

# **Covalon Technologies Ltd.**

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

**March 31, 2018**

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

### **For the six months ended March 31, 2018**

**May 28, 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, 2017, and with our unaudited condensed consolidated interim financial statements for the six month period ended March 31, 2018. Additional information on Covalon Technologies Ltd. can be obtained on SEDAR at [www.sedar.com](http://www.sedar.com), as well as the Company's website at [www.covalon.com](http://www.covalon.com). Unless otherwise indicated, all references to the terms "we", "us", "our", "Covalon" and "Company" refer to Covalon Technologies Ltd. and its subsidiaries.

In this management discussion and analysis document ("MD&A"), financial information for the six months ended March 31, 2018 and 2017 is based on the unaudited condensed consolidated interim 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 May 28, 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 offices 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 over twenty 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

<b>Surgical and Peri-Operative Products</b>	
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 approximately 12 to 18 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.

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 six months ended March 31, 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.

### **Operational Highlights Subsequent to March 31, 2018**

- 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 Wound Care Spring ("SWAC Spring") in Charlotte,



North Carolina. In addition to the posters, 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.

#### **Financial Highlights for the three months ended March 31, 2018**

- Total revenue for the three months ended March 31, 2018, decreased 5% to \$5,727,275 compared to \$6,005,381 for the same period of the prior year.
- Product revenue for the three month period ended March 31, 2018, decreased 10% to \$5,079,373 compared to \$5,625,575 for the same period last year. This decrease relates to the timing of major shipments under our previously announce tenders awarded to the Company in the Middle East. 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 was \$326,664 for the three months ended March 31, 2018, compared to \$109,192 in 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 March 31, 2018, were \$321,238 compared to \$270,614 for the three months ended March 31, 2017.
- Gross margin for the three month period ended March 31, 2018, decreased to 76% compared to 78% for the same period of the prior year. Gross margins are influenced by product and revenue mix during any given quarter.
- Operating expenses for the three months ended March 31, 2018, increased \$586,743 to \$4,813,898 compared to \$4,227,115 for the prior year's comparative period. The increase in operating expenses is primarily related to an increase in personnel costs. The Company increased headcount in operations, sales and marketing and administration as a result of the Company's efforts to expand its penetration of new markets, including Europe and the United States. In addition, the

Company added new staff in research and development to support its continued efforts to commercialize new products and technologies. The Company also incurs agency fees 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.

- Net income for the three months ended March 31, 2018, was \$(479,082) or \$(0.02) per share, on a diluted basis, compared to a net income of \$473,524 or \$0.02 per share for the three months ended March 31, 2017.

### **Financial Highlights for the six months ended March 31, 2018**

- Total revenue for the six months ended March 31, 2018, increased 5% to \$12,131,980 compared to \$11,571,115 for the same period of the prior year.
- Product revenue for the six month period ended March 31, 2018, decreased slightly to \$11,054,013 compared to \$11,107,120 for the same period last year. This decrease relates to the timing of major shipments under our previously announce tenders awarded to the Company in the Middle East. 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 was \$726,953 for the six months ended March 31, 2018, compared to \$116,538 in 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 six months ended March 31, 2018, were \$351,014 compared to \$347,457 for the six months ended March 31, 2017.
- Gross margin for the six month period ended March 31, 2018, decreased to 73% compared to 79% for the same period of the prior year. Gross margins are influenced by product and revenue mix during any given quarter.
- Operating expenses for the six months ended March 31, 2018, increased \$713,435 to \$8,829,773 compared to \$8,116,338 for the prior year's comparative period. The increase in operating expenses is primarily related to an increase in personnel costs. The Company increased headcount in operations, sales and marketing and administration as a result of the Company's efforts to expand its penetration of new markets, including Europe and the United States. In addition, the Company added new staff in research and development to support its continued efforts to commercialize new products and technologies. The Company also incurs agency fees 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.
- Net income for the six months ended March 31, 2018, was \$44,263 or \$0.00 per share, on a diluted basis, compared to a net income of \$1,011,188 or \$0.05 per share for the six months ended March 31, 2017.



