

## **Covalon Technologies Ltd.**

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

**December 31, 2018**

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

### **For the three months ended December 31, 2018**

#### **February 25, 2019**

The following discussion of Covalon Technologies Ltd.'s ("Covalon" or the "Company") financial condition and results of operations should be read in conjunction with our audited consolidated financial statements for the year ended September 30, 2018, and with our unaudited condensed consolidated interim financial statements for the three month period ended December 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 three months ended December 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 February 25, 2019. Disclosure contained in this document is current to that date, unless otherwise noted.

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

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

#### **Non-IFRS Financial Measures**

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

## **Forward-looking Statements**

This MD&A contains forward-looking statements which reflect the Company's current expectations regarding future events. The forward-looking statements are often, but not always, identified by the use of words such as "seek", "anticipate", "plan", "estimate", "expect", "intend" and statements that an event or result "may", "will", "should", "could", or "might" occur or be achieved and other similar expressions. These forward-looking statements involve risk and uncertainties, including the difficulty in predicting product approvals, acceptance of and demands for new products, the impact of the products and pricing strategies of competitors, delays in developing and launching new products, the regulatory environment, fluctuations in operating results, and other risks, any of which could cause results, performance, or achievements to differ materially from the results discussed or implied in the forward-looking statements. Many risks are inherent in the industry; others are more specific to the Company. Investors should consult the "Risks & Uncertainties" section of this MD&A as well as the Company's ongoing quarterly filings for additional information on risks and uncertainties relating to these forward-looking statements. Investors should not place undue reliance on any forward-looking statements. Management assumes no obligation to update or alter any forward-looking statements whether as a result of new information, further events, or otherwise.

## **Nature of Our Business**

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

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

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

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

On October 1, 2018, Covalon completed the acquisition of AquaGuard, a Seattle, Washington-based division of medical technologies company Cenorin, LLC. AquaGuard's specialized products provide patients with crucial moisture protection for wound, surgical, and vascular access sites throughout the body while showering. As part of the acquisition, the Company acquired all of the operating assets of the business, including AquaGuard's specialized product line and employed its experienced sales force that has been building relationships with clinicians and hospital staff throughout the United States.

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

<b>Moisture Barriers</b>	
AquaGuard Sheet	AquaGuard moisture barriers make it easy to keep wounds, dressing, and intravenous sites dry and reduce the changes of infection. Specifically tailored for general body protection.
AquaGuard Glove	AquaGuard moisture barriers make it easy to keep wounds, dressing, and intravenous sites dry and reduce the changes of infection. Specifically tailored for upper extremities.
AquaGuard Boot	AquaGuard moisture barriers make it easy to keep wounds, dressing, and intravenous sites dry and reduce the changes of infection. Specifically tailored for lower extremities.

### **Our Product Pipeline**

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

### **Our Business Model**

The Company distributes products under the Covalon brand name through multiple channels to market, including through third-party distribution networks and directly through the Company's direct sales force. The Company also sells certain of its products through private label arrangements with other medical device companies and licenses certain of its technologies and provides services through an OEM business model to realize value in the marketplace.

Currently the Company has a direct sales force in the United States and the United Kingdom that sell directly into acute care hospitals and associated institutions.

The Company has set up distribution relationships with a number of companies in North America, the Middle East, Latin America, Asia, and Europe.

Covalon continues to 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 incorporation 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.

Covalon's technology also lends itself to developing and consulting projects. These projects allow Covalon to showcase our proprietary technology, explore new areas of application, and build industry relationships with larger companies.

OEM models, and project-based activities, 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, and project based, 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 three months ended December 31, 2019**

- On October 1, 2018, Covalon announced that it had closed the acquisition of AquaGuard, a Seattle, Washington-based division of medical technologies company Cenorin, LLC. The consideration of approximately \$16m was comprised of a combination of cash, 178,027 common shares of the Company, and contingent consideration.
- On October 24, 2018, Covalon announced that it would be attending the 2018 American Nurses Credentialing Center National Magnet Conference from October 24<sup>th</sup> to October 26<sup>th</sup>, 2018. This represented Covalon's first conference showcasing AquaGuard and IV Clear together as a part of Covalon's product portfolio.
- On October 30, 2018, Covalon announced the that it had successfully completed the integration of AquaGuard with its operations.
- On December 27, 2018, Covalon announced the issuance of 425,000 stock options to employees and consultants of the Company. The stock options will vest over three years and will be exercisable for a period of five years at an exercise price of \$4.28 per stock option.

