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**ARCH BIOPARTNERS INC.**

**MANAGEMENT DISCUSSION AND ANALYSIS:**

**FOR THE YEAR ENDED SEPTEMBER 30, 2019**

**DATED JANUARY 28, 2020**

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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, 2019 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 has four technology platforms in its portfolio under development (each within its own subsidiary):

- **Dipeptidase-1 (DPEP-1) Inhibitors** – currently the Company’s lead platform targeting the enzyme DPEP-1. Lead drug candidate Metablok has the potential to treat or prevent DPEP-1 mediated organ inflammation which often results in organ damage or failure, including in the case of sepsis;
- **AB569** – a new drug candidate for treating or preventing antibiotic resistant bacterial infections, primarily in the lungs and wounds;
- **Borg: Peptide-Solid Surface Interface** – Binding of proprietary peptides to solid metal and plastic surfaces to inhibit biofilm formation and to reduce corrosion; and,
- **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 listing of the Company’s common shares moved from the Canadian Securities Exchange (“CSE”) to the TSX Venture Exchange (“TSXV”) on February 23, 2015 and trades under the ticker

“ARCH”. On May 16, 2018, the Company’s common shares began trading 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 59,882,302 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 library of DPEP-1 inhibitor drug candidates. Metablok is also referred to as “LSALT peptide” in Company communications, particularly with the U.S. FDA, other health regulatory bodies and committees.

Metablok has the potential to be a major breakthrough in the treatment of diseases where inflammation plays a major role, as well as in sepsis and cancer metastasis. The inventors of Metablok have recently published the details of the mechanism of action and efficacy of Metablok in the journal *Cell*. The publication, titled “*Dipeptidase-1 is an adhesion receptor for neutrophil recruitment in lungs and liver*” by Choudhry et. al. was published by *Cell* in August, 2019.

Metablok was invented by Arch scientists Dr. Stephen Robbins, Dr. Donna Senger, Dr. Jennifer Rahn and their University of Calgary colleague, Dr. Paul Kubes. The inventors have assigned the Metablok related intellectual property to the Company.

Arch is currently pursuing further clinical development of Metablok and is currently nearing the end of a Phase I human trial in Australia. The trial was designed to evaluate the safety and pharmacokinetic profile of Metablok. The clinical team has completed the planned dosing of 44 healthy, normal volunteers and no adverse effects were observed.

The Company is currently considering adding an additional cohort of eight more healthy, normal volunteers to evaluate the safety and pharmacokinetic profile of Metablok using the designated high dose, once a day, for three consecutive days. The same “high dose” was already tested in a cohort of eight volunteers for a single day and no adverse effects were observed.

### **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 kidney injury.

## Sepsis

Sepsis represents a large unmet medical need in the world today. Sepsis alone occurs in 1 to 2% of all hospitalizations in the US. It affects at least 700,000 individuals per year.

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

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

Permanent organ damage can occur in patients who survive sepsis. Under current standard of care, mortality rates are over 20% for sepsis and over 50% for septic shock.

## Human trial and Drug Application Plans for Metablok

In pre-clinical studies, Arch scientists have demonstrated Metablok's ability, among other successful pre-clinical inflammation studies in the liver and lungs, to prevent acute kidney injury by blocking the inflammatory response triggered by ischemia/reperfusion and other insults to the kidney. Currently, there are no specific or effective treatments to prevent acute kidney injury.

The Company completed initial toxicology, including a maximum tolerable dose and pharmacokinetic studies for Metablok, to support a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA).

Arch successfully completed this pre-IND meeting via teleconference in April, 2018, with members of U.S. FDA Division of Cardiovascular and Renal Products and the Office of Clinical Pharmacology. The FDA members addressed questions from the Arch team and confirmed key components of the planned IND application for Metablok.

Arch received approval during March, 2019 from the Alfred Health Human Research Ethics Committee (HREC) in Melbourne, Australia to start the Phase I human trial and the study is now nearing completion.

The Phase I human trial is a double-blind, placebo-controlled, randomized, single and multiple ascending dose study to evaluate the safety and pharmacokinetic profile of Metablok in healthy participants. A successful Phase I trial will be followed by a Phase II trial to investigate Metablok's efficacy in the prevention of acute kidney injury in cardiac surgery patients.

