

## Covalon Technologies Ltd.

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

**September 30, 2018** 



# MANAGEMENT'S DISCUSSION & ANALYSIS For the year ended September 30, 2018

### **December 17, 2018**

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, 2018. Additional information on Covalon Technologies Ltd. can be obtained on SEDAR at <a href="www.sedar.com">www.sedar.com</a>, as well as the Company's website at <a href="www.covalon.com">www.covalon.com</a>. Unless otherwise indicated, all references to the terms "we", "us", "our", "Covalon" and "Company" refer to Covalon Technologies Ltd. and its subsidiaries.

In this management discussion and analysis document ("MD&A"), financial information for the year ended September 30, 2018 and 2017 is based on the audited consolidated financial statements of the Company, which were prepared in accordance with International Financial Reporting Standards ("IFRS"), and are 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 approved this MD&A on December 13, 2018. Disclosure contained in this document is current to that date, unless otherwise noted.

#### Management's Responsibility for Financial Reporting

The consolidated financial statements and 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. 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.

#### **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.

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

Covalon Technologies Ltd. is a researcher, developer, manufacturer, and marketer of patent-protected medical products that improve patient outcomes and save lives in the areas of advanced wound care, infection management and surgical procedures. Our head office and laboratories are located in Mississauga, Ontario, Canada.

Covalon leverages its patented medical technology platforms and expertise in two ways: (i) we develop products that we sell under Covalon's name; and, (ii) we develop and commercialize medical products for other medical companies under development and license contracts.

The majority of Covalon-branded products are sold through independent distributors to various health care providers such as hospitals, wound care centers, burn centers, extended/alternate care facilities, acute care facilities, home health care agencies, and physicians' offices. Many of our products require regulatory clearances and are sold on a prescription basis in the United States, Canada, the Middle East, Europe, Asia, Latin America and a number of international countries.

We also license our technologies and products to large medical device companies as well as work with niche start-ups to create novel technology to advance their product offerings in various medical device markets. Covalon has worked with many medical companies including leaders in vascular access devices, I.V. infusion, orthopedics, device and patient care distributors, wound care product companies, specialty medical device manufacturers and major contract manufacturers.

Covalon currently has three proprietary platform technologies that have the potential to be developed into dozens of medical devices: (i) Collagen matrix; (ii) Antimicrobial silicone adhesive; and, (iii) Medical coating technology. These platform technologies are protected by patents, patent applications and patents pending, patented and proprietary manufacturing processes, trade secrets, brands, trademarks, and trade names.

Collagen Matrix: The Company's patented collagen matrix platform is used to manufacture a family of products that treat chronic and infected wounds including diabetic ulcers (including diabetic foot ulcers), pressure ulcers, venous ulcers (including venous leg ulcers), donor and graft sites, traumatic wounds healing by secondary intention, dehisced surgical wounds, and first and second degree burns. 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 exudate from the wound. Covalon's patented manufacturing process for creating our collagen matrix results in products that have certain clinical advantages over other dressings, such as open binding sites for destructive enzymes, effective antimicrobial activity, and exudate management properties that help chronic wounds heal.

**Antimicrobial Silicone Adhesive Platform:** Covalon's patent-pending antimicrobial silicone adhesive platform is the basis for a family of pre-surgical, post surgical and vascular access products that are designed to kill 99.99% or more of any bacteria or yeast that comes into contact with the antimicrobial silicone. The Company's Antimicrobial silicone adhesive platform is unique because the silicone



adhesive contains both silver and chlorhexidine which provides broad-spectrum antimicrobial activity for a minimum of 7 days, while maintaining the beneficial properties of a silicone adhesive. Our technology meets the current United States Food and Drug Administration's "greater than 4 log reduction" standard for an antimicrobial claim against bacteria, and yeast, most commonly associated with healthcare acquired infections. The soft silicone adhesive also provides greater patient comfort, does not macerate or damage the skin, and was shown to be up to 10 times less painful upon removal when compared to acrylic adhesives, which are commonly used in medical products containing adhesives.

Medical Coating Platforms ("CovaCoat" and "Centaur"): Covalon's patented coating technology is a proprietary "grafting from" process which utilizes photo-polymerization to create active grafting sites where new polymer chains are initiated and propagated from the surface of an existing medical device. The CovaCoat and Centaur processes enable these grafting sites to slightly penetrate the surface of the medical device forming a strong, permanent continuum, rather than a discreet coating layer, which is more susceptible to delamination and particulate generation as compared to the resulting CovaCoat surface. This is unlike many competitors' coatings, which use a cure catalyst. As a result, the CovaCoat and Centaur processes create a functionalizable micron level covalently bound polymeric surface while preserving the bulk mechanical properties of the underlying medical device. The Company's CovaCoat and Centaur processes will not decrease or adversely affect the physical properties of the underlying device, which is critical for regulatory submissions and clinical use. The new coated surface created during the CovaCoat and Centaur processes has inherent lubricious and biocompatible properties and can be further functionalized to meet the specific needs of an application. CovaCoat has been proven effective on many polymeric medical device surfaces including silicones, polyurethanes, polyethylenes, polycarbonates, polyesters, Pebax®, Nylon, and PEEK. Centaur is ideally suited to improve the safety and functionality of intravascular medical devices such as vascular access catheters, where the presence of unwanted particulate can cause significant patient complications.

#### **Our Products**

We have obtained regulatory clearance on approximately 25 families of medical devices and approximately 150 separate sku's, many of which are derived from our platform technologies. Our products that are currently available for sale include the following:

<b>Advanced Wound Care Dressings</b>	
ColActive Plus	Collagen matrix dressing
ColActive Plus Ag	Collagen matrix dressing with silver
ColActive Transfer	Wound contact layer
CovaWound Silicone	Self-adherent soft silicone foam dressing
CovaWound Silicone with Border	Self-adherent soft silicone foam dressing with border
CovaWound Silicone Sacrum	Self-adherent soft silicone foam dressing with border
	for use on the sacrum
CovaWound Silicone Heel	Self-adherent soft silicone foam dressing with border
	for use on the heel
CovaWound Foam	Non-adherent foam dressing
CovaWound Foam with Border	Non-adherent foam dressing with adhesive border
CovaWound Alginate	Alginate dressing
CovaWound Alginate Ag	Alginate dressing with silver
CovaWound Super Absorbent	Soft hydrophilic wound contact layer with super
	absorbent polymer core
CovaWound Hydrocolloid	Absorbent hydrocolloid matrix dressing
CovaView Transparent IV Dressing	Transparent IV vascular access dressing



