# Covalon Technologies Ltd.

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

**December 31, 2012**

# MANAGEMENT'S DISCUSSION & ANALYSIS
## For the three months ended December 31, 2012

***February 28, 2013***

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, 2012 and with our unaudited condensed consolidated interim financial statements with related notes for the three month period ended December 31, 2012. Additional information on Covalon Technologies Ltd. can be obtained on SEDAR at www.sedar.com, as well as the Company's website at www.covalon.com. Unless otherwise indicated, all references to the terms "we", "us", "our", "Covalon" and "Company" refer to Covalon Technologies Ltd. and its subsidiaries.

In this MD&A, financial information for the three month periods ended December 31, 2012 and 2011 is based on the unaudited condensed consolidated interim financial statements of the Company, which was prepared in accordance with International Financial Reporting Standards ("IFRS"), and is presented in Canadian dollars unless otherwise specified. In accordance with its terms of reference, the Audit Committee of the Company's Board of Directors reviews the contents of the MD&A and recommends its approval to the Board of Directors. The Board of Directors has approved this MD&A, on February 28, 2013. Disclosure contained in this document is current to that date, unless otherwise noted.

On January 1, 2011, as issued by the International Accounting Standards Board ("IASB"), IFRS became the basis of preparation of financial statements for publicly accountable enterprises in Canada. The information presented in this MD&A, including information relating to comparative periods in 2011, is presented in accordance with IFRS unless otherwise noted as being presented under Canadian generally accepted accounting principles ("Canadian GAAP") and not IFRS. A discussion regarding the Company's transition to IFRS, including the impact of significant accounting policies choices and the selection of IFRS 1 elections and exemptions, can be found in Note 24 of the audited consolidated financial statements.

***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 expressed in Canadian dollars unless otherwise specified.

***Non-IFRS Financial Measures***

In this MD&A, we refer to terms that are not specifically defined under IFRS. These non-IFRS measures may not be comparable to similar measures presented by other companies.

***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 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 focused on large medical markets that are related to:

- *Advanced Wound Care products for chronic wounds and negative pressure wound therapy;*
    - *Sophisticated tissue repair products for advanced wound care dressings, trauma, and surgical applications;*
    - *Unique transparent film dressings with antimicrobials embedded in the silicone adhesive;*
    - *Cell therapy technology focused on regeneration of damaged tissue;*
- *Medical Coatings;*
    - *Superior medical coatings with customized physical properties, drug delivery capabilities and infection control applications that include temporary as well as implantable devices;*
    - *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 distributes its products through third party distributors and 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 leaders in vascular access devices, I.V. infusion, orthopedics, device and patient care distributors, wound care products, specialty medical device manufacturers and major contract manufacturers.

These and other major medical companies, in management's opinion, are likely to be impressed with Covalon because of our:

- *Knowledgeable team of medical researchers, scientists, engineers and regulatory specialists;*
- *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;*
- *Strong knowledge and focus on product developments that seek to maximize available reimbursement in the various jurisdictions such as Medicare and Medicaid;*
- *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;*

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 market driven 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***

We engage our customers by developing novel medical devices for clients, licensing our technology and products to medical companies and marketing and selling our own products through distribution channels. We sell our technologies and products globally to medical companies and distributors. Some medical companies and distributors license our technologies for incorporating into their own product offerings, which they sell to healthcare providers under their own brand names. 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 product sales, 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.

In addition to the OEM business model, over the past 18 months Covalon has begun to develop distribution channels for Covalon branded products with the potential for Medicare & Medicaid reimbursement opportunities. We have a rich pipeline of products under development which we believe are products that can be marketed under the Covalon brand name. The Company has attended a number of medical products trade shows and the Covalon branded products are gaining awareness and interest. Our distribution channels are early stage and revenue is still unpredictable. However, the Company has been successful in securing a number of distribution relationships in growth markets such as the United States, Middle East and Asia.

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, development and marketing company that will continue to discover and commercialize new and exciting technologies that improve patient outcomes and save lives.

## Our 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. Covalon believes it has an advantage over other products on the market because the dressings use a more patient-friendly active silver compound that is present in concentrations that position ColActive® Plus Ag as the only effective antimicrobial collagen dressing. The Company markets and licenses these wound dressings globally under the brand name ColActive® through a number of independent distributors and under the private labelled brand BIOSTEP™ which is marketed and sold by a large wound care company.