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

- On January 24, 2019, Covalon announced that it had appointed PricewaterhouseCoopers LLP as auditors of the Company. Covalon also announced that the Board of Directors had decided to amend and restate the Company's rolling stock option plan in order to align the provisions of the 2007 plan with current market standards. The amended plan will be presented for Shareholder approval at the Company's Annual Shareholder's Meeting.
- On January 28, 2019, Covalon announced that Dr. Myrna Francis had joined Covalon's Board of Directors. Dr. Francis has an extensive background in healthcare and is well-known in both private and public sectors; her experience spans the international marketplace – Canada, the US, and Europe. Dr. Francis is currently the President of Mfran Healthcare Advisory Services, the Vice Chair of OCAD University's Board of Governors, serving on the Board of Directors of Medavie

Inc., and is a volunteer advisory for BioMedical Zone, MaRS Discovery District, as well as Health Ventures Group.

- On January 30, 2019, Covalon announced that John Suk had joined Covalon's Board of Directors. Mr. Suk is an experienced executive within Canada's pharmaceutical and healthcare industries and comes to Covalon after holding senior executive roles at McNeil Labs (Johnson & Johnson), GlaxoSmithKline plc, and Hoffman La Roche, and Byk Canada (later known as Nycomed).

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

- Total revenue for the three months ended December 31, 2018, increased 13% to \$7,261,486 compared to \$6,404,705 for the same period of the prior year.
- Product revenue for the three month period ended December 31, 2018, increased 6% to \$6,355,538 compared to \$5,974,640 for the same period last year. This increase relates to the inclusion of revenue from the acquisition of AquaGuard and offset by the timing of major shipments under our previously announced tenders awarded to the Company in Saudi Arabia. During the period, the Company continued deliveries to fulfil the tenders awarded by the Ministry of Health in Saudi Arabia.
- Development and consulting services revenue for the three month period ended December 31, 2018, increased by 108% to \$830,897 compared to \$400,289 for the same period of the prior year. Revenue from development and consulting services varies based on opportunities and the length of the sales cycle for given projects.
- Licensing and royalty fees for the three months ended December 31, 2018, were \$75,051 compared to \$29,776 for the three months ended December 31, 2017.
- Gross margin for the three month period ended December 31, 2018, decreased to 63% compared to 71% for the same period of the prior year. The gross margin is significantly influenced by source of revenue and by the relative mix of products sold in any given financial period. The margin is also impacted by the newly acquired AquaGuard product line.
- Operating expenses for the three months ended December 31, 2018, increased \$2,159,452 to \$6,175,327 compared to \$4,015,875 for the prior year's comparative period. The increase is largely driven by the operating costs of AquaGuard, and costs associated with the closing of the acquisition. Included in operating expenses for the fourth quarter was approximately \$500,000 of costs related to the acquisition of AquaGuard. No such expenses were included in the comparative period.
- Net loss for the three months ended December 31, 2018, was \$1,909,411 or \$(0.09) per share, compared to a net income of \$523,345 or \$0.02 per share for the three months ended December 31, 2017.