Surgical and Peri-Operative Products	
SurgiClear	Antimicrobial clear silicone adhesive post-surgical dressing with chlorhexidine and silver
MediClear Post-Op Absorb	Self-adherent silicone dressing with absorbent pad
MediClear Scar	Self -adherent silicone dressing for scar care

<b>Infection Management Products</b>	
IV Clear	Antimicrobial clear silicone adhesive vascular access dressing with chlorhexidine and silver
MediClear Pre-Op	Antimicrobial silicone film for pre-operative skin
SilverCoat Foley Catheter	Silicone Foley catheter with silver

## **Our Product Pipeline**

The Company continues to leverage its strong research and development capabilities and talented technical staff to continuously add to our product pipeline. The Company currently has a number of new products in its development pipeline that are expected to be ready for regulatory clearance within the next 24 months and numerous additional products that are under investigation for technical and market viability. Covalon utilizes an internal development team to invent and commercialize new products, as well as continuously investigating in-licensing opportunities for intellectual property that can be commercialized by the Company into successful products. The Company believes that a number of the technologies and product prototypes have significantly large market opportunities once they have been cleared by the relevant regulatory authorities.

#### **Our Business Model**

The Company distributes products under the Covalon brand name through third-party distribution networks as well as utilizing an OEM business model to realize value in the marketplace. We also have a direct sales force in the United States and the United Kingdom.

The Company has set up distribution relationships with a number of companies in North America, the Middle East, Asia, and is in the process of expanding into other important global markets, such as Europe. The Company's attendance at selected medical products trade shows has led to increased awareness of the Covalon brand and end user interest in our products.

In addition to our distribution efforts, Covalon continues to also utilize an OEM revenue model based on selling or licensing our technologies to large medical companies. 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.

OEM models may 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, performance of services, 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.

### Operational Highlights for the Year Ended September 30, 2018

- On October 5, 2017, Covalon announced that it would be showcasing its full portfolio of Advance Wound Management and Infection Prevention products at the Limb Salvage and Woundcare Symposium in Cleveland, Ohio from October 6-7, 2017.
- On October 27, 2017, the Company announced the issuance of 60,000 stock options to financial advisors of the Company. A second tranche of 60,000 options were to be issued to the financial advisors in January 2018. The aggregate issuance of 120,000 stock options is in lieu of warrants that had been previously announced by the Company on May 16, 2017.
- November 14, 2017, Covalon announced that Major General (ret.) Gale S. Pollock, CRNA, FACHE, FAAN, has agreed to join Covalon's Board of Directors.
- December 21, 2017, Covalon announced the issuance of 187,500 stock options to employees and consultants of the Company. The stock options will vest over three years and will be exercisable for a period of five years at an exercise price of \$4.65 per stock option.
- On January 24, 2018, further to its press release dated October 27, 2017, the Company announced the second tranche issuance of a further 60,000 stock options to certain financial advisors of the Company. The stock options will vest over three years and will be exercisable for a period of five years at an exercise price of \$6.02.
- On February 5, 2018, Covalon announced that it will be featuring its commercially available platform technologies, including the recently launched Centaur coating as first-time exhibitors at North America's largest annual MedTech event. MD&M West took place at the Anaheim Convention Center, from February 6-8, 2018.
- On February 20, 2018, Covalon announced its participation in Medical Japan 2018. Covalon showcased its proprietary advanced wound and infection control products as part of the Ontario Government's Life Sciences Trade Mission to Japan. Medical Japan is the country's largest trade show focusing on products, services, and technologies for healthcare.
- On March 5, 2018, Covalon announced that MediClear PreOp had received Frost & Sullivan's 2018 North American Surgical Site Infection Prevention New Product Innovation Award. MediClear PreOp is a novel pre-operative film drape designed to reduce the level of bacteria on a patient's skin before a surgical procedure. Frost & Sullivan is a global research organization that monitors more than 300 industries and 25,000 companies.
- On March 8, 2018, Covalon held its annual shareholder meeting. Shareholders voted in favour of all proposed items of business and received a business update from the CEO.
- On March 26, 2018, Covalon announced that it would be featuring its perioperative suite of innovative products including MediClear PreOp at the Association of perioperative Registered Nurse's (AORN) Surgical Conference and Expo, the largest international gathering of perioperative registered nurses worldwide.
- On April 26, 2018, Covalon announced that two clinical case studies demonstrating the clinical effectiveness of ColActive Plus and ColActive Transfer biological matrix products will be presented at the 2018 Symposium on Advanced Would Care Spring ("SWAC Spring") in Charlotte, North Carolina. In addition to the posers, Covalon was also showcasing its full line of advanced wound care dressings in the symposium's exhibition hall during the three-day event.



- On April 30, 2018, Covalon announced that it would be showcasing its perioperative suite of
  innovative products, including MediClear PreOp, at the American Association for Thoracic
  Surgery ("AATS") Annual Meeting. The AATS Annual Meeting is the primary opportunity for
  cardiothoracic surgeons and their teams to receive continuing medical education and learn about
  the latest products and services in cardiothoracic treatment and care.
- On May 7, 2018, Covalon announced a major sales breakthrough. Covalon was informed that it has won a series of competitive contracts in the Middle East with an estimated sales value of \$100 million over a three-year period. The series of competitive contracts awarded to Covalon includes the granting of approximately ten categories of products under the Executive Board of Health Ministers' Council for Gulf Cooperation Council States (called "SGH"), as well as several contracts outside of the SGH in Saudi Arabia and other countries in the region that extend up to three years to supply Covalon's highly-regarded IV Clear, ColActive Plus, and CovaWound products.
- On May 22, 2018, Covalon announced, further to the press release on May 7, 2018, that Covalon has been awarded every single Vascular Assess dressing category for the next three years in the Gulf Cooperation Council States in the Middle East. As a result of the Company being exclusively awarded the contract to supply all Vascular Access dressings under the SGH contracts, all institutions that provide government-funded healthcare services to over 50 million people in the GCC will now be supplied with Covalon's IV Clear as their antimicrobial IV dressing for the next three years.
- On May 28, 2018, Covalon announced major corporate initiatives along with the second quarter results. These initiatives included: the formation of a Special Committee of the Board of Directors to evaluate strategic initiatives; Significant progress on the evaluation of potential acquisitions; the consideration for Covalon to buy back common shares; and, the ability to use non-dilutive sources of funds to pursue these activities.
- On June 12, 2018, Covalon announced that it would be exhibiting at the APIC 2018 Conference in Minneapolis, Minnesota, that ran from June 13<sup>th</sup> to June 15<sup>th</sup>, 2018. APIC featured leading-edge science and technology dedicated to infection prevention, as well as innovative products and services from more than 270 companies. Covalon was feature its unique line of antimicrobial self-adherent silicone products, including MediClear PreOp (the market's first breathable and transparent antimicrobial self-adherent silicone drape for preoperative skin).
- On July 26, 2018, Covalon announced that Martin Bernholtz was retiring from the Company's Board of Directors effective July 31<sup>st</sup>, 2018.
- On August 9, 2018, Covalon announced it has entered into a new acquisition and operating banking credit facility with HSBC Bank Canada that provides the Company with up to approximately \$17 million of credit. This facility includes a \$9 million (Canadian Dollar) acquisition demand line, a \$5 million (Canadian Dollar) revolving operating facility and a \$2 million (US Dollar) bank guarantee facility. HSBC will also provide the Company a foreign currency hedging facility and corporate credit card facility in support of the Company's ongoing operations. The term of the acquisition demand line is repayable over five years.
- On August 20, 2018, Covalon announced that it has received \$3.5 million USD under a new license agreement with a large global medical company. The agreement provides the medical partner with certain rights to use Covalon's patented antimicrobial medical coating technology with some of its devices. The agreement was entered into in the ordinary course of business of Covalon and is subject to confidentiality provisions.