Currently, there are no specific or effective treatments to prevent acute kidney injury or kidney failure.

The Phase I trial serves as a precursor to future Phase II clinical trials to test Metablok's efficacy for several indications in different organs other than the kidney.

## **II. AB569: Treatment for Drug Resistant Bacterial infections**

AB569 is a new drug candidate for treating antibiotic resistant bacterial infections, primarily in the lungs. It also has potential to be modified for use in other indications, including adaptation as a topical cream for preventing bacterial skin infections.

AB569 has a mechanism of action that differs from the mechanism of action of antibiotics. 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).

### **Respiratory *Pseudomonas aeruginosa* Infections**

Two deadly diseases, cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD), are exacerbated by airway bacterial infections that significantly impact the overall quality of patient's lives. There are approximately 40,000 CF patients and over 14 million individuals diagnosed with COPD in the United States. In both diseases, antibiotic resistant Gram-negative bacteria, such as *Pseudomonas aeruginosa* (*P. aeruginosa*), often constitute a significant and problematic cause of the pulmonary exacerbations that result in frequent hospitalizations of these patients.

In particular, the mucoid form of *P. aeruginosa* is a very challenging infection to treat due to its high resistance to both antibiotics and phagocyte-mediated killing. Once patients present with the mucoid form of *P. aeruginosa*, their overall lung function precipitously declines resulting in a poor prognosis.

CF patients are predisposed to lung infections due to abnormal mucus production in the lungs and airways. *P. aeruginosa* infects 40% of CF patients between the ages of 6 and 10 years of age. By the age of 17, the frequency of infection increases to 60% and reaches approximately 70% of all CF patients between the ages of 25 and 34. Thus, there is an urgent clinical need for the development of novel effective treatments in this area.

AB569 constitutes an innovative, bactericidal method to potentially treat mucoid and nonmucoid *P. aeruginosa* pulmonary infections, as well as other types of bacterial pulmonary infections, that are resistant to traditional antibiotics.

The Company's AB569 is a non-antibiotic drug that could be a viable alternative or adjunct therapy to current standard of care antibiotics.



## **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.

Pursuant to the license with UC, the maintenance of issued patents and new patent applications relating to AB569 are being managed by the Company's patent attorneys in the U.S. at the Company's expense.

## **Orphan Drug Designation for AB569 for *P. aeruginosa* lung infections in Cystic Fibrosis**

In November 2015, Arch Biopartners received Orphan Drug Designation on AB569 from the U.S. Food and Drug Administration for the treatment of *P. aeruginosa* lung infections in CF patients.

The Orphan Drug Designation has been granted for the combination of two active ingredients of AB569: sodium nitrite and ethylenediaminetetraacetic acid (EDTA). AB569 is to be administered to the respiratory airways as a nebulized (inhaled) solution.

In pre-clinical studies, Dr. Daniel Hassett and his team at the University of Cincinnati demonstrated the potency of acidified sodium nitrite and EDTA in killing drug resistant bacteria including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Burkholderia cepacia* under both aerobic and anaerobic planktonic (free-living) and biofilm (surface-attached) conditions. These bacteria are among the most common pathogens to chronically infect the lungs of patients with chronic obstructive pulmonary disease (COPD) or cystic fibrosis (CF).

Arch formed an Irish based subsidiary, named Arch Bio Ireland Ltd, to sponsor and submit an orphan medicinal product application for AB569 to the European Medicines Authority (EMA), which was subsequently granted in 2016 by the European Commission for the treatment of patients with CF.

## **Human Trial Plans for AB569**

In April, 2017, Arch announced that the Cincinnati Veterans Affairs Medical Center (CVAMC) would conduct an investigator-initiated Phase I human trial in healthy volunteers to evaluate the safety and pharmacokinetic profile of AB569 as an inhalation drug candidate for treating antibiotic-resistant bacterial infections in the lungs.

The clinical team at CVAMC and Arch have since decided to first seek regulatory guidance from the FDA and to secure long term funding of future clinical development of AB569, before resuming clinical development of inhaled AB569. Such funding is not expected during the next year as the Company is focusing on the development of Metablok at the present time.

