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**ARCH BIOPARTNERS INC.**

**MANAGEMENT DISCUSSION AND ANALYSIS:  
FOR THE QUARTER ENDED DECEMBER 31, 2021  
DATED MARCH 1, 2022**

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The following Management Discussion and Analysis (“MD&A”) should be read in conjunction with Arch Biopartners Inc’s (the “Company”) unaudited condensed interim consolidated financial statements and related notes for the three months ended December 31, 2021, 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 Arch Biopartners Inc, may be found on SEDAR at [www.SEDAR.com](http://www.SEDAR.com).

## **Disclosure Regarding Forward-Looking Statements**

This Management Discussion and Analysis contains forward-looking statements that involve various risks and uncertainties, including, without limitation, statements regarding the future plans and objectives of the Company. There can be no assurance that such statements will prove to be accurate. Actual results and future events could differ materially from those anticipated in such statements. These and all subsequent written and oral forward-looking statements are based on the estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. The Company assumes no obligation to update forward-looking statements should circumstances or management's estimates or opinions change; however, these risks may be detailed from time to time in Arch Biopartners Inc.'s public disclosures.

Arch Biopartners Inc.  
Management Discussion and Analysis  
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## ITEM 1 - Overview

### Company Profile

Arch Biopartners Inc. (“Arch” or the “Company”) 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 in the area of targeting dipeptidase-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** has completed an international Phase II trial targeting organ inflammation often experienced in hospitalized COVID-19 patients. LSALT peptide has recently been accepted into the Canadian Treatments for COVID-19 Phase III trial (CATCO) which is funded by the Canadian Institutes of Health Research. Health Canada provided CATCO a *No Objection Letter* in February 2022 to proceed with the dosing of LSALT peptide in a new arm of the CATCO trial.

Continuing ongoing development as a potential therapeutic product is AB569, an anti-infective candidate for treating or preventing antibiotic resistant bacterial infections, primarily as a topical treatment for wounds.

The Company has additional technology platforms in its portfolio, currently not under active development, namely: (i) 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 (ii) MetaMx™: proprietary synthetic molecules that target brain tumor initiating cells and invasive glioma cells.

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

### Formation of Arch Biopartners Inc.

Arch Biopartners Inc. 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 (“RTO”) involving three private Canadian biotechnology firms: Arch Biotech Inc., Arch Biophysics Ltd. and Arch Cancer Therapeutics Ltd. The Company formed Arch Bio Ohio Inc. in 2014, Arch Bio Ireland Ltd. in 2016 and Arch Clinical Pty Ltd in 2018 to facilitate future activity in the U.S., Europe and

Australia respectively. These six companies continue to operate as separate, 100% owned subsidiaries of the Company.

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 62,120,292 common shares outstanding. Please see ITEM 14 below for more information on the Company's outstanding shares, warrants and options

## Technology Overview

### I. Metablok™ - 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.

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 "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 of 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 of COVID-19.

## **Human Trial Plans for LSALT Peptide**

### *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.

### *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.

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.

### **Phase II Top-Line results and Canadian Treatments for Covid-19 Trial**

On December 1, 2021, the Company announced that LSALT peptide will 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.

Based on results of the Phase II study, the primary endpoint of the confirmatory 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 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.

### **Overview of Phase II results**

LSALT has entered the CATCO trial on the basis of a positive clinical effect observed in the Phase II trial completed earlier this year and funded in part by 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](#).

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  $\text{PaO}_2/\text{FiO}_2$  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.

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 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.

## **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. The AB569 topical cream is currently under development.

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 (CF).

### **Exclusive License with University of Cincinnati on Patents relating to AB569**

The Company has an exclusive license agreement with the University of Cincinnati (UC) for the commercial rights to the U.S. patents and patent applications protecting AB569 as an antimicrobial treatment of bacterial infections, including antibiotic resistant infections in the lungs and wounds.

## **ITEM 2 - Overall Performance**

The Company has not yet generated sales revenue. During the three months ended December 31, 2021 the Company spent approximately \$130,000 per month on research including human trial costs and approximately \$70,000 per month on patents, operations, and governance. The spending rate of the Company during the last quarter has been consistent with operations in prior quarters and the current period of lower clinical trial expenses following the completion of hospital activities in the Phase II trial for Metablok in 2021.

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. Lab expenditures to date have been predominantly funded through various research grants.

During the quarter ended December 31, 2021, cash flow from operating activities totaled \$1,039,014 and the Company reported a net loss of \$174,753.

### *Comment Regarding Operating Segments*

The annual consolidated financial statements for the year ending September 30, 2021 and the interim consolidated financial statements for the three months ending December 31, 2021 include the accounts of the Company and its subsidiaries. Each subsidiary is considered an operating segment. The Company and its subsidiaries represent one reporting segment as all activity is effectively in the same line of business.