- On September 14, 2018, announced that it would be attending the 2018 Scientific Meeting for the Association for Vascular Access ("AVA") from September 15<sup>th</sup> to September 17<sup>th</sup>, 2018. Covalon announced that it would be showcasing IV Clear as well as co-sponsoring a presentation on patient advocacy.
- On September 20, 2018, Covalon announced that it had entered into an agreement to acquire AquaGuard, the Seattle, Washington-based division of medical technologies company Cenorin, LLC. AquaGuard's specialized products provide patients with crucial moisture protection for wound, surgical, and vascular access sites throughout the body while showering.
- September 28, 2018, Covalon announced the issuance of 155,000 stock options to employees and consultants of the Company. The stock options will vest over three years and will be exercisable for a period of five years at an exercise price of \$8.50 per stock option.

## Operational Highlights Subsequent to September 30, 2018

- On October 1, 2018, Covalon announced that it had closed the acquisition of AquaGuard, a Seattle, Washington-based division of medical technologies company Cenorin, LLC. The consideration of approximately \$16m was comprised of a combination of cash, shares, and contingent consideration.
- On October 23, 2018 Covalon announced that it had successfully completed the integration of AquaGuard with its operations.
- On October 24, 2018, Covalon announced that it would be attending the 2018 American Nurses Credentialing Center National Magnet Conference from October 24<sup>th</sup> to October 26<sup>th</sup>, 2018. This represented Covalon's first conference showcasing AquaGuard and IV Clear together as a part of Covalon's product portfolio.

#### Financial Highlights for the three months ended September 30, 2018

- Total revenue for the three months ended September 30, 2018, decreased 32% to \$6,657,686 compared to \$9,836,953 for the same period of the prior year.
- Product revenue for the three month period ended September 30, 2018, decreased 39% to \$5,862,276 compared to \$9,542,692 for the same period last year. This decrease relates to the timing of major shipments under our previously announced tenders awarded to the Company in Saudi Arabia. During the period, the Company continued deliveries to fulfil the tenders awarded by the Ministry of Health in Saudi Arabia.
- Development and consulting services revenue for the three month period ended September 30, 2018, increased by 219% to \$760,326 compared to \$238,479 for the same period of the prior year. Revenue from development and consulting services varies based on opportunities and the length of the sales cycle for given projects.
- Licensing and royalty fees for the three months ended September 30, 2018, were \$35,084 compared to \$55,782 for the three months ended September 30, 2017.
- Gross margin for the three month period ended September 30, 2018, decreased to 64% compared to 76% for the same period of the prior year. The gross margin is significantly influenced by source of revenue and by the relative mix of products sold in any given financial period.
- Operating expenses for the three months ended September 30, 2018, decreased \$2,077,437 to \$4,908,954 compared to \$6,986,391 for the prior year's comparative period. The decrease in



operating expenses is a result of reduction in agency fees incurred by the Company to deliver product and support services for the tenders awarded to the Company by the Ministry of Health in Saudi Arabia. As part of the tenders awarded to the Company, Covalon is required to provide sales, distribution and clinical training and support of its products and to accomplish this the Company engaged a third-party agent to fulfil these duties on behalf of the Company. Included in operating expenses for the fourth quarter was approximately \$1,100,000 of costs related to the acquisition of AquaGuard. No such expenses were included in the comparative period.

• Net loss for the three months ended September 30, 2018, was \$625,082 or \$(0.03) per share, on a diluted basis, compared to a net income of \$259,160 or \$0.01 per share for the three months ended September 30, 2017.

#### Financial Highlights for the year ended September 30, 2018

- Total revenue for the year ended September 30, 2018 was \$26,723,342 compared to \$27,309,757 in the prior year.
- Fiscal 2018 saw the Company end the year with a strengthened and more diversified revenue base. In fiscal 2018, approximately 49% of revenue was from the Middle East, compared to 80% last year. By comparison, revenue in the United States for the year was up 175% year-over-year to \$12.8 million, which included increases in product revenue and development services, licenses, and royalties.
- Product revenue for the year ended September 30, 2018 decreased 19% to \$19,990,663 compared to \$24,681,335 for the same period last year. Contracted revenue in the Middle East is derived from bulk purchases throughout the year which are not equally recognized in each of the Company's quarterly results. The decline in revenue from the Middle East in fiscal 2018 was simply due to the timing of the shipments under contracts. Revenue from the \$100 million series of Middle East contracts will begin to materially impact revenue in fiscal 2019 and beyond. The decrease was partially offset by an 80% increase in product sales in the United States.
- Development and consulting services revenue for the year ended September 30, 2018 was \$1,782,368 compared to \$866,139 for the same period of the prior year. Revenue from development and consulting services varies based on opportunities and the length of the sales cycle for given projects.
- Licensing and royalty fees for the year ended September 30, 2018 were \$4,950,311 compared to \$1,762,283 for the year ended September 30, 2017. Included in licensing revenue is the first payment of US \$3.5 million under a licensing agreement with a large global medical company, whereby the customer was provided with certain rights to use Covalon's patented antimicrobial medical coating technology with some of its medical devices.
- Gross margin on product sales for the year ended September 30, 2018 decreased to 74% compared to 77% in the prior year. The gross margin is significantly influenced by source of revenue and by the relative mix of products sold in any given financial period
- Operating expenses for the year ended September 30, 2018, decreased \$1,153,777 to \$18,047,188 compared to \$19,200,965 for the prior year. The decrease in operating expenses is primarily a result of agency fees incurred by the Company to deliver product and support services for the tenders awarded to the Company by the Ministry of Health in Saudi Arabia. As part of the tenders awarded to the Company, Covalon is required to provide sales, distribution and clinical training and support of its products and to accomplish this the Company engaged a third-party agent to fulfil these duties on behalf of the Company. During the year the Company



also incurred costs associated with the acquisition of the assets of AquaGuard (a division of Cenorin LLC). These costs included legal, accounting and consulting fees customary with these types of transactions and are one time in nature. The total of the one time costs associated with this subsequent transaction were approximately \$1,100,000. During fiscal 2018, the Company invested a net amount of approximately \$2,000,000 into operating costs to establish sales channels into the United Kingdom, Europe, and Latin America. The Company expects that revenue from these locations will begin to materially impact the Company's operations in fiscal 2019.

