



# ARCH BIOPARTNERS INC.

**MANAGEMENT DISCUSSION AND ANALYSIS:** 

FOR THE YEAR ENDED SEPTEMBER 30, 2015

**DATED JANUARY 28, 2016** 



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, 2015 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 <a href="https://www.SEDAR.com">www.SEDAR.com</a>.



## **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.



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## ITEM 1 - Overview

# **Company Profile**

Arch Biopartners Inc (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 five technology platforms in its portfolio under development (each within its own subsidiary):

- **AB569** a new drug candidate for the treatment of Pseudomonas *aeruginosa* infections in the respiratory tracts of patients with Cystic Fibrosis;
- **MetaMx**<sup>™</sup> proprietary synthetic molecules that target brain tumor initiating cells and invasive glioma cells;
- **MetaBlok**<sup>™</sup> a new drug candidate for the potential treatment of sepsis and cancer metastasis;
- Borg: Peptide-Solid Surface Interface Binding of proprietary peptides to solid surfaces to inhibit biofilm formation and reduce corrosion; and,
- **Arch Inflammation** Novel treatments for chronic kidney and bowel diseases caused by non-infectious inflammation.

Continuing product development work is ongoing at various third party facilities. The Company owns, or has exclusive licensing rights on, the intellectual property ("IP") emanating from the programs listed above. Both the University of Alberta and the University of Calgary became shareholders of the Company in return for their rights to future revenue from certain IP upon formation of Arch Biopartners in May 2010

The Company presently has an option to license the patents pertaining to AB569 from the University of Cincinnati. This option is described below in the section titled "Arch Biopartners Technology Overview", section IV.

# **Formation of Arch Biopartners**

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 take over transaction ("RTO") involving three private Canadian biotechnology firms: Arch Biotech Inc, Arch Biophysics Ltd. and Arch Cancer Therapeutics Ltd. These 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 under the ticker "ACH".

The Company had 47,360,179 Common Shares outstanding as of May 7, 2010. As of the date hereinabove, the Company has 53,189,679 common shares outstanding. Please see ITEM 13 below for more information on the Company's outstanding shares, warrants and options

# Arch Biopartners' Technology Overview

# I. AB569: Treatment for Respiratory Pseudomonas aeruginosa Infections

Two deadly diseases, cystic fibrosis (CF) and chronic obstructive pulmonary disease (COPD), are characterized by airway bacterial infections that significantly impact the overall quality of patient's lives. There are approximately 40,000 CF patients and some 14.2 million individuals diagnosed with COPD in the United States. In both diseases, the Gram-negative bacterium, *Pseudomonas aeruginosa* (*P. aeruginosa*), often constitutes 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 75% 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 treat mucoid and nonmucoid *P. aeruginosa* pulmonary infections that are resistant to traditional antibiotics.

## **Orphan Drug Designation for AB569**

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 cystic fibrosis (CF) patients.

The Orphan Drug Designation has been granted for the combination of two active ingredients of AB569: sodium nitrite and ethylenediaminetetraacetic acid. AB569 is to be administered to patients as a nebulized (inhaled) solution. AB569 was invented at the University of Cincinnati in the lab of Dr. Daniel Hassett.



The FDA Office of Orphan Products Development grants Orphan Drug Designation to drugs and biologics to encourage the development of new medicines for the safe and effective treatment of underserved, rare diseases or disorders that affect less than 200,000 patients in the U.S.

The Orphan Drug Designation qualifies Arch for a seven-year term of market exclusivity to sell AB569 in the U.S. following FDA approval of the drug. Additionally, as Arch takes AB569 through the regulatory and human trial process, the Orphan Drug Designation provides an accelerated review and approval process, potential grant funding, tax benefits and an exemption from certain user fees.

## **Human Trial Plans**

Arch Biopartners, d3 Medicine and Dr. Hassett's team at the University of Cincinnati are preparing to conduct a human trial to test the efficacy of AB569 for the treatment of *P. aeruginosa* lung infections in CF patients.

