*

Extensive preclinical and clinical trials (collectively "**Clinical Trials**") are required to commercialize the Company's pipeline of products, which involves, among other things, demonstrating safety and efficacy. Clinical Trials are capital intensive undertakings, take years to complete and can oftentimes yield unintended outcomes, including, among other things, harmful side effects that may delay or bar regulatory approval or limit commercial use of the product, if approved. The Company's future success will depend, to a significant degree, on obtaining successful outcomes to Clinical Trials. In general, Clinical Trials are risky, time-consuming endeavours and can oftentimes result in complete failure after material expenditures are made, especially where a novel use or chemical is proposed or tested, which can also increase the risk of harmful side effects. The Company's developmental pipeline may never evolve into commercially viable products if adverse outcomes or failures arise in connection with Clinical Trials. The scope, duration and number of Clinical Trials will vary according to the relevant governmental agency. Failure to obtain regulatory approval or successful commercialization of the product pipeline could result in a material adverse effect on the business and financial condition of the Company.

*The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials.*

The outcome of preclinical testing and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials. LSALT and any other product candidates we may develop may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. Numerous companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing authorization of their products. Furthermore, the failure of any product candidate to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of any other product candidates then under

development and/or cause applicable Health Authorities to require additional testing before approving any other product candidates.

*We may not achieve our projected development goals in the announced and expected time frames.*

From time to time, we set goals for and make public statements regarding the expectations for and timing of the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials, expected results, anticipated regulatory submission and approval dates, and timing of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in clinical trials, the uncertainties inherent in the marketing authorization process, and delays in achieving manufacturing or marketing arrangements sufficient to commercialize products. There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned, or that we will be able to adhere to our current schedule for the launch of LSALT or any other future product candidates we may develop. If we fail to achieve one or more of these milestones as planned, the price of our common shares would likely be adversely affected.

#### *Negative Results of External Clinical Trials or Studies*

From time to time, studies, or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors, or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's prescription drug product candidates, or the therapeutic areas in which the Company's prescription drug product candidates compete, could adversely affect its share price and the Company's ability to finance future development of its prescription drug product candidates, and its business and financial results could be materially and adversely affected.

#### *Completion of Clinical Trials*

As the Company's prescription drug product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and the Company may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect the Company's ability to enroll patients are largely uncontrollable and include, but are not limited to, the size and nature of the patient population, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, and the number, availability, location, and accessibility of clinical trial sites.

### *Reliance on Third Parties for Clinical Development Activities*

The Company relies and will continue to rely on third parties to conduct a significant portion of its preclinical and clinical development activities. For example, clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in its relationship with third parties, or if it is unable to provide quality services in a timely manner and at a feasible cost, the Company's active development programs will face delays. Further, if any of these third parties fails to perform as the Company expects or if their work fails to meet regulatory requirements, the Company's testing could be delayed, cancelled or rendered ineffective.

### *Risks Related to Marketplace Acceptance of the Resulting Issuer's Products*

The Company's product pipeline may appear promising but may ultimately fail to reach a defined market. Additionally, the Company's products may have limited or no commercial success. Market acceptance of the Company's products will be impacted by several factors, none of which (collectively or individually) can necessarily be eliminated, adequately mitigated or managed, even with careful and prudent planning and evaluation, experience, knowledge, and managerial and operational know-how. Such factors include, but are not limited to, the following (in no particular order): (i) timing of regulatory approvals, (ii) competition from more established firms, (iii) safety of the proposed product as compared to existing treatments, including the availability of alternatives, (iv) scope of approved use and marketing approval, (v) costs to produce the product and (vi) price.

### *Risks Related to Intellectual Property (Licenses, Patents and Proprietary Rights)*

The patent positions of other persons are oftentimes uncertain and tend to involve an examination of increasingly complex legal and factual questions. The patent situation outside the U.S. and Canada is even more uncertain. The business of the Company will be characterized by a significant amount of potential litigation risk in relation to patent defence and patent infringement claims. The success of the Company will depend upon its ability to protect its own intellectual property while simultaneously conducting its affairs in a manner that does not infringe upon the proprietary rights of others. Existing patent holders, or others, may seek to oppose or challenge some or the Company's entire portfolio of patents or may actively attempt to circumvent the Company's patents. Additionally, the Company may discover that existing patents may impede its ability to capitalize on the outcomes of its research projects. The Company can provide no assurances that it can successfully defend its patents and can provide no comfort that a court will ultimately uphold their validity. The costs of litigation, if any, may be material and may quickly strain the limited financial resources of the Company. In addition to cost any litigation could be time-consuming and place severe operational strains upon senior management team and technical personnel. The

loss of actual litigation, if any, could result in monetary damages being levied against the Company or subject the Company to an interlocutory or permanent injunction.