• Net income for the year ended September 30, 2018, was \$1,617,648 or \$0.07 per share, on a diluted basis, compared to a net income of \$1,811,694 or \$0.09 per share for the year ended September 30, 2017.



•	Three months ended September 30,		Year ended September 30,	
	2018	2017	2018	2017
Revenue				
Product	\$5,862,276	\$9,542,692	\$19,990,663	\$24,681,335
Development and consulting services	760,326	238,479	1,782,368	866,139
Licensing and royalty fees	35,084	55,782	4,950,311	1,762,283
Total revenue	6,657,686	9,836,953	26,723,342	27,309,757
Cost of product sales	2,373,814	2,591,402	7,058,506	6,297,098
Gross profit before operating expenses	4,283,872	7,245,551	19,664,836	21,012,659
<b>Operating Expenses</b>				
Operations	499,087	366,738	1,990,549	1,433,900
Research and development activities	306,795	363,466	1,416,640	1,125,848
Sales, marketing, and agency fees	2,030,524	3,845,644	8,186,811	11,484,990
General and administrative	2,072,548	2,410,543	6,453,188	5,156,227
-	4,908,954	6,986,391	18,047,188	19,200,965
Net income	\$(625,082)	\$259,160	\$1,617,648	\$1,811,694
Other comprehensive income				
Foreign currency translation adjustment	(225,839)	(452,435)	376,321	(452,435)
Total comprehensive income	\$(850,921)	(\$193,275)	\$1,993,969	1,359,259
Basic earnings (loss) per share	<b>\$(0.03)</b>	\$0.01	\$0.08	\$0.09
Diluted earnings (loss) per share	\$(0.03)	\$0.01	\$0.07	\$0.09

#### **Revenue and Gross Profit**

Total revenue decreased \$586,415 or 2% to \$26,723,342 for the year ended September 30, 2018, compared to \$27,309,757 in the prior year. Product revenue was \$19,990,663 for the year ended September 30, 2018, compared to \$24,681,335 in the prior year. Development and consulting services revenue for the year ended September 30, 2018, was \$1,782,368 which represents revenue earned from the Company's work on development and consulting projects; an increase from prior year services revenue of \$866,139. Licensing revenue was \$4,950,311 for the year ended September 30, 2018, compared to \$1,762,283 for the prior year's comparative period. Included in licensing revenue is the first payment of US \$3.5 million under a licensing agreement with a large global medical company, whereby the customer was provided with certain rights to use Covalon's patented antimicrobial medical coating technology with some of its medical devices.



Revenue fluctuates from quarter to quarter depending on the composition of contractual arrangements entered into in each quarter, the timing of product shipments, and completion of services in any period.

The Company utilizes an outsourced manufacturing model for the production of its products. This allows the Company to control operating expenses, maintain margins and focus internal resources on high margin advanced wound care product development and sales.

Gross margin fluctuates as a result of the mix of products sold in any given quarter, or year, by product type and geography. Gross margin was 74% for the year ended September 30, 2018, compared to 77% for the prior year. Gross margin is highly influenced by the mix of collagen-based dressings, silicone-based dressings, medical coated devices, passive dressings and related service revenues generated in the periods.

## **Operating Expenses**

	Three m	onths ended	Year ended September 30,		
	Se	eptember 30,			
	2018	2017	2018	2017	
Operations					
Wages, benefits and consulting fees	\$407,857	\$298,864	\$1,615,919	\$1,226,092	
Depreciation and amortization	1,259	1,125	4,992	5,775	
Other	89,971	66,749	369,638	202,033	
	499,087	366,738	1,990,549	1,433,900	
Research and development activities					
Wages, benefits and consulting fees	256,113	339,803	1,261,901	1,033,069	
Depreciation and amortization	3,464	2,571	12,021	12,388	
Other	47,218	21,092	142,718	80,391	
	306,795	363,466	1,416,640	1,125,848	
Sales, marketing, and agency fees					
Wages, benefits and consulting fees	493,477	566,036	2,370,177	1,700,019	
Travel	95,200	112,513	354,190	537,451	
Other	1,441,847	3,167,095	5,462,444	9,247,520	
	2,030,524	3,845,644	8,186,811	11,484,990	
General and administrative					
Wages, benefits and consulting fees	536,948	660,486	3,031,118	1,997,972	
Directors compensation	43,838	35,086	178,156	143,293	
Professional and related costs	980,173	241,569	1,900,576	741,977	
Facility	184,388	140,815	673,948	623,020	
Depreciation and amortization	31,594	18,174	106,468	80,627	
Provision for doubtful accounts	6,251	1,215,216	6,251	1,215,216	
Other	289,356	99,197	556,671	354,122	
	2,072,548	2,410,543	6,453,188	5,156,227	
Total operating expenses	\$4,908,954	\$6,986,391	\$18,047,188	\$19,200,965	



Operating expenses for the three months ended September 30, 2018, decreased \$2,077,437 to \$4,908,954 compared to \$6,986,391 for the prior year's comparative period. During the September 30, 2018 fiscal year, the Company incurred lower expenses related to agency fees related to the distribution and service activities for tenders award to the Company. These agency fees fluctuate as revenue is recognized on deliveries under these competitive contracts. As part of the contracts awarded to the Company, Covalon is required to provide sales, distribution and clinical training and support of its products and to accomplish this the Company engaged a third-party agent to fulfil these duties on behalf of the Company.

Wages, benefits, and consulting fees (for all departments) include a non-cash expense related to stock options that the Company had previously granted. The year ended September 30, 2018 had stock option related expenses of \$1,252,577 compared to \$623,312 in the prior year. This expense is a reflection of the number of options outstanding and their respective exercise prices.