During 2015, AB569 successfully completed pre-clinical *in vivo* and *in vitro* validation studies. In all studies, AB569 has demonstrated significant efficacy against *P. aeruginosa*. This includes a recent study involving a chronic pulmonary infection model in mice.

The Arch team believes these results provide the scientific rationale for pursuing a human trial to test the safety and efficacy of AB569 for cystic fibrosis (CF) patients whose airways are chronically infected with *P. aeruginosa*. In this regard, Arch management is currently arranging the necessary toxicology program to support an Investigational New Drug Application for the first human trial for AB569.

## Option To License University Of Cincinnati Patents relating to AB569

In March 2015, the Company renewed a one year option agreement with the University of Cincinnati (UC) to exclusively license the commercial rights to the U.S. patent and patent applications protecting AB569 for treating bacterial respiratory infections.

Pursuant to the option to license with UC, these patent applications are being prosecuted by the Company's patent attorneys in the U.S. at the Company's expense.

In the fourth quarter of 2014, the Company incorporated a new U.S. subsidiary called Arch Bio Ohio Inc in the event that the Company exercises the option to license the University of Cincinnati patents relating to AB569.

## II. MetaMx<sup>TM</sup>

Arch Cancer Therapeutics Ltd. ("ACT"), was incorporated under the ABCA on November 19, 2009, to hold legal and beneficial title to the intellectual property produced by Dr. Stephen Robbins, Dr. Donna Senger and Jennifer Rahn of the University of Calgary in connection with a



project specializing in malignant glioma type brain tumours. The assets of Arch Cancer Therapeutics Ltd. presently consist of a patent issued by the United States Patent and Trademarks Office and patent applications filed with various Patent Cooperation Treaty ("PCT") countries.

# About MetaMx<sup>TM</sup> and Malignant Glioma

Worldwide, there are approximately 70,000 new patients with malignant glioma each year and clinical outcomes for these patients have not changed substantially over the past 30 years. Average survival rates, for adults with more aggressive glioblastoma multiforme, remain at a dismal 12-15 months and long-term survivors (i.e. those surviving more than 3 years) are rare.

This poor survival rate is linked to brain tumor initiating cells (BTICs) and invasive glioma cells which represent disease reservoirs that are not detectable using current diagnostic techniques as they are indiscernible from normal tissue. As a result, these cells are usually left behind in brain tissue post surgery and often lead to tumor relapse and poor patient outcomes.

Therefore, a significant unmet medical need and commercial opportunity lies in the ability to target BTICs and invasive glioma cells for the purpose of imaging, diagnosing and developing targeted therapies to improve patient outcomes and survival rates. MetaMx has been developed to meet these objectives.

Proofs of principle studies have confirmed that MetaMx<sup>TM</sup> effectively identifies human brain tumor disease reservoirs. Arch scientists have achieved the imaging of human BTICs and invasive glioma cells in mice using both magnetic resonance imaging and fluorescent imaging.

Arch continues to prepare for a human trial in patients with malignant glioma to characterize the safety and pharmacokinetics of MetaMx and to demonstrate the efficacy of MetaMx to cross the human blood brain barrier and detect BTICs and invasive glioma cells. Such results in human patients will increase the value of MetaMx not only as a diagnostic and imaging tool but also as a potential drug delivery platform to destroy BTICs and invasive glioma cells

Arch Biopartners is working with d3 Medicine to complete pre-clinical preparation. Pre-clinical tasks recently completed include confirmation of MetaMx chemistry, manufacturing and controls; planning of toxicology and regulatory strategy to pursue an Investigational New Drug application.

Leading the d3 team is Dr. Patrick Smith, D3's Chief Science Officer and former head of US Clinical Pharmacology for Roche. Dr. Michael Taylor, Founder and Principal at Non Clinical Safety Assessment, will be responsible for planning the toxicology needs of MetaMx.

Dr. Krishnan Viswanadha, will have the Regulatory Lead for MetaMx. Dr. Viswanadhan is Vice President of Advyzom, a leading regulatory affairs boutique consulting company.



## III. MetaBlok<sup>TM</sup>

In October of 2014, the Company acquired the rights to MetaBlok<sup>TM</sup>, a new drug candidate as a potential treatment for sepsis and cancer metastasis.