The following Collagen product families have regulatory approval for sale:

| Product | Description | Clearance | Since |
|---|---|---|---|
| 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, Other | 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 surgical wound care markets (IV Clear™ and SurgiClear™, respectively). Health Canada approval was received for both products in early 2012, and FDA clearance in May 2012 and August 2012 respectively.

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, waterproof and provides maximum patient comfort. Unlike most other products containing silver, silver discoloration is deterred, ensuring the dressing stays transparent for seven days.

Management believes IV Clear™ dressings offer significant advantages over existing products in the market. IV Clear™ elutes or releases the active antimicrobials directly from the adhesive to the skin 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.

Management believes the potential for IV Clear™ is great; according to Nursing 2009 more than 7 million central venous access devices (CVADs) and 350 million peripheral I.V. catheters are placed each year in the United States. An average of 2.1 million critical care patients require CVADs, and nearly 250,000 cases of catheter-related blood stream infections (CRBSI) occur among ICU patients. Healthcare-associated infections cost billions of dollars each year. Patients with CRBSI spend more time in the ICU and in the hospital, need more medications and diagnostic studies, have higher catheter removal and reinsertion costs, use more supplies, and need additional healthcare provider visits. One CRBSI can cost $34,500 to $56,000.

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. SurgiClear is one of the only waterproof semi-occlusive dressings on the market allowing patients to bathe within the first 24 hours of surgery.

The Company believes the potential for SurgiClear™ is also significant. According to the US Centre for Disease Control and Prevention, 45 million surgical procedures were performed in the US in 2011 and approximately 1.5 million surgical site infections occurred at a cost of approximately $10 billion annually to treat. Many of these procedures require multiple dressing changes until the surgical incision heals.

***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).

***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 some of our patents are included below:

| Patent | Jurisdiction |
|---|---|
| *Method of Making Antimicrobial Polymeric Surfaces* | 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* | 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 |
| *Method for treating a surface with a coating comprising a therapeutic agent and device with a treated surface* | USA provisional patent application filed |

**Analysis of Operating and Financial Results**

Covalon is transitioning from solely a research lab to a successful market focused technology business with a broad platform of patented technologies and products. The Company currently uses a combination of distribution under the Covalon brand name and an OEM business model to realize value in the marketplace. Covalon is developing an international distribution channel for its rich pipeline of products. The Company has 6 products in various stages leading up to regulatory approval, with SurgiClear® and IVClear® recently cleared by the US FDA. A number of these products have good potential for product branding. Over the past 12 months the Company has set up distribution relationships with a number of companies in North America and in the Middle East and Asia and is in the process of expanding into other important global markets. The Company's attendance at important medical products trade shows has lead to increased awareness of the Covalon brand and end user interest in its products. Covalon continues to also utilize an OEM revenue model based on selling our technologies to large medical companies. OEM models do 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. The start and finish of projects is dependent on many factors, many of which are outside the control of Covalon.

During the first quarter of the fiscal year 2013, management continued to focus the operations of the Company on expanding sales and marketing activities initiated in 2011. As a precursor to new distribution, licensing and revenue agreements, the sales and marketing team continued to build on its efforts to increase its credibility with potential customers and establish relationships with new medical products companies. This included attending or exhibiting at international medical conferences, presenting at clinical symposiums, submitting for and securing scientific publications for new products developed by the Company and a continued improvement of marketing collateral sales and distribution support as well as the expansion of the newly launched web site to improve customer contact and brand awareness.

As a result of the work done in fiscal 2011 and 2012, the Company continues to expand its sales funnel and engage in confidential business discussions with a number of potential customers domestically and internationally. As a precursor to entering into license and revenue agreements with Covalon, a number of medical companies have dedicated resources to evaluating Covalon's technology and have entered into confidential business discussions which Covalon anticipates may lead to lucrative growth in revenue. However, the sales and evaluation cycles in the medical product market is lengthy. Management anticipates that these investments will lead to increased revenue as the discussions move through the sales cycle and results in the expansion of the Company's customer base.

On October 26, 2012, the Company announced the closing of a non-brokered private placement comprised of 9.55 million units at a price of $0.052 per unit for gross proceeds of $496,600. Each unit was comprised of one common share and one common share purchase warrant. Each common share purchase warrant entitled the holder to acquire an additional common share at a price of $0.10 per share for a period of five years from the closing date. All securities issued pursuant to the Offering will be subject to a hold period expiring February 27, 2013. Directors and officers of Covalon participated in the non-brokered private placement for an aggregate of 1.8 million units. The remaining units were subscribed for by an individual who subsequently became a Director of the Company. Proceeds of the private placement will be used by Covalon to develop and commercialize new wound care products, expand international distribution channels and for general working capital.