## **ITEM 3 - Selected Annual Information**

This section is not applicable to the interim MD&A pursuant to Form 51-102F1 contained in National Instrument 51-102. To view selected annual information, please refer to the Company's annual financial statements for the year ended September 30, 2021, and MD&A filed on SEDAR at [www.sedar.com](http://www.sedar.com)

## **ITEM 4 - Results of Operations**

The Company reported a *loss from operations* of \$179,389 for the quarter ended December 31, 2021 versus a *loss from operations* of \$1,652,563 for the three months ending December 31, 2020.

The decrease in net loss during the quarter compared with the first quarter of 2020 is partly due to the increase in industry grants to \$434,903 from \$nil a year earlier. Net loss also improved by the reduction in research expenses to \$389,448 from \$1,307,505 in the first three months of 2020 as a result of a decrease in costs related to the Phase II human trial for Metablok, which was completed before the first quarter of fiscal year 2022.

There was also a decrease in share-based payments to \$12,488 during the quarter, down from \$84,628 in the first quarter last year, further improving the net loss year over year.

During the first quarter of 2022, the Company accrued interest on short term debt of \$26,904 versus \$nil for the same quarter a year earlier. This short-term financing agreement is with an arm's length party. The note is in the amount of \$1 million and carries interest at 10% per annum for a term of up to 90 days with a Company option to extend the term. The purpose of the note was to reduce accounts payable until amounts are received from industry grants as described in note 13 of the financial statements.

The remaining expenses associated with managing the Company, including patent costs, professional fees, wages and general and administrative expenses, were similar to the prior year as the company maintained stable operating costs. The resulting net loss was \$174,753 for the first quarter of 2022.

Management of the Company expects to maintain a controlled cost environment for progressing each of the technology development projects described in ITEM 2 - Overall Performance. Management expects an increased pace of expenditures during the next six to twelve months, if required, to advance certain proprietary technologies through new 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 ITEM 6 – Liquidity, for more information.

## ITEM 5 - Summary of Quarter Results

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:	Dec 31 2021 Q1	Sept 30 2021 Q4	June 30 2021 Q3	Mar 31 2021 Q2	Dec 31 2020 Q1	Sept 30 2020 Q4	June 30 2020 Q3	Mar 31 2020 Q2
<b>Revenue</b>	434,903	1,851,776	1,997,078	21,085	16,681	12,234	-	29,571
Income (loss) BEFORE discontinued operations	(174,753)	653,311	881,969	(1,052,513)	(1,652,475)	(1,610,013)	(2,190,259)	(95,343)
Income (loss) BEFORE other items	(174,753)	653,311	881,969	(1,052,513)	(1,652,475)	(1,610,013)	(2,190,259)	(95,343)
Per share	(0.003)	0.011	0.014	(0.017)	(0.027)	(0.027)	(0.037)	(0.002)
<b>Results Surrounding Extraordinary/Other Items:</b>								
Discontinued Operations	-	-	-	-	-	-	-	-
Extraordinary/Other Items	-	-	-	-	-	-	-	-
<b>Income (Loss)</b>	(174,753)	653,311	881,969	(1,052,513)	(1,652,475)	(1,610,013)	(2,190,259)	(95,343)
Per share*	(0.003)	0.011	0.014	(0.017)	(0.027)	(0.027)	(0.037)	(0.002)

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

## ITEM 6 - Liquidity

The Company's primary source of cash flow is from the issuance of its own securities, as it has not yet generated positive cash flows from its operations. Economic downturn, a weak stock market, restriction of global capital similar to the global financial crisis of 2008-09 or the current global COVID-19 pandemic are examples that could make it more difficult for the Company to raise money in the future if it so requires. 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's working capital deficit as at December 31, 2021 was approximately \$219,593 not including interest expense on convertible debt payable in shares. This working capital deficit 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.

The Company has taken the following steps to improve liquidity and working capital since 2020 and subsequent to the year ending September 30, 2021:

- 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 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 are received from industry grants as described in note 15 of the financial statements. In August 2021, this note was replaced with a new one of \$1.775 million, as described in Note 14 of the financial statements for the quarter ending June 30, 2021. 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.
- On December 29, 2020, the Company closed a non-brokered, private placement financing of USD \$500,000 (approx. \$645,000 CAD) by issuing 430,000 common shares at \$1.50 per share. These shares have a four month hold period from the close date and all investors are considered non-insiders to the Company.
- On December 15, 2020, the Government of Canada announced it will support Arch Biopartners for up to \$6.7 million CAD to help cover the costs of the Phase II trial for Metablok. The funding will be paid to Arch on a reimbursement basis as the Company incurs expenses for the trial and other related costs to support the clinical development of Metablok (LSALT peptide).
- On June 30, 2020, the Company closed a non-brokered, private placement financing of \$1,350,000 CAD by issuing 900,000 common shares at \$1.50 per share. These shares have a four month hold period from the close date and all investors are considered non-insiders to the Company.
- Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is \$261,244 as at December 31, 2021. During January 2015 the Company agreed to pay 6% per annum paid semi-annually on these funds. 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.

