

# **Covalon Technologies Ltd.**

Management's Discussion and Analysis of Financial  
Condition and Results of Operations

**March 31, 2011**



## **MANAGEMENT'S DISCUSSION & ANALYSIS**

**For the three and six month period ended March 31, 2011**

***May 27, 2011***

The following discussion of Covalon Technologies Ltd.'s ("Covalon" or the "Company") financial condition and results of operations should be read in conjunction with our audited consolidated financial statements for the year ended September 30, 2010 and our unaudited consolidated financial statements with related notes for the three and six month period ended March 31, 2011. 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 the 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. 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***

In 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***

This MD&A contains forward-looking statements, which reflect the Company's current expectations regarding future events. The forward-looking statements are often, but not always, identified by the use of words 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. 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. Many risks are inherent in the industry; others are more specific to the Company. Investors should consult the "Risks & Uncertainties" section of this MD&A as well as the Company's ongoing quarterly filings for additional information on risks and uncertainties relating to these forward-looking statements. Investors should not place undue reliance on any forward-looking statements. Management assumes no obligation



to update or alter any forward-looking statements whether as a result of new information, further events or otherwise.

## **Company Overview**

### ***Nature of Our Business***

Covalon Technologies Ltd. is a unique public medical technologies company that researches, patents, develops and commercializes advanced medical technologies that improve patient outcomes and save lives. Our offices and laboratories are located in Mississauga, Ontario, Canada.

The medical device market in which Covalon is engaged offers tremendous opportunities. Any medical product or wound dressing in contact with the human body has the potential to facilitate an infection or cause other life-threatening complications that can place patients at risk and incur additional hospitalization days and expensive treatment regimes. These issues have forced medical companies to seek advanced technologies, such as those offered by Covalon, which typically command more advantageous reimbursement rates and offer product differentiation.

Covalon has a broad footprint of proprietary technologies, intellectual property, and patents related to:

- Advanced Wound Care;
- Sophisticated tissue repair products for advanced wound care dressings, trauma, and surgical applications;
- Unique transparent film dressings with antimicrobials embedded in the silicone adhesive;
- Stem cell technology focused on genetic regeneration of damaged tissue;
- Medical Coatings;
- Superior medical coatings with customized physical properties, drug delivery capabilities and infection control applications;
- Infection Control & Drug Delivery;
- Covalon is known for novel photo-stable silver ion antimicrobial technology, which is used in both wound dressings and coatings for medical devices;
- Covalon has experience with the delivery of a number of therapeutics and biologics which is applied in both wound dressings and coatings for medical devices to make them therapeutically active;
- Innovations for over-the-counter offerings, antimicrobial consumer products and veterinary applications.

Covalon licenses its technologies and products to some of the largest medical device companies in the world. Covalon also works with niche start-ups to create novel technology to advance their product offerings in the medical device markets. Covalon has worked with over twenty medical companies and our clients include C.R. Bard, Inc. a leader in vascular access devices; Medline Industries, Inc., a leading device and patient care distributor; Smith and Nephew Inc., a leader in wound care products; CareFusion Corporation, a leading specialty medical device manufacturer; Amsino International, Inc., a major contract manufacturer.

These and other major medical companies are likely to be impressed with Covalon because of our:

- Knowledgeable team of medical researchers, scientists and engineers;

- Broad footprint of technologies and associated patents and applications;
- Extensive experience in commercialization of ideas that lead to marketed products;
- Rapid customization of technologies for specific applications with accelerated time-to-market;
- Flexibility in structuring licensing and technology transfer arrangements;
- Ability to perform low-volume commercial manufacturing or have its high quality products contract-manufactured in high volumes and low cost, if so desired by the client;
- Relatively strong balance sheet.

Once a company partners with Covalon, there is a strong likelihood they will continue to work with us for other new product opportunities and contract renewals.

Clients value our collaborative approach in delivering innovative proprietary technologies. Key stakeholders in each company; from R&D, business development, and finance, to regulatory, sales and marketing work with Covalon's experts on everything from brainstorming on a potential offering, up to turnkey product development and technology transfer. Companies leverage our in-depth knowledge and commercialization success to assist in establishing product specifications, testing of efficacy, microbiology and file preparation for market approvals. Where appropriate, we design a client's product to meet the requirements of the most beneficial billing codes.

We leverage our in-house manufacturing facility to perfect commercialization processes and to manufacture client products in smaller commercial volumes. The relationships that Covalon has with contract manufacturing organizations ("CMO") provide us or our clients with additional resources, flexibility, and expertise for large-scale production, without the burden of substantial committed facilities. As an ISO 13485 quality-systems company, Covalon ensures all technology developments conform to quality guidelines and all transfers of technology are easily integrated into a partner company's processes.

### ***Business Model***

Currently, we sell our technologies to medical companies and distributors. These medical companies and distributors license our technologies for incorporating into their own product offerings, which they sell to healthcare providers. Referred to by the industry as an OEM sales model (original equipment manufacturer), this approach assigns the major cost of selling to our customers, who are able to penetrate the market with a large sales force in geographical locations where Covalon does not have staff or offices. Our revenue streams are typically generated from services, technology licensing fees, and royalties from the sale or commercialization of products.

Most OEM sales models involve a long sales cycle – from initial discussion, product evaluation, regulatory filings, contract negotiation and then to market roll-out. This process generally takes twelve to eighteen months – although there are exceptions for both shorter and longer times for the completion of a project. On the other hand, once a company invests time and money in choosing our technology, it is likely to use it for some time to come.

We are confident that as we succeed in signing further new contracts with major medical companies and distributors, Covalon will become a self-sustaining medical research and development company that will continue to discover new and exciting technologies that improve patient outcomes and save lives.

### **Our Technologies**

Covalon's accomplished team of scientists individually are recognized in the medical industry as experts in Customized medical device coatings; Antimicrobial and infection control technologies; Accelerated



tissue healing and regenerative technologies; Advanced drug delivery technologies; and many other areas.

Covalon's staff complement is largely comprised of scientists and engineers. Over eighty-five percent hold an advanced academic degree in chemistry, biology or physics and the Company's engineers have decades of collective experience in commercializing innovative technologies.

Together, our technology platforms, wound care products, and consulting services deliver a suite of cost-effective solutions to help our customers achieve product differentiation through improved patient outcomes and help save lives. Covalon's technologies address important healthcare issues such as infection control, medical device biocompatibility, and healthy tissue repair.

### ***Advanced Wound Care***

Covalon's expertise in wound care has led to the development of proprietary technologies comprising collagen, antimicrobial silicone adhesive dressings and advanced tissue repair technology.