***Financial Highlights for three months ended December 31, 2012***

Financial highlights are as follows:

- Total revenue for the three months ended December 31, 2012 decreased by $117,162 or 17% to $572,005 over the same period of the prior year.
- Revenue from advanced wound care for the three months ended December 31, 2012 increased $284,809 or 120% over the same period of the prior year.
- Revenue from specialized medical device coatings were suspended during three months ended December 31, 2012. Sales for the same period of the prior year were $401,971.
- Gross margin on product sales and services (excluding licensing fees) for the quarter decreased to 42% compared to 46% for the same period of the prior year.
- Revenue from licensing fees remained consistent at $51,482 for the three month periods ended December 31, 2012 and 2011
- Operating expenses for the three months ended December 31, 2012 decreased $83,871 or 8% to $1,018,752 compared to $1,106,623 for the same period of the prior year
- Loss per share for three month period ended December 31, 2012 and 2011 was to $0.01 and $0.01 respectively.

**Consolidated Statement of Comprehensive Loss**

| (Canadian $) | Three months ended December 31, 2012 | 2011 |
|---|---|---|
| **Revenue** | | |
| Product and Services | | |
| Advanced wound care | **$ 520,523** | $ 235,714 |
| Specialized medical device coatings | **0** | 401,971 |
| Licensing fees | **51,482** | 51,482 |
| **Total revenue** | **572,005** | 689,167 |
| **Cost of sales** | **353,997** | 398,137 |
| **Gross Profit** | **218,008** | 291,030 |
| **Operating Expenses** | **1,018,751** | 1,106,623 |
| **Loss before undernoted** | **(800,743)** | (815,593) |
| Interest income | **(6,262)** | (15,539) |
| **Net loss and comprehensive loss for the period** | **$ (794,481)** | $ (800,054) |
| Loss per share | **$ (0.01)** | $ (0.01) |

***Product and Service Revenue, Licensing and Gross Profit***

Total product and service revenue decreased in the three months ended December 31, 2012 to $520,523 from $637,685 in the prior year. Quarter-to-quarter revenue continues to be inherently unpredictable due to our OEM 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 in any period.

Sales of advanced wound care products increased 120% over the same period last year to $520,523. The improvement is an encouraging indication of revenues being delivered by new distributors resulting from sales and marketing investments made by the Company over the past eighteen months. The trend in revenue growth is positive but is early stage in the execution of the Covalon branded distribution business model and as such distribution derived revenues are unpredictable.

Sales of specialized medical device coatings were suspended during the three months ended December 31, 2012. Sales for the same period last year were $401,971. Specialized medical coatings consisted of revenue derived from development services funded by customers and from ongoing coating manufacturing services. The Company's customer for coating manufacturing services did not place any purchase orders during the quarter as a result of a slow-down in the demand for the coated medical device, which the customer informs the Company is temporary in nature. At the same time, the customer-funded development projects underway during the last quarter of fiscal 2012 were completed, resulting in no revenue recognized during the three months ended December 31, 2012.

Licensing fees remained consistent at $51,482 for the three months ended December 31, 2012 and 2011.

The products and services revenue mix changes reflect the sales and marketing efforts of the past 12 months. The changes from the comparative period are as follows:

- 100% of product and services revenue in the first quarter of 2013 was derived from advanced wound care compared with 40% in the same period of the previous year;
- There was no revenue from specialized medical device coatings products and services in the current period. In the first period of 2012, 60% of the revenue in the first quarter of 2012 came from this line of services.

Gross margin on product sales and services, which does not include licensing fees, decreased as a result of the mix of products sold in any given quarter by product type and geography. The gross margin was 42% in the three months ended December 31, 2012 compared to 45.6% 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.

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.