## ITEM 2 - Overall Performance

The Company has not yet generated revenue. During the year ended September 30, 2019 the Company spent approximately \$150,000 per month on research, all aspects of the Phase I human trial for Metablok, patents, product development, operations, and governance. This spending rate of the Company during the last year has been similar to the previous year due to the ongoing research expenses and clinical trial expenses incurred to advance the clinical development of Metablok..

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.

Cash flow used by operating activities totaled \$1,804,585 and the Company reported a net loss of \$2,357,611 for the year ending September 30, 2019.

### *Comment Regarding Operating Segments*

The annual consolidated financial statements for the year ending September 30, 2019 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

The Company's fiscal year end is September 30. The following information has been prepared in accordance of Canadian GAAP and all values are in Canadian dollars.

	<b>Sep 30 2019</b>	<b>Sep 30 2018</b>	<b>Sep 30 2017</b>
Revenue	\$93,876	\$nil	\$nil
Net Loss before extraordinary items	2,357,611	3,049,749	1,904,426
<i>per share (basic and fully diluted)</i>	<i>0.056</i>	<i>0.053</i>	<i>0.035</i>
Net Loss	2,357,611	3,049,749	1,904,426
<i>per share (basic and fully diluted)</i>	<i>0.04</i>	<i>0.053</i>	<i>0.035</i>
Total assets	567,981	855,090	67,938
Long term liabilities	2,885,137	1,440,354	Nil
Shares Outstanding (basic)	58,962,302	58,495,179	55,299,679

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

The Company reported a net loss for the fiscal year ended September 30, 2019 of \$2,357,611 or \$0.04 loss per share based on 58,646,338 weighted average shares outstanding, versus a net loss of \$3,015,820 a year earlier.

The Company has not yet paid any dividends.

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

The Company reported a *loss from operations* of \$2,362,030 for the year ended September 30, 2019 versus a *loss from operations* of \$3,049,749 for the year ending September 30, 2018.

The decrease in operational loss year-over-year is mostly explained by the decrease in non-cash, stock based compensation of \$1,049,602 during 2019. During 2019, the Company's board of directors did not authorize stock-based compensation to management, scientists or directors of the Arch board, unlike in the previous two fiscal years.

Research expense increased to \$1,574,946 from \$1,251,949 a year earlier, as a result of the Company incurring the costs of a phase I human trial for Metablok, which began during the year. Included in the research expense total are the final costs of clinical drug product development and drug product testing required before the phase I safety human trial for Metablok could begin.

Interest on long-term debt increased to \$108,062 in 2019 from \$63,154 in 2018 due to increased non-cash interest on \$2,600,000 of delayed convertible notes issued by the Company and outstanding at year end, compared with \$1,100,000 of the delayed convertible notes outstanding at the end of the 2018. Please see notes 7 and 8 of the 2018 financial statements for more detail.

Patent expense decreased to \$173,496 in 2019 versus \$216,787 a year earlier due to the decreased amount of patent work performed by the Company's patent lawyers during the year.

Professional fees increased to \$163,764 during 2019 from \$110,251 a year earlier due to increased financing and contractual activity by the Company and related legal oversight.

Regulatory and exchange fees increased to \$53,048 from \$35,366 a year earlier due to the increased financing activities by the Company during the year and the mandatory fees charged by securities commissions and exchanges for such financings.

Wages and employee benefits increased to \$172,089 from \$104,025 a year earlier due to the addition of a new scientist on the Arch team who was predominantly funded by a National Research Council—Industry grant awarded to the Company during the year. The increase in wages was correspondingly offset by the grant, noted as revenue on the income statement in the amount of \$93,876.

The remaining expenses associated with managing the Company, including 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 \$2,357,611 for the year.