#### Collagen:

Covalon's advanced collagen dressing technologies are essentially collagen-based substances that can hold and release a variety of materials, and/or allow materials to pass through the dressing. These dressings begin from a collagen base, which is generally biocompatible with the human body, and enable the release of beneficial materials, such as antimicrobials, into the wound site and/or enhance the removal of undesirable materials, such as wound exudates from the wound. Variations in Covalon's basic formulation will yield different rates of release, duration of release and/or size of particles removed. Covalon's unique collagen construct is ideally designed for wound healing because it provides a scaffold for cellular growth. By combining these characteristics with the many materials that can be added to the dressing, Covalon has a broad range of potential applications for this technology.

Covalon initially developed and received regulatory approval for a suite of advanced collagen-based wound dressings. These wound dressings improve wound healing by removing wound bed enzymes that otherwise slow down the healing process. Certain of the collagen wound dressing formulations contain active silver, which is released into the wound as an antimicrobial agent to further improve the wound healing process. The Company markets and licenses these wound dressings under the brand name ColActive™ through a number of independent distributors and under the private labeled brand BIOSTEP™ which is marketed and sold by a large wound care company.

The following Collagen product families have regulatory approval for sale:

<b>Product</b>	<b>Description</b>	<b>Clearance</b>	<b>Date</b>
ColActive™	Collagen Wound Dressing	FDA, Health Canada	2007
ColActive Ag™	Collagen with Silver	FDA, Health Canada	2007
ColActive Plus™	Collagen Wound Dressing	FDA, Health Canada, CE	2007
ColActive Plus Ag™	Collagen with Silver	FDA, Health Canada	2007
CovaClear™ Ag	Collagen Hydrogel with Silver	FDA, Health Canada	2007

We have a number of new and novel wound care technologies under development that combine biocompatible materials with a variety of therapeutics to address specific needs in the wound care market.

The experience that Covalon has gained in developing collagen wound care products is now being leveraged to enter into the high value surgical products market.

#### Silicone Adhesive Technology:

Covalon has developed the first silicone adhesive with two antimicrobial agents embedded directly in the adhesive. Based on this proprietary technology, Covalon has developed a line of transparent antimicrobial film dressings for the vascular access and wound care markets (IV Clear and SurgiClear, respectively). Health Canada approval has been received for both products. The Company intends to file for FDA and CE mark approval.

IV Clear™ is a unique transparent antimicrobial cover dressing designed to cover and protect infusion therapy sites. Covalon's latest wound care innovation is engineered from a novel transparent polyurethane film which is coated with a patented blend of silicone adhesives, chlorhexidine and silver. It is gentle to the skin, and provides maximum patient comfort. Unlike most other products containing silver, silver discoloration is deterred, ensuring the dressing stays transparent for seven days.

IV Clear dressings offer significant advantages over existing products in the market. IV Clear elutes or releases the active antimicrobials directly from the adhesive continuously for at least seven days, thereby providing maximum protection against direct microbial colonization as well as creating an antimicrobial shield around an IV line entry point. The combination of silver and chlorhexidine provides a much broader spectrum of powerful killing activity than any competitive product currently on the market, and also decreases the likelihood of encouraging resistant organisms.

Covalon developed SurgiClear, based on the same technology as IV Clear to address the shortcomings of other surgical site cover dressings in the market. SurgiClear is a unique transparent antimicrobial silicone based dressing designed to cover and protect surgical sites. Engineered from a novel transparent polyurethane film coated with a patent-pending blend of silicone adhesives and antimicrobials, SurgiClear is gentle to the skin for maximum patient comfort. Its removal will not tear or damage fragile skin, and the novel adhesive film provides excellent tissue contact and infection management. The use of silicone materials on wounds is known to help reduce excessive scarring during the healing process. We expect this product to be adopted for use on surgical site closures such as breast surgery, caesarean sections, facial surgery, vascular surgery and orthopaedic surgery.

#### Genetic Regeneration of Damaged Tissue:

Covalon's intellectual property portfolio includes patents and intellectual property for stem cell engineering utilizing the EPAS1 gene and a proprietary method of introducing the EPAS1 gene into stem cells ("EPAS1"). This acquired technology is thought to enhance the efficacy of delivering stem cells to repair diseased tissue. EPAS1 is believed to be capable of stimulating the growth of new blood vessels 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.

Covalon performed early mouse model experiments with EPAS1 that showed some promise for stimulating the growth of new blood vessels. The Company's previous CEO, Dr. Frank DiCosmo championed a pre-clinical research program that targeted EPAS1 on heart regeneration in Congestive Heart Failure ("CHF") patients who previously suffered a myocardial infarction ("MI") or heart attack. Dr. DiCosmo's approach was for Covalon to fully fund the research and the Company invested approximately \$1.7 million into a series of pre-clinical studies. The preliminary results of these pre-clinical porcine model experiments did not demonstrate that EPAS1-modified allogeneic (non-donor specific) stem cells improved both perfusion (volume of blood flow) and cardiac function better than either un-modified allogeneic stem cells or no stem cells.



Management believes it would require significant financial investments in further studies to advance the medical application of EPAS1 in human heart regeneration treatments and then bring the perfected technology to the commercial market. While Covalon intends to pursue other potential funding sources, commercialization partners and medical applications of the underlying intellectual property, management has determined that it is not prudent to continue further pre-clinical research studies in the technology, without proper funding.

The Company recorded a non-cash impairment charge of \$1,700,350 in the income statement against the deferred development cost asset during the year ended September 30, 2010.

The Company continues to believe that the underlying intellectual property may have potential for a number of gene therapy applications and intends to continue to investigate other commercialization opportunities related to the underlying patents and intellectual property.

### ***Specialized Medical Device Coatings***

Covalon developed a patented coating process for medical devices that enter the body. The Covalon coating technology advantage is in its unique flexibility, as it has broad applicability across many of the large medical device companies' product lines and divisions. This is advantageous because it allows the investment these companies make to be spread across many divisions and products. In the past many large device companies had multiple specialized coating technologies to deal with each product application making coatings a costly investment.

Covalon's coating process applies a biocompatible coating that is permanently bound to medical devices through a method known as covalent bonding. Our coating technology is ideally suited to be a delivery surface for therapeutics such as drugs, antimicrobials, peptides, anti-proliferatives and biologics. The Company has focused on two areas in this market, which include; 1) devices that are designed to enter the body for a limited period of time; and 2) devices that are designed to be implanted in the body forever. Many of these life-saving devices, when left uncoated, can carry a high risk of medical device failure due to biocompatibility issues between a patient and the medical device.