***Interest Income***

Interest income on investments was $6,262 in the three months ended December 31, 2012 compared to $15,539 in the same period of the previous year. 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 $) | Three months ended December 31, 2012 | 2011 |
|---|---|---|
| **Operations** | | |
| Wages, benefits and consulting fees | **$ 137,925** | $ 118,575 |
| Depreciation and amortization | **3,460** | 3,460 |
| Other | **24,803** | 19,165 |
| | **166,188** | 141,200 |
| **Research and development activities** | | |
| Wages, benefits and consulting fees | **112,598** | 125,591 |
| Depreciation and amortization | **11,399** | 10,323 |
| Other | **6,912** | 17,719 |
| | **130,909** | 153,633 |
| **Sales and marketing** | | |
| Wages, benefits and consulting fees | **270,400** | 288,234 |
| Travel | **36,268** | 65,968 |
| Other | **49,256** | 51,889 |
| | **355,924** | 406,091 |
| **General and administrative** | | |
| Wages, benefits and consulting fees | **175,010** | 164,007 |
| Directors compensation | **62,400** | 25,787 |
| Professional fees | **30,881** | 83,472 |
| Facility | **39,863** | 42,292 |
| Depreciation and amortization | **19,520** | 28,055 |
| Other | **38,056** | 62,085 |
| | **365,730** | 405,698 |
| **Total Operating Expenses** | **$ 1,018,751** | $ 1,106,623 |

Total operating expenses for the three month period and year ended December 31, 2012 decreased 8% or $87,872 from the same period last year. During the six months ended December 31, 2012, Management took steps to reduce operating costs, including reducing headcount, use of outside professional services, travel and other expenses. A number of these initiatives have the potential to impact future quarters operating expenses.

**Related Party Transactions**

The following is a summary of the Company's related party transactions related to key management compensation for the three month and year ended December 31, 2012:

| | Three months ended December 31, | |
|---|---|---|
| | **2012** | 2011 |
| Short term employee benefits | **$ 177,589** | $ 127,342 |
| Share-based payments | **4,671** | 37,932 |
| | **$ 182,260** | $ 165,274 |

## Critical Accounting Estimates and Judgements

The preparation of financial statements requires that management makes estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from estimates and such differences would be material.

**ESTIMATES**

The effect of a change in an accounting estimate is recognized prospectively by including it in comprehensive income in the period of the change, if the change affects that period only, or in the period of the change and future periods, if the change affects both.

**i) Share-based Payment Transactions**

The Company measures the cost of equity-settled transactions with directors, officers and employees by reference to the fair value of the equity instruments at the date at which they are granted.. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in Note 14 of the Consolidated Financial Statements.

**ii) Intangible Assets**

The values calculated for intangible assets involve significant estimates and assumptions, including those with respect to future cash flows, discount rates and asset lives. These significant estimates and judgments could impact the Company's future results if the current estimates of future performance and fair value change and could affect the amount of amortization expense on intangible assets in future periods.

**iii) Impairment of non-financial assets**

The Company reviews the carrying value of non-financial assets for potential impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. The impairment test is carried out by comparing the carrying amount of the asset against the value computed using the discounted cash flow method values which requires numerous assumptions to estimate future cash flows. The recoverable amount is impacted significantly by the discount rate selected to be used in the discounted cash flow model, as well as the quantum and timing of expected future cash flows and the growth rate used for the extrapolation.

**iv) Income taxes**

The Company recognizes deferred tax assets, related tax-loss carryforwards and other deductible temporary differences where it is probable that sufficient future taxable income can be generated in order to fully utilize such losses and deductions. This requires significant estimates and assumptions regarding future earnings, and the ability to implement certain tax planning opportunities in order to assess the likelihood of utilizing such losses and deductions.

Uncertainties exist with respect to the interpretation of complex tax regulations and the amount and timing of future taxable income. Given the cross border business relationships, differences arising between the actual results and the assumptions made, or future changes in such assumptions, could necessitate future adjustments to tax income and expense already recorded. The Company established provisions, based on reasonable estimates, for possible consequences of audits by the tax authorities of the restive countries in which it operates. The amount of such provisions is based on various factors, such as experience of previous tax audits and differing interpretations of tax regulations by the taxable entity and the responsible tax authority. Such differences of interpretation may arise on a wide variety of issues depending on the conditions prevailing in the respective Company domicile.

**JUDGMENTS**

Information about critical judgments in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the consolidated financial statements within the next financial year are discussed below:

**i) Foreign Currency translation:**

The determination of functional currency for each of the Company's entities requires considerable judgment. The functional currency is determined based on the currency of the primary economic environment in which that entity operates. As the Company generates and expends cash in both the US and Canadian currencies, management considers several factors, including: the currency in which it receives its various revenue

streams and the magnitude of each; the currency in which it purchases materials and pays its employees and the geographic environment influencing each of its consolidated entities and products.

