

## MANAGEMENT'S DISCUSSION & ANALYSIS

### For the twelve month period ended September 30, 2008

#### **January 23, 2009**

*The following discussion of Covalon Technology Ltd's (Covalon or the "Company") financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes for the year ended September 30, 2008. We have prepared these financial statements according to Canadian generally accepted accounting principles ("GAAP").*

#### **Management's Responsibility for Financial Reporting**

*The Consolidated Financial Statements and Management's Discussion and Analysis (MD&A) have been prepared by management, who, when necessary, have made informed judgments and estimates of the outcome of events and transactions, with due consideration given to materiality. Management acknowledges its responsibility for the fairness, integrity and objectivity of all information provided in the consolidated financial statements and in MD&A thereof. As a means of fulfilling its responsibility, management relies on the Company's system of internal controls. This system has been established to ensure, within reasonable limits, that assets are safeguarded, transactions are properly recorded and are executed with management's authorization and that the accounting records provide a solid foundation from which to prepare the Consolidated Financial Statements and the MD&A. The Board of Directors carries out its responsibility for the consolidated financial statements principally through its Audit Committee, consisting solely of non-management directors. This committee meets periodically, reviews the scope of the external audit, the adequacy of the systems of internal control and the appropriateness of financial reporting and then makes its recommendations to the Board of Directors. Based on those recommendations, the Board approves the Consolidated Financial Statements and the MD&A.*

*All dollar amounts included in the MD&A are Canadian dollars unless otherwise specified.*

#### **Non-GAAP Measures**

*This MD&A, we refer to terms that are not specifically defined in the CICA Handbook and do not have any standardized meaning prescribed by GAAP. These non-GAAP measures may not be comparable to similar measures presented by other companies.*

#### **Additional Information**

*Additional information on Covalon, including our information circular and quarterly reports is available on SEDAR at [www.sedar.com](http://www.sedar.com) and in the investor relations section of our web site at [www.covalon.com/Investors](http://www.covalon.com/Investors).*

## **Forward-looking Statements**

The MD&A contains forward-looking statements within the meaning of securities law. These statements relate to future events or future performance and reflect management's expectations and assumptions regarding future events such as growth, results in operations, performance and business prospects and opportunities of the Company. In some cases, the forward-looking statements can be identified by terminology such as "seek", "anticipate", "plan", "estimate", "expect", "intend" and statements that an event or

result “may”, “will”, “should”, “could” or “might” occur or be achieved and other similar expressions concerning matters that are not historical facts. These forward-looking statements involve risk and uncertainties, including the difficulty in predicting product approvals, acceptance of and demands for new products, the impact of the products and pricing strategies of competitors, delays in developing and launching new products, the regulatory environment, fluctuations in operating results and other risks, any of which could cause results, performance, or achievements to differ materially from the results discussed or implied in the forward-looking statements. Although the forward-looking statements contained in this discussion are based on what management considers to be reasonable assumptions based on the information currently available to it, there can be no assurance that actual results, performance or achievements will be consistent with these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from expectations. These include but are not limited to the risk factors included in this MD&A (including those listed under the heading “Risks and Uncertainties”) in addition to the risks itemized in the Company’s ongoing securities filings. Readers are advised to review these risk factors for a detailed discussion of the risks and uncertainties affecting the Company’s business. Many risks are inherent in the industry; others are more specific to the Company. Readers should not place undue reliance on any forward-looking statements. Other than as required by applicable Canadian Securities Law, the Company does not update or alter any forward-looking statements whether as a result of new information, further events or otherwise.

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## 1. Vision and Strategy

Covalon's long term vision is to be the leading enterprise in the world in biomaterials for medical device coatings, collagen-based products including advanced wound dressings and tissue coverings. As well, the Company has made a significant investment in its strategy to develop a stem cell based therapy for tissue regeneration in treating ischemic disease. Notably, the technology is expected to help repair heart muscle damaged by clogged arteries and consequent poor blood flow. The innovative approach using stem cell therapy is designed to assist the body's damaged heart tissue in rebuilding new blood vessels using Covalon's patented EPAS1 technology that is known to increase the body's own ability to produce new blood vessels in heart tissue damaged by poor blood flow. We plan to leverage our research and development capabilities through partners that will contribute financially and technically to accelerate the number and volume of products brought to market. The strategy is expected to yield increased business opportunities and increased value for stakeholders while improving the quality of life for patients locally and globally.

The Company's short-term strategy is to concentrate on coating and wound dressing products that can be brought to market relatively quickly (typically through the FDA 510(K) regulatory pathway in the USA and equivalent routes in the rest of the world that do not require human trials). This will result in revenue streams and a reputation in the industry that will lead to financial investments in higher-value projects. Our focus will shift to these opportunities as we gain financial and technical traction. Throughout this evolution, we will continue work on the longer-term stem cell therapy development for repair of ischemic heart-tissue dysfunction.

Over the summer and fall, we have worked on building an infrastructure that will support a roll-out of expected new products to markets. Investment in strategic areas will continue as we build a pipeline of projects and expand on our partner-base, and should result in growing revenues in the coming year. Adjustments to our staff and management have been made to strengthen our infrastructure and we are confident that we have the resources we need to support our strategy and vision.

## 2. Company Overview

### *Our Business*

Covalon's core competencies include three platforms:

- patented advanced therapeutic collagen biomaterials;
- therapeutic medical device coatings; and
- ongoing research program on the use of cell therapy for regenerating damaged heart tissue for treating congestive heart failure.

The initial commercial applications were for advanced wound care, surgical applications and medical devices that inhibit microbial invasion to help reduce infections. The Company has global distribution in place for its collagen wound products and US distribution for its antimicrobial Foley catheter. Work continues on the development of the

Company's antimicrobial coating technology for vascular access with another major medical device company. There remains a strong pipeline of applications for development partnering in the Company's research and development department of increasingly sophisticated products using its coatings and collagen matrices. In the future, the technologies can be extended to deliver a variety of therapeutics. This will enable the Company to participate in broader and higher margin markets.

The Company's core competencies in polymer chemistry and surface coatings have been combined to generate several proprietary technologies that create a range of time-release platforms that can be applied to many medical devices for treating unmet medical needs including antimicrobials, antithrombosis and localized drug delivery. The Company has successfully developed products, received regulatory approvals and is manufacturing products that contain antimicrobial silver ion. These silver ions combat microbial attachment and invasions, thereby helping to reduce hospital acquired infections. The antimicrobial silver ion-releasing technology has been shown to be effective against many microbes including antibiotic resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus* (VRE), *Pseudomonas aeruginosa*, *E. coli*, yeasts and other microbes.

The Company intends to develop its collagen-based scaffolds to deliver other therapeutics and "biologicals" for inducing hemostasis, soft tissue stabilization, bone re-apposition, pain management as well as treating problems related to ischemic diseases.

The Company acquired EPAS1 technology that is intended to be used in developing a genetic-based approach to wound healing and recovering from congestive heart failure. EPAS1 technology relies on hypoxia inducible-factor-activity to stimulate angiogenesis (new blood vessel formation) for regenerative medicine. The innovative and powerful aspect of the technology lies in the ability of EPAS1 to initiate new blood vessel formation at the site of tissue damage since ischemic organs lack adequate blood supply. New blood vessels are essential in tissue regeneration or wound healing because any regenerating or healing tissue requires blood flow via newly formed blood vessels to deliver nutrients and oxygen to the tissue.

The technology is complimentary to Covalon's tissue repair program and research is ongoing at a world-renowned contract research facility specializing in coronary and angiogenesis research. Covalon's cell therapy program is designed to generate cells that express useful genes at a site of cell therapy for treating ischemic conditions, such as congestive heart failure, chronic wounds, peripheral vascular disease and other conditions. Numerous studies have shown that bone marrow-derived stem cells may assist in tissue repair and regeneration of many tissues including myocardium, heart valves, damaged bone, skin, blood vessels and other tissues. Optimum healing and tissue regeneration requires new blood vessel formation. The cell therapy technology aims to stimulate the growth of new blood vessels through a process of therapeutic angiogenesis.

### **Covalon Collagen Dressings**

Covalon collagen materials are bioresorbable collagen-based devices developed by the Company for delivery of therapeutics ranging from antimicrobial silver technology to cell therapy. The technology allows the Company to produce a variety of advanced convergent drug-devices including anti-infective wound dressings as well as cellular scaffolds for tissue regeneration.

The Company's initial focus with scaffolds was to develop, get regulatory approval for and sell a series of CMO (contract manufacturing organization) manufactured silver ion releasing collagen-based wound dressings. This resulted in FDA-approved product lines (ColActive and Biostep™) that improve wound care by inactivating wound bed enzymes that are known to result in slowing down healing in wounds, including chronic and diabetic ischemic wounds. Sales of these products through an exclusive distribution contract with Smith & Nephew were significant during product launch and inventory buildup, but the shipments have subsequently slowed as market demand is filled through established inventories. We continue to work with our distributor in a effort to gain market share and use the products in new applications. We expect volumes to improve in the second half of the fiscal year.

The collagen technology platform is being used in R&D for a number of products for surgical interventions. It is expected that such products will enhance the Company's value proposition for the platform and lead to future contracts for the design, development, manufacturer, sale and/or licensing of new collagen-based devices.

### **Current Collagen Products**

The following are products developed by Covalon and approved for sale in the US and Canada.

<b>Product</b>	<b>Distribution</b>	<b>Launch</b>
ColActive™ Collagen Wound Dressing	Smith & Nephew Inc.	April 2007 US
ColActive Ag™ Collagen with Silver	Smith & Nephew Inc.	April 2007 US
Biostep™	Smith & Nephew Inc.	October 2007 US
Biostep™ Ag	Smith & Nephew Inc.	October 2007 US

### **Collagen Technology Development Pipeline**

Covalon has identified a number of product applications for its collagen-based technology platform. The applications are increasingly more sophisticated over its current products in therapeutic delivery and functions. The Company's strategy is to take advantage of the collagen platform as an advanced combination device for delivery of certain therapeutics and biologicals (e.g. biological growth factors and cells). The current pipeline of collagen devices includes topical hemostatic dressings, a rapid hemostatic trauma dressing, a biologics delivery device for hormones and growth factors, and EPAS1- engineered altered cells for modulating angiogenesis (to be discussed later) amongst others.