Covalon's coating process applies a very thin coating on a medical device that will generally be slippery when moistened and can hold and release a variety of antimicrobial or other therapeutic agents to the surrounding tissue while in use. This ensures biocompatibility and improves the functionality and performance of the medical device implant. Our technology has already proven effective on many polymer surfaces, and is currently being tested and evaluated on other materials, including various metals.

These proprietary processes can be modified and enhanced coatings with specific characteristics that meet customer needs which may include lubricity (slippery when wet), antimicrobial activity, hemo-compatibility, bio-compatibility (to prevent tissue encrustation), or controlled release of therapeutics (drug elution).

Covalon has a number of commercialized coating successes that are currently marketed by our clients under private labelled brand names. As well, existing and new clients are continuously evaluating new coating opportunities for existing products that can benefit from our advanced coating technology, including new materials, existing products on the market or new products under development, as exemplified in the list below:

- Urinary Catheter and IV lines – to prevent infections
- Endoscopic implants – to prevent infection
- Venous access catheter – to prevent blood clots and infections on the device

- Neuro-vascular devices such as shunts and stents – to prevent bio-fouling (attachment of blood and proteins to the device surface) and infections on the device
- Cardiac devices – to prevent expensive surgical interventions required to replace the devices due to infections on the device
- Implantable infusion devices – to prevent blood clots and infections on the device
- Surgical wound drain – to prevent infections
- Orthopaedic devices – to extend the coatings technology to metals
- Breast implants and tissue expanders – to prevent infections

### ***Infection Control & Drug Delivery***

The targeted delivery of therapeutics from the surfaces of medical devices is an emerging segment of the medical device industry known as combination devices. The FDA has even set up a new category for this segment to accommodate the increasing demand for such devices. Covalon's initial focus has been on antimicrobial and device combinations. Covalon is known for novel photo-stable silver ion antimicrobial technology, which is used in both wound dressings and coatings of medical devices. Our expertise is now being used to develop other unique antimicrobial solutions that target a number of infection control issues. Covalon maintains a fully equipped research and development lab with top research scientists that work at characterizing different combinations of antimicrobial agents that are extensively performance tested in its in-house microbiology lab.

These new antimicrobial combinations allow us to offer customization around customer set specifications. Infection control problems vary for medical devices, consumer products or wound dressings that come into contact with the human body (or animals, in the case of the veterinary market). There is no one set solution for all problems. Some of the key issues addressed by combining antimicrobials are speed at which it works, effectiveness and the duration of its effectiveness, and the species of microbes being targeted.

Covalon's antimicrobial technologies can be used for applications in the following areas: Medical device coatings; Wound care products; Polymer mixes for extrusion; Skin Sanitizers; Surface Sanitizers; Cosmetics; Consumer products; Veterinary applications, and others.

Over the past number of years Covalon has developed expertise in the controlled delivery of antimicrobials that can be applied to other therapeutics. The Company continues to develop promising customer driven combinations of drugs and medical devices. Covalon assesses new applications for its drug delivery technology and know-how with partners who want to enhance existing products or introduce new solutions into their respective markets.

### ***Patent Portfolio***

Covalon's intellectual property strategy actively pursues new patents on our discoveries as they are made. Covalon currently has patents approved or pending in various jurisdictions around the world. A summary of these patents is included below:

- *Method of Making Antimicrobial Polymeric Surfaces* (patent in USA, EU, Australia, other jurisdictions patent pending)
- *System and Method For Coating Medical Devices* (USA and International patent applications filed)

- *Drug Delivery via Therapeutic Hydrogels* (patent in USA, Canada, EU and Australia)
- *Antimicrobial Photo-Stable Coating Composition* (USA and International patent applications filed)
- *Non-Adhesive Elastic Gelatine Matrices* (USA, EU, Eurasia, Canada and other jurisdictions patent applications filed)
- *EPAS1 Gene Transfer to Improve Cell Therapy* (USA, EU, Canada, and International patent applications filed)
- *Hypoxia Inducing Factors and Uses Thereof for Inducing Angiogenesis and Improving Muscular Functions* (USA, EU and Canada patent applications filed)
- *Self-Reinforced Membrane* (USA patent application filed)
- *Antimicrobial Silicone Wound Dressings* (USA patent application filed)

## **Analysis of Operating and Financial Results**

Covalon is in the process of transitioning from solely a research lab to a successful commercial technology business with a broad platform of patented technologies. The Company currently uses an OEM business model to realize value in the marketplace. Our current OEM revenue model based on selling our technologies to large medical companies does not produce consistent revenues on a quarterly basis. Consequently, any one quarter's results are not particularly indicative of the Company's prospects. Most OEM sales models involve a long sales cycle – from initial discussion, product evaluation, regulatory filings, contract negotiation and then to market roll-out. This process generally takes twelve to eighteen months – although there are exceptions for both shorter and longer times for the completion of a project. Revenues are typically realized based on the completion of milestones outlined in contractual agreements. The start and finish of projects is dependent on many factors, many of which are outside the control of Covalon.

The past twelve months have seen numerous changes made to the operations of the Company, including the recent hiring of the Company's first dedicated sales, marketing and business development team, re-alignment of development and operations, addition of leadership to senior management and a stronger focus on market driven technology. As a result, the Company is generating interest in its products and services to a greater extent than in the past. The Company anticipates that this activity will lead to increased revenue as the sales cycle results in expansion of the Company's customer base.

During the quarter, the Company ended its exclusive agreement with Smith and Nephew. As a result, licensing fees were up significantly due to the amortization of the remaining balance of the deferred exclusivity fee of approximately \$421,000 related to the Smith & Nephew contract. The Company continues to supply product to Smith and Nephew on a non-exclusive basis. Management believes that the full potential of the Company's collagen platform had not been realized under the exclusive arrangement with Smith and Nephew and Covalon is now poised to pursue the market for collagen wound care products aggressively, both within the United States and internationally. Moving quickly to take advantage of the opportunity, the Company has commenced an agreement with a Canadian company to distribute wound care dressings in the Middle East. This agreement is subject to regulatory approval and United States and Canadian export compliance.

During the quarter, IV Clear™/ SurgiClear, Covalon's novel antimicrobial silicone adhesive dressings were cleared for marketing in Canada. The Company is investing resources to complete the data required for filing with the FDA in the United States. Initial clinician response has been positive and the Company is actively pursuing opportunities with a number of potential distribution partners.

### ***Financial Highlights for the three and six month period ended March 31, 2011***

Financial highlights are as follows:

- Quarterly revenue was \$1,011,436, up 22.1% over the same period of the prior year and year-to-date revenue was \$1,672,551 compared to \$1,623,195 in the comparative period.
- Licensing Fees increased by 426.7% to \$582,822 during the second quarter as a result of the signing of two new licensing agreements announced in June 2010 and the amortization of the remaining balance of the exclusivity fee related to the Smith & Nephew contract. The Company has ended its exclusive agreement with Smith & Nephew and is currently supplying product to Smith and Nephew on a non-exclusive basis.