## **ITEM 7 - Capital Resources**

The Company is currently winding down the activities related to the Phase II human trial for Metablok as described in ITEM I herein. The Company has remaining commitments to contract

research organizations and various sub-contractors for approximately \$1,000,000 CAD in total to assist in closing out the human trial and complete various R&D studies currently under contract to support future human trials and potential commercialization efforts. The industry grants mentioned hereinabove will be used to mostly offset these commitments.

Management expects during the next 12 months to make additional expenditures of at least \$150,000 in the area of protecting intellectual property emanating from its subsidiaries. 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.

Management intends to pursue further clinical development of the Company's lead drug candidates when deemed ready and after sufficient capital has been secured to fund such costs.

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

## **ITEM 8 - Off-Balance Sheet Arrangement**

### *Intellectual Property Transfer Agreements*

The University of Calgary scientists in Arch contractually assigned ownership of current and future intellectual property relating to the Arch Biotech and Arch Cancer Therapeutics' research projects to the Company.

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 Metablok program.

The scientists of Arch Biophysics Ltd, the University of Alberta and the Company executed a similar intellectual property assignment to the Company for the rights to the Peptide-Solid Surface Interface.

The Company has entered an exclusive licensing contract with the University of Cincinnati on the intellectual property relating to AB569.

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

### *Scientist Engagement Contracts*

Scientists managing the Company's technology development within the Company's subsidiaries have executed scientist engagement contracts with the Company. Pursuant to the contracts, the scientists are obliged, among other things, to work on the Company's respective research programs

exclusively for the Company without detracting from their responsibilities as members of the university faculty.

## **ITEM 9 - Transactions with Related Parties**

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

- 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.
- During June 2020, the Company's Board of Directors approved a grant totaling 950,000 stock options to officers and directors of the Company, representing remuneration for serving on the board and managing the Company's scientific and business affairs during the 1-year terms ending April 1, 2020, and April 1, 2021 respectively. Each of the director and officer stock options is exercisable into one common share of the Company for a period of ten years, exercisable at \$1.48 per share.
- During January 2020, a director and officer of the Company exercised a total of 420,000 stock options to buy 420,000 common shares for proceeds to the Company of \$176,000.
- Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is approximately \$261,000 as at September 30, 2021. 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. \$45,500 was paid back to the lender during the year ended September 30, 2021.

## **ITEM 10 - Proposed Transactions**

The Company does not have any proposed transactions as at the date hereinabove.

For more information regarding past transactions, please consult the Company's public filings at [www.SEDAR.com](http://www.SEDAR.com)



## ITEM 11 - 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.

## ITEM 12 - 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, 2021 and the unaudited interim condensed financial statements for the quarter ending December 31, 2021.

## ITEM 13 - Other MD&A Requirements

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 62,120,292 common shares issued and outstanding. The following stock options and warrants are outstanding:

Type	Quantity	Exercise Price	Expiry Date
Stock Options	210,000	1.48	June 11, 2022
	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
Warrants		<b>NONE</b>	

Please see ITEM 6 – “Liquidity” and ITEM 9 – “Transactions with Related Parties” for details on the options.

In addition, the Company had the convertible securities outstanding as detailed in Note 7 of the financial statements for the quarter ending December 31, 2021.

## Summary of Significant Accounting Policies

Please refer to Note 3 of the Company's audited annual financial statements for the quarter ending December 31, 2021 for a summary of significant accounting policies and future accounting changes.

## Discussion on 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 fulsome 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.

## Business Risks and Uncertainties

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. 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.

*Debt and Interest Risk*

The Company does not have any external debt at the moment other than the deferred convertible debt described in Note 7 and short-term note described in Note 14. As previously mentioned, the Company has a loan of approximately \$261,000 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.

*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 Therapeutic Products Directorate (the "TPD") 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 TBD 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, TPD 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 often times be unpredictable and yield unanticipated outcomes. The time involved, and the potential failure to obtain, FDA, TPD 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.

#### *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 Resulting Issuer. 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.

#### *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.

*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.

*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. In order 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.

*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.

#### *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. A large number 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 actually 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.

#### *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 as its overall financial condition.

#### *Foreign Exchange Risk*

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.