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 remainder of 2020 in order to advance certain proprietary technologies through initial 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:	Sept 30 2019 Q4	June 30 2019 Q3	Mar 31 2019 Q2	Dec 31 2018 Q1	Sept 30 2018 Q4	June 30 2018 Q3	Mar 31 2018 Q2	Dec 31 2017 Q1
<b>Revenue</b>	64,348	29,528	-	-	-	-	-	-
Income (loss) BEFORE discontinued operations	(983,615)	(81,172)	(477,554)	(818,270)	(786,228)	(1,486,131)	(584,096)	(341,764)
Income (loss) BEFORE other items	(983,615)	(81,172)	477,554	818,270)	(786,228)	(1,486,131)	(584,096)	(341,764)
Per share	(0.016)	(0.001)	(0.009)	(0.014)	(0.006)	(0.026)	(0.011)	(0.006)
<b>Results Surrounding Extraordinary/Other Items:</b>								
Discontinued Operations	-	-	-	-	-	-	-	-
Extraordinary/Other Items	-	-	-	-	-	-	-	-
<b>Income (Loss)</b>	(983,615)	(81,172)	(477,554)	(818,270)	(786,228)	(1,486,131)	(584,096)	(341,764)
Per share*	(0.016)	(0.001)	(0.009)	(0.014)	(0.006)	(0.026)	(0.011)	(0.006)

\* 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 are examples that could make it more difficult for the Company to raise money in the future if it so requires. In 2019, 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 Sept 30, 2019, was approximately \$16,571. This 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.

The Company has taken the following steps to improve liquidity and working capital during 2018 and 2019 and subsequent to Sept 30, 2019:

- On January 24, 2020, a director of the Company exercised 420,000 stock options to purchase 420,000 common shares for proceeds of \$176,000 to the Company.
- During October and December 2019, certain directors of the Company and a consultant exercised a total of 500,000 stock options for proceeds of \$150,000 to the Company;
- During the quarter ending September 30, 2019, 300,000 warrants were exercised at \$0.50 per common share for net proceeds of \$150,000.
- On May 22, 2019, the Company closed a non-brokered, unsecured deferred convertible note financing for gross proceeds of \$1,000,000. The Note matures on November 22, 2019 and will be convertible, at the option of the holder, into common shares of the Company at a price per share of \$1.21 in the thirty-day period prior to the maturity of the Note. The Note bears interest of 5% per annum, which is payable in-kind by the Company with Common Shares to be issued at the then market price for the Common Shares and subject to TSX Venture Exchange approval in each instance. The holder has the option starting October 22, 2019 until November 21, 2019 to extend the term of the note another three years to November 22, 2022.
- On January 28, 2019, the Company closed a non-brokered, unsecured deferred convertible note financing for gross proceeds of \$500,000. The Note matures on January 24, 2022 and will be convertible, at the option of the holder, into common shares of the Company at a price per share of \$1.27 in the thirty-day period prior to the maturity of the Note. The Note bears interest of 5% per annum, which is payable in-kind by the Company with Common Shares to be issued at the then market price for the Common Shares and subject to TSX Venture Exchange approval in each instance. The holder has the option starting October 24, 2021 until December 24, 2021 to extend the term of the note another two years to January 24, 2024.
- During the quarter ending June 30, 2018, 665,500 warrants were exercised at \$0.50 per common share for net proceeds of \$332,750.
- On March 10, 2018, the Company announced it completed a non-brokered private placement offering of 2,500,000 common shares priced at \$0.50 per common share for gross proceeds of up to \$1,250,000 (the "Offering"). The Offering closed in two equal tranches of \$625,000 on February 2, 2018 and March 10, 2018 respectively and was subject to certain conditions including, but not limited to, the receipt of applicable regulatory approvals, including approval of the TSX Venture Exchange as well as the satisfaction of other customary closing conditions. All Common Shares issued in connection with the Offering are subject to a hold period of four months and one day from the closing date of each tranche.

- On February 15, 2018, the Company closed a non-brokered, unsecured deferred convertible note financing for gross proceeds of \$600,000. The Note matures on February 28, 2021 and will be convertible, at the option of the holder, into common shares of the Company at a price per share of \$0.60, in the thirty-day period prior to the maturity of the Note. The Note bears interest of 5% per annum, which is payable in-kind by the Company with Common Shares to be issued at the then market price for the Common Shares and subject to TSX Venture Exchange approval in each instance. The holder has the option until November 30, 2020 to extend the term of the note another two years to February 28, 2023.
- Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is \$285,137 as at September 30, 2019. 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 does not currently have any commitments to capital expenditures nor does it have any externally imposed capital requirements at this time.

Management expects during the next 12 months to make additional expenditures of at least \$100,000 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 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.