During the fiscal year ended September 30, 2018, the Company incurred costs associated with the acquisition of the assets of AquaGuard (a division of Cenorin LLC). These costs included legal, accounting, and consulting fees customary with these types of transactions and are one time in nature. The total of the one time costs associated with this subsequent transaction were approximately \$1,100,000. During fiscal 2018, the Company invested a net amount of approximately \$2,000,000 into operating costs to establish sales channels into the United Kingdom, Europe, and Latin America. The Company expects that revenue from these locations will begin to materially impact the Company's operations in fiscal 2019.

## **Related Party Transactions**

The following is a summary of the Company's related party transactions related to key management compensation.

	r ear ended September 30,		
	2018	2017	
Compensation and short-term employee benefits	\$ 1,365,291	\$ 1,319,298	
Share-based payments	603,233	261,135	
	\$ 1,968,523	\$ 1,580,433	

During the year ended September 30, 2018, the Company had compensation to related parties included in the preceding table.

During the year ended September 30, 2018, related parties exercised 275,000 previously issued Common Share purchase options for proceeds of \$282,317; and, 120,000 warrants were exercised for proceeds of \$120,000.

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

The Company reviews the carrying value of, definite life, 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 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.

## ii) Inventory allowance

The Company states its inventories at the lower of cost and net realizable value, and records a provision for obsolete inventories. The Company determines its provision for obsolete inventory based on the quantities on hand at the reporting dates, compared to foreseeable needs over the upcoming periods.

## iii) Allowance for doubtful accounts

The Company is exposed to credit risk associated with its trade receivables. The risk is reduced by having customers' trade receivables insured by Export Development Canada ("EDC"), and the use of Letters of Credit, wherever possible. Management reviews the trade receivables at each reporting date and assesses and makes an allowance for doubtful accounts when the expected recovery could be less than the actual trade receivable. The expected recovery amount can vary from the actual cash received.

#### **Judgements**

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) Functional currency:

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 predominantly 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 that a liability will arise and estimate the amount.

## iii) Revenue Recognition

Certain contracts may include terms regarding the timing of provision of goods or services and/or multiple deliverable elements and management is required to make significant judgements and estimates based on various assumptions including the timing of recognition of deliverables in satisfying the revenue recognition criteria as well as the relative fair value of each deliverable to which an allocation of the consideration is made.

## **Summary of Quarterly Results and Financial Position**

	2018 Fourth	2018 Third	2018 Second	2018 First	2017 Fourth	2017 Third	2017 Second	2017 First	2016 Fourth	2016 Third	2016 Second	2016 First
	Quarter	Quarter										
Revenue	\$ 6,657,686	\$ 7,933,676	\$ 5,727,275	\$ 6,404,631	\$ 9,836,938	\$ 5,901,622	\$ 6,005,336	\$ 5,608,927	\$ 872,624	\$ 2,600,002	\$ 797,748	\$ 2,440,633
Net income (loss) before amortization	(268,687)	2,322,108	(402,173)	597,755	328,116	614,051	536,080	608,112	(1,964,065)	(90,560)	(999,873)	331,900
Net income (loss)	(625,082)	2,198,467	(479,082)	523,345	259,160	541,346	473,524	537,664	(2,139,063)	(156,792)	(1,065,517)	266,224
Net income (loss) per share	(0.03)	0.09	(0.02)	0.02	0.01	0.03	0.02	0.03	(0.18)	(0.02)	(0.10)	0.03
Cash and cash equivalents	\$5,483,087	\$1,721,427	\$1,833,771	4,217,358	4,155,883	2,551,330	494,117	1,221,893	1,454,389	670,956	499,332	940,937
Net working capital	10,685,114	10,662,108	7,877,345	8,006,986	6,975,333	6,627,254	3,090,662	2,621,971	2,165,440	3,124,482	2,399,855	3,258,168
Current ratio	2.7	4.8	3.9	3.8	3.5	3.6	2.1	2.2	2.0	2.4	1.7	2.1

Revenue of the Company continues to be inherently unpredictable due to our business model and fluctuates from quarter to quarter depending on both the composition of contractual arrangements entered into in each quarter and the timing of completed coating and development services milestone in any period.



#### **Liquidity & Capital Resources**

Cash and cash equivalents	September 30, 2018 \$5,483,087	September 30, 2017 \$4,155,883
Short-term investments	-	-
Total assets	\$19,707,833	\$11,966,991
Deferred revenue	\$206,811	\$524,885

On September 30, 2018, cash, cash equivalents, restricted cash, and short-term investments totaled \$5,483,087 compared to \$4,155,883 at September 30, 2017. During the year ended September 30, 2018, the Company had positive cash flow of \$1,327,204. As at December 13, 2018, cash, cash equivalents, restricted cash, and short-term investments totaled approximately \$1.5 million.

Accounts receivable from customers at September 30, 2018, increased \$2,383,532 from the prior year end. The timing of cash flows from customers will continue to be unpredictable due to payment terms which may include upfront advances, payment on shipment as well as standard and extended credit terms. The Company also accepts letters of credit on large transactions which provides more certainty of collection. The Company uses EDC insurance, when appropriate, to allow it to extend credit terms to specific customers.

Cash equivalents with less than three months to maturity totaled \$nil at September 30, 2018. At September 30, 2018, the Company had an additional \$36,052 assigned as collateral to secure the Company's credit cards. These funds are expected to be restricted for more than one year and are not included in cash and cash equivalents.

Total assets at September 30, 2018, were \$19,707,833 compared to \$11,966,991 at September 30, 2017. Cash, cash equivalents and short-term investments comprised 28% of total assets at September 30, 2018. The Company's accounts receivable and inventories are liquid, with collection periods and turnover ratios generally in the 60 to 180 day range. The balance of the Company's 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 decreased by \$318,074 to \$206,811 at September 30, 2018, compared to \$524,885 at September 30, 2017.

#### **Share Capital and Reserves**

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

During the year ended September 30, 2018, there were 452,170 options exercised for proceeds of \$520,985.

During the year ended September 30, 2018, 231,373 warrants were exercised for common shares of the Company for aggregate proceeds of \$376,158.

During the year ended September 30, 2017, 54,001 options were exercised for proceeds of \$93,636.

On June 1, 2017, the Company completed a non-brokered private placement offering comprised of 1,190,671 units (each, a "Unit") of the Corporation at a price of \$1.96 per unit for aggregate gross



proceeds of \$2,333,715 (the "Offering"). Each Unit is comprised of one common share of the Company (a "Common Share") and one Common Share purchase warrant (a "Warrant"). Each Warrant entitles the holder to acquire an additional Common Share at a price of \$2.30 per share for a period of three years from the closing date. Directors and investors who owned more than 10% of the issued and outstanding shares, at the time, participated in the Offering for an aggregate of 765,351 Units for gross proceeds of \$1,500,088. All securities issued pursuant to the Offering were subject to a hold period that expired October 2, 2017.