	<b>Three months ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Revenue</b>		
Product	<b>\$6,355,538</b>	\$5,974,640
Development and consulting services	<b>830,897</b>	400,289
Licensing and royalty fees	<b>75,051</b>	29,776
<b>Total revenue</b>	<b>7,261,486</b>	6,404,705
<b>Cost of product sales</b>	<b>2,657,312</b>	1,865,485
<b>Gross profit before operating expenses</b>	<b>4,604,174</b>	4,539,220
<b>Operating expenses</b>		
Operations	<b>309,414</b>	388,879
Research and development activities	<b>374,990</b>	359,535
Sales, marketing, and agency fees	<b>3,261,051</b>	2,155,942
General and administrative	<b>2,229,872</b>	1,111,519
	<b>6,175,327</b>	4,015,875
<b>Financing expenses</b>		
Finance cost	<b>338,258</b>	-
<b>Net income (loss)</b>	<b>\$(1,909,411)</b>	\$523,345
<b>Other comprehensive income (loss)</b>		
Foreign currency translation adjustment	<b>1,001,866</b>	45,455
<b>Other comprehensive income (loss)</b>	<b>\$(907,545)</b>	\$568,800
Basic earnings (loss) per share	<b>\$(0.09)</b>	\$0.02
Diluted earnings (loss) per share	<b>\$(0.09)</b>	\$0.02

### Revenue and Gross Profit

Total revenue increased \$856,781 or 13% to \$7,261,486 for the quarter ended December 30, 2018, compared to \$6,404,705 in the comparative period. Product revenue was \$6,355,538 for the quarter ended December 31, 2018, compared to \$5,974,640 in the prior year. Development and consulting services revenue for the quarter ended December 31, 2018, was \$830,897 which represents revenue earned from the Company's work on development and consulting projects; an increase from prior period's services revenue of \$400,289. Licensing revenue was \$75,051 for the quarter ended December 31, 2018, compared to \$29,776 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 predominantly 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. On October 1, 2018, the Company completed the acquisition of AquaGuard, a Seattle, Washington-based division of medical technologies company Cenorin, LLC. The acquisition gives Covalon access to the AquaGuard family of moisture barrier products as well as their specialised salesforce in the United States.

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 63% for the quarter ended December 31, 2018, compared to 71% for the prior period. Gross margin is highly influenced by the mix of collagen-based dressings, silicone-based dressings, medical coated devices, passive dressings, moisture barriers, and related service revenues generated in the periods.

## Operating Expenses

	<b>Three months ended</b>	
	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Operations</b>		
Wages, benefits and consulting fees	<b>\$214,509</b>	\$303,388
Depreciation and amortization	<b>1,481</b>	1,240
Other	<b>93,424</b>	84,251
	<b>309,414</b>	388,879
<b>Research and development activities</b>		
Wages, benefits and consulting fees	<b>327,508</b>	325,705
Depreciation and amortization	<b>8,974</b>	2,553
Other	<b>38,508</b>	31,277
	<b>374,990</b>	359,535
<b>Sales, marketing, and agency fees</b>		
Wages, benefits and consulting fees	<b>1,847,813</b>	599,983
Travel	<b>386,592</b>	72,134
Other	<b>1,026,646</b>	1,483,825
	<b>3,261,051</b>	2,155,942
<b>General and administrative</b>		
Wages, benefits and consulting fees	<b>1,246,930</b>	660,007
Directors compensation	<b>43,486</b>	46,645
Professional and related costs	<b>692,666</b>	228,043
Facility	<b>185,237</b>	148,082
Depreciation and amortization	<b>34,766</b>	21,843
Other	<b>26,786</b>	6,899
	<b>2,229,872</b>	1,111,519
<b>Total operating expenses</b>	<b>\$6,175,327</b>	\$4,015,875

Operating expenses for the three months ended December 31, 2018, increased \$2,159,452 to \$6,175,327 compared to \$4,015,875 for the prior year's comparative period. During the December 31, 2018 quarter, the Company incurred higher operating expenses as a result of the AquaGuard acquisition which has been consolidated into the Company's statements as of October 1, 2018.

Wages, benefits, and consulting fees (for all departments) include a non-cash expense related to stock options that the Company had previously granted. The quarter ended December 31, 2018 had stock option related expenses of \$327,416 compared to \$257,560 in the prior year. This expense is a reflection of the number of options outstanding and their respective exercise prices.