- Loss per share for the three month period ended March 2011 and 2010 were \$0.006 and \$0.028 respectively. Year-to-date loss per share was \$0.014 this year compared to \$0.034 in the prior year.
- Year-to-date marketing expenses increased by 88.3% to \$339,142 compared to \$180,043 in the same period of the prior year.

### **Consolidated Statement of Operations and Comprehensive Loss**

(Canadian \$)	Three month period ended		Six month period ended	
	March 31,		March 31,	
	2011	2010	2011	2010
<b>Revenue</b>				
Product Sales				
Advanced wound care	\$ 267,134	\$ 332,501	\$ 562,500	\$ 576,895
Specialized medical device coatings	161,480	385,367	365,847	824,986
Total Product Sales	428,614	717,868	928,347	1,401,881
Licensing fee	582,822	110,657	744,204	221,314
<b>Total Revenue</b>	<b>1,011,436</b>	<b>828,525</b>	<b>1,672,551</b>	<b>1,623,195</b>
<b>Cost of Sales</b>	<b>319,587</b>	<b>425,929</b>	<b>677,188</b>	<b>777,182</b>
<b>Gross Profit</b>	<b>691,849</b>	<b>402,596</b>	<b>995,363</b>	<b>846,013</b>
Operating expense before undernoted items	1,049,201	685,401	1,907,233	1,467,273
<b>Loss before undernoted</b>	<b>(357,352)</b>	<b>(282,805)</b>	<b>(911,870)</b>	<b>(621,260)</b>
Amortization and depreciation	90,376	109,104	178,923	223,592
Loss on disposal of capital asset	-	9,290	-	9,290
Write-down of deferred development costs	-	1,700,350	-	1,700,350
Interest income	(17,118)	(8,615)	(30,942)	(18,200)
<b>Net Loss</b>	<b>\$ (430,610)</b>	<b>\$ (2,092,934)</b>	<b>\$ (1,059,851)</b>	<b>\$ (2,536,292)</b>
<b>Loss per share</b>	<b>\$ (0.006)</b>	<b>\$ (0.028)</b>	<b>\$ (0.014)</b>	<b>\$ (0.034)</b>

### **Product and Service Revenue and Gross Profit**

Quarter-to-quarter revenue is inherently unpredictable due to our business model and fluctuates from quarter to quarter depending on the composition of contractual arrangements entered into in each quarter and the timing of completed coating and development services milestone in any period. Total revenues for the quarter and six month period increased. While licensing fee revenue for the three month period ended March 31, 2011 was up from the same period of the prior year, revenues from advanced wound care and specialized medical device coatings were down. The products and services revenue mix changed from the comparative period as follows:

- 79% of total revenue in the second quarter of 2011 was derived from advanced wound care compared with 53% in the same period of the previous year;
- 21% of total revenue in the current period were derived from specialized medical device coatings compared to 47% in the second quarter fiscal of 2011;

Gross margin as a percentage of total revenue for the three month period ended March 31, 2011 was 68.4%, compared to 48.6% in the comparative period of fiscal 2010. Gross margin as a percentage of total revenue for the first six month was 59.5% compared to 52.1% in the same period of the prior year. Gross margin is highly influenced by product mix between advanced wound care and specialized medical device coatings; the mix of silver-based and non-silver based collagen dressings sold in the periods; and the amount of funded coating services included in revenue and costs. Management continues to focus on improving gross margins by rationalizing resources and focusing on business opportunities with greater profit potential.

On October 1, 2009, the Company disclosed two product segments, namely, Advanced Wound Care and Specialized Medical Device Coatings. These segments have been disclosed based on the underlying technology of the product.

For the three and six month period ended March 31, 2011, product and services revenue and licensing fees from advanced wound care increased by 80.2% and 50.8% respectively over the comparative periods of fiscal 2010. Gross Profit related to advanced wound care for the three and six month periods ended March 31, 2011 was \$624,542 and \$818,518 or 78.2% and 68.0% respectively of revenue compared to \$240,398 and \$411,458 or 54.2% and 51.5% in the comparative periods of the prior year.

Products and services revenue and licensing fees for the three and six month periods ended March 31, 2011 from specialized medical device coatings decreased by \$172,404 and \$356,174 or 44.7% and 43.2% respectively over the same period in fiscal 2010. This decrease reflects the unpredictability of the start of new development projects and the timing of revenue recognition that occurs as milestones are completed. Gross profit related to our specialized medical device coatings for the three and six month period ended March 31, 2011 was \$67,307 and \$176,845 or 31.6% and 37.7% of specialized medical device coating revenue compared to \$162,198 and \$434,555 or 42.1% and 52.7% in the same periods of the prior year. The strengthening of the sales and marketing team has resulted in increased customer interest in Covalon's coating platform. Given the long sales cycle in the medical industry, it is difficult to predict when the increase in customer discussions and interest will translate into revenue generating projects.

### ***Licensing Fees***

Licensing fees increased due to (1) the amortization of the remaining deferred exclusivity fee related from the Smith and Nephew contract as a result of the Company ending its exclusive agreement with Smith and Nephew (2) the signing of two new licensing agreements announced in June 2010, where fees of approximately US\$1,000,000 were collected by the Company, but are deferred and recognized in revenue over the term of the licensing agreements.

### ***Interest Income***

Interest income on investments during the three month period increased to \$17,118 from \$8,615 in the prior period. All investments are made in accordance with the Company's audit committee investment guidelines of investing cash of the Company in low-risk interest-bearing instruments.