Sepsis and cancer metastasis represent large unmet medical needs 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.

Management of the Company believes MetaBlok<sup>TM</sup> has the potential to be a major break through in the treatment of both sepsis and cancer metastasis.

MetaBlok<sup>TM</sup> 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 intellectual property to the Company.

## **About Sepsis**

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.

#### **About Cancer Metastasis**

Cancer is a life threatening disease because of its ability to spread from its original tumour site to other tissues and organs in the body. This process of metastasis occurs through the bloodstream or lymphatic system.

Metastasis is of great importance since most of the cancer deaths are caused by spread of the primary cancer to other sites in the body. Recent evidence shows that 60% to 70% of patients have started the metastatic process by the time of diagnosis. Additionally, patients that do not have tumor spread at diagnosis are at risk for metastatic disease. New therapeutic treatments that protect patients against metastasis would be a major breakthrough in the treatment of cancer.



MetaBlok<sup>™</sup> is currently under pre clinical development.

## IV. Borg: Peptide –Solid Surface Interface

Arch Biophysics Ltd., was incorporated under the Alberta Business Corporations Act ("ABCA") on October 29, 2009, to hold legal and beneficial title to the intellectual property produced by Dr. Randall Irvin and his co-inventors at the University of Alberta in connection with a new technology. The assets of Arch Biophysics Ltd. presently consist of patents and patent applications filed with the United States Patent and Trademarks Office and PCT countries.

Arch Biophysics' lead technology is "Borg", a library of peptides that bind strongly to non-biological solid surfaces to:

- i) Reduce corrosion of various metals
- ii) Inhibit bacterial attachment to the surfaces of various materials, particularly medical materials; and,
- iii) Improve the biocompatibility of medical devices/implants.

The Company intends to develop these applications toward commercial use since they address important unmet medical and industrial challenges.

On February 24, 2015 and August 4, 2015, the United States Patent and Trademark Office issued patent numbers 8,961,984 and 9,096,775 respectively and both titled "Surface Coated Structures and Methods" protecting claims in the areas above.

## V. Arch Biotech (or "Arch Inflammation") Technology Developments

Arch Biotech's lead technology platform is called Arch Inflammation ("AI"). AI is developing anti-inflammatory small molecules that target proteins in the innate immune system.

Sterile inflammation (i.e. inflammation not caused by an infection or microbe) is a significant component of most chronic diseases. Chronic inflammation associated with disease often leads to a cycle of ongoing injury, progressive scarring and organ damage. For example, in both the gastrointestinal tract and in the kidney, the nature of the injury or inflammation determines which patients recover and which patients go on to develop chronic kidney failure or inflammatory bowel disease. The innate immune system represents a relatively new group of pathways that are involved in sterile inflammation and the tissue response to injury. Many of these pathways are implicated in a wide variety of chronic diseases and represent an attractive therapeutic target.

The AI team continues to work toward developing new drug candidates and technologies that target and block inflammation pathways.



## **Disposal of Shares in Colorado Cancer Therapeutics Inc**

Arch Biopartners Inc. formed an American subsidiary in late 2010, Colorado Cancer Therapeutics Inc ("CCT") with two University of Colorado ("CU") scientists. The Company owned 2/3s of CCT with the remainder owned by the scientists.

CCT acquired an option to enter into an exclusive license to commercialize specific pre-clinical, anti-cancer compounds invented at the University of Colorado and Emory University. The Company did not exercise the option before January 1, 2012 and did not seek an extension. CCT has been inactive since this time without any assets or liabilities.

The Company sold its entire interest in CCT to the lead CU scientist for nominal consideration on August 28, 2014.

## **ITEM 2 - Overall Performance**

The Company has not yet generated revenue. During the year ended September 30, 2015 the Company spent approximately \$40,000 per month on patents, product development, operations, and governance. This spending rate of the Company during the last year has been greater than previous years due to increases in patent expenses; one time fees related to listing on the TSXV; accelerated R&D expenses; and, preparing for upcoming human trials for AB569 and MetaMx.