The following chart outlines the various collagen applications in the active development pipeline:

Application	Design Phase	Prototype	Animal Testing
Hemostatic dressing	Completed	yes	In progress
Antimicrobial tissue reinforcement film closure of surgical wound closure	Completed	yes	In progress
Dental dressing for dry socket and cosmetic dentistry	In progress	yes	In progress
Antimicrobial Ocular dressing	In progress	yes	-
Negative pressure wound therapy sponge	In progress	yes	-
Scaffold for delivery of synthetic osteostimulants for bone grafting	In progress	yes	-

### Coatings

Covalon has developed an advanced proprietary coating platform for the emerging combination device market. The technology uses a proprietary ultraviolet light-mediated process to create biocompatible surface coatings capable of carrying a number of therapeutics. The initial focus is to use the platform for delivery of antimicrobial ionic silver from medical devices, such as urinary (Foley) catheters where the risk of catheter associated infection in hospitals is high. It has been widely estimated that 40% of all hospital-acquired infections are due to the use of Foley catheters. The same technology can be applied to a number of post surgical wound drains such as chest, abdominal gastric and orthopedic drains. Covalon recently announced that it has successfully completed the development of its new anti-microbial / anti-thrombogenic coating to prevent blood clotting on blood access catheters and devices. The development allows the Company to market the technology for application on central venous lines, Peripherally inserted central catheters, IV lines, hemodialysis lines and implantable infusion ports where an antimicrobial and anti-thrombogenic coating would offer a clinical advantage in minimizing microbial ingress.

Covalon's antimicrobial and low-thrombogenic coating can be applied to a wide variety of in-dwelling, blood contacting devices for reducing the incidence of hospital acquired infection as well as reducing thrombogenicity. Effective antimicrobial and low-thrombogenic coated catheters may reduce infection and thrombus formation thus improving patient outcome.

Antimicrobial CVC are expected to experience a growth rate approximately 5-fold greater than that of un-coated CVC. It is estimated that by 2009, sixty-nine percent (69%) of all CVC used will be antimicrobial (data from Frost and Sullivan, U.S. Antimicrobial Devices Markets, 2003). Hospital-acquired infections affect approximately 2 million people in the United States each year, and cost over \$11 billion to the U.S. healthcare system (data from Frost and Sullivan, U.S. Antimicrobial Coating Markets, 2006). The total antimicrobial catheters market is projected to attain revenues of US \$375 million by 2009 (Frost and Sullivan 2006).

Covalon announced in late 2007 that it has begun the development work to apply its antimicrobial coatings to metals for orthopedic implants and trauma products. The infections in orthopedics are relatively low but the damage caused by a bone infection (osteomyelitis) leads to implant failure and can be catastrophic. Orthopedics implants and trauma products have a global market well over \$10 billion.

### **Current Coating Products**

The Company provides coating services for Medline Industries, Inc., one of the largest distributors in the US. FDA 510(K) approval for the silver ion releasing coating for Foley catheters was received by Medline on February 16, 2006. Medline launched the “Silvertouch” Foley catheter in June 2006. In 2007, Medline initiated a number of in-market case studies to show the efficacy of the coating. It is anticipated that these studies will show the coatings advantage over other anti-microbial coatings and accelerate adoption in the market.

### **Coating Development Pipeline**

Covalon has provided prototype, antimicrobial coated samples for a number of new customers for a variety of other applications including: peripherally inserted central catheters, central venous lines, sutures, intravenous lines, feeding tubes, stomach anchors, stents and metal for orthopedic applications. The Company is in “fee for service” co-development with a number of customers for these coating applications and is considering other exclusive licensing opportunities.

The chart below outlines the status of coating applications in the development pipeline:

<b>Application</b>	<b>Design Phase</b>	<b>Prototype</b>	<b>Process / Production Scale up</b>
Central venous / hemodialysis lines	Completed	yes	In progress
PICC lines	Completed	yes	In progress
Catheter ports	Completed	yes	In progress
IV lines / securement device	Completed	yes	-
Surgical wound drains	In progress	yes	-
Endo tracheal tubes	In progress	yes	-
Anti-stricture therapeutics delivery off endo tracheal tubes and Foley catheters	In progress	yes	-
Metals for orthopedics	In progress	yes	-

### *Tissue Regeneration Project*

Covalon is developing a stem-cell engineering platform for heart regeneration in Congestive Heart Failure (“CHF”) patients who previously suffered a myocardial infarction or heart attack (“MI”). This platform is based on the use of the EPAS1 gene to enhance the efficacy of cellular cardiomyoplasty (i.e. the injection of cells into the infarcted heart tissue). The technology aims to improve heart pumping function and blood flow of the diseased heart tissue in CHF patients by both restoring the elasticity of the damaged heart tissue with a cell therapy treatment and stimulating the growth of new blood vessels in the heart, through a process of therapeutic angiogenesis. New blood vessel formation is referred to as “angiogenesis” and/or “vasculogenesis”. The processes are integral to regenerative medicine, including wound healing, treating ischemic heart disease, peripheral vascular disease as well as other diseases related to poor blood flow to tissues and organs.

According to the American Heart Association, CHF afflicts over 5.4 million Americans with approximately 550,000 new cases annually. The prevalence of CHF is expected to grow in industrialized countries as the population ages and as a result of re-perfusion therapy leading to more patients surviving acute myocardial infarction with diminished cardiac capacity. In Europe, the estimate of current CHF patients approaches 7 million cases. Current pharmacological therapies reduce symptoms and slow progression of the disease and half of all CHF patients will nonetheless die within five years of diagnosis.

It is estimated that about half of CHF cases result from a MI, which can lead to necrosis of a zone of the heart muscle (the scar tissue). It is those post-MI patients that are expected to be targeted for Covalon’s EPAS1 cell therapy technology.

Covalon has successfully achieved an important milestone with its EPAS1 technology that is expected to allow the Company to genetically engineer human mesenchymal stem cells (hMSCs) for increased expression of EPAS1, a hypoxia inducible factor. EPAS1 is a “master” gene that is a regulator of the production of vascular endothelial growth factor and several other important angiogenic proteins crucial to new blood vessel growth required to deliver blood, oxygen and nutrients to regenerative tissues by cell transplantation.

This project has successfully produced porcine and human mesenchymal stem cells with EPAS1 and demonstrated that the transcription factor (EPAS1 protein) can effectively be produced in both human and porcine MSCs. The pre-clinical results show the ability of porcine and human MSCs to over-produce the transcription factor and that it binds DNA (regulatory genetic material) in the nucleus of modified cells. The transcription factor is known to act as a molecular switch that regulates production of vascular endothelial growth factor and several other angiogenic factors required for new blood vessel growth to deliver blood, oxygen and nutrients to regenerating tissues.

Covalon’s genetically engineered cells that produce EPAS1 protein have been shown to “switch-on” in these cells, the production of vascular endothelial growth factor (VEGF), Angiopoietin (ANG2) as well as several other growth factors that are essential for the growth and maturation of new blood vessels. EPAS1-engineered cells have been used in preclinical experiments using a rodent (mouse) model to mimic ischemic (scar tissue)

heart conditions. In the preclinical animal model EPAS1-cells were shown to induce the formation of new blood vessels that matured into health vessels. Furthermore, the animals treated with EPAS1-cells demonstrated significant improvement in heart-pumping efficiency over that of animals that were either untreated or treated with non-EPAS1-cells.

In using Covalon's EPAS1 cell therapy, therapeutic angiogenesis within the scar is possible because the implanted cells are used as a delivery system for the "master" angiogenic gene EPAS1. Covalon's proprietary EPAS1 gene is a biological "switch" able to turn on many genes essential for producing new blood vessels resulting in a more robust response. Furthermore, EPAS1 significantly turns on genes involved in cell survival and cardio-protection. The functional outcome of EPAS1 gene therapy is a significant improvement in heart function recovery compared to cell therapy alone. Although the implantation of EPAS1-cells can be performed as part of bypass surgery, the technology is ultimately intended to be administered by a less invasive endovascular route using an injection catheter. The expected goal is to load precursor cells with Covalon's proprietary gene construct that stimulates blood vessel growth (EPAS1). The altered cells are intended to stimulate blood vessel growth and improve cardiac function in a model of MI. The demonstration of the EPAS1 protein to bind nuclear DNA in MSCs is an important milestone toward the objective since it demonstrates that cells can be effectively and efficiently manipulated at the genetic level to produce essential growth factors that may contribute to improved angiogenesis and tissue regeneration required for increased and improved heart function.

Covalon has already established *in vivo* the increased angiogenic potential of EPAS1-modified cells and shown that EPAS1 significantly stimulated VEGF synthesis in many human cell types such as skeletal myoblasts, dermal fibroblasts, mesenchymal stem cells and bone marrow mononuclear cells.

Preclinical results demonstrated that EPAS1-modified cells delivery improves both perfusion and cardiac function better than cells alone. More specifically, EPAS1 modified cells support an important production of large blood vessels within the scar tissue, allowing for a better blood flow in the area. Furthermore and importantly, EPAS1-cells delivery improves heart function recovery following cell therapy. In our rodent model, cardiac function improvement more than doubled in the EPAS1 group. The expected goal is to load precursor cells with Covalon's proprietary gene construct that stimulates blood vessel growth (EPAS1). The altered cells are intended to stimulate blood vessel growth and improve cardiac function in a model of MI. An efficacy study in a porcine model and a series of safety studies have been designed and are ongoing.

Covalon's program offers the potential for a minimally invasive alternative to open heart surgery for those suffering from congestive heart failure. Furthermore, the technology has broad application in areas where improved blood flow is required. The initial target patients population for EPAS1-cell therapy are expected to be moderate CHF patients (classes II and III) who initially suffered myocardial infarction.