#### *Risks Related to Competition and Technological Change*

The biotechnology industry is extremely competitive and is subject to rapid and significant technological change which, among other things, places immense pressure on the business of the Company. The Company competes against other, more established research teams and firms who may be examining the same subject matter being researched by the Company. Many of the Company's competitors, which include, among others, major pharmaceutical and chemical companies, specialized contract research organizations, research-and-development firms, universities and other research institutions will have superior financial and operational resources and more experience in research and development. Competitors may develop new treatments or technologies that compete with the Company's products or even render the Company's technologies obsolete.

#### *Risks Related to Product Liability Claims*

Product liability claims may arise against the Company in connection with the testing and administration of pharmaceuticals, whether in Clinical Trials or commercially, and may arise regardless of whether the Company's product is at fault. In general, product liability claims may produce product recalls, result in protracted litigation, and could cause adverse publicity, any of which outcomes could adversely affect the regulatory approval process and/or cause a long-term decline in the value of the Common Shares. The defense of product liability claims (which oftentimes comes in the form of a class proceeding) can be extremely time consuming and costly, even against bogus claims, and may place significant strains on the financial resources of the Company. The Company does not carry any product liability insurance at this time but intends to do so as its business develops, and its product pipeline is commercialized. However, product liability insurance coverage is very expensive, is oftentimes difficult to obtain, may not be available on commercially reasonable terms or may be capped at certain thresholds, which may result in uninsurable risks to the Company. The Company can provide no assurances that product liability insurance, if any, will be obtained or if obtained will be adequate in scope.

#### *Management of Growth*

The Company may be subject to growth-related risks including pressure on its internal systems and controls. The Company's ability to manage its growth effectively will require it to continue to implement and improve its operational and financial systems. The inability of Company management to deal with this growth could result in a material adverse impact on its business, operations, and prospects. While management believes that it will make the necessary investments in infrastructure to process anticipated volume increases in the short term, the Company may experience growth in the scope of its operating and financial systems, resulting in increased responsibilities for the Company's personnel, the hiring of additional personnel and, in general, higher levels of operating expenses. To manage its current operations and any future growth effectively, the Company will also need to continue to implement and improve its operational,



financial and management information systems and to hire, train, motivate, manage and retain its employees. There can be no assurance that the Company will be able to manage such growth effectively, that its management, personnel, or systems will be adequate to support the Company's operations.

#### *Key Personnel*

The Company's business involves a high degree of risk, which a combination of experience, knowledge and careful evaluation may not be able to be managed or overcome. As such, the Company's success is dependent on the services of its senior management and the members of its Scientific Advisory Board. The loss of one or more of the Company's key employees or consultants could have a material adverse effect on the Company's operations and business prospects. In addition, the Company's future success will depend on its ability to attract and retain skilled technical, management and marketing personnel. There can be no assurance that the Company will be successful in attracting and retaining such personnel and the failure to do so could have a material adverse effect on the Company's business, its operating results as well its overall financial condition.

#### *Lack of Significant Product Revenue*

To date, the Company has generated little product revenue and cannot predict when and if it will generate significant product revenue. The Company's ability to generate significant product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop its prescription drug product candidates, obtain regulatory approval, and commercialize products, including any of its current prescription drug product candidates or other prescription drug product candidates that it may develop, in-license or acquire in the future. The Company does not anticipate generating revenue from the sale of products for the foreseeable future. The Company expects its research and development expenses to increase in connection with its ongoing activities, particularly as it advances its prescription drug product candidates through clinical trials.

#### *Negative Cash Flow and Absence of Profits*

The Company has not earned any operating profits from product sales to date and there is no assurance that it will earn any such profits in the future. The Company expects to continue to incur significant operating losses as continued development and clinical trials occur. Such losses are anticipated to have an adverse effect on shareholders' equity and working capital. The Company will need to generate significant revenues in order to achieve and maintain profitability and there can be no guarantees that profitability, if ever achieved, will be sustained.