During the fiscal quarter ended December 31, 2018, the Company incurred costs associated with the acquisition of the assets of AquaGuard (a division of Cenorin LLC). These costs included legal, accounting, and consulting fees customary with these types of transactions and are one time in nature. The total of the one time costs associated with this transaction were approximately \$500,000. During fiscal 2018, the Company invested a net amount of approximately \$550,000 into operating costs to establish sales channels into the United Kingdom, Europe, and Latin America. The Company expects that revenue from these locations will begin to materially impact the Company's operations later in fiscal 2019.

### **Related Party Transactions**

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

	<b>Three months ended December 31,</b>	
	<b>2018</b>	2017
Compensation and short-term employee benefits	<b>\$641,959</b>	\$291,432
Share-based payments	<b>168,276</b>	120,468
	<b>810,235</b>	411,900

During the quarter ended December 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.

### Business Combinations

The acquisition method of accounting is used to account for business combinations. The consideration transferred in a business combination is measured at fair value at the date of acquisition. Acquisition-related transaction costs are recognized in the condensed consolidated interim statements of operations (loss) and comprehensive income (loss) as incurred. At the acquisition date, the identifiable assets acquired and the liabilities assumed are initially recognized at their fair value. Goodwill is measured as the excess of the sum

of the consideration transferred and the fair value of the acquirer's previously held equity interest in the acquiree (if any) over the net of the acquisition-date amounts of the identifiable assets acquired and liabilities assumed. When the consideration transferred by the Company in a business combination includes assets or liabilities resulting from a contingent consideration arrangement, the contingent consideration is measured at its acquisition date fair value and is included as part of the consideration transferred in a business combination. Changes in the acquisition date fair values of the identifiable assets, liabilities and contingent consideration that qualify as measurement period adjustments are adjusted retrospectively, with corresponding adjustments against goodwill. Measurement period adjustments are adjustments that arise from additional information obtained during the measurement period (which cannot exceed one year from the acquisition date) about facts and circumstances that existed at the acquisition date.

Other than measurement period adjustments, contingent consideration that is classified as a financial liability is remeasured at subsequent reporting dates, with the corresponding gain or loss recognized in the condensed consolidated interim statements of operations and comprehensive income (loss).

### Goodwill

Goodwill represents the excess fair value of the consideration transferred over the fair value of the underlying net assets in a business combination and is measured at cost less accumulated impairment losses. Goodwill is not amortized but is tested for impairment on an annual basis or more frequently if there are indications the goodwill may be impaired. For the purposes of impairment testing, goodwill is allocated to each of the Company's cash generating units (CGUs) or group of CGUs that are expected to benefit from the synergies of the acquisition. If the recoverable amount of the CGU or group of CGUs is less than the carrying amount, the impairment loss is allocated first to reduce the carrying amount of any goodwill and then to other assets of the CGU or group of CGUs.

### IFRS 15 – Revenue from Contracts with Customers

IFRS 15, Revenue from Contracts with Customers ("IFRS 15") – replaces IAS 18, Revenue. IFRS 15 clarifies the principles for recognizing revenue and cash flows arising from contracts with customers. The standard became effective for annual periods beginning on or after January 1, 2018, and the Company adopted IFRS 15 as of October 1, 2018.

The Company has adopted IFRS 15 without practical expedients on a full retrospective basis. The effect of initially applying this standard as of the date of initial application has no impact on the comparative information presented. Note disclosures to the condensed consolidated interim financial statements have been updated to reflect the requirements of this standard.

The Company generates revenue from product sales, development and consulting services, as well as licensing, and royalty fees.

Product revenue is recognized when control over products has been transferred to the customer and this either occurs when products are shipped or delivered based upon the contractual agreements in place. The amount of revenue is recorded as the amount that the Company expects to be entitled to in exchange for transferring the promised goods net of estimated returns, chargebacks, or discounts.

Development, and consulting revenue is recognized over the period in which the services are performed.