## Operating expenses

(Canadian \$)				
Expenses before depreciation, amortization and interest income	Three months ended		Six months ended	
	March 31, 2011	2010	March 31, 2011	2010
<u>Operations</u>				
Wages and benefits	\$ 102,976	\$ 101,980	\$ 234,316	\$ 236,380
Consulting fees	27,978	3,720	43,811	7,190
Other	7,280	15,395	13,183	29,929
Total Operations	\$ 138,234	\$ 121,095	\$ 291,310	\$ 273,499
<u>Research and development activities</u>				
Wages and benefits	\$ 212,796	\$ 168,840	\$ 354,850	\$ 333,194
Consulting and Outside Testing	164,796	6,148	212,509	6,691
Recovery of refundable investment tax credit	-	(249,489)	-	(249,489)
Other	41,233	24,087	76,877	40,796
Government grants	(39,111)	-	(77,955)	-
Total Research and Development	\$ 379,714	\$ (50,414)	\$ 566,281	\$ 131,192
<u>Marketing</u>				
Wages and Benefits	\$ 214,956	\$ 63,000	\$ 286,546	\$ 115,168
Travel	16,990	18,716	30,044	39,669
Investor Relations	9,556	16,493	10,786	19,675
Other	7,887	1,999	11,766	5,531
Total Marketing	\$ 249,389	\$ 100,208	\$ 339,142	\$ 180,043
<u>General and administrative</u>				
Wages and Benefits	\$ 123,488	\$ 138,647	\$ 359,696	\$ 265,454
Director's Compensation	1,295	79,582	14,685	119,444
Advisor expense	7,707	58,020	24,160	138,927
Professional Fees	54,129	136,030	96,849	141,780
Facility	41,551	41,850	86,258	84,435
Foreign exchange loss	7,767	32,583	35,638	47,535
Other	45,927	27,800	93,214	84,964
Total General and Administrative	\$ 281,864	\$ 514,512	\$ 710,500	\$ 882,539
<b>Total expenses before depreciation, amortization and interest income</b>	<b>\$ 1,049,201</b>	<b>\$ 685,401</b>	<b>\$ 1,907,233</b>	<b>\$ 1,467,273</b>

Total expenses before depreciation, amortization and interest income for the three month period ended March 31, 2011 increased by 53.1% or \$363,800 over the same period of the prior period. The increase is primarily attributable to increases in marketing and R&D expenditures. The Company's focus on increasing sales required investment of resources to expand the business development team, accordingly sales and marketing expenses more than double compared to the prior year. As IV Clear™ and SurgiClear approach the final phases of regulatory approval substantial outside R&D testing was required. A decrease in the recovery of refundable investment tax credit also impacted the increase in R&D expenses for the period.

The Company is party to legal proceedings. Although the result of litigation cannot be predicted with certainty, management is of the opinion that the proceedings have no merit and will not result in a material loss to the Company.

### **Related Party Transactions**

During the six month period ending March 31, 2011, the Company paid fees to related parties as follows:

- (i) Management fees totaling \$99,865 (2010 – \$221,473) to a corporation controlled by an officer and director. Included in management fees are stock option benefits that have been valued at \$12,365 (2010 – \$21,473). The management fees are paid pursuant to a single management agreement, expiring August 31, 2011. The commitment for the 2011 fiscal year is \$175,000.
- (ii) Directors fees include cash compensation of \$Nil (2010 - \$23,500) paid to certain of the independent directors and stock option benefits that have vested during the period amounted to \$14,686 (2010 – \$94,944).

These transactions are in the normal course of operations and are measured at the amount of consideration established and agreed by the related parties.

### **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 deferred development costs, stock based compensation and impairment of long lived assets.

#### ***Deferred Development Costs***

Development costs that meet generally accepted criteria are deferred and amortized from the beginning of commercial production and sales. Deferred development costs for each technology platform are amortized when the product regulatory approval to sell related products 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 in the statement of operations.

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. The forfeiture rate for stock based compensation is estimated at the date of grant and revised as necessary until the award has vested.

#### ***Impairment of Long-Lived Assets***

An impairment charge is recognized for long-lived assets, including intangible assets with definite lives, when an event or change in circumstances causes the assets' carrying value to exceed the total



undiscounted cash flows expected from its use and eventual disposition. The impairment loss is calculated as the difference between the fair value of the asset and its carrying value.

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.

## Summary of Quarterly Results and Financial Position

The quarterly financial information presented below represents eight quarters of operating results and financial position:

in Canadian \$)	2011 Second Quarter	2011 First Quarter	2010 Fourth Quarter	2010 Third Quarter	2010 Second Quarter	2010 First Quarter	2009 Fourth Quarter	2009 Third Quarter
Revenue (1)	\$ 1,028,554	\$ 674,939	\$ 618,939	\$ 1,024,047	\$ 837,140	\$ 804,255	\$ 614,549	\$ 427,376
Operating loss before amortization	\$ 357,352	\$ 554,518	\$ 659,498	\$ 317,306	\$ 282,805	\$ 338,455	\$ 822,670	\$ 1,120,493
Net loss	\$ 430,610	\$ 629,241	\$ 751,432	\$ 647,223	\$ 2,029,034	\$ 443,358	\$ 844,459	\$ 1,201,228
Net loss per share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.01)	\$ (0.01)	\$ (0.02)
Cash and cash equivalents	\$ 3,431,454	\$ 4,960,874	\$ 5,838,578	\$ 6,431,954	\$ 4,970,623	\$ 5,428,742	\$ 6,036,626	\$ 7,788,427
Net working capital	\$ 4,078,834	\$ 4,556,347	\$ 5,217,531	\$ 5,970,058	\$ 5,760,650	\$ 6,132,019	\$ 6,429,103	\$ 7,141,868
Current Ratio	5.34	4.05	3.9	3.7	5.9	6.4	6.0	6.1

(1) includes Product Revenue, Licensing Revenue and interest income for comparative purposes to prior quarters

Our quarterly revenue is inherently unpredictable due to our business model and fluctuates from quarter to quarter depending on the composition of contractual arrangements entered into in each quarter and the timing of completed coating and development services milestone in any period.

Highlights of the second quarter operating results are:

- Quarterly revenue for the three months ended March 31, 2011 was \$1,028,554, an increase of 52.4% over revenues of \$674,939 recorded in the previous quarter ended December 31, 2010;
- Quarterly loss from operations before amortization improved by 35.6% to \$357,352 from \$554,518 in the first quarter of 2011.
- Loss per share was \$0.01 in the second quarter of 2011 and \$0.03 in the same quarter of the prior year;

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 our ability to pay short-term obligations. Current assets include cash and cash equivalents, short-term investments, accounts receivable,

inventories and prepaid expenses. Current liabilities include accounts payable and accrued liabilities, and the current portion of deferred revenue. Net Working Capital is calculated as current assets minus current liabilities. At March 31, 2011, the Company had 5.34 times the current assets needed to pay its current liabilities.

## Liquidity & Capital Resources

(Canadian \$)	As at	
	March 31, 2011	September 30, 2010
Cash and cash equivalents	\$ 3,431,454	\$ 5,838,578
Short-term investments	\$ 500,000	\$ 500,000
Total assets	\$ 8,248,594	\$ 10,319,792
Deferred revenue	\$ 840,844	\$ 1,585,048

### Highlights

Cash flows as a result of entering into customer contracts will continue to be unpredictable quarter-to-quarter, due to the timing of receipt of upfront payments under new contracts and the timing of receipt of ongoing royalty payments. During the quarter, the company made substantial investments in sales and marketing and in R&D for the final phase data collection leading up to the regulatory filing IV Clear™ and SurgiClear™ products. For the three month period ended March 31, 2011, we had a net cash outflow of \$1,529,420 compared to \$877,704 in the quarter ended December 31, 2010. Approximately \$612,000 of the increase in cash outflow relates to changes in non-cash operating working capital excluding deferred revenue. We anticipate cash flow will improve as a result of the completion of R&D on IV Clear™ and SurgiClear™ and as new revenue generating projects come on stream through increased sales activities.