During the year ended September 30, 2017, 805,000 previously issued Common Share purchase warrants were exercised for aggregate proceeds of \$805,000.

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.

During the year ended September 30, 2018, the Company issued four new tranches of options:

- On September 27, 2018, 155,000 options with a weighted average fair value of \$5.86 were granted. Trading price of the stock at the time of the grant was \$8.50. The fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest 2.2%, dividend rate NIL, average volatility 92.5% and an average term of 5 years. The estimated forfeiture rate is 6.71%.
- On January 18, 2018, 60,000 options with a weighted average fair value of \$4.44 were granted. Trading price of the stock at the time of the grant was \$6.02. The fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest 1.77%, dividend rate NIL, average volatility 103.31% and an average term of 5 years. The estimated forfeiture rate is 6.07%.
- On December 21, 2017, 187,500 options with a weighted average fair value of \$3.51 were granted. Trading price of the stock at the time of the grant was \$4.65. The fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest 1.57%, dividend rate NIL, average volatility 107.36% and an average term of 5 years. The estimated forfeiture rate is 5.87%.
- On October 25, 2017, 60,000 options with a weighted average fair value of \$3.05 were granted. Trading price of the stock at the time of the grant was \$3.80. The fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest 1.73%, dividend rate NIL, average volatility 119.81% and an average term of 5 years. The estimated forfeiture rate is 6.23%.

During the year ended September 30, 2017, the Company issued two new tranches of options:

• On June 20, 2017, 422,500 options with a weighted average fair value of \$2.14 were granted. Trading price of the stock at the time of the grant was \$2.47. The fair market value of options



- granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest -0.85%, dividend rate NIL, average volatility -140.54% and an average term of 5 years. The estimated forfeiture rate is 6.1%.
- On February 9, 2017, the Company issued 265,000 options with a weighted average fair value of \$1.96. Trading price of the stock at the time of the grant was \$2.20. The fair market value of options granted was determined using the Black-Scholes valuation model with the following implicit assumptions: average risk-free rate of interest 1.08%, dividend rate NIL, average volatility 150.22% and an average term of 5 years. The estimated forfeiture rate is 5.65%.

#### Sources and Uses of Cash

	Year ended September 30,		
	2018		
Cash flows from operating activities	(655,470)	15,147	
Cash flows from investing activities	(740,213)	(349,945)	
Cash flows from financing activities	2,418,614	3,190,540	

#### **Operating Activities**

Cash used in operating activities for the year ended September 30, 2018, was \$655,470 compared to \$15,147 generated for the prior year's comparative period. Non-cash working capital used \$3,893,515 of cash during the year ended September 30, 2018, compared to \$2,694,670 for the prior year's comparative period. At September 30, 2018, accounts receivable had increased \$2,316,843 over September 30, 2017, due mainly to the timing of shipments and the granting of credit terms to key customers. The Company also accepts letters of credit on large transactions which provides more certainty of collection. The Company continues to insure certain receivables with EDC, allowing the Company to extend credit terms on select occasions.

#### **Investing Activities**

Investing activities comprise expenditures on general office furniture, lab equipment, investing cash, and expenditures on intangible assets relate to filing and maintaining patents and trademarks.

### **Financing Activities**

During the year ended September 30, 2018 the Company took on \$1,521,470 of debt. Additionally, during the year ended September 30, 2018, the Company had net proceeds from the exercise of Stock Options and Warrants for aggregate proceeds of \$897,144.

#### **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 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.



The majority of the Company's cash is maintained by two of the major financial institutions located in Canada.

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

#### **Risks and Uncertainties**

There are numerous and varied risks, both known and unknown, that may prevent the Company from achieving its goals. An investor should carefully consider the risks described in this document, the financial statements, and any other publicly available information from the Company. If any of the risks mentioned below, or other risks that are not mentioned below, are realized it is likely that Covalon's operations, financial condition, and overall business will see a material adverse effect. The risks and uncertainties described in this document contain forward-looking statements and our actual results may differ.

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

## Covalon stock price may be volatile, which could result in substantial losses for investors.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- sales of our common stock, particularly under any registration statement for the purposes of selling any securities, including management shares;
- our ability to execute our business plan;
- the uncertainty regarding whether we will continue to generate sufficient revenues;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market price of our common stock.

### Covalon has not yet achieved consistent profitability year to year.

Covalon achieved a net income for the year ended September 30, 2018, of \$1,617,648 and a net income of \$1,811,694 for the year ended September 30, 2017. There is no guarantee that Covalon will be able to consistently 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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about Covalon's business, our stock price and trading volume could decline.



The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Although we currently do not have research coverage by securities and industry analysts, you should not invest in our common stock in anticipation that we will increase such coverage. If one or more analysts covering us at any given time downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If analysts cease coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

# Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a significant number of common shares could harm the market price of our common shares and make it more difficult for us to raise funds through future offerings of common shares. As additional shares of Covalon's common stock become available for resale in the public market, the supply of our common shares will increase, which could decrease the price of our common stock. In addition, if our shareholders sell substantial amounts of our common stock in the public market, or upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang," in anticipation of which the market price of our common shares could fall. The existence of an overhang, whether or not sales have occurred or are occurring, could also make it more difficult for us to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

### Covalon may not be able to correctly estimate future operating expenses, leading to cash shortfalls.

Covalon's operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors may include, but not be limited to:

- the time and resources required to develop, test, perform clinical assessments, and obtain or maintain regulatory approvals for our products;
- the costs to attract and retain personnel with the skills required for effective operations; or,
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

If we do not accurately predict our operating expenses, we may not allocate resources appropriately, which could lead to cash shortfalls and force us to seek additional capital or curtail other projects or initiatives, all of which could have a significant negative effect on our business, results of operations and financial condition

## Covalon may require additional capital in order to execute the Company's goals and objectives.

Covalon's goals and strategy will result in the increasing of our fixed costs. As a result of the time delay between outlays for working capital expenditures, such as costs to acquire rights to additional products, the hiring of personnel, marketing costs, the purchasing of inventory, and the collection of revenue, we expect to have a net cash outflow from operating activities as a result of these expenditures. Future results of operations involve significant risks and uncertainties, some of which are discussed in this document. In order to complete our future growth strategy, additional equity and/or debt financing may be required. If we are unable to raise additional capital or if we encounter circumstances that place unforeseen constraints on capital resources, we will be required to take even stronger measures to conserve liquidity, which may include, but are not limited to, eliminating all non-essential positions and ceasing all marketing efforts. We would have to curtail business development activities and suspend the pursuit of



our business plan. There can be no assurance that we will be successful in improving revenues, reducing expenses, or securing additional capital both in sufficient amounts and on favorable terms.