The Company may enter into product development, consulting, licensing, and royalty agreements with customers. The terms of the agreements may include non-refundable signing fees, milestone payments, hourly rates, or royalty fees. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting. Upfront fees are recognized as revenue when persuasive evidence of an arrangement exists, the fee is fixed or determinable, delivery or performance has been substantially completed and collection is reasonably assured. If there are no substantive performance obligations over the life of the contract, the upfront non-refundable payment is recognized when the underlying performance obligation is satisfied. If substantive contractual obligations are satisfied over time or over the life of the contract, revenue may be deferred and recognized over the performance period. The term over which upfront fees are recognized is revised if the period over which the Company maintains substantive contractual obligations changes. Service revenue is recognized over the period in which the services are performed.

In some instances, cash is received before the Company has satisfied the performance obligations and this amount is recorded as deferred revenue.

#### IFRS 9 – Financial Instruments

IFRS 9, Financial Instruments (“IFRS 9”) – replaces IAS 39, Financial Instruments: Recognition and Measurement (“IAS 39”). IFRS 9 simplifies the classification and measurement requirements for financial instruments, which replaces the multiple classification and measurement models in IAS 39. The standard became effective for annual periods beginning on or after January 1, 2018, and the Company adopted this standard on October 1, 2018. The adoption of this standard has no impact on the measurement of the Company’s financial instruments in the condensed consolidated interim financial statements, however additional disclosures have been provided. The following are new accounting policies for financial instruments under IFRS 9.

#### *FINANCIAL ASSETS*

The Company classifies its financial assets in the following categories: at Fair Value Through Profit or Loss (“FVTPL”); or, at Amortized Cost. The classification depends on the purpose for which the financial assets were acquired. Management determines the classification of its financial assets at initial recognition. Measurement and classification of financial assets is dependent on the Company’s business model for managing the financial assets and the contractual cash flow characteristics of the financial asset.

Financial assets at FVTPL: Financial assets carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the condensed consolidated interim statements of operations and comprehensive income (loss). Changes in the fair value of a financial asset held at FVTPL are included in the condensed consolidated interim statements of operations and comprehensive income (loss) in the period in which they arise.

Financial assets at amortized cost: Financial assets at amortized cost are initially recognized at fair value and subsequently carried at amortized cost less any impairment. They are classified as current assets or non-current assets based on their maturity date. Financial assets are derecognized when they mature or are sold, and substantially all the risks and rewards of ownership have been transferred. Gains and losses on derecognition of financial assets classified as FVTPL or amortized cost are recognized in the condensed consolidated interim statements of operations and comprehensive income (loss).

*FINANCIAL LIABILITIES*

Financial liabilities are recognized initially at fair value, net of transaction costs incurred and are subsequently measured at amortized cost. Any difference between the amounts originally received, net of transaction costs, and the redemption value is recognized in profit and loss over the period to maturity using the effective interest rate method. The effective interest rate method is a method of calculating the amortized cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period.

The Company completed an assessment of its financial instruments at October 1, 2018. The following table shows the original classification under IAS 39 and the new classification under IFRS 9:

<b><u>Instrument</u></b>	<b><u>Classification under IAS 39</u></b>	<b><u>Classification under IFRS 9</u></b>
Cash and cash equivalents	Amortized cost	Amortized cost
Accounts receivable	Amortized cost	Amortized cost
Restricted cash	Amortized cost	Amortized cost
Bank debt	Amortized cost	Amortized cost
Contingent consideration	Fair value through profit or loss	Fair value through profit or loss
Trade and other payables	Amortized cost	Amortized cost

*IMPAIRMENT OF FINANCIAL ASSETS AT AMORTIZED COST*

The Company recognizes a loss allowance for expected credit losses on financial assets that are measured at amortized cost. At each reporting date, the loss allowance for the financial asset is measured at an amount equal to the lifetime expected credit losses if the credit risk on the financial asset has increased significantly since initial recognition. If at the reporting date, the financial asset has not increased significantly since initial recognition, the loss allowance is measured for the financial asset at an amount equal to twelve month expected credit losses. For trade receivables, the Company applies the simplified approach to providing for expected credit losses, which allows the use of a lifetime expected loss provision. Impairment losses on financial assets carried at amortized cost are reversed in subsequent periods if the amount of the loss decreases and the decrease can be objectively related to an event occurring after the impairment was recognized. Given the nature and balances of the Company’s receivables, the Company has no material loss allowance at adoption or as at December 31, 2018.