**ii) Provisions**

A provision is a liability of uncertain timing or amount. Provisions are recognized when the Company has a present obligation (legal or constructive) as a result of a past event, it is probable that the Company will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. A legal obligation can arise through a contract, legislation or other operation of law. A constructive obligation arises from an entity's actions; whereby, through an established pattern of past practice, published policies or a sufficiently specific current statement, the entity has indicated it will accept certain responsibilities and has thus created a valid expectation that it will discharge those responsibilities. The amount recognized as a provision is the best estimate, at each period end, of the expenditures required to settle the present obligation considering the risks and uncertainties associated with the obligation. Judgment is necessary to determine the likelihood that pending litigation or other claims will succeed or a liability will arise and then to estimate the amount.

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## Summary of Quarterly Results and Financial Position

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

| (in Canadian $) | IFRS 2013 First Quarter | IFRS 2012 Fourth Quarter | IFRS 2012 Third Quarter | IFRS 2012 Second Quarter | IFRS 2012 First Quarter | IFRS 2011 Fourth Quarter | IFRS 2011 Third Quarter | IFRS 2011 Second Quarter |
|---|---|---|---|---|---|---|---|---|
| Revenue (1) | $ 578,268 | $ 951,134 | $ 1,085,791 | $ 1,100,222 | $ 704,706 | $ 581,599 | $ 355,630 | $ 1,028,554 |
| Operating loss before amortization | $ 712,592 | $ 1,406,202 | $ 650,181 | $ 528,710 | $ 730,388 | $ 1,212,961 | $ 1,129,389 | $ 357,352 |
| Net loss | $ 794,481 | $ 1,854,874 | $ 732,308 | $ 604,146 | $ 800,054 | $ 1,294,531 | $ 1,207,559 | $ 430,610 |
| Net loss per share | $ (0.01) | $ (0.02) | $ (0.01) | $ (0.01) | $ (0.01) | $ (0.01) | $ (0.02) | $ (0.01) |
| Cash and cash equivalents | $ 727,024 | $ 1,142,667 | $ 1,594,075 | $ 2,851,504 | $ 3,926,152 | $ 4,763,152 | $ 2,659,901 | $ 3,431,454 |
| Net working capital | $ 584,019 | $ 928,220 | $ 2,338,111 | $ 3,069,155 | $ 3,732,626 | $ 4,456,098 | $ 2,939,202 | $ 4,078,834 |
| Current Ratio | 1.3 | 1.4 | 2.5 | 2.6 | 3.1 | 3.6 | 3.8 | 5.3 |

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

Revenues of the Company continues to be 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.

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 December 31, 2012, the Company had 1.3 times the current assets needed to pay its current liabilities.

## Liquidity & Capital Resources

| (Canadian $) | As at December 31, 2012 | As at September 30, 2012 | As at October 1, 2011 |
|---|---|---|---|
| Cash and cash equivalents | $ 727,024 | $ 1,142,667 | $ 4,763,152 |
| Short-term investments | $ 500,000 | $ 500,000 | $ 500,000 |
| Total assets | $ 5,304,931 | $ 5,963,729 | $ 9,322,121 |
| Deferred revenue | $ 1,293,236 | $ 1,118,057 | $ 1,103,512 |

### *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 royalty payments.

On December 31, 2012 cash, cash equivalents, restricted cash and short-term investments amounted to $1,290,024. Covalon follows a policy of investing its surplus cash resources in high quality, liquid, short-term deposits. Cash equivalents as of December 31, 2012 had less than three months to maturity and are cashable without penalty. At December 31, 2012, the Company had $63,000 assigned as collateral to secure the Company's credit card and automated clearing house (ACH) facilities with a major financial institution. These funds are expected to be restricted for more than one year and are not included in Cash and cash equivalents.