On March 31, 2011 cash, cash equivalents, and short-term investments amounted to \$3,931,454. Covalon follows a policy of investing its surplus cash resources in high quality, liquid, short-term deposits. Cash equivalents as of March 31, 2011 had less than three months to maturity and are cashable without penalty. As at March 31, 2011, there were no restrictions on the flow of these funds nor have any of these funds been committed in any way. Management believes that the Company has the capital resources and liquidity necessary to meet its current commitments, support its operations, and finance its current growth strategies.

Total assets at March 31, 2011 were \$8,248,594 compared to \$10,319,792 at September 30, 2010. Cash and cash equivalents and short-term investments comprised almost 48% of total assets at March 31, 2011. Of the remaining assets, the Company's accounts receivable and inventory are liquid, with collection periods and turnover ratios in the 60 to 180 day range. The balance of our assets is comprised of capital assets and the Company's intangible assets. These have low liquidity but represent much of the intellectual property assets that are used to generate Covalon's revenue streams.

Deferred revenue decreased by \$582,822 to \$840,844 at March 31, 2011 from the previous quarter ended December 31, 2010. The decrease in deferred revenue is due to the amortization recorded during the period including the remaining balance of the deferred exclusivity fee related to the Smith & Nephew contract.

**Commitments**

Covalon has signed an offer to lease for its premises at 405 Britannia Road East, Mississauga commencing December 1, 2009 and expiring on November 30, 2014. The annual rental payment for the first year was \$80,719 and increases annually over the term of the lease. The Company has also entered into an operating lease for some of its office equipment. The equipment is leased at \$477 per month under a lease expiring in 2013.

The minimum annual lease payments for the next 3 fiscal years are:

2012 Fiscal Year	\$90,988
2013 Fiscal Year	\$95,965
2014 Fiscal Year	\$91,627

**Shares Outstanding**

	<u>Number of Common Shares</u>	<u>Stated Capital</u>
Balance, September 30, 2009	74,303,915	\$ 29,173,085
Exercise of stock options	587,793	282,231
Balance, September 30, 2010 and March 31, 2011	<u>74,891,708</u>	<u>29,455,316</u>

Included in Common Shares are 950,000 shares held in trust related to the Company's acquisition of technology from Perfusion Therapeutics Inc. in 2006.

There were no share transactions during the period.

### **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:

	<b>Number of Shares</b>	<b>Value</b>	<b>Weighted Average Exercise Price</b>
Balance, September 30, 2009	5,270,673	\$ 2,347,028	\$ 0.91
Granted to related parties	1,055,000	198,712	\$ 0.29
Granted to employees	2,380,000	64,611	\$ 0.20
Vested to related parties		48,445	\$ 2.05
Vested to consultants		180,799	\$ 0.50
Vested to employees		26,257	\$ 1.62
Exercised	(587,793)	(125,894)	
Expired	(3,019,948)	(1,408,871)	
Forfeited	(162,932)	(111,124)	
Balance, September 30, 2010	<u>4,935,000</u>	<u>1,219,963</u>	\$ 0.91
Vested to related parties	-	27,051	\$ 0.71
Vested to consultants	-	24,159	\$ 0.50
Vested to employees	-	111,582	\$ 0.32
Expired	(100,000)	(34,090)	
Forfeited	<u>(170,000)</u>	<u>-</u>	
Balance, March 31, 2011	<u>4,665,000</u>	<u>\$ 1,348,665</u>	\$ 0.45

During the six month period ending March 31, 2011, 100,000 options valued at \$34,090 expired and 170,000 options with an expiry date of September 30, 2015 were forfeited.



## Sources and Uses of Cash

	Three month period ended March 31,		Six month period ended March 31,	
	2011	2010	2011	2010
<b>Cash Provided By (Used In)</b>				
<b>Operating Activities</b>				
Cash used in operating activities before change in non-cash working capital	\$ (266,801)	\$ (102,534)	\$ (704,640)	\$ (318,210)
Change in non-cash working capital	(1,195,129)	(197,307)	(1,573,028)	(618,725)
	<b>\$ (1,461,930)</b>	<b>\$ (299,841)</b>	<b>\$ (2,277,668)</b>	<b>\$ (936,935)</b>
<b>Investing Activities</b>				
Purchase of capital assets	\$ (4,938)	\$ (27,603)	\$ (21,409)	\$ (32,968)
Expenditure on deferred development cost	-	(109,179)	-	(162,602)
Purchase of other assets	(56,919)	(19,132)	(94,551)	(46,700)
	<b>\$ (61,857)</b>	<b>\$ (155,914)</b>	<b>\$ (115,960)</b>	<b>\$ (242,270)</b>
<b>Financing Activities</b>				
Net proceeds on issuance of share capital	\$ -	\$ -	\$ -	\$ 116,337
Foreign exchange loss on cash held	\$ (5,633)	\$ (2,364)	\$ (13,496)	\$ (3,135)
Decrease in cash and cash equivalents	<b>\$ (1,529,420)</b>	<b>\$ (458,119)</b>	<b>\$ (2,407,124)</b>	<b>\$ (1,066,003)</b>

### **Operating Activities**

Cash used in operating activities for the three month period ended March 31, 2011 was \$1,461,930 compared to \$299,841 in the same period of the prior year. The increase in cash outflow was due primarily due to a combination of the operating loss resulting from the increases in sales and marketing investments and the late stage R&D expenditures required to complete the data for the regulatory filing of IV Clear™ and SurgiClear products as well as an increase in accounts receivable of approximately \$372,000 and decrease in deferred revenue of approximately \$583,000.

### **Investing Activities**

Expenditures on other costs relates to patents and trademarks.

### **Financing Activities**

There were no financing activities during the three month period ended March 31, 2011.

### **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 or credit risks arising from these financial instruments. The Company is exposed to currency risk arising from fluctuations in foreign exchange rates and the degree of volatility in those rates. The Company does not use derivative instruments to reduce its exposure to foreign currency risk.

Short term investments consists of Ontario Savings Bonds (step up interest rates of 1.5%, 2.5%, 3.5% and 4.5% in each respective year, redeemable every 6 months and maturing on June 21, 2014) and the carrying value approximates fair market value.