## **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 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 into 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 two years ending, and subsequent to, September 30, 2019:

- 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.
- During December, 2019, a director of the Company exercised a total of 350,000 stock options to buy 350,000 common shares for proceeds to the Company of \$105,000.
- During October, 2019, two directors of the Company exercised a total of 100,000 stock options to buy 100,000 common shares for proceeds to the Company of \$30,000.
- On March 19, 2019, a director and officer of the Company exercised 130,000 stock options expiring in October, 2019 to buy 130,000 common shares for proceeds to the Company of \$39,000.
- On May 8, 2018, the Company granted a total of 1,200,000 incentive stock options to its directors and officers pursuant to the Company's 2018 stock option plan. Each stock option is exercisable into one common share of the company for a period of ten years, exercisable at \$0.78 per share.
- Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is approximately \$285,000 as at September 30, 2019. 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. \$60,000 of the outstanding principal was paid back to the lender during August, 2019.

### **ITEM 10 - Fourth Quarter ending September 30, 2019**

The Company recorded a *loss from operations* of \$983,615 for the quarter ended September 30, 2019 versus a *loss from operations* of \$786,228 for the same quarter in 2018. The losses are the sum total of all research expenses, general and administrative expenses, patent expense, professional fees, research fees and regulatory fees associated with managing the Company in the ordinary course of its operations.

The majority of the increase in losses is the result of research expenses increasing to \$708,066 in the fourth quarter ending September 30, 2019, up from \$397,394 in the fourth quarter in 2018. As mentioned above, the Company has incurred greater human trial costs this year as a result of a first-time human trial for Arch and lead drug Metablok.

Revenue for the fourth quarter of 2019 was \$64,348 versus nil in the same quarter of 2018 as a result of the 2019 funding by the National Research Council—Industry Research Assistance Program.

The remainder of the expenses for Q4 were otherwise similar year-over-year with no other significant differences to report.

### **ITEM 11 - 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 12 - 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 13 - 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, 2019.



## ITEM 14 - 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 the date of this Management Discussion and Analysis there were 59,882,302 common shares issued and outstanding. In addition, the Company had the following convertible securities outstanding:

Type	Quantity	Exercise Price	Expiry Date
Stock Options	150,000	0.30	October 24, 2019 <sup>1</sup>
	300,000	0.45	January 28, 2021
	350,000	0.50	August 29, 2021
	100,000	0.60	March 15, 2023
	2,050,000	0.50	April 18, 2024
	250,000	0.60	March 27, 2025
	1,200,000	0.78	May 8, 2028
	75,000	1.24	June 20, 2021
	50,000	1.24	January 9, 2022
	20,000	1.25	May 16, 2029
Warrants		NONE	

\* Please see ITEM 6 – Liquidity, for details regarding the warrants. Please see ITEM 9 – Transactions with Related Parties for more details on the options.

<sup>1</sup> The group of options, originally expiring Oct 24, 2019, was extended and are still valid as of the date hereinabove, pursuant to TSX Venture Exchange Policy 4.4 - Incentive Stock Options"

## Summary of Significant Accounting Policies

Please refer to Note 3 of the Company's audited annual financial statements for the year ending September 30, 2019 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 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.

## **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. As previously mentioned, the Company has a loan of proximately \$285,000 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 extremely volatile. Several major international financial institutions and other large, international enterprises have either filed for bankruptcy or are being actively rescued by governmental intervention. Access to public and private capital and financing continues to be negatively impacted by many factors as a result of

the global financial crisis and global recession. 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 the global recession continue, the Company's operations and financial condition could be adversely impacted.

#### *Risks Related to Early Stage Development*

The Company is currently at an early stage of development and subject to start up risks, including start-up losses, lack and uncertainty of revenues, unproven markets for its products, risks in the commercialization process, lack of profitability and the need to raise additional funding.

#### *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 TPD 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 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 profits to date and there is no assurance that it will earn any 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.

### *Limited Operating History*

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

### *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 its overall financial condition.

#### *Foreign Exchange Risk*

The majority of expenses are now in Canadian dollars only. Less than 30% of the Company's expenses are denominated in US dollars.

At the present time, the Company does not use any foreign exchange risk management tools such as currency forward or options contracts.