The current operations of the Company do not show a build up capital expenditures or significant research and development expenses, 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 \$474,816 and the Company reported a net loss of \$839,004 for the year ending September 30, 2015.

Comment Regarding Operating Segments

The annual consolidated financial statements for the year ending September 30, 2015 include the accounts of the Company and its four 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.

	Sep 30 2015	Sep 30 2014	Sep 30 2013
Revenue	\$37,641	\$51,125	\$0
Loss before extraordinary items	839,004	398,507	189,950
per share (basic and fully diluted)	0.016	0.008	0.004
Net Loss	839,004	398,507	189,950
per share (basic and fully diluted)	0.016	0.008	0.004
Total assets	649,504	405,791	36,826
Long term liabilities	Nil	Nil	Nil
Shares (basic and fully diluted)	53,189,679	50,975,179	48,260,179

The Company shows revenue for the fiscal years ending September 30, 2014 and 2015 as a result of industry related grants. 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, 2015 of \$841,054 or \$0.016 loss per share based on 52,541,679 weighted average shares outstanding, versus a net loss of \$398,507 a year earlier.

The Company has not yet paid any dividends.

# **ITEM 4 - Results of Operations**

The Company reported a *loss from operations* of \$906,894 for the year ended September 30, 2015 versus a *loss from operations* of \$373,029 for the year ending September 30, 2014.

The increase in net loss year over year is mostly explained by a non-cash charge of \$211,994 for stock based compensation in 2015 that did not occur the previous year. Contributing further to the year over year difference in net loss were one time regulatory and exchange fees of \$93,657. These costs were incurred in connection with the listing of the Company's shares on the TSX Venture exchange in February 2015.

Patent expense for the year ended September 30, 2015 was \$211,937, up from \$151,558 a year earlier. The increase is the result of successful patent issuance for the company's technology innovations as well as new patent filing expenses related to new inventions that occurred in the Company's technology programs during the year.



Research expense was \$171,245 during the year compared to \$70,152 last year primarily due to an increase in company sponsored research contracts for the pre-clinical development of AB569 and MetaMx at the University of Cincinnati and McMaster University respectively during the year.

Wages and employee benefits increased to \$90,214 for the year up from \$46,825 a year earlier due to an increase in key management compensation in 2015.

The remaining expenses associated with managing the Company including general and administrative expenses, communication costs, marketing expenses and professional fees were similar to the prior year as the company maintained stable operating costs. The Company's net loss was \$839,004 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 2016 in order to advance certain of its products to human trials and proof of efficacy data. 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 2015 Q4	Jun 30 2015 Q3	Mar 31 2015 Q2	Dec 31 2014 Q1	Sept 30 2014 Q4	June 30 2014 Q3	Mar 31 2014 Q2	Dec 31 2013 Q1
Revenue	-	-	-	37,641	51,125	-	-	-
Income (loss) BEFORE discontinued operations	(146,107)	(165,869)	(168,163)	(358,865)	(121,266)	(130,860)	(93,617)	(52,764)
Income (loss) BEFORE other items	(146,107)	(165,869)	(168,163)	(358,865)	(121,266)	(130,860)	(93,617)	(52,764)
Per share	(0.003)	(0.003)	(0.003)	(0.007)	(0.0025)	(0.003)	(0.002)	(0.001)
Results Surrounding Extraordinary/Other Items: Discontinued Operations	-	-	-	-	-	-	-	-
Extraordinary/Other Items	-	-	-	-	-	-	35,000	-
Income (Loss)	(146,107)	(165,869)	(168,163)	(358,865)	(121,266)	(130,860)	(58,617)	(52,764)
Per share	(0.003)#*	(0.003)#*	(0.003)#*	(0.007)#	(0.0025)#	(0.003)**	(0.001)**	(0.001)*

<sup>\*</sup> Based on 48,260,179 shares outstanding since Sept 30, 2013

<sup>\*\*</sup> Based on 49,634,679 shares outstanding since March 31, 2014

<sup>#</sup> Based on 50,979,179 shares outstanding since August, 2014;