### **Significant Milestones**

Covalon's management reorganization was completed in the first quarter of the current year resulting in the following executive team:

Dr. Frank DiCosmo  
Mr. William Jackson  
Mr. Peter Hobbes  
Dr. Val DiTizio  
Dr. Sonia Sanhueza

CEO and President  
Chief Business Officer  
Chief Financial Officer  
Chief Scientific Officer  
Chief Operations Officer

This restructuring has led to the building of a strong team that can support Mr. Jackson's and Dr. DiCosmo's greater focus on business development and marketing. There are now strong various operational and support systems in place that are becoming critical to our evolution as a commercial entity. Mr. Jackson added internal support for liaising with distribution partners and field support for investigating new market opportunities in the United States. He also hired Wayne Dennis as VP of Business Development based in New Jersey to identify and develop new collagen-based device opportunities out of the United States. Dr. DiTizio brought in talent to help formalize the preparation and documentation out of the research function to ready it for technology transfer into commercial activity. Dr. Sanhueza built up the quality control and assurance, regulatory, technology transfer and project management talents in the organization to systemize the commercialization process. Mr. Hobbes joined the team at the end of the fiscal year and continued the enhancement of information and communication systems to provide support for management and reporting requirements.

Altogether, the Company grew from approximately 20 employees at the end of the previous fiscal year to a complement of 37 at the end of September 2008. The composition of the Covalon Board was also enhanced during the year with the addition of 2 new members that bring business and industry experience to the organization.

Mr. Abe Schwartz joined the Board of Directors in March 2008, bringing a background of entrepreneurial success in a variety of industries. Mr. Schwartz has spent much of his time leading small businesses from start-up to profitable operations for over 25 years. He has successfully founded, developed and sold several businesses over his career. Mr. Schwartz will provide valuable guidance in corporate governance, strategy and tactics.

Mr. Joseph Cordiano also joined the Covalon Board in March of 2008. Mr. Cordiano was initially elected to the Ontario legislature in 1985. He was named Deputy Leader of the Opposition in 1996 and held the position for two years. On October 23, 2003, Mr. Cordiano was named Minister for Economic Development and Trade and held the position until he resigned from public duty in September 2006. Mr. Cordiano brings Covalon valuable experience from an international development perspective.

On October 2, 2008, Mr. Hobbes was hired as CFO; Mr. Hobbes brings 13 years experience in medical device distribution with Stryker Canada and 4 years experience in technical product manufacturing to the Covalon team. He also has experience with several enterprise resource planning system implementations over his career. These attributes will be valuable for the Company as it plans to upgrade its Enterprise Resource Planning system in the near future and broaden its product base.

These personnel changes give Covalon much more of an international, commercialized and entrepreneurial business attitude and position the Company to execute more effectively on opportunities. Vision from the management team is guiding the Company towards projects that will bring cash flow earlier in the process and Company staff is building capability and experience to execute the its business plan more systematically and efficiently.

During the 2008 fiscal year, the Company passed several milestones that did not show up significantly in its financial results. However, they were important in terms of its development:

- Coatings Products
  - The Company developed an initial prototype for a metal coating that met several project goals. This provided a solid stepping stone in extending technology to metal surfaces
  - Experience from early partnered projects has led to better priced and structured agreements going forward. This should result in quicker results and revenues in the future. The Company also has a better understanding of its costs on these projects. Current development work should lead to manufacturing requirements above our current capacity, pushing the Company into research on improving its manufacturing capabilities
- Wound Dressings
  - The Company completed a small and successful development project in this product line establishing another potential partner.
  - Animal testing on a surgical film prototype was completed during the year, with promising results
  - Animal tests on antithrombogenic prototypes were performed in November 2008 yielding valuable performance and user feedback
- EPAS1
  - Phase A and B of the Pig Pilot Study were successfully completed in November 2008

### 3. Investments and Capitalization

Covalon became a publicly listed company on the Toronto Venture Exchange (TSXV) on December 21, 2004, trading under the symbol (COV). At the beginning of the current fiscal year, October 1, 2007, the Company had 72,712,034 common shares issued and outstanding.

The table below sets out the number of issued and outstanding common shares as well as the number of issued and outstanding warrants and options to purchase common shares, in each case as at September 30, 2008.

Common shares	74,303,915
Options to purchase common shares	3,688,175
Total diluted shares outstanding	77,992,080

On October 24, 2006, Covalon completed the acquisition of a cell engineering platform for improving blood vessel development (“angiogenesis”) from Perfusion Therapeutics Inc. of Montreal. Covalon acquired the technology in exchange for 1,100,000 of its common shares to be released upon the completion of various milestones. To date, 75,000 shares have been released from escrow. The technology uses the endothelial PAS domain protein 1 (EPAS1) which is covered by several US and European patent applications that Covalon has assumed through the acquisition.

### 4. Results of Operations

#### Highlights

- Total Product Sales Revenues increased by \$117,195 or 9% over the previous year to \$1,402,868;
- Coating Services are becoming a more significant source of revenue, providing a revenue stream earlier in the development process and helping subsidize operations;
- Total Interest Income increased by \$377,117 or 151% over the previous year to \$626,260;
- Net loss for the year 2008 was \$3,740,847 compared to net loss of \$3,076,377 for the same period in 2007;
- Covalon lost \$0.05 per share for the year 2008 which is the same loss compared to the same period in 2007 and 2006;

Cash used in operating activities before change in non-working capital balances for the year 2008 was \$3,060,037 compared to \$2,458,889 for the same period in 2007



## Operating and Financial Results

<i>(Canadian \$)</i>	Three months ended September 30,		Year ended September 30,	
	2008	2007	2008	2007
Product Sales				
Wound care	\$ 167,039	\$ 375,731	\$ 1,175,667	\$ 1,077,483
Device Coatings	45,712	(3,221)	107,737	182,720
Coating services	48,069	14,574	119,464	25,470
	\$ 260,820	\$ 387,084	\$ 1,402,868	\$ 1,285,673
Cost of goods sold	226,250	330,130	825,727	856,406
Gross Profit	\$ 44,570	\$ 56,954	\$ 577,141	\$ 429,267
Other Revenue				
Interest income	\$ 48,243	\$ 84,325	\$ 626,260	\$ 249,143
Licensing fee	110,657	(98,641)	443,850	249,999
Total Expenses	\$ 1,801,785	\$ 1,467,684	\$ 5,388,098	\$ 4,004,786
Net Loss	\$ (1,608,315)	\$ (1,425,046)	\$ (3,740,847)	\$ (3,076,377)
Loss per share	\$ (0.02)	\$ (0.02)	\$ (0.05)	\$ (0.05)

### Analysis of Operating and Financial Results Fiscal 2008 compared to Fiscal 2007

#### Revenue

Total Product Sales increased in 2008 by 9% compared to results in 2007. However, the 4<sup>th</sup> quarter results showed a decline of \$126,264 from the prior year. Results in our Wound Care products were disappointing, but our Coatings business is beginning to show some traction.

#### Wound Care Sales

In the 4<sup>th</sup> quarter of 2007, Covalon launched Biostep™/Biostep™ Ag through Smith & Nephew to the US market and experienced a jump in its sales in that quarter. That increase carried on through the 1<sup>st</sup> quarter of the 2008 year as the product launch required significant product volumes from Covalon. Unfortunately, competitive pressures limited the success of the launch and purchases by Smith & Nephew declined to match their ongoing sales pace. In the 4<sup>th</sup> quarter of fiscal 2008, our distributor satisfied its customers' demand through inventory and significantly reduced their shipments from Covalon.

Looking forward to 2009, we are planning to work with Smith & Nephew on initiatives to re-energize their support of the product line and hope to see improvements in the second quarter. Covalon's ColActive™ product has some interesting opportunities that we hope to capitalize on in the coming year. We will work to support Smith & Nephew in making them happen.

### ***Coatings Sales and Services***

Sales declined on coated catheters for the 2008 year by \$74,983 compared to 2007. Nevertheless, the final quarter of the year represented 41% of the total year's sales. This reflects the initial stages of the growing demand for anti-microbial coatings in hospitals due to the October 1, 2008 edict from the Centers for Medicare and Medicaid Services ceasing reimbursement for the care and treatment of catheter associated urinary tract infections acquired during a hospital stay. Our current distribution partner, Medline Industries, Inc., has accelerated its orders for coated catheters since the fiscal year end, and we are hopeful that this increased pace will hold throughout the year.

The Company continues to do contract research and development applying its anti-microbial coating on medical devices. Revenues from this source more than tripled in the 4<sup>th</sup> quarter of 2008 compared to the prior year, and total year revenues more than quadrupled over the 2007 year. Covalon currently has 3 active contracts with two partners for development of products planned to be brought to market by the contractors in calendar 2009. Licensing and contract manufacturing contracts are planned to be signed early in the new calendar year, and we expect to see material revenues from these contracts in the second half of calendar 2009.

This division of the Company has the most short term opportunity as the market is demanding anti-microbial versions of medical devices in response to the CMS ruling. The Company has built its technical competencies in this area through the 3<sup>rd</sup> and 4<sup>th</sup> quarters of 2008 and continues to develop its infrastructure to support this growing demand. As a result of the reimbursement changes in the market and our increasing capacity, we expect to see substantial growth in this portion of the business in the coming year.

### ***Product Sales & Services less Product Expenses***

As the actual sales grow, the company has the opportunity to see its gross profit percentage increase through economies of scale and favourable mixes. With the increase in coating services revenue (no costs included in Cost of Goods Sold), margins were pushed up by a positive mix factor – gross margins rose to 41% from 33% in 2007. Eliminating this revenue from the calculation, the gross margin percentage comparison is 36% versus 32% reflecting an improvement in margins on actual product sales.