## Covalon's strategic business plan may not produce the intended revenue and income growth.

Covalon's growth goals rely on a strategy that includes making large investments in sales, marketing, product research, and controlling expenses. If we do not achieve the expected benefits from these investments, or otherwise fail to execute on our strategic initiatives, we may not achieve the growth we are targeting which could adversely affect our operations and financial position.

## Covalon's acquisition strategy may not produce the intended growth in revenue and operating income

As part of Covalon's strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures or development agreements. Covalon may not be able to identify suitable acquisition candidates, complete acquisitions, integrate acquisitions successfully, or our strategic alliances may not prove to be successful. Such acquisitions could reduce shareholders' ownership, cause us to incur debt, expose us to liabilities and result in amortization expenses related to intangible assets with definite lives. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering new markets with which we have limited experience or where distribution alliances with experienced distributors are not available. Our future profitability may depend in part upon our ability to further develop our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. Moreover, we may fail to realize the anticipated benefits of any acquisition as rapidly as expected, if at all, or the acquired business may not perform in accordance with our expectations. We may also incur significant expenditures in anticipation of an acquisition that is never realized. There can be no assurance that difficulties encountered in connection with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

### Covalon is dependent on significant customers.

A large portion of Covalon's revenue has been generated from a limited number of clients. Covalon has increased the number of customers over the prior periods, while we believe that an increase in revenue will correspond to an increase in customers it is not always the case. During the year Covalon entered tenders to bid on various contracts associated with a significant amount of revenue to Covalon. The certainty of the contracts being awarded to Covalon is uncertain but this would further increase the concentration of revenue associated to individual customers. The loss of any of our significant customers would have a significant negative effect on our overall operations.

### It may be difficult to replace some of Covalon's suppliers.

In general, raw materials essential to our businesses are readily available from multiple sources. However, for reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Covalon works with contract manufacturers, in various capacities, to produce salable products. In order to mitigate any potential negative effects, Covalon works to ensure that inventory levels of both raw materials and finished products are at an adequate level for future forecasts. However, there is no guarantee that our inventory will be sufficient to carry us through any periods of turmoil. Covalon has no direct control over third-party suppliers and therefore interruptions or delays, in the products and services provided, may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be



unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs, or quality control problems and all of these would likely have a materially adverse effect on our business and operations.

#### 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 global 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 Covalon to make minimum guarantees or milestone payments. These guarantees 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 competes in a highly competitive industry against large multination competitors, and new market entrants.

Competition from other companies, research facilities, and academic institutions is intense and Covalon expects it will only intensify further. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights to products or technologies from those institutions. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. There can be no assurance that our products will receive market acceptance in a commercially viable period of time, if at all. Furthermore, there can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete. Our competitors enjoy several competitive advantages over us, including some or all of the following:

• large and established distribution networks;



- greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;
- greater name recognition;
- more expansive portfolios of intellectual property rights;
- established relations with physicians, hospitals, other healthcare providers and third party payors;
- products which have been approved by regulatory authorities for use in the U.S. or Europe, supported by long-term clinical data; and
- greater experience in obtaining and maintaining regulatory approvals or clearances from regulatory agencies.

Our competitors' products will compete directly with our products. In addition, our competitors as well as new market entrants may develop or acquire new treatments, products or procedures that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

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.

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.

## Some of Covalon's existing, and potential future products will require regulatory approval before they can be marketed and sold to customers.

Inherent in the development of new medical products is the potential for delay because product testing, including clinical evaluation, is required before most products can be approved for human use. As Covalon has worldwide sales there are various requirements depending on regions and governing bodies. Though the process differs by location, outlined below are some of the potential issues and pathways with respect to the FDA of the United States as an example.

With respect to medical devices, such as those that we manufacture and licence, before a new medical device, or a new use of, or claim for, an existing product can be marketed, unless it is a Class I device, it must first receive either premarket clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or premarket approval from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that the proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The premarket approval pathway requires an applicant to demonstrate the safety and effectiveness of the device for its intended use based, in part, on extensive data including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The premarket approval process is typically required for devices that are deemed to pose the greatest risk, such as life sustaining, life-supporting or implantable devices. Both the 510(k) and premarket approval processes can be expensive and lengthy and entail significant user fees.



Failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. Meeting regulatory requirements and evolving government standards around the world may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us. We cannot assure you that the FDA, or other regulatory agencies, will approve any products developed by us, on a timely basis, if at all; or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

# 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 expenses adversely affecting the development of product candidates, sales of the challenged products, or sales of intellectual property. The litigation would also divert the efforts of Covalon's technical and management personnel whether or not such litigation is resolved in Covalon's favour. Some of Covalon's competitors may be able to sustain the costs of complex patent litigation more effectively than Covalon 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, to develop, or acquire non-infringing intellectual property;
- discontinue processes incorporating infringing technology; and,
- 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 United States Patent and Trademark Office (or other proceedings outside the United States). The proceedings may include 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 are frequently required to 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 both 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; and,
- 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. Covalon does not know whether any clinical studies will be successful, if regulatory approvals will be received, or if regulatory approvals will be obtained in a timely manner. Despite the time and resources expended by Covalon regulatory approval is never guaranteed.

### Covalon's future success depends upon market acceptance of our existing and future products.

Covalon believes that our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals, physicians, other health care providers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective, technologically advanced, or cost-competitive than other similar products. For our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, if at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

# 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 Covalon fails to comply with applicable post-market regulatory requirements a regulatory agency may impose restrictions on that product or on Covalon. These may include the requirement to withdraw the product from the market; close the facility; suspend manufacturing; change the product's labels; or, pay substantial fines.

Covalon cannot determine what effect changes in regulations or legal interpretations by the various regulatory bodies or the courts, when and if promulgated or issued, may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or



limitations on product distribution. These changes, or others required by a regulatory body could have an adverse effect on the sales of these products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the regulatory bodies and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Modifications to Covalon's current products may require new marketing clearances or approvals or require Covalon to cease marketing or recall the modified products until such clearances or approvals are obtained.

Any modifications made to a product that has previously been cleared by a regulatory body could significantly affect its safety, effectiveness, or intended use would likely require clearance with the regulatory authorities. As an example, the FDA requires every manufacturer to make its own determination as to whether a modification requires a new 510(k) clearance or premarket approval, but the FDA may review and disagree with any decision reached by the manufacturer. In the future, Covalon may make additional modifications to our products after they have received FDA clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulatory authorities may disagree with our past or future decisions not to seek new clearance or approval and may require us to obtain clearance or approval for modifications to our products. If that were to occur for a previously cleared or approved product, we may be required to cease marketing or recall the modified device until we obtain the necessary clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. If any of the foregoing were to occur, our financial condition and results of operations could be negatively impacted.