<sup>#\*</sup>Based on 53,189,679 shares outstanding since March, 2015



# 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 2016, 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 surplus as at September 30, 2015, excluding loans and accrued interest owing to a shareholder, was approximately \$487,000. 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 2014 and 2015:

- During January and February 2015, the Company raised \$750,050 by closing a non-brokered private placement it announced in a press release January 8, 2015. Pursuant to the terms of the private placement, Arch issued 2,143,000 Units at a price of \$0.35 per unit (the "Units"). Each Unit consists of one common share of the Company and one common share purchase warrant (the "Warrant"). Each Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$0.70 per common share until 5:00PM EST on January 13, 2017.
- On August 5, 2014, the Company announced it raised \$175,140 via a non-brokered private placement of 625,500 Units at a price of \$0.28 per Unit. Each Unit comprises of one common share and one common share purchase warrant. Each warrant allows the holder to purchase an additional common share at \$0.50 cents during the 24-month period following the close of the private placement. The proceeds will be used for the Company's working capital and general corporate purposes. The common shares and any common shares issued from the exercise of the warrants will be subject to a hold period of 4 months from the closing date.
- On July 7, 2014, the Company announced it raised \$200,200 via a non-brokered private placement of 715,000 Units at a price of \$0.28 per Unit. Each Unit comprises of one common share and one common share purchase warrant. Each warrant allows the holder to purchase an additional common share at \$0.50 cents during the 24-month period following the close of the private placement. The proceeds will be used for the Company's working capital and general corporate purposes. The common shares and any common shares issued from the exercise of the warrants will be subject to a hold period of 4 months from the closing date.



- On March 25, 2014, the Company announced it raised \$155,960 via a non-brokered private placement of 557,000 Units at a price of \$0.28 per Unit. Each Unit comprises of one common share and one common share purchase warrant. Each warrant allows the holder to purchase an additional common share at \$0.50 cents during the 24-month period following the close of the private placement. The proceeds will be used for the Company's working capital and general corporate purposes. The common shares and any common shares issued from the exercise of the warrants will be subject to a hold period of 4 months from the closing date.
- On February 25, 2014, the Company announced it raised \$228,900 via a non-brokered private placement of 817,500 Units at a price of \$0.28 per Unit. Each Unit comprises of one common share and one common share purchase warrant. Each warrant allows the holder to purchase an additional common share at \$0.50 cents during the 24-month period following the close of the private placement. The proceeds will be used for the Company's working capital and general corporate purposes. The common shares and any common shares issued from the exercise of the warrants will be subject to a hold period of 4 months from the closing date.
- On February 25, 2014, the Company also announced that the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP) has approved funding up to \$91,000 to assist Arch in the development of its bioorganic metal surfaces technology.
- Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is approximately \$328,227 as at September 30, 2015. During January, 2015 the Company agreed to extend this loan to mature on January 15, 2017 and 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. The funds were also used to restructure the Company and complete the transactions that led to the formation of Arch Biopartners Inc. on May 7, 2010.

# **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 \$200,000 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.



Presently, the Company does not have sources of capital other than issuing new equity.

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

Intellectual Property Transfer Agreements

University of Calgary policy dictates that all scientific intellectual property is 100%-owned by the inventor. In 2010, 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.

This intellectual property represents one of the 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 subsequent to and during the year ending September 30, 2015 and during 2014:

- On January 28, 2016, the Company granted a total of 300,000 incentive stock options to its directors as the only compensation for serving as a director for the year which began on March 30, 2015, the day of the company's last annual meeting of shareholders. Each stock option grant is for 50,000 options to each of the Board's six directors. Each stock option is exercisable into a common share of the company for a period of five years, exercisable at \$0.45 per share.
- On October 24, 2014 the Company granted 1,200,000 incentive stock options to its directors, officers, and consultants pursuant to its 2014 stock option plan. Each stock option is exercisable into a common share of the company for a period of five years. A total of 900,000 options exercisable at \$0.30 per share; 100,000 are exercisable at \$0.40 per share and 200,000 are exercisable at \$0.50 per share.