### ***Interest Income***

Covalon started the year with just over \$16MM in cash and short term investments. It used \$3.5MM in cash during the year, resulting in an average of about \$14.3MM outstanding through the year. The \$626,260 in interest income reflects a 4.4% realized average interest rate over the fiscal period. The relatively low return of \$48,243 reported in the 4<sup>th</sup> quarter reflects an accounting adjustment on the income calculation of the Provincial Bond maturing December 4, 2008 that was held throughout the year.

All investments continue to be made in accordance with the Company's audit committee investment guidelines.

### ***License Revenues***

License revenues increased as a result of the recognition of a full year's amortization of the US\$2 million milestone payment the Company received from Smith & Nephew Inc. In 2007, there were only 6 months of amortization reflected in the statements. The final

quarter comparison is impacted by an adjustment in 2007 for the change from a 2-year to a 5-year amortization period.

### Expenses

Total Expenses increased 35% in fiscal 2008, increasing costs from \$4.0MM in 2007 to \$5.39MM in the current year. The largest increases were in Regulatory and Marketing. These expenditure areas translate to greater opportunity in the future – Regulatory yielding the Company the ability to get quicker and more certain approvals; Operations (part of Regulatory) systemizing the transition from prototype to commercial product; and Marketing finding and developing new opportunities. General and Administrative increased less than the average growth in expenses and Research and Development actually declined from the prior year (excluding the Abandoned Development charges) with costs shifting from external support to internal capability. The Abandoned Development charges reflect a project that failed to meet its required targets and was abandoned in the fall. Detailed analysis follows:

Selected expenses and expenditures for the three month period and year ended September 30 for 2008 and 2007 are highlighted below.

<i>(in Canadian \$)</i> <b>Expenses</b>	3 months ended September 30,		Year ended September 30,	
	<b>2008</b>	2007	<b>2008</b>	2007
<u>Regulatory</u>				
Wages and Benefits	\$ 479,124	\$ 181,468	\$ 970,726	\$ 416,795
Consulting fees	9,930	3,822	83,653	39,263
Other	<u>48,620</u>	<u>47,509</u>	<u>173,104</u>	<u>132,775</u>
Total Regulatory	\$ <u>537,674</u>	\$ <u>232,799</u>	\$ <u>1,227,483</u>	\$ <u>588,833</u>
<u>Research and Development</u>				
Wages and Benefits	\$ 266,894	\$ 108,493	\$ 734,177	\$ 371,752
Consulting and Outside Testing	1,386	124,033	115,151	311,038
Amortization of Def. Dev. Costs	29,183	26,765	116,733	113,315
Abandoned Development Costs	145,800		145,800	
Other	<u>41,537</u>	<u>115,648</u>	<u>108,107</u>	<u>368,768</u>
Total Research and Development	\$ <u>484,800</u>	\$ <u>374,939</u>	\$ <u>1,219,968</u>	\$ <u>1,164,873</u>
<u>Marketing</u>				
Wages & Benefits	\$ 90,255	\$ 11,522	\$ 295,678	\$ 50,644
Travel	48,522	4,983	94,100	37,517
Investor Relations	11,479	20,566	74,749	84,386
Other	<u>1,130</u>	<u>5,255</u>	<u>17,534</u>	<u>47,499</u>
Total Marketing	\$ <u>151,386</u>	\$ <u>42,326</u>	\$ <u>482,061</u>	\$ <u>220,046</u>
<u>General and Administrative</u>				
Wages & Benefits	\$ 114,768	\$ 260,799	\$ 866,462	\$ 720,420
Directors' Compensation	124,240	191,874	443,993	448,448
Professional Fees	157,742	90,163	406,226	146,042
Depreciation and Amortization	94,730	37,559	230,097	139,673
Facility	45,305	39,326	175,243	155,015
Other	<u>91,140</u>	<u>197,899</u>	<u>336,565</u>	<u>421,436</u>
Total General and Administrative	\$ <u>627,925</u>	\$ <u>817,620</u>	\$ <u>2,458,586</u>	\$ <u>2,031,034</u>
<b>Total Expenses</b>	<b>\$ 1,801,785</b>	<b>\$ 1,467,684</b>	<b>\$ 5,388,098</b>	<b>\$ 4,004,786</b>

Note: Certain 4th Quarter details were reallocated to match the Total Year presentation format.

### **Regulatory**

The Smith & Nephew contract requires support from Covalon in extending the BioStep™ into new markets beyond the USA. In 2008, significant work was done by the regulatory team to obtain approvals for sale in Canada and preparing a submission to the EU. There was also much preparation done for upgrading the internal processes and increasing the capacity in our Coatings Manufacturing line. This was achieved with increases in the staffing of the Regulatory, Tech Transfer and Quality teams, many in the 4<sup>th</sup> quarter. By September 30, 2008, capacity and internal capabilities were greatly improved.

### **Research and Development**

Consulting and Outside Testing costs were reduced dramatically in the 2008 year as priorities were shifted to working on projects internally. A new scientist was added during the year and an R&D Director in August to bring the total of PhD's in the department to 6. The product pipeline remains full and the department plans to bring new ideas to a Tech Transfer stage much more systematically in the coming year.

During the year, the Company planned to submit a Drug Master File for one of its raw materials and subcontracted the work out. Towards the end of the fiscal year, there were indications that the project may not be proceeding towards successful completion. This was confirmed by a failure in a critical test and the project was terminated by the company. The contract costs invoiced to the end of September were expensed in the fiscal year. Settlement on the contract is pending.

The department was also responsible for oversight of spending on longer-term Projects whose development costs are deferred on the Balance Sheet. Total spending on these projects was \$487,418 in 2008 (2007 - nil). The vast majority of the cost relates to the EPAS 1 Project which is discussed in more detail in the Company Overview section of this report.

### **Marketing**

As Covalon transitioned from being predominantly a research & development company into commercial activities with the signing of the Smith & Nephew contract in March 2007, priorities moved towards revenue generating activities. In December 2007, William Jackson's responsibilities with the Company were focused on business development as he was named the company's Chief Business Officer. In the 4<sup>th</sup> quarter of 2008, a marketing associate and a VP Business Development were hired to add to the team.

Several development work contracts were signed during 2008 that began revenue generation on the commercialization process. These should also lead into manufacturing/licensing deals in the coming year. As R&D efforts become more systematic, operational capacities and capabilities improve, and our reputation for execution is developed, we expect to dramatically increase the volume of new contracts.

### **General and Administration**

General and Administrative expenses increased by \$427,552 in 2008. The largest area of increase was professional fees at \$260,184 – reflecting added costs on reporting related to the IFRS requirements and accounting issues related to new contracts, plus costs supporting legal actions, corporate matters and trademark maintenance. These costs are

in part a result of the evolution of the organization, but they will be reviewed and managed more closely in the future.

Wages and Benefits also increased \$146,042 during the year. There was effectively no headcount increase in the group as William Jackson was replaced by Francis Lindayen as CFO in December 2007, but compensation increased as a result of higher Stock Option expense recorded in the second quarter (higher stock price yields a greater Black-Scholes valuation) and some rate increases in the group. It is worth noting that while the cost recognized in March 2008's option issues is about \$410,000, these options are currently unlikely to be exercised at their \$2.79 strike price, so dilution is not automatic despite the recorded accounting expense.

Depreciation and Amortization expense is the final area of increase. All capital equipment and patent costs are currently included as General and Administrative costs. As detailed in Note 6, Lab Equipment makes up the majority of the company's Capital Assets and thereby the majority of its depreciation. As we enhance our financial systems and transfer assets from the lab into production activities, we will enhance our accounting for allocating depreciation. For the moment, note that a significant portion of the \$90,424 increase in G&A is due to lab equipment and patents.

### **Net Income (Loss)**

The Company had a net loss of \$3,740,847 or \$0.05 per share in 2008 compared to net loss of \$3,076,377 or \$0.05 per share in 2007.

The following items were significant changes in the year:

- 3 additional positions in Research & Development to reduce reliance on external support and to establish a more reliable and consistent product pipeline.
- Grow and enhance the Quality and Tech Transfer teams to develop the procedures to bring an R&D project to the commercial manufacturing stage. This supported several contracts for coating services and paved the way for smoother commercialization in the future.
- Establish a dedicated business development function by moving William Jackson to Chief Business Officer for the Company, and beginning to build a field team.
- Begin a stream of coating service revenues from partners during the commercialization phase of the product cycle. This brought in \$119,464 in coating services in 2008 compared to \$25,470 in the prior year, but more importantly, started the revenue stream earlier in the commercialization process than we experienced with the wound dressing products.

With new revenue streams started, we are hopeful that this year's loss is the deepest valley in the Company's financial history.

### Selected Annual Financial Data

The following table is a summary of selected audited consolidated financial information of the Company for each of the most recently completed financial years for the year ended September 30th:

<i>(in Canadian \$)</i>	2008	2007	2006	2005
Revenue (1)	\$2,472,978	\$1,784,815	\$1,059,986	\$27,173
Net loss	\$(3,740,847)	\$(3,076,377)	\$(2,204,990)	\$(1,861,542)
Net loss per share	\$(0.05)	\$(0.05)	\$(0.05)	\$(0.05)
Deferred Development Costs	\$2,576,036	\$2,205,350	\$2,410,189	\$2,604,300
Total Assets	\$17,292,486	\$20,244,461	\$8,793,388	\$4,500,484

(1) Includes Other Revenues

The Company's revenues continued to grow in 2008 on the strength of the Smith & Nephew contract signed back in March 2007, plus the additional interest revenue earned on the proceeds from the warrant exercise in late 2007. The pace of growth has slowed as the Company did not bring any new products to market during the year. In 2009, Covalon expects many items in the pipeline to translate into active development and/or commercial products.

In the past 2 years, Covalon has built its infrastructure and pipeline and it is now poised to start seeing these investments translate into contracts. It will be another year or two before the Company becomes profitable, but the trend of the past 3 years is expected to reverse in the coming year. Net Loss per Share will shrink and become a Net Profit per Share over the same term.

Deferred Development Costs represent the costs the Company incurs in developing technologies and carrying them through often extensive regulatory procedures until they are commercialized. Regulatory requirements include safety and efficacy tests of the product, as well as proof of manufacturability on a commercial scale. Once the related products receive regulatory approval, the deferred development costs are amortized to expense over the life of related patents.