## Summary of Quarterly Results and Financial Position

	2019 First Quarter	2018 Fourth Quarter	2018 Third Quarter	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	\$ 7,261,486	\$ 6,657,686	\$ 7,933,676	\$ 5,727,275	\$ 6,404,631	\$ 9,836,938	\$ 5,901,622	\$ 6,005,336	\$ 5,608,927	\$ 872,624	\$ 2,600,002	\$ 797,748
Net income (loss) before amortization	(1,791,878)	(268,687)	2,322,108	(402,173)	597,755	328,116	614,051	536,080	608,112	(1,964,065)	(90,560)	(999,873)
Net income (loss)	(1,909,411)	(625,082)	2,198,467	(479,082)	523,345	259,160	541,346	473,524	537,664	(2,139,063)	(156,792)	(1,065,517)
Net income (loss) per share	(0.09)	(0.03)	0.09	(0.02)	0.02	0.01	0.03	0.02	0.03	(0.18)	(0.02)	(0.10)
Cash and cash equivalents	2,569,986	\$5,483,087	\$1,721,427	\$1,833,771	4,217,358	4,155,883	2,551,330	494,117	1,221,893	1,454,389	670,956	499,332
Net working capital	5,892,662	10,685,114	10,662,108	7,877,345	8,006,986	6,975,333	6,627,254	3,090,662	2,621,971	2,165,440	3,124,482	2,399,855
Current ratio	1.4	2.7	4.8	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

	<b>December 31, 2018</b>	September 30, 2018
Cash and cash equivalents	<b>\$2,569,986</b>	\$5,483,087
Short-term investments	-	-
Total assets	<b>\$38,283,345</b>	\$19,707,833
Deferred revenue	<b>\$198,955</b>	\$206,811

On December 31, 2018, cash, cash equivalents, and short-term investments totaled \$2,569,986 compared to \$5,483,087 at September 30, 2018. During the quarter ended December 31, 2018, the Company had negative cash flow of \$4,140,881. As at February 25, 2019, cash, cash equivalents, and short-term investments totaled approximately \$2.5 million.

Accounts receivable at December 31, 2018, increased \$2,254,578 from the prior year end. The timing of cash flows from customers will continue to be unpredictable due to payment terms which may include upfront advances, payment on shipment as well as standard and extended credit terms. The Company also accepts letters of credit on large transactions which provides more certainty of collection. The Company uses EDC insurance, when appropriate, to allow it to extend credit terms to specific customers.

The Company had an additional \$38,090 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 December 31, 2018, were \$38,283,345 compared to \$19,707,833 at September 30, 2018. Cash, cash equivalents and short-term investments comprised 7% of total assets at December 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 \$7,856 to \$198,955 at December 31, 2018, compared to \$206,811 at September 30, 2018.

The Company continually monitors working capital to ensure sufficient cash is available to meet operational and capital expenditure requirements. The Company has contractual obligations related to short term debt and accounts payable and accrued liabilities that are due within a year.

	<b>Carrying amount (\$)</b>	<b>Future cash flows (\$)</b>	<b>Less than 1 year (\$)</b>	<b>Between 1 and 5 years (\$)</b>	<b>Greater than 5 years (\$)</b>
Accounts payable and accrued liabilities	5,775,736	5,775,736	5,775,736	-	-
Contingent consideration	1,227,780	1,227,780	1,227,780	-	-
Short-term debt	4,561,146	4,561,146	4,561,146	-	-
Long-term debt	2,953,334	3,936,871	-	3,936,871	-
Acquisition note payable	9,594,987	9,669,210	3,267,710	6,401,500	-
<b>Total</b>	<b>24,112,983</b>	<b>25,170,743</b>	<b>14,832,372</b>	<b>10,338,371</b>	-

During the year ended September 30, 2018, the Company entered into a banking credit facility agreement (the “Facility”) with HSBC Bank Canada (“HSBC”). This multifaceted Facility provides credit of up to approximately \$17 million. The