#### Covalon is dependent on proprietary know-how.

Our manufacturing know-how as to mixing, coating and cross-linking may be able to be duplicated, even if it is difficult to do so. There is no assurance that, should we apply for intellectual property protection for our intellectual property, we would be able to obtain such protection. Further, with the international nature of our business there are no guarantees that even if Covalon is granted protection for intellectual property, that it would be legally enforceable around the world. Therefore, our competitors may develop or market technologies that are more effective or more commercially attractive than ours.

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

Despite our efforts to protect our proprietary rights, there is no assurance that such protections will preclude our competitors from developing and/or marketing similar products. While we are not aware of any third party intellectual property that would materially affect our business, our failure or inability to obtain patents and protect our proprietary information could result in our business being adversely affected.



## Covalon's products risk exposure to product liability claims.

Covalon is, and expects to increasingly be, exposed to potential product liability risks, which are inherent in the testing, manufacturing and marketing of such products. It is likely we will be contractually obligated, under any distribution agreements that we enter into with respect to products we sell, to indemnify the individuals and/or entities that distribute our products against claims relating to the manufacture and sale of products distributed by such distribution partners. This indemnification liability, as well as direct liability to consumers for any defects in the products sold, could expose us to substantial risks and losses. While we have obtained product liability insurance, there can be no assurance that we will be able to maintain such insurance on acceptable terms or that such insurance will provide adequate coverage against potential liabilities. As we begin to sell and distribute our new line of proprietary products, we intend to increase the limits of our product liability insurance. A successful product liability claim or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Covalon may face intellectual property infringement claims that could be time-consuming, costly to defend and could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages.

On occasion, we may receive notices of claims of our infringement, misappropriation or misuse of other parties could result in our loss of significant rights and, in the case of patent infringement claims, the assessment of treble damages. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of its outcome, is expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. In addition, the outcome of such litigation may be unpredictable. If there is a successful claim of infringement against us, we may be required to pay substantial damages—including treble damages if we were to be found to have willfully infringed a third party's patent—to the party claiming infringement, and to develop non-infringing technology, stop selling our products or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, modifying our products to exclude infringing technologies could require us to seek re-approval or clearance from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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:

• Outsourced manufacturing production may not be achieved within Covalon's timelines;



- Production quality measures may not be achieved;
- Sales expectations are not achieved; and,
- New products are not launched expeditiously.

If Covalon is not able to establish and maintain successful arrangements with third parties or successfully build our own sales and marketing infrastructure, we may not be able to commercialize our products, which would adversely affect our business and financial condition.

We are currently expanding our sales and marketing capabilities. To commercialize our products, we must continue to develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. The third parties may not be capable of successfully selling any of our products. We will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all.

Covalon and our manufacturers will be required to comply with current good manufacturing practices and could be subject to suspensions or product withdrawals if found non-compliant.

The FDA regulates the facilities, processes and procedures used to manufacture and market medical products in the U.S. Manufacturing facilities must be registered with the FDA and all products made in such facilities must be manufactured in accordance with "current good manufacturing practices," or cGMP, regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. The FDA periodically inspects the manufacturing facilities of our subcontractors and procedures to assure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility for a particular drug or medical device is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in product delay, which could adversely affect our business, results of operations, financial condition and cash flow.

Healthcare policy changes, including recent laws to reform the U.S. healthcare system, may have a material adverse effect on Covalon.

Covalon operates around the world but a significant portion of business is dependent on the United States. There have been, and continue to be, proposals by legislators, regulators, and third-party payors to keep healthcare costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a material adverse effect on our financial position and results of operations. Various healthcare reform proposals have emerged at the federal and state levels. We cannot predict the exact effect newly enacted laws or any future legislation or regulation will have on us. However, the implementation of new legislation and regulation may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. In addition, the enacted excise tax may materially and adversely affect our operating expenses and results of operations.

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 both 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. To obtain and retain the high quality of employee which Covalon desires will also come with potentially large expenditures. Covalon may not be able to successfully attract and retain skilled and experienced personnel which could harm its ability to develop products and generate revenues. If Covalon is unable to retain key employees, or hire quality candidates, this could have a material adverse effect.

## There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us, cause downgrades in our future debt ratings leading to higher borrowing costs and affect how our stock trades. This could in turn negatively affect our ability to access public debt or equity markets for capital.

## There are risks associated with our acquisition of AquaGuard and any future acquisitions.

We may encounter difficulties completing or integrating our acquisition which could adversely affect our operating results. We expect to expand our presence in the United States hospital market, new end-markets and expand our capabilities, some of which may occur through acquisitions. These transactions may involve acquisitions of entire companies and/or acquisitions of selected assets of companies.

Potential difficulties related to our acquisitions include:

- integrating acquired operations, systems and businesses;
- retaining customer, supplier, employee or other business relationships of acquired operations;
- addressing unforeseen liabilities of acquired businesses;
- limited experience with new technologies; and
- not achieving anticipated business volumes.



Any of these factors could prevent us from realizing the anticipated benefits of an acquisition, including additional revenue, operational synergies and economies of scale. Our failure to realize the anticipated benefits of acquisitions could adversely affect our business and operating results. Our failure to support the carrying value of goodwill and intangible assets in periods subsequent to the acquisitions could require write-downs that adversely affect our operating results.

## **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 January 1, 2017 or later periods. None of these are 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, 2018. The Company is in the process of evaluating the impact of the new standard.

#### IFRS 15 Revenue From Contracts with Customers

IFRS 15, Revenue From Contracts with Customers establish the principles that an entity shall apply to report useful information to users of financial statements about the nature, amount, timing, and uncertainty of revenue and cash flows arising from a contract with a customer. The standard is effective for annual periods beginning on or after January 1, 2018. The Company is in the process of evaluating the impact of adopting this standard.

#### IFRS 16, Leases

IFRS 16, Leases specifies how to recognize, measure, present and disclose leases. It also provides a single lessee accounting model, requiring lessees to recognize assets and liabilities for all leases unless the lease term is 12 months or less or the underlying asset has a small value. Accounting for the lessor will remain substantially unchanged. The standard is effective for periods beginning on or after January 1, 2019, with earlier application permitted for companies that also apply IFRS 15, *Revenue from Contracts with Customers*. The Company is in the process of evaluating the impact of the new standard.

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, 2017, 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.