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

The Company has not entered into any futures or forward contracts, or other derivative instruments as at the date of this MD&A.

### **Subsequent Event**

There were no subsequent events.

### **Risks and Uncertainties**

An investment in the securities of the Company is speculative due to the proposed nature of the Company's business and the fact that Covalon Technologies Ltd. has not yet achieved an annual profit. 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.

Medical Device and 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, commercialization and/or distribution 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.

Without limiting the foregoing, the following risks are discussed in more detail:

#### ***Covalon has a history of net losses and may not achieve or maintain profitability.***

Covalon has not yet achieved profitability and there is no guarantee that Covalon will be able to achieve profitability in the future. Covalon has never paid a dividend on its common shares and does not expect to do so in the foreseeable future. Covalon's business and prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in new and rapidly evolving markets such as healthcare.

Covalon cannot predict if profitability will ever be achieved and, if it is, whether or not it will be sustainable on a quarterly or an annual basis. Even if Covalon is not able to successfully further commercialize its products, Covalon believes that it has sufficient capital to fund its business and operations through at least fiscal 2011. However, Covalon may need to raise additional capital in the future. Additional financing may not be available, and even if available, may not be on acceptable terms.

#### ***Any failure to obtain or protect intellectual property could adversely affect Covalon.***

Covalon's success depends, in part, on its ability to obtain patents, or licenses to patents, maintain trade secret protection, and enforce its rights against others. Covalon has filed and is actively pursuing patent applications in Canada, the United States and other jurisdictions. Covalon may not be able to obtain patent protection for key elements of its technology.

There can be no assurance that:

- patent applications will result in the issuance of patents;
- additional proprietary products developed will be suitably protected from infringement;
- patents issued will provide adequate protection or any competitive advantages;
- patents will not be successfully challenged by any third parties; and
- patents of others will not impede Covalon's ability to commercialize its technology.

Covalon may need to obtain licenses for the development of its products. Licenses may not be available on satisfactory terms or at all. If available, these licenses may obligate Covalon to exercise diligence in bringing its technology to market and may obligate it to make minimum guarantee or milestone payments. These diligence and milestone payments may be costly and could seriously harm Covalon's business. Covalon may also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and may be responsible for the costs of filing and prosecuting patent applications. These costs could affect Covalon's results of operations and decrease its earnings.

Covalon's intellectual property includes trade secrets and know-how that may not be protected by patents. There can be no assurance that Covalon will be able to protect its trade secrets. To help protect its rights, Covalon requires employees, consultants, advisors and collaborators to enter into confidentiality agreements. These agreements may not adequately protect Covalon's trade secrets, know-how, or other proprietary information in the event of any unauthorized use or disclosure.

***Covalon's development programs and products subject it to the risk of product liability claims for which Covalon may not be able to obtain adequate insurance coverage.***

Human therapeutic products and medical devices involve the risk of product liability claims and associated adverse publicity. Covalon's principal risks relate to the sales of its products and currently their use in clinical trials. Claims may be made by consumers, healthcare providers, third party strategic collaborators or others selling Covalon's products. There can be no assurance that Covalon will be able to obtain or maintain sufficient and affordable insurance coverage for any of these claims. Without sufficient coverage, any claim, any threat of such a claim or any product withdrawal could seriously harm Covalon's business.

***Covalon may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.***

Covalon's future success and competitive position depends in part on its ability to obtain and maintain certain proprietary intellectual property rights used in its principal products. Any such success may be achieved in part by prosecuting claims against others who Covalon believes are infringing its rights and by defending claims of intellectual property infringement brought by its competitors and others. Covalon's involvement in intellectual property litigation could result in significant expense, adversely affecting the development of product candidates or sales of the challenged product or intellectual property and diverting the efforts of its technical and management personnel, whether or not such litigation is resolved in its favour. Some of Covalon's competitors may be able to sustain the costs of complex patent litigation more effectively than it can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could affect Covalon's ability to continue its operations.

In the event of an adverse outcome as a defendant in any such litigation, Covalon may, among other things, be required to:

- pay substantial damages;
- cease the development, manufacture, use or sale of product candidates or products that infringe upon the intellectual property of others;

- expend significant resources to design around a patent or to develop or acquire non-infringing intellectual property;
- discontinue processes incorporating infringing technology;
- obtain licenses to the infringed intellectual property.

If third-parties file patent applications, or are issued patents claiming technology also claimed by Covalon in pending applications, Covalon may be required to participate in interference proceedings with the U.S. Patent and Trademark Office, or other proceedings outside the United States, including oppositions, to determine priority of invention or patentability, which could result in substantial cost to Covalon even if the eventual outcome were favourable.

Covalon or its clients must receive regulatory approval for each of Covalon's product candidates before they can be sold commercially in North America or internationally, which can take significant time and be very costly.

The development, manufacture and sale of medical devices and human therapeutic products in Canada, the United States and internationally is governed by a variety of statutes and regulations.

These laws require, among other things:

- approval of manufacturing facilities and practices;
- adequate and well-controlled research and testing of products in pre-clinical and clinical trials;
- review and approval of submissions containing manufacturing, pre-clinical and/or clinical data in order to obtain marketing approval based on establishing the safety and efficacy of the product for each use sought, including adherence to good manufacturing practices during production and storage;
- control of marketing activities, including advertising and labelling.

Some product candidates currently under development by Covalon will require significant development, pre-clinical and clinical testing, pre-market review and approval, and investment of significant funds prior to their commercialization. The process of completing clinical testing and obtaining such approvals (if required) is likely to take many years and require the expenditure of substantial resources, and Covalon does not know whether any clinical studies by it will be successful, that regulatory approvals will be received, or that regulatory approvals will be obtained in a timely manner. Despite the time and resources expended by Covalon, regulatory approval is never guaranteed.

***Even if some of Covalon's products and manufacturing facilities receive regulatory approval, those products and facilities may still face subsequent regulatory difficulties.***

If Covalon receives regulatory approval to sell any of its products, regulatory agencies will limit the approval to certain diseases, conditions, or categories of patients who can use them. In addition, regulatory agencies subject a marketed product, its manufacturer, and the manufacturer's facilities to ongoing regulatory requirements. Regulatory agencies may also require expensive post-approval studies. Any adverse effects associated with Covalon's products must also be reported to regulatory authorities. If new data are developed, previously unknown adverse experiences with a product occur, deficiencies in Covalon's manufacturing and laboratory facilities are discovered, or it fails to comply with applicable post-market regulatory requirements, a regulatory agency may impose restrictions on that product or on Covalon including the requirement to withdraw the product from the market, close the facility, suspend manufacturing, change the product's label or pay substantial fines.