• Company management has secured loans from a director and a shareholder of the Company. The outstanding amount is approximately \$328,227 as at September 30, 2015. During January, 2015 the Company agreed to extend this loan to mature on January 15, 2017 and 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. The funds were also used to restructure the Company and complete the transactions that led to the formation of Arch Biopartners Inc. on May 7, 2010.

The principal together with any accrued interest will become due and will be paid in full by the Company on demand so long as such payment does not reduce the Company's ability to complete its product development work plan for any given 12 month period from date of repayment.

# ITEM 10 - Fourth Quarter ending September 30, 2015

The Company recorded a *loss from operations* of \$146,107 for the quarter ended September 30, 2015 versus a *loss from operations* of \$121,266 for the same quarter in 2014. The losses are the sum total of all general and administrative expenses, including 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 higher research and patent expenses. Patent expense for the quarter ending September 30, 2015 was \$86,014, up from \$21,043 a year earlier. Research expense was also up to \$42,144 in the fourth quarter, compared with \$27,494 last year.

Offsetting the increase in patent and research expenses in the fourth quarter was a decrease in professional fees of approximately \$30,000 and a decrease in wages of approximately \$20,000 that were incurred in the quarter ending September 30, 2014.

# **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 <a href="https://www.SEDAR.com">www.SEDAR.com</a>



# ITEM 12 - <u>Critical Accounting Estimates</u>

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, 2014.

# 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 of the date of this Management Discussion and Analysis there were 53,189,679 common shares issued and outstanding. In addition, the Company had the following convertible securities outstanding:

Type	Quantity	<b>Exercise Price</b>	<b>Expiry Date</b>
Stock Options			
-	250,000	0.90	April 15, 2016
	50,000	0.30	October 15, 2018
	900,000	0.30	October 24, 2019
	100,000	0.40	October 24, 2019
	200,000	0.50	October 24, 2019
	50,000	0.40	April 16, 2018
	300,000	0.45	January 28, 2021
Warrants	0	0.60	April 16, 2014
	0	0.60	June 24, 2014
	0	0.50	August 6, 2015
	0	0.50	August 19, 2015
	817,500	0.50	February 25, 2016
	557,000	0.50	March 25, 2016
	715,000	0.50	July 7, 2016
	625,500	0.50	August 5, 2016
	2,143,000	0.70	January 13, 2017

Any warrants or stock options expired in the above table were not exercised by the holders. Please see ITEM 6 – Liquidity, for details regarding the warrants. Please see ITEM 9 – Transactions with Related Parties for more details on the options.



# **Summary of Significant Accounting Polices**

Please refer to Note 3 of the Company's audited annual financial statements for the year ending September 30, 2015.

## **Future Accounting Changes**

## (i) International Financial Reporting Standards

In February 2008, the Canadian Institute of Chartered Accountants (CICA) announced that Canadian GAAP for publicly accountable enterprises would be replaced by IFRS for interim and annual financial statements for fiscal years beginning on or after January 1, 2011. The standard also requires that comparative figures for 2010 be based on IFRS. Accordingly, the Company adopted IFRS on October 1, 2011, with restatement for comparative purposes of amounts reported by the Company for the fiscal year beginning October 1, 2010.

The significant accounting policies adopted under IFRS are included in Note 3 to the consolidated financial statements for the years ended September 30, 2013 and 2014. These accounting policies have been applied consistently to all periods presented in the financial statements. They also have been applied in preparing an opening IFRS statement of financial position as at October 1, 2011, the Company's transition date, as required by IFRS 1. The accounting policies were selected to be consistent with IFRS, effective on September 30, 2012, the Company's first annual IFRS year end reporting date. The standards and interpretations within IFRS were finalized when the first full IFRS financial statements were prepared for the year ending September 30, 2012.

Reconciliations and descriptions of the effect of the transition from Canadian GAAP to IFRS are included in Note 2 to the audited consolidated financial statements for the year ended September 30, 2012 and can be found in the Company's filings at www.SEDAR.com

The transition from Canadian GAAP to IFRS had no impact on total comprehensive income (loss).

## **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 \$330,000 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 commercially 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 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 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 depends 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.