	Three months ended March 31,		Six months ended March 31,	
	2018	2017	2018	2017
<b>Revenue (Note 3)</b>				
Product	\$5,079,373	\$5,625,575	\$11,054,013	\$11,107,120
Development and consulting services	326,664	109,192	726,953	116,538
Licensing and royalty fees	321,238	270,614	351,014	347,457
<b>Total revenue</b>	<b>5,727,275</b>	<b>6,005,381</b>	<b>12,131,980</b>	<b>11,571,115</b>
<b>Cost of product sales</b>	<b>1,392,459</b>	<b>1,304,702</b>	<b>3,257,944</b>	<b>2,443,589</b>
<b>Gross profit before operating expenses</b>	<b>4,334,816</b>	<b>4,700,679</b>	<b>8,874,036</b>	<b>9,127,526</b>
<b>Operating Expenses</b>				
Operations	518,219	313,870	907,098	584,822
Research and development activities	384,277	270,909	743,812	463,340
Sales, marketing, and agency fees	2,489,083	2,588,441	4,645,025	5,334,533
General and administrative	1,422,319	1,053,935	2,533,838	1,733,643
	<b>4,813,898</b>	<b>4,227,155</b>	<b>8,829,773</b>	<b>8,116,338</b>
<b>Net income (loss)</b>	<b>\$(479,082)</b>	<b>\$473,524</b>	<b>\$44,263</b>	<b>\$1,011,188</b>
<b>Other comprehensive income (loss)</b>				
Foreign currency translation adjustment (Note 2d)	292,504	(17,947)	337,959	63,002
<b>Total comprehensive income (loss)</b>	<b>\$(186,578)</b>	<b>\$455,577</b>	<b>\$382,222</b>	<b>1,074,190</b>
Basic earnings (loss) per share (Note 14)	\$(0.02)	\$0.02	\$0.00	\$0.05
Diluted earnings (loss) per share (Note 14)	\$(0.02)	\$0.02	\$0.00	\$0.05

### Revenue and Gross Profit

Total product revenue decreased \$546,202 or 10% to \$5,079,373 for the three months ended March 31, 2018, compared to \$5,625,575 for the prior year's comparative period. Development and consulting services revenue for the three months ended March 31, 2018, was \$326,664 which represents revenue earned from the Company's work on development and consulting projects; for the same period of the prior year services revenue was \$109,192. Licensing revenue was \$321,238 for the three months ended March 31, 2018, compared to \$270,614 for the prior year's comparative period.

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 76% for the three months ended March 31, 2018, compared to 78% for

the prior year's comparative period. 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 months ended		Six months ended	
	March 31,		March 31,	
	2018	2017	2018	2017
<b>Operations</b>				
Wages, benefits and consulting fees	\$440,835	\$271,275	\$ 744,223	\$515,071
Depreciation and amortization	1,234	1,513	2,474	3,051
Other	76,150	41,082	160,401	66,700
	<b>518,219</b>	<b>313,870</b>	<b>907,098</b>	<b>584,822</b>
<b>Research and development activities</b>				
Wages, benefits and consulting fees	334,262	251,963	659,967	423,297
Depreciation and amortization	2,540	3,198	5,093	6,443
Other	47,475	15,748	78,752	33,600
	<b>384,277</b>	<b>270,909</b>	<b>743,812</b>	<b>463,340</b>
<b>Sales, marketing, and agency fees</b>				
Wages, benefits and consulting fees	589,982	299,305	1,189,965	654,133
Travel	93,831	161,074	165,965	285,528
Other	1,805,270	2,128,062	3,289,095	4,394,872
	<b>2,489,083</b>	<b>2,588,441</b>	<b>4,645,025</b>	<b>5,334,533</b>
<b>General and administrative</b>				
Wages, benefits and consulting fees	819,223	440,249	1,479,230	800,503
Directors compensation	43,744	36,069	90,389	72,000
Professional and related costs	317,900	369,116	545,943	466,816
Facility	156,438	168,860	304,520	321,994
Depreciation and amortization	21,437	20,368	43,280	40,756
Provision for doubtful accounts	-	-	-	-
Other	63,577	19,273	70,476	31,574
	<b>1,422,319</b>	<b>1,053,935</b>	<b>2,533,838</b>	<b>1,733,643</b>
<b>Total Operating Expenses</b>	<b>\$4,813,898</b>	<b>\$4,227,155</b>	<b>\$8,829,773</b>	<b>\$8,116,338</b>

Operating expenses for the three months ended March 31, 2018, increased \$586,743 to \$4,813,898 compared to \$4,227,155 for the prior year's comparative period. During the three months ended March 31, 2018, the Company incurred additional expenses related to:

- Development and launching costs associated with new products;
- Costs associated with new facilities; and
- Marketing, and business development costs associated with geographic expansion.