The Condensed Consolidated Interim Financial Statements have been prepared on a going-concern basis, which presumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of operations for the foreseeable future. The Company incurred a net loss of $794,481 during the three month period ended December 31, 2012 and, as of that date the Company's accumulated deficit was $33,224,268. The Company's ability to continue as a going concern depends on its ability to achieve profitable operations through; (i) the success of its two recently cleared-for-sale products IV Clear and SurgiClear, as it earns revenue from these products in the form of royalties and product sales, (ii) continued growth in the form of revenues and cash collections from product sales of its cleared-for-sale products ColActive Plus and ColActive Plus Ag, (iii) the ability for the Company to significantly reduce its operating costs, and (iv) the ability to obtain additional capital through financing. Whether or when the Company can achieve the above is uncertain. The Company is still an early revenue stage medical device biotechnology commercialization company, and is subject to a number of risks and uncertainties that are inherent to the commercialization of new technology. The Company has invested in technology and patents, which represent a large amount of the Company's value. The Company's current business model includes a combination of distribution under the Covalon brand name and an OEM business model where it licenses and sells its technology to medical device companies and distributors. Most OEM sales models involve long sales cycles – from initial discussion, product evaluation, regulatory filings, contract negotiation and market roll-out and as such the timing of revenue agreements is unpredictable. There can be no assurance that the Company will have sufficient capital to fund its ongoing operations, develop or commercialize any further products without future financings. There can be no assurance, especially considering the current economic environment, that additional financing will be available on acceptable terms or at all. These material uncertainties cast significant doubt upon the Company's ability to continue as a going concern.

These Consolidated Financial Statements do not include any adjustments to the amounts and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern.

Total assets at December 31, 2012 were $5,304,931 compared to $5,963,729 at September 30, 2012. Cash and cash equivalents and short-term investments comprised 23% of total assets at December 31, 2012. Of the remaining assets, the Company's accounts receivable and inventories are liquid, with collection periods and turnover ratios in the 60 to 180 day range. The balance of our assets is comprised of property, plant and equipment 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 increased by $175,179 to $1,293,236 at December 31, 2012 from the previous year.

## *Share Capital and Reserves*

*a) Common Shares*

The Company is authorized to issue an unlimited number of common shares with no par value. All shares are fully paid.

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 December 31, 2012, 150,000 (September 30, 2012 – 150,000) shares valued at $213,875 (2012 - $213,875) have been released from trust. The remaining balance of 950,000 shares are still held in trust.

During the quarter end December 31, 2012 the Company raised gross proceeds of $496,600 through a non-brokered private placement comprised of 9.55 million units at a price of $0.052 per unit. Each unit is comprised of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to acquire an additional common share at a price of $0.10 per share for a period of five years from the closing date. All securities issued pursuant to the Offering are subject to a hold period expiring February 27, 2013. Directors and officers of Covalon participated in the non-brokered private placement for an aggregate of 1.8 million units. The remaining units were subscribed for by an individual who subsequently became a Director of the Company. Proceeds of the private placement will be used by Covalon to develop and commercialize new wound care products, expand international distribution channels and for general working capital. Net proceeds raised from the offering were $481,736 and allocated as follows:

| | |
|---|---|
| Share Capital | $254,214 |
| Warrants | $227,522 |

The following is a summary of changes in common share capital from October 1, 2011 to December 31, 2012:

| | Number of Shares | Issue Price | Amount |
|---|---|---|---|
| **Balance at October 1, 2011 and September 30, 2012** | 83,211,708 | | $31,911,359 |
| Shares issued via private placement | 9,550,000 | $0.05 | 496,600 |
| Less value attributed to warrants | | | (227,522) |
| Less share and warrant issue costs | | | (14,865) |
| **Balance at December 31, 2012** | 92,761,708 | | $ 32,165,572 |

*b) Contributed Surplus*

There were no changes in Contributed Surplus from October 1, 2011 to December 31, 2012:

| | | |
|---|---|---|
| Balance October 1, 2011 and September 30, 2012 | $ | 1,805,586 |
| Balance December 31, 2012 | $ | 1,805,586 |

***Share-based Payments***

*a) Option Plan Details*

The Company has an incentive Stock Option Plan ("the Plan") under which non-transferable options to purchase common shares of the Company may be granted to directors, officers, employees or service providers of the Company. The terms of the Plan provide that the Directors have the right to grant options to acquire common shares of the Company at not less than the closing market price of the shares on the day preceding the grant at terms of up to five years. No amounts are paid or payable by the recipient on receipt of the option, and the options granted are not dependent on any performance-based criteria. Unless the board of directors decides otherwise, options granted under the plan will vest as follows: 33% of the options vest in one year, with a further 33% vesting in each of the subsequent two years on the anniversary of the initial grant date.