Costs accumulated through 2005 relate to the technologies supporting our Collagen and Coatings products and reflects the costs of discovery, process design and regulatory approvals. These accumulated costs began to shrink as we commercialized CoActive, BioStep™ and the Silvertouch Catheter. In 2008, costs rose again as we began studies and development work on the EPAS1 technology. The EPAS1 spending of \$487,418 was offset by \$116,732 in amortization on the pre-2005 costs.

Total Assets grew up through 2007 with significant additions of capital, culminating in a \$14.9MM injection through the exercise of warrants at the end of 2007. In the latest fiscal year, the company used \$3.5MM in cash and saw its total assets reduced by approximately that amount.

### Summary of Quarterly Results

The quarterly financial information presented below represents eight quarters of operating results.

<i>(in Canadian \$)</i>	2008 Fourth Quarter	2008 Third Quarter	2008 Second Quarter	2008 First Quarter	2007 Fourth Quarter	2007 Third Quarter	2007 Second Quarter	2007 First Quarter
Revenue (1)	\$419,721	\$467,739	\$654,625	930,893	\$372,768	\$560,241	\$461,511	\$390,295
Net loss	\$(1,608,315)	\$(498,949)	\$(957,576)	\$(676,007)	\$(1,425,046)	\$(742,604)	\$(507,356)	\$(401,371)
Net loss per share	\$(0.02)	\$(0.01)	\$(0.01)	\$(0.01)	\$(0.02)	\$(0.01)	\$(0.01)	\$(0.01)

(1) Includes Other Revenues

The Company's ongoing quarterly losses relate primarily to the continuing buildup of the regulatory and research and development departments. There was a significant non-cash stock option compensation expense incurred in the fourth quarter to recognize employees, directors and management employees for past service to the Company. All of these factors are discussed in greater detail in other sections of this document.

### Other Performance Indicators

In addition to the key financial, revenue, and earnings-related metrics described above Management regularly reviews the following working capital metrics:

	2008 Fourth Quarter	2008 Third Quarter	2008 Second Quarter	2008 First Quarter	2007 Fourth Quarter	2007 Third Quarter	2007 Second Quarter	2007 First Quarter
Current Ratio	11.1	17.7	7.0	6.9	6.4	3.0	2.5	9.2
Net Working Capital	\$12,007,901	\$13,652,270	\$13,274,549	\$13,832,958	\$14,322,821	\$5,341,353	\$4,346,329	\$4,815,698

The Current Ratio is a model for measuring the liquidity of the Company by calculating the ratio between all current assets and all current liabilities. It is an indicator of the Company's ability to pay short-term obligations. Current assets includes cash and cash equivalents, short term investments, accounts receivable, refundable investment tax credits, inventories and prepaid expenses. Current liabilities include accounts payable and accrued liabilities and deferred revenue. Net Working Capital is calculated as current assets minus current liabilities. Net Working Capital as a percentage of Revenue is calculated as the ratio between Net Working Capital and Revenue.

The exercise of the warrants has significantly strengthened the liquidity of the Company and consequently allows us to invest in research and development and build infrastructure in our operations.

## 5. Liquidity & Capital Resources

### Financial Position

<i>(Canadian \$)</i>	As at	
	September 30, 2008	September 30, 2007
Total assets	\$ 17,292,486	\$ 20,244,461
Deferred revenue	\$ 1,527,251	\$ 1,977,904

#### Total Assets

Total assets at September 30, 2008 were \$17,292,486 compared to \$20,244,461 at September 30, 2007. The decrease is predominantly due to the reduction in Cash, Cash Equivalents and Short Term Investments over the fiscal year. These in turn reflect the building of structure and talent in the Company while revenue streams are being developed.

#### Deferred Revenue

There were no new additions to Deferred Revenue in the fiscal year. The reduction in the balance is primarily the amortization of one-fifth of the gross balance over the term of the contract.

Additional payments under the minimum US \$5,000,000 clause of the Smith & Nephew distribution contract may be payable beginning April 2010 if Product Purchases by Smith & Nephew from Covalon do not exceed minimum targets.

#### Liquidity

The Company follows a policy of investing its surplus cash resources in high quality, liquid, short-term notes. Cash equivalents as of September 30, 2008 and 2007 had less than three months maturity. Short-term investments matured on December 1, 2008 and were renewed in high-quality instruments maturing within 120 days. As at September 30, 2008 there were no restrictions on the flow of these funds nor have any of these funds been committed in any way. The Company believes that it has the capital resources and liquidity necessary to meet its commitments, support its operations and finance its current growth strategies.

#### Commitments

The Company has entered into an operating lease for its premises at 405 Britannia, Mississauga commencing December 1, 2004 and expiring November 30, 2009. The annual rental payments for the first two years are \$68,627 payable monthly and \$94,900 payable monthly for the remaining portion of the lease.

The Company has also entered into an operating lease for some of its equipment. The equipment is leased at \$477 per month under a lease expiring in 2010.

The minimum annual lease payments for the next five years are as follows:

2009	\$	100,624
2010		21,541
2011		5,724
2012		5,724
2013		<u>5,724</u>
	\$	<u>139,337</u>

The Company intends to continue to use its capital resources to fund research and development activities, including EPAS1. The amount of capital resources to be allocated to these activities will depend upon the scale of programs undertaken and a number of factors, such as the terms of our partnering agreement, input from outside experts and regulatory authorities on clinical programs. The Company has agreed to fund the development of EPAS1 through various milestones and has committed \$1,491,000 for the twelve month period ending September 30, 2009.

## Shares Outstanding

Authorized – Unlimited number of Common Shares

Issued – Common shares and warrants

	Number of Common Shares	Number of Warrants	Stated Capital	Warrants
Balance, September 30, 2006	56,322,784	14,792,328	\$ 15,828,922	\$ 927,479
Options exercised	501,194		265,920	
Warrants granted		1,095,728	(2,338,229)	2,338,229
Warrants exercised	15,888,056	(15,888,056)	14,907,819	(3,265,708)
Balance, September 30, 2007	72,712,034	-	28,664,432	-
Issued to Perfusion Therapeutics Inc.	75,000	-	192,500	-
Issued in trust	1,025,000	-	-	-
Options exercised	491,881	-	294,778	-
Balance, September 30, 2008	74,303,915	-	\$ 29,151,710	\$ -

In fiscal 2007, 501,194 options to purchase common shares with a value of \$71,287 were exercised for cash consideration of \$194,633. 200,000 options to purchase common shares expired, resulting in a corresponding increase to contributed surplus of \$12,400.

In fiscal 2007, 1,095,728 broker warrants were exchanged for Series III warrants.

In fiscal 2007, 15,888,056 Series III warrants to purchase 15,888,056 common shares, with a value of \$3,265,708 were exercised for cash consideration of \$11,642,111.

During fiscal 2007, the Company issued a total of 16,389,250 common shares.

In fiscal 2006, Covalon acquired technology from Perfusion Therapeutics Inc. for 1,100,000 fully paid non-assessable common shares of Covalon Technologies Ltd., issued in escrow to be released on various success milestones. At September 30, 2008, 75,000 shares valued at \$192,500 have been released from escrow. The remaining balance of 1,025,000 shares are still being held in escrow. In December 2008, the third milestone in the EPAS1 Project was completed and an additional 75,000 were requested for release from escrow.

In fiscal 2008, 491,881 options to purchase common shares with a value of \$102,059 were exercised for cash consideration of \$192,719.

At September 30, 2008, 6,640,502 (2007 – 8,335,599) shares are held in escrow.

### Stock Option Plan

The Company has Stock Option Agreements with its employees, directors and consultants, granting options to them exercisable in whole or part. Common shares have been reserved for fully exercisable stock options on the following basis:

	Number of Shares	Value	Exercise Price
Balance, September 30, 2006	\$ 3,103,082	\$ 418,739	
Options reinstated to consultant	112,500	23,693	\$ 0.33
Granted to related parties	975,000	473,336	\$ 1.53
Granted to employees	100,000	40,494	\$ 1.22
Vested to related parties		53,050	\$ 0.50
Exercised	(501,194)	(71,287)	
Expired	(200,000)	(12,400)	
Balance, September 30, 2007	3,589,388	925,625	
Granted to related parties	375,000	302,629	\$ 2.79
Granted to employees	380,000	310,880	\$ 2.83
Vested to related parties		278,634	\$ 1.03
Vested to employees		15,911	\$ 1.22
Exercised	(491,881)	(102,059)	
Forfeited	(164,332)	(130,529)	
Balance, September 30, 2008	\$ 3,688,175	\$ 1,601,091	

In fiscal 2007, the fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: risk-free rate of interest – 4.5%, dividend rate NIL, volatility – 66% and a term of 3 and 5 years respectively.

Total value of options granted to related parties during fiscal 2007 was \$728,475, of which \$473,336 vested, total value of options granted to employees during fiscal 2007 was \$57,300 of which \$40,494 vested. Stock Options granted to related parties during fiscal 2007 expire on March 27, 2010 (675,000), July 10, 2010 (150,000), July 10, 2012 (150,000), Stock options granted to employees (100,000) during fiscal 2007 expire on March 20, 2010.

501,194 stock options with a value of \$71,287 were exercised for common shares for cash consideration of \$194,633.

200,000 stock options granted to related parties with an exercise price of \$0.30 expired in February 2007.

In fiscal 2008, the fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest – 3.5%, dividend rate NIL, average volatility – 77% and a term of 5 years.

Total value of options granted to related parties during the fiscal 2008 was \$698,401 of which \$302,629 vested, total value of options granted to employees during fiscal 2008 was \$693,684 of which \$310,880 vested. Stock options granted to related parties during fiscal 2008 expire on March 31, 2013. Stock options granted to employees during fiscal 2008 expire on September 30, 2012 (100,000), March 31, 2013 (260,000) and on September 3, 2013 (20,000). 164,332 of these options granted to employees valued at \$130,529 with expiry dates of September 30, 2012 and March 31, 2013 were forfeited in fiscal 2008.