***Covalon's success is partly dependent on its partners' success and the relationship with partners is governed by contracts.***

Covalon is reliant on partners to execute certain key business processes. If its partners do not perform to Covalon's expectations, Covalon may be unable to enforce a change due to contractual terms. This may significantly impact Covalon's ability to generate revenues and profits.

Examples of such issues include:

- Manufacturing may be prioritized other than as Covalon's customers desires;
- Production quality measures may not be achieved;
- Sales expectations are not achieved;
- New products are not launched expeditiously.

***If Covalon fails to hire and retain key management, scientific and technical personnel, it may be unable to successfully implement its business plan.***

Covalon is highly dependent on its senior management and its scientific and technical personnel for their domain knowledge and technical expertise. The competition for qualified personnel in the healthcare field is intense, and Covalon relies heavily on its ability to attract and retain qualified managerial, scientific, and technical personnel. Covalon's ability to manage growth effectively will require continued implementation and improvement of its management systems and the ability to recruit and train new employees. Covalon may not be able to successfully attract and retain skilled and experienced personnel, which could harm its ability to develop product candidates and generate revenues.

## **Accounting Policies**

### ***International Financial Reporting Standards (IFRS)***

#### ***Background, project structure and project progress***

In March 2006, the CICA released its plan to adopt International Financial Reporting Standards. After a five year transitional period, at the end of 2011, Canadian GAAP will cease to exist as a separate basis of financial reporting for public companies. The Company will issue consolidated financial statements in accordance with IFRS as issued by the International Accounting Standards Board ("IASB") for the year ended September 30, 2012, with comparative information.

#### ***Preliminary Impact Assessment***

The Company has completed a diagnostic study of the conversion of its consolidated financial statements to IFRS, with the assistance of external consultants. The study identified the principal differences between the Company's records using existing Canadian GAAP and IFRS standards.

The results of this assessment identified:

- Preliminary analysis of all Canadian GAAP to IFRS differences and IFRS 1 elections and resulting prioritization of high, medium and low impact areas of focus for the Company based on potential impact;
- Preliminary resource requirements;
- A preliminary IFRS Transition Plan (details outlined below).

#### ***IFRS Transition Plan***

During the year, the Company has established a formal IFRS Transition Plan. This plan includes:

- An established project structure and governance practices;

- Detailed timetable with milestones and deliverables;
- Identification and allocation of resources (combination of internal and external);
- Development and execution of a training program;
- Detailed analysis of all Canadian GAAP to IFRS differences;
- Detailed analysis and selection of all IFRS 1 elections;
- Assessment of impact on data systems, internal controls over financial reporting, and business activities, such as financing and compensation arrangements.

The Company has completed the detailed assessment of all standards that affect the transition.

The Company has scheduled the solutions development and the implementation for the second and third quarter of next year including construction of full financial statements. Specifically, the items identified are being analysed and any differences quantified.

### ***Potential accounting changes as a result of transition to IFRS***

The Company has implemented a detailed review of the potential impact of International Financial Reporting Standards, IFRS, on its accounting policies. Outlined below is a very brief summary of select IFRS that may impact the Company, their differences from Canadian Generally Accepted Accounting Principles (“GAAP”) and their potential impact. Based on the impact analysis performed with the assistance of the external consultants, the Company is currently considering what IFRS 1 exemptions to elect. The list below is not comprehensive and does not include all of the differences from GAAP for the standards noted. Also, the list does not include all the standards that may require changes for the transition to IFRS. Some of the standards not presented below could have a significant impact on the Company’s consolidated financial statements.

**Revenue Recognition** – The Company has contracts which generate revenue from licensing fees. Many of these contracts provide upfront payments and under GAAP have been deferred over the life of the contract. Each contract must be reviewed to ensure that the accounting is appropriate under IFRS to determine whether any differences in timing or amount of revenue recognized exist. IFRS 1 does not contain any special exemptions for revenue for first-time adoption. All accounting policies related to revenue will be assessed against the appropriate standard including IAS 18, Revenue for compliance.

**Stock-based Compensation** – The Company intends to use the IFRS 1 exemption to prevent full retrospective restatement of stock options under IFRS. However, retrospective restatement will still be required for any outstanding equity instruments that are unvested and liabilities that have not been settled prior to the date of transition to IFRS.

Under IFRS 2 *Share-based payments*, stock options with graded vesting must be accounted for as separate awards. In addition, forfeitures must be estimated when the stock options are issued. The Company is reviewing all stock options.

**Foreign Exchange Translation** - The Company sells products to customers in U.S. dollars and purchases some services and raw materials from suppliers invoiced in U.S. dollars. All labour costs are denominated and settled in Canadian dollars. An analysis is currently underway to determine if there is any impact on the functional currency under IFRS.

**Property, Plant & Equipment (PP&E)** – Analysis of all material PP&E accounts is required to ensure that any components with different useful lives are identified and amortized appropriately. Net book values as at the date of transition will be reviewed to ensure that any material components are identified. The Company is reviewing componentization of PP&E.

**Presentation and Disclosure** – IFRS requires significantly more disclosure than GAAP for certain standards. In some cases, IFRS also requires different presentation on the balance sheet and income statement.

At this time, Covalon cannot quantify the impact of IFRS to its financial statements. The Company is in the process of finalizing preliminary conclusions and accounting policy choices on the standards noted above. Those conclusions and accounting policy choices will be reported on when finalized.

The IASB has several projects slated for completion in 2011 that may significantly impact the transition to IFRS and the financial statements of the Company. The Company continues to monitor the IASB's progress on these projects and their impact on Covalon's transition to IFRS.

#### ***Impact on Information Systems and Technology***

It is anticipated that the adoption of IFRS will have some impact on information systems requirements. The main drivers for systems changes include:

- Additional information required as a result of enhanced note disclosures;
- Tracking of IFRS to GAAP differences during the transition;
- Tracking sufficient level of details within the accounting records to allow management to maintain adherence with IFRS going forward.

The impact and changes to systems are on-going and will be prioritized as part of the project.

#### ***Impact on Reporting and Internal Controls***

In accordance with Covalon's approach to certification of internal controls required under Canadian Securities Administrators' National Instrument 52-109, all entity-level, information technology, disclosure and business process controls will require updating and testing to reflect changes arising from Covalon's conversion to IFRS. Where material changes are identified, these changes will be mapped and tested to ensure that no material control deficiencies exist as a result of the Corporation's conversion to IFRS.

#### ***Impact on Business***

The transition to IFRS may have an impact on the Company's business practices. The Company is currently considering the contractual implications of IFRS on any licensing and other arrangements.

### **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 March 31, 2011, 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.