A significant component 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. The Company also incurred additional costs associated with efforts to increase our sales team, research and development, investing in new markets, and increased investment in our new product pipeline.

### **Related Party Transactions**

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

	<b>Three months ended March 31,</b>		<b>Six months ended March 31,</b>	
	<b>2018</b>	2017	<b>2018</b>	2017
Compensation and short-term benefits	<b>\$252,839</b>	\$305,980	<b>\$544,271</b>	\$606,309
Share-based payments	<b>184,706</b>	45,134	<b>305,174</b>	81,366
	<b>437,545</b>	351,114	<b>849,445</b>	687,675

During the three months ended March 31, 2018, the Company had compensation to related parties included in the preceding table.

### **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) Intangible Assets**

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

##### **ii) 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.

iii) **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.

iv) **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) **Foreign Currency translation**

The determination of functional currency for each of the Company's entities requires considerable judgment. The functional currency is determined based on the currency of the primary economic environment in which that entity operates. As the Company generates and expends cash in 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 Second Quarter	2018 First Quarter	2017 Fourth Quarter	2017 Third Quarter	2017 Second Quarter	2017 First Quarter	2016 Fourth Quarter	2016 Third Quarter	2016 Second Quarter
Revenue	\$ 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
Net income (loss) before amortization	(402,173)	597,755	328,116	614,051	536,080	608,112	(1,964,065)	(90,560)	(999,873)
Net income (loss)	(479,082)	523,345	259,160	541,346	473,524	537,664	(2,139,063)	(156,792)	(1,065,517)
Net income (loss) per share	(0.02)	0.02	0.01	0.03	0.02	0.03	(0.18)	(0.02)	(0.10)
Cash and cash equivalents	\$1,833,771	4,217,358	4,155,883	2,551,330	494,117	1,221,893	1,454,389	670,956	499,332
Net working capital	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
Current Ratio	3.9	3.8	3.5	3.6	2.1	2.2	2.0	2.4	1.7

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

(Canadian \$)	March 31, 2018	September 30, 2017
Cash and cash equivalents	<b>\$1,833,771</b>	\$4,155,883
Short-term investments	-	-
Total assets	<b>\$13,228,273</b>	\$11,966,991
Deferred revenue	<b>\$315,101</b>	\$524,885

On March 31, 2018, cash, cash equivalents, restricted cash, and short-term investments totaled \$1,869,416 compared to \$4,191,678 at September 30, 2017. During the six months ended March 31, 2018, the Company had a negative cash flow of \$(2,322,112). As at May 28, 2018, cash, cash equivalents, restricted cash and short-term investments totaled approximately \$2.5 million.

Accounts receivable from customers at March 31, 2018, increased \$1,910,892 from the prior year end. The timing of cash flows from customers will continue to fluctuate 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 March 31, 2018. At March 31, 2018, the Company had an additional \$35,645 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 March 31, 2018, were \$13,228,273 compared to \$11,966,991 at September 30, 2017. Cash, cash equivalents and short-term investments comprised 14% of total assets at March 31, 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 \$209,784 to \$315,101 at March 31, 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 six months ended March 31, 2018, 150,500 warrants were exercised for common shares of the Company for aggregate proceeds of \$190,150

During the six months ended March 31, 2018, 66,666 options were exercised for proceeds of \$118,983

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.

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%.

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 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%.

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%.

### Sources and Uses of Cash

	<b>Six months ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Cash flows from operating activities	<b>(2,347,046)</b>	(876,275)
Cash flows from investing activities	<b>(484,506)</b>	(115,390)
Cash flows from financing activities	<b>309,132</b>	-

### Operating Activities

Cash used in operating activities for the six months ended March 31, 2018, was \$2,347,046 compared to \$876,275 for the prior year's comparative period. Non-cash working capital used \$3,171,515 of cash during the six months ended March 31, 2018, compared to \$2,216,013 for the prior year's comparative period. At March 31, 2018, accounts receivable had increased \$1,910,892 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 six months ended March 31, 2018, 150,500 warrants were exercised for common shares of the Company for aggregate proceeds of \$190,150.

During the six months ended March 31, 2018, 66,666 options were exercised for proceeds of \$118,983.

### 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 of \$44,263 for the six months ended March 31, 2018. 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 period 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.

## **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 expects the changes associated with the adoption of this standard to have a minimal impact on the financial statements.

#### *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 expects the changes associated with the adoption of this standard to have a minimal impact on the financial statements.

#### *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.