491,881 stock options with a value of \$102,059 were exercised for common shares for cash consideration of \$192,719.

As at September 30, 2008, 3,042,131 (2007 – 2,474,431) options were available for exercise

In October, the Company acquired new software for tracking and reporting stock option activity. This software enabled more objective assumptions on the risk-free rate of interest and stock volatility which the Company decided to implement retroactively to the beginning of calendar 2008. The effect of these assumptions is incorporated in the Annual Financial Statements and this MD&A, but result in different costs than were disclosed in the previous MD&A's for fiscal 2008.

The changes are summarized as follows:	Final Estimates	Original Estimate
Risk-free interest rate	2.88%	3.75%
Volatility Calculation	80.6%	66.0%
Option Value per Share	\$1.862	\$1.600
Total Option Value	\$1,182,370	\$1,016,000

This resulted in an understatement of Stock Option Expense of \$78,733 at the end of the 3<sup>rd</sup> Quarter. This has been corrected in the year end Financial Statements.

## Sources and Uses of Cash

	Three month period ended September 30,		Year ended September 30,	
	2008	2007	2008	2007
<b>Cash Provided By (Used in)</b>				
<b>Operating Activities</b>				
Cash flow from operating activities before change in non-cash working capital	\$ (1,415,376)	\$ (921,654)	\$ (3,060,037)	\$ (2,458,889)
Change in non-cash working capital	374,244	268,888	296,450	2,312,679
	\$ (1,041,132)	\$ (652,766)	\$ (2,763,587)	\$ (146,210)
<b>Investing Activities</b>				
Purchase of capital assets, net	\$ (171,485)	\$ (107,748)	\$ (431,474)	\$ (260,227)
Expenditure deferred development costs	(50,091)	-	(487,418)	-
Purchase of patents and technology rights	(9,396)	(10,109)	(56,878)	(218,679)
Short term investments	169,404	(9,252,103)	169,404	(9,252,103)
	\$ (61,568)	\$ (9,369,960)	\$ (806,366)	\$ (9,731,009)
<b>Financing Activities</b>				
Issuance of share capital, net	\$ 83,610	\$ 9,969,642	\$ 192,719	\$ 11,836,743
Foreign exchange gain (loss) on cash held	\$ (2,119)	\$ (14,070)	\$ (7,109)	\$ (53,269)
Increase (decrease) in cash and cash equivalents	\$ (1,021,209)	\$ (67,154)	\$ (3,384,343)	\$ 1,906,255

### Operating Activities

Cash flow used in operating activities was up \$388,366 in the 4<sup>th</sup> quarter of 2008 compared to the same period a year earlier. In both cases, the 4<sup>th</sup> quarter was substantially higher than the run rate for the year due to year end expenses, and 2008 was higher due to the build in infrastructure in the last half of the year. In both of the past 2 years, working capital has increased in the final quarter, reflecting accruals for many of the year end costs and declines in accounts receivable.

Total year operating cash flows show an increased use of cash in 2008 of \$2,617,377. This was due primarily to the lump sum payment of USD\$2MM from Smith and Nephew in fiscal 2007. Otherwise, the increase in structural costs was covered by increases in cash revenues.

### Investing Activities

In the final quarter of fiscal 2007, the Company invested a substantial portion of its proceeds from the warrant exercise in a provincial bond due over a year after its purchase. This accounted for the vast majority of the investments in both last year's 4<sup>th</sup> quarter and full year.

In 2008, the Company also invested highly in several projects, including:

- The EPAS1 project \$487,418
- Upgrade Coatings Production Equipment \$220,000

The spending on the EPAS1 project will continue as long as results are positive. Annual costs will tend to rise as safety and efficacy experiments become more extensive and approach human trials. The budget for fiscal 2009 is just under \$1.5MM.

Spending on manufacturing and operational capability will continue through 2009 as we increase capacity and build systems to support commercialization of our research work.

### ***Financing Activities***

Cash flow from financing activities for the fourth quarter of 2007 and the year was \$9,969,642 and \$11,836,743 respectively. The increase quarter over quarter and year over year in cash provided by financing activities is due to the exercise of options and warrants to purchase a total of 16,389,250 common shares.

In 2008, all cash from financing was generated by the exercise of stock options.

### ***Off-Balance Sheet Arrangements***

The Company does not have any off-balance sheet arrangements.

### ***Financial Instruments***

Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest and currency risks arising from its financial instruments. The Company is exposed to currency risk arising from fluctuations in foreign exchange rates and the degree of volatility of those rates. The Company does not use derivative instruments to reduce its exposure to foreign currency risk.

All of the Company's cash is maintained by one of the major financial institutions.

Short term investments consist of Ontario Savings Bonds (interest rate of 5.7% and maturing on December 1, 2008) and the carrying value approximates fair market value.

For the year ended September 30, 2008, three customers accounted for 100% (2006 – 95%) of the year end accounts receivable balance. These customers, who act as distributors of the Company's product, represent substantially all of the Company's sales. Credit risk exposure is mitigated by strong credit granting policies and due diligence procedures for new customers.

The Company has not entered into any futures or forward contracts or other derivative instruments as at September 30, 2008.

## 6. Risk and Uncertainties

An investment in the securities of the Company is speculative due to the proposed nature of the Company's business and the present stage of Covalon's development.

Consequently, an investment in the Company is subject to certain risks and investors should not invest in securities of the Company unless they can afford to lose their entire investment. In addition to the factors disclosed elsewhere in this MD&A, investors should consider the following risk factors in assessing the investment merits of such securities.

Biotechnology companies in the early revenue stage are subject to a number of risks and uncertainties that are inherent to the development of any new technology. General business risks include, among other things, uncertainty in product development and related clinical trials, the regulatory environment including delays or denial of approval to market products, the impact of technological change and competing technologies, the ability to protect and enforce its patent portfolio and intellectual property assets, the availability of capital to finance continued and new product development, the ability to secure strategic collaborators and its reliance on these collaborators for the development, regulatory approval, testing, manufacturing and commercialization of its products and the risk of product liability claims. In addition, market prices for securities of biotechnology companies are generally volatile, and may or may not move in a manner consistent with the progress being made by such company. To the extent possible, the Company's management pursues and implements strategies to reduce or mitigate the risks and uncertainties associated with its business. See "Information concerning the Resulting Issuer – Risk Factors" outlined in Seder Capital Corp.'s Filing Statement dated December 9, 2004 and available for review on SEDAR at [www.sedar.com](http://www.sedar.com).

## 7. Related Party Transactions

During the year the Company paid fees to related parties as follows:

- (i) Management fees totaling \$619,013 (2007 – \$527,994) to two corporations controlled by officers and directors, included in management fees are stock option benefits that have been valued at \$248,680 (2007 - \$217,994).
- (ii) Directors fees include cash compensation of \$145,708 (200 - \$140,057) paid to the four independent directors and stock option benefits that have been valued at \$298,285 (2007 – \$308,391).

The management fees are paid pursuant to two separate management agreements, expiring September 30, 2008. The commitments for the 2009 fiscal year are \$400,000. These transactions are in the normal course of operations and are measured at the amount of consideration established and agreed by the related parties.

Subsequent to the signing of the Distribution Agreement with Smith & Nephew, Dr. DiCosmo signed a Consulting Agreement with the same. The agreement called for Dr. DiCosmo to speak on behalf of Smith & Nephew at conferences, sales meetings and customer presentations for the promotion of Covalon's products. Dr. DiCosmo received, total payments of \$26,500 from Smith & Nephew according to the contract terms. In 2008 the Company determined that this arrangement was in conflict with its policies. Smith and Nephew agreed to the cancellation of the contract and Dr. DiCosmo agreed to repay the \$26,500 to Covalon as a deduction from his remuneration in the 2009 fiscal year.

## 8. Critical Accounting Estimates

The preparation of financial statements in accordance with Canadian generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reported period. Actual results could differ from management's best estimate as additional information becomes available in the future. Management believes that the estimates and assumptions upon which the Company relies are reasonable based upon information available at the time these estimates and assumptions are made. Estimates and assumptions may be revised as new information is acquired, and are subject to change. Areas of significant estimates include, research and development costs, and stock based compensation.

### *Deferred Development Costs/Research and Development*

During the development stage, research costs were expensed as incurred. Development costs which meet generally accepted criteria, including reasonable assurance regarding recoverability, are deferred and amortized from the beginning of commercial production and sales. Annually the Company reviews the recoverability of deferred development costs through evaluation of the expected future cash inflows from commercialization of the associated products to determine if there is impairment in the recoverable amount.

Development costs for each product (project) are amortized when the product regulatory approval to sell the product is received, on a straight-line basis over the years remaining on the patent.

### *Stock Based Compensation*

Direct awards of stock are based on the price of common stock measured at fair value at the date of grant and the corresponding expense is recognized.

The Company uses the fair value based method of accounting for all its stock-based compensation. Accordingly, the fair value method of accounting is applied for stock options granted to directors, officers, employees and consultants whereby the weighted average fair value of options granted is recognized in the financial statements over the vesting period. When the awards are exercised, share capital is credited by the sum of the consideration paid together with the related portion previously credited to options.

## 9. Accounting Policies

### *Policies Adopted in Fiscal 2008*

CICA Handbook New Section 1506, based in International Reporting IAS 8 – Accounting Policies, Changes in Accounting Policies together with the accounting treatment and disclosures of changes in accounting policies, changes in accounting estimates, and the correction of errors. The notes describe disclosure, on an interim basis, of the description and impact on financial statements of any new primary source of GAAP that has been issued but not yet instituted. It is effective for interim and annual reports beginning on or after January 1, 2007. At this time, there is no impact of this section on our financial position or on the results of our operations.