The Company's ability to generate revenue in the future is dependent, in large part, on completing product development, obtaining regulatory approvals and successful commercialization and marketing of the Company's patents for pharmaceuticals or therapies for the treatment related of human diseases. The Company cannot provide any assurances that the products it may develop, or license will ever successfully commercialize or achieve revenues from sales. There can be no



assurance that future revenues will be sufficient to generate the required funds to continue in the biotechnology industry.

#### *Debt and Interest Risk*

The Company does not have any external debt other than the Deferred Convertible Debt described in Note 7 and Promissory Note described in Note 15. As previously mentioned, the Company has a loan of approximately \$260,532 outstanding from a director and a shareholder for working capital purposes.

Management of the Company does not consider this debt exposure to have material sensitivity to changes in interest rates.

#### *Currency Risk*

The Company is exposed to currency risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions and balances denominated in currencies other than the Canadian dollar.

The majority of expenses that are not hedged are currently in Canadian dollars. At the present time, the Company does not use any foreign exchange risk management tools such as currency forward or options contracts.

#### *No Anticipated Dividends*

The Company does not expect to pay dividends on its issued and outstanding Common Shares in the foreseeable future. If the Company generates any future earnings such cash resources will be retained to finance further growth and current operations. The Board of Directors of the Company will determine if and when dividends should be declared and paid in the future based on the financial position of the Company and other factors relevant at the particular time. Until the Company pays dividends, which it may never do, a shareholder will not be able to receive a return on his or her investment in the Common Shares unless such Common Shares are sold. In such event, a shareholder may only be able to sell his or her Common Shares at a price less than the price the shareholder originally paid for them, which could result in a significant loss of such shareholder's investment.

#### *Estimates or Judgments Relating to Critical Accounting Policies*

The preparation of financial statements in conformity with the International Financial Reporting Standards requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, as provided in the notes to the financial statements of the Company, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. The Company's operating

results may be adversely affected if the assumptions change or if actual circumstances differ from those in the assumptions, which could cause its operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the share price of the Company. Significant assumptions and estimates used in preparing the financial statements include those related to income tax credits receivable, share based payments, impairment of non-financial assets, fair value of biological assets, as well as cost recognition.

#### *Significant Future Capital Requirements, Future Financing Risk and Dilution*

No assurances can be provided that the Company's financial resources will be sufficient for its future needs. Current projections for revenues from operations are insufficient to meet the Company's future capital requirements. As such, the Company will likely be required to undertake future financings that may be in the form of a sale of equity, debt secured by assets or forward purchase payments. No assurances can be made that the Company will be able to complete any of these financing arrangements or that the Company will be able to obtain the capital that it requires. In addition, the Company cannot provide any assurances that any future financings will be obtained on terms that are commercially favourable to the Company. Any such future sale of Common Shares or other securities convertible into Common Shares will lead to further dilution of the equity ownership of existing shareholders.

#### *Market for the Common Shares*

There can be no assurance that an active trading market for the Common Shares will develop or, if developed, that any market will be sustained. The Company cannot predict the prices at which the Common Shares will trade. Fluctuations in the market price of the Common Shares could cause an investor to lose all or part of its investment in Common Shares. Factors that could cause fluctuations in the trading price of the Common Shares include: (i) announcements of new offerings, products, services or technologies; commercial relationships, acquisitions or other events by the Company or its competitors; (ii) price and volume fluctuations in the overall stock market from time to time; (iii) significant volatility in the market price and trading volume of companies commercializing similar pharmaceuticals; (iv) fluctuations in the trading volume of the Common Shares or the size of the Company's public float; (v) actual or anticipated changes or fluctuations in the Company's results of operations; (vi) whether the Company's results of operations meet the expectations of securities analysts or investors; (vii) actual or anticipated changes in the expectations of investors or securities analysts; (viii) litigation involving the Company, its industry, or both; (ix) regulatory developments; (x) general economic conditions and trends; (xi) major catastrophic events; (xii) sales of large blocks of the Common Shares; (xiii) departures of key employees or members of management; or (xiv) an adverse impact on the Company from any of the other risks cited herein.

### **Additional Information**

Additional information relating to the Company can be found on SEDAR at [www.sedar.com](http://www.sedar.com).