*b) Fair Value of Options Issued During the Period*

No options were granted during the three months ended December 31, 2012 or 2011

*c) Expenses Arising from Share-based Payment Transactions*

Total expenses arising from share-based payment transactions recognized during the period were $13,840 (three months ended December 31, 2011: $70,254).

## Sources and Uses of Cash

For the three months ended,

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss and comprehensive loss for the period | **$ (794,481)** | $ (800,054) |
| Adjustments to reconcile net loss and comprehensive loss to net cash used in operating activities: | | |
| Depreciation - property, plant and equipment | **37,173** | 29,967 |
| Amortization - intangible assets | **44,717** | 55,238 |
| Share based payments | **13,840** | 70,254 |
| Foreign exchange loss (gain) on cash held | **8,000** | (1,262) |
| Cash used by operating activities before change in non-cash working capital balances | **(690,751)** | (645,857) |
| Change in non-cash working capital | **(122,924)** | **(165,010)** |
| **Total cash outflows from operating activities** | **(813,675)** | (810,867) |
| **Cash flows from investing activities** | | |
| Purchase of property, plant and equipment | **(17,035)** | (649) |
| Purchase of intangible assets | **(58,669)** | (26,746) |
| **Total cash outflows from investing activities** | **(75,704)** | (27,395) |
| **Cash flows from financing activities** | | |
| Net proceeds on issuance of share capital and warrants | **481,736** | |
| **Total cash inflows from financing activities** | **481,736** | - |
| Foreign exchange loss (gain) on cash held | **(8,000)** | 1,262 |
| **Total net decrease in cash and cash equivalents during the period** | **(415,643)** | (837,000) |

### *Operating Activities*

Cash used in operating activities for the three months ended December 31, 2012 was relatively constant at $813,675 compared to $810,867 in the same period of the prior year.

### *Investing Activities*

Expenditures on property, plant and equipment relate to furniture and fixtures and lab equipment and expenditures on intangible assets relate to patents and trademarks.

### *Financing Activities*

The Company raised net proceeds of $481,736 through a private placement that comprised of 9.55 million units. Each unit entitles the holder to one common share and one warrant to purchase an additional common share at a $.10 per share for a period of 5 years.

***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 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 two 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.

## 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 2012. 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.

## International Financial Reporting Standards
## Standards, Amendments and Interpretations Not Yet Effective

Certain pronouncements were issued by the IASB or the IFRS Interpretations Committee that are mandatory for accounting periods beginning after October 1, 2011 or later periods. None of these is expected to have a significant effect on the consolidated financial statements, except for the following standards and interpretations that have been issued but are not yet effective:

*IFRS 9 Financial Instruments*

IFRS 9 Financial Instruments is part of the IASB's wider project to replace IAS 39 Financial Instruments: Recognition and Measurement. IFRS 9 retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets: amortized cost and fair value. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. The standard is effective for annual periods beginning on or after January 1, 2015. The Company is in the process of evaluating the impact of the new standard.

*IFRS 10 Consolidated Financial Statements*

IFRS 10 builds on existing principles by identifying the concept of control as the determining factor in whether an entity should be included within the consolidated financial statements of the parent company. The standard provides additional guidance to assist in the determination of control where this is difficult to assess. The Company is yet to assess the full impact of IFRS 10 and intends to adopt the standard no later than the accounting period beginning on January 1, 2013.

*IFRS 12 Disclosure of Interests in Other Entities*

In May 2011, the IASB issued IFRS 12 Disclosure of Interests in Other Entities. IFRS 12 is a comprehensive new standard on disclosure requirements for all forms of interests in other entities, including subsidiaries, joint arrangements, associates and unconsolidated structured entities. This new standard is effective for the Company’s interim and annual consolidated financial statements commencing on or after January 1, 2013.

*IFRS 13 Fair Value Measurement*

IFRS 13 aims to improve consistency and reduce complexity by providing a precise definition of fair value and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements which are largely aligned between IFRSs and US GAAP, do not extend the use of fair value accounting but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs or US GAAP. The Company is yet to assess the full impact of IFRS 13 and intends to adopt the standard no later than the accounting period beginning October 1, 2013

The Company is currently assessing the impact of the adoption of these standards on its Consolidated Financial Statements.

There are no other IFRSs or IFRIC interpretations that are not yet effective that would be expected to have a material impact on the Company.

## 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, 2012, 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.