For interim and fiscal years beginning on or after October 1, 2007, the CICA Handbook Section 3862, Financial Instruments – Disclosure, and CICA Handbook Section 3863, Financial Instruments – Presentation apply. These new standards revise and enhance the disclosure requirements, and carry forward, substantially unchanged, the presentation requirements. Sections 3862 and 3863 emphasize the significance of financial instruments for the entity's financial position and performance, the nature and extent of risks arising from financial instruments, and how these risks are managed. Management has determined that the application of Sections 3862 and 3863 did not have any impact on the consolidated financial statements for the year ending September 30, 2008.

For interim and fiscal years beginning on or after October 1, 2007, the CICA Handbook Section 1535, Capital Disclosures applies. This section specifies disclosures of information about a company's objectives, policies and processes for managing its capital structure; quantitative data about what the company regards as capital; and whether the company has complied with externally imposed capital requirements, like bank covenants, and if it has not complied, the consequences of such non-compliance. The adoption of this new accounting standard did not impact the amounts reported in the Company's financial statements.

The CICA amended Handbook Section 1400 to include requirements for management to assess and disclose an entity's ability to continue as a going concern. These standards are effective for interim and annual financial statements for the Company's reporting period beginning on or after October 1, 2008. The Company early adopted this standard and asserts that the Company is considered to be a going concern.

### ***Accounting Policies Not Yet Implemented***

In February 2008, the CICA issued Handbook Section 3064, Goodwill and Intangible Assets, effective for interim and annual financial statements relating to fiscal years beginning on or after October 1, 2008. Section 3064, which replaces Section 3062, Goodwill and other Intangible Assets, and Section 3450, Research and Development Costs, establishes standards for the recognition, measurement and disclosure of goodwill and intangible assets. Management is assessing the impact of this new standard on its consolidated financial statements.

In March 2006, the Accounting Standards Board of the CICA released its new strategic plan which will abandon GAAP and affect a complete convergence to the International Financial Reporting Standards (IFRS). At the end of a transitional period of approximately five years, Canadian GAAP will cease to exist as a separate, distinct basis of financial reporting for public companies. Management is addressing this issue through research on the process and specific impact to Covalon Technologies. In the upcoming fiscal year, the Company will identify the specific areas that will be impacted by the transition and will put any necessary systems in place to comply. The first year that Covalon plans to issue IFRS-compliant Financial Statements is the year ending September 30, 2012. To provide comparative information, an opening Balance Sheet will be necessary at October 1, 2010, so the Company must be prepared in less than 2 years for the formal change. By September 30, 2009, the Company will have identified the material issues related to the transition to IFRS and will have a plan to deal with them by the end of the following year, and will need to disclose its plan in the MD&A.

Section 3031, Inventories, is effective for annual and interim periods beginning on or after January 1, 2008. This new section requires inventory to be measured at the lower of cost or net realizable value and provides guidance on the methodology used to assign costs to inventory, it disallows the use of last-in first-out inventory costing methodology and requires that, when circumstances which previously caused inventories to be written down below cost no longer exist, the amount of the write-down is to be reversed. Upon adoption, the impact on the financial statements is not expected to be material.

## 10. Income Taxes

The Company follows the asset and liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are recognized for the future income tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Future income tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on future income tax assets and liabilities of a change in tax rates is recognized in operations in the year in which the change occurs.

### (a) Reconciliation between statutory rate and actual rate

	2008	2007
Income tax recovery computed at statutory combined basis rate of 34% (2007 - 36%)	\$(1,271,900)	\$ (1,107,500)
Permanent differences	268,400	207,400
Expiring losses	233,100	162,800
Change in future tax rates	274,600	87,900
Prior year adjustment for R&D claim	161,900	-
Other	133,600	81,800
Valuation Allowance	200,300	567,600
	<u>\$ -</u>	<u>\$ -</u>

### (b) Future tax assets

The tax effect of the temporary differences that gives rise to future tax assets (liabilities) as of September 30, 2008 and 2007 is presented below. No benefit has been recorded in these financial statements as there is no assurance that the Company will generate taxable income to utilize these differences.

	2008	2007
Non-capital loss carry forwards	\$2,691,500	\$ 2,457,000
Capital loss carry forwards	148,300	166,200
Capital and other assets	165,400	114,000
Deferred development costs	89,700	(50,100)
Deferred revenue	443,000	642,800
Other		7,700
Valuation allowance	(3,537,900)	(3,337,600)
	<u>\$ -</u>	<u>\$ -</u>

- (c) The Company has non-capital losses carry forward available for income tax purposes as at September 30, 2008 of approximately \$9,281,000 which are available to reduce taxable incomes of future years. These losses expire as follows:

<u>Year</u>	<u>Amount</u>
2009	\$ 880,000
2010	844,000
2014	787,000
2015	1,963,000
2026	1,494,000
2027	235,000
2028	<u>3,078,000</u>
	<u>\$ 9,281,000</u>

- (d) The Company has capital losses carry forward for income tax purposes as at September 30, 2008 of approximately \$1,022,000 which are available to reduce taxable capital gains in future years. These losses do not expire.
- (e) The Company is eligible for a 20% federal credit on its SR&ED expenditures which can only be used to offset against income taxes payable. The Company is also eligible for the Ontario Innovation Tax Credit ("OITC") at the rate of 10% and refundable in cash to the Company.

The refundable tax credits ultimately received by the Company are subject to review by Canada Revenue Agency and the Ontario Ministry of Finance.

Under the Income Tax Act of Canada, certain expenditures are classified as SR&ED expenditures and for tax purposes are grouped into a pool, which is 100% deductible in the year incurred. This SR&ED expenditure pool can also be carried forward indefinitely and deducted in full in any subsequent year. The balance of the federal SR&ED expenditure pool at September 30, 2008 is \$2,814,387 (2007 - \$1,556,672) and \$2,856,498 for Ontario tax purposes (2006 - \$2,382,512).

At September 30, 2008, the Company has \$359,685 (2007 - \$17,119) of unclaimed investment tax credits available to reduce federal income taxes payable in future years. If not utilized, these investment tax credits will start expiring in 2013.

## 11. Opportunities

While our business continues to focus on our current platforms, there are opportunities to leverage the technologies to areas in the ophthalmology, orthopedics, pharmaceuticals and biotechnology industries. The broad applicability of our technology and licensing business model allows Covalon to participate in diverse product offerings used for treating patients.

The Company's focus in addressing unmet clinical needs complements our passion for innovation and could potentially position us at the forefront of the convergence of drugs, cells (EPAS1 technology) and devices. Below are a few of these opportunities we are focusing on in the coming fiscal year.

### *Antimicrobial Coatings*

Indwelling catheters are associated with very serious infections such as catheter associated urinary tract infection and catheter-related bloodstream infection. Central venous catheters (CVC) and urinary catheters are the most susceptible to bacterial growth causing infection; each year 200,000 catheter-related blood stream infections are caused by CVCs in U.S. hospitals. Together, these two categories of devices account for over 50% of total hospital-acquired infections. Antimicrobial coatings are expected to be an effective solution to this growing concern. Furthermore, blood-contacting medical devices such as peripherally inserted central catheters (PICC) and CVC, etc. are susceptible to vascular access-related infections and blood-clotting. Blood clots on the surface of devices raise significant concerns for stroke, heart attack, pulmonary embolism and conditions related to impaired blood flow. Prolonged hospital stay, morbidity or mortality and serious economical consequences are a result of infections and blood-clotting-related events caused by a variety of vascular access devices.

Recently, the Centers for Medicare and Medicaid Services (CMS, USA) issued a ruling that updates the USA hospital inpatient prospective payment system for 2008. The new ruling requires that hospitals and other patient care facilities identify conditions present at admission. Furthermore, guidelines were provided that emphasized that re-imburement payment would not be made for certain (eight identified) conditions determined to be hospital-acquired. Two of the eight conditions affect patients with incontinence; they are: catheter-associated urinary tract infections and pressure ulcers. The conditions, if noted in a patient on admission to an acute care facility, must be identified by the clinical staff and attending physician. When patients are admitted without these conditions, evidence-based, preventive protocols must be implemented in order to provide optimal care and prevent costly complications.

In essence, all hospital-acquired conditions identified should be of concern for all facilities; the two conditions that impact patients with incontinence are catheter-associated UTIs and pressure ulcers. The CMS included this complication with the objective to reduce the rate of UTIs through decreased use of indwelling catheters in the hospitalized Medicare patient. According to information in the final rule within this guideline,<sup>12</sup> catheter-associated UTIs are the most common nosocomial infection; thus, this condition meets the criteria of high volume with associated costs.

CDC (Center for Disease Control, USA) reports that there are 561,667 catheter-associated urinary tract infections per year. For FY 2006, there were 11,780 reported cases of Medicare patients who had a catheter-associated urinary tract infection as a secondary diagnosis. The cases had average charges of \$40,347 for the entire hospital stay. According to a study in the American Journal of Medicine, catheter-associated urinary tract infection is the most common nosocomial infection, accounting for more than 1 million cases in hospitals and nursing homes nationwide. Approximately 11.3 million women in the United States had at least one presumed acute community-acquired urinary tract infection resulting in antimicrobial therapy in 1995, with direct costs estimated at \$659 million and indirect costs totaling \$936 million. Nosocomial urinary tract infection necessitates one extra hospital day per patient or nearly 1 million extra hospital days per year. It is estimated that each episode of symptomatic urinary tract infection adds \$676 to a hospital bill. In total, according to the study, the estimated annual cost of nosocomial urinary tract infection in the United States ranges between \$424 and \$451 million.

According to the CDC, "Catheter-associated urinary tract infections are caused by a variety of pathogens, including *Escherichia coli*, *Klebsiella*, *Proteus*, *Enterococcus*, *Pseudomonas*, *Enterobacter*, *Serratia*, and *Candida*. Many of these microorganisms are part of the patient's endogenous bowel flora, but they can also be acquired by cross-contamination from other patients or hospital personnel or by exposure to contaminated solutions or non-sterile equipment." (cited in Hess & Rook, Understanding Recent Regulatory Guidelines for Hospital-Acquired Catheter-Related Urinary Tract Infections and Pressure Ulcers, OWM Wound Ostomy Management 53:34-42, 2007).

Furthermore, vascular catheter-associated infection, that is those caused by central venous catheters use or other vascular catheter, was also identified by CMS as a non-reimbursable condition if acquired by a patient during treatment within an acute care facility.

Management expects that the ruling by CMS will generate significant and renewed interest with medical professionals, acute care facilities and medical device distributors in the use of effective antimicrobial coatings, such as Covalon's coating on urinary catheters, to reduce hospital acquired infections.

Covalon's antimicrobial and low-thrombogenic coating can be applied to a wide variety of in-dwelling, blood contacting devices for reducing the incidence of hospital acquired infection as well as reducing thrombogenicity. Effective antimicrobial and low-thrombogenic coated catheters may reduce infection and thrombus formation thus improving patient outcome.

Antimicrobial CVC are expected to experience a growth rate approximately 5-fold greater than that of un-coated CVC. It is estimated that by 2009, sixty-nine percent (69%) of all CVC used will be antimicrobial (data from Frost and Sullivan, U.S. Antimicrobial Devices Markets, 2003). Hospital-acquired infections affect approximately 2 million people in the United States each year, and cost over \$11 billion to the U.S. healthcare system (data from Frost and Sullivan, U.S. Antimicrobial Coating Markets, 2006). The total antimicrobial catheters market is projected to attain revenues of US \$ 375 million by 2009 (Frost and Sullivan 2006).

### ***Collagen Matrices***

The Covalon collagen matrix is a proprietary technology platform targeted at tissue regeneration. The science team at Covalon started with the hypothesis that “if one can develop a biomaterial that offers an optimal biological environment for specific tissue regeneration, cellular functions can be activated and functional tissues can be regenerated”.

The Covalon Research Team investigated a variety of biomaterials and determined that Type I collagen was the best biomaterial for the intended uses, but that the triple helix structure of collagen has inherent limitations with respect to cell activation, migration, tissue integration and regeneration. It was determined that a hybrid structure of Type I triple helix collagen and open helix denatured collagen would be ideal. The Covalon Collagen matrix has portions of open structure of denatured collagen where well –known and specific molecular sequences containing the amino acids; arginine, glycine and aspartic acid, referred to as “RGDs sites” are exposed for interaction with cell receptors called integrins leading to the stimulation of cellular functionality, while maintaining portions of triple helix structures for cellular support. These unique features create the optimal conditions for functional tissue regeneration.

The Covalon strategy is to define applications for the platform by first exploiting opportunities that require relatively rapid, low-risk 510(k) regulatory approvals that are expected to yield products that therefore are quick to market. These applications will create the revenue base to internally develop more research-intensive and sophisticated applications. As the Company shifts its focus to the more sophisticated applications the returns on the investments should increase substantially.

### ***Wound Care***

Covalon has developed and received regulatory approval for five collagen-based wound care products. The products have broad application in advanced wound care for difficult to heal wounds such as pressure ulcers, diabetic ulcers, venous ulcers and dehiscent wounds. According to MedMarket Diligence Worldwide Wound Management 2005-2014 report, the world wide market for advanced wound care is approximately \$2.6 billion reaching \$5 billion by 2014. The Covalon products Biostep and Biostep Ag (step up wound healing) was launched in mid 2007 by Smith and Nephew, the world leader in advanced wound care. Covalon expects that the product advantages of Biostep products combined with Smith and Nephew’s distribution power will make this product a sector leader.

The Covalon team is investigating a number of product line extensions in the wound care market niche to expand the product positioning of the technology platform and capture an increasing share of the market. The Company looks forward to more communication of progress in the wound care market.

### ***Pressure Ulcers***

As noted in the report by Hess & Rook (ibid 2007) pressure ulcers represent a high-cost and high-volume condition. According to the final rule in FY 2006, 322,946 cases of Medicare patients with a secondary diagnosis of pressure ulcer with an associated average cost of \$40,381 per patient were reported.

Pressure ulcers are ruled as a hospital acquired condition and hence “the CMS hopes to:

1. improve screening of patients for pressure ulcers on admission,
2. promote early identification of pressure ulcers to improve treatment, and
3. greatly improve patients’ quality of care.” (ibid)

As of October 1, 2008, physicians and hospitals will be expected to perform more accurate skin assessments at patients’ admissions in order to diagnose pressure ulcers and potential skin complications earlier and implement appropriate treatments and management. “Therefore, the use of accurate assessment skills, coupled with coordinated skin care formularies and management pathways based on clinical practice guidelines, should be initiated on all patients incontinent of urine and feces admitted to the facility. These pathways should be initiated as either a prevention pathway (patients with intact skin) and/or intervention pathway (patients with skin injury)” (ibid).

In the USA, Medicare reimbursement rulings will affect how facilities are reimbursed or paid for services in the next several years. The rulings will necessitate re-educating clinical staff and attending physicians on the absolute need for accurate assessments, prevention and management implementation. Accurate diagnoses and documentation will impact reimbursement. And most importantly from a healthcare perspective, reinforce the need for best practice in the care of individuals whose incontinence threatens skin integrity.

Covalon’s ColActive and Biostep line of wound collagen dressings were specifically designed for the treatment of pressure ulcers, as well as other conditions. Management expects that the ruling by CMS relating to pressure ulcers will generate significant and renewed interest with medical professionals, acute care facilities and medical device distributors in the use of Covalon’s wound care products. Management views the rulings by CMS as positive indicators for the continuing and increasing need and sales of Covalon’s products.

### **Ocular**

The Covalon team has identified the Ocular market as a priority target. The Company has identified a number of high value applications for its Collagen platform. Applications include a variety of high value post-surgical bio-resorbable antimicrobial dressings that are placed on the surface of the eye. The developments of these applications will begin to transition Covalon’s product offerings into higher value opportunities. The US market opportunity alone exceeds \$100 million. These new products are in the early design and development phase but are anticipated to have a low regulatory risk. The Covalon team looks forward to providing news on these opportunities.

### **Hemostatics**

The market opportunities for topical and surgical hemostats have been identified by the Covalon team as niches where the Company’s collagen platform has significant advantages over the existing competitive product offerings. The Company is in the development stage of at a topical hemostatic dressing. The dressings will be targeted for military, trauma, surgical interventions and puncture site wounds. The Company estimates that there are approximately 6 million trauma and surgical wounds in the US that require a hemostatic, according to the Centers for Disease Control, as well as approximately 6.2 million puncture site wounds according to Millennium Research Group’s report on US Markets for Vascular Access. The US market when combined with the military

requirements exceeds \$150 million. The topical hemostatic is anticipated to require a 510(k) and poses a low regulatory risk. The Covalon team is investigating the value of entering the surgical hemostatic market. Although the market is large the regulatory risk is greater. The Covalon platform for this application has advantages over the current market leaders. As expected, limited clinical trials are expected. The Company intends to evaluate the risk/return of entering this market and make a decision in 2008.

### ***Dental***

Dental extractions in the US exceed 50 million per year and incidence of alveolar osteitis ranges between 5% and 40%. The treatment of the condition is painful, time consuming and expensive and no current product offering is effective. The Covalon team has determined that its collagen platform could be useful for developing a product for this need. The regulatory pathway for the product has low to moderate risk. The Company is in the design and development phase for this product and looks forward to providing news of its development.

### ***Vascular***

The Covalon collagen platform appears to have advantages for a variety of applications in the vascular market including coatings on stents and vascular wraps. The properties of the denatured collagen portion of the technology appear to offer some advantages that may be desired by the current device manufacturers in this market. The Company recognizes that development in this market will require consideration of the higher regulatory risks. The Company has received "freedom to operate" opinions for the intended applications. The returns are high for successful technologies in this market niche but development is expensive. The Company is evaluating its development strategy and looks forward to more communications on this development.

### ***Orthopedics***

Soft tissue repair, connective tissue damage, bone/tissue integration continues to be a significant problem in orthopedics, as do post-surgery infections. The Covalon Coatings and Collagen platform appears to have some unique features that may be beneficial. Developments may include collagen pads for shoulder cuff repairs, ACL scaffolds, small joint plugs and coatings on implants. The regulatory risk in this niche is moderate to high but the relative return is high. The Covalon directors and executive have a wide range of experience in this market niche and are currently working on selecting the best targets for the technology platform.

## 12. Disclosure Controls and Procedures and Internal Controls over Financial Reporting

Effective as of December 15, 2008, the Ontario Securities Commission approved the revised *National Instruments 52-109, Certification of Disclosure in Issuers' Annual and Interim Filings* ("NI 52-109"). The revised NI 52-109 extends the exemption for venture issuers from certifications relating to the establishment and maintenance of disclosure controls and procedures ("DC&P) and internal controls over financial reporting ("ICFR"), as defined in NI 52-109. Additional risks to the quality, reliability, transparency and timeliness of the Company's interim and annual filings may result from the inherent limitations on management's ability to design and implement on a cost effective basis DC&P and ICFR. The Company recognizes the importance of DC&P and ICFR, and will endeavour to have sufficient controls in place to ensure financial statements are materially correct and sufficiently disclosed.

The Company continues to formalize procedures and control measures that are already in place and to introduce new ones to ensure good evaluation and control practices. As of September 30, 2008, the Company's management evaluated the effectiveness of the design and operation of its disclosure controls and procedures as defined under the rules. The evaluation was performed under the supervision, and with the participation, of the Chief Executive Officer (CEO) and Chief Financial Officer (CFO). Based on the evaluation of the DC&P, the CEO and the CFO have concluded that, subject to the fact that an evaluation of controls can provide only reasonable, not absolute, assurance that all control issues and instances of fraud or error, if any, within the Company have been detected, the Company's DC&P are effective in providing reasonable assurance that material information relating to the Company is made known to management. Changes and new controls are evaluated and implemented as required to provide greater business control.

The design of ICFR within the Company is management's responsibility to provide reasonable assurance that the reliability of financial reporting and that the preparation of financial statements for external purposes follow Canadian generally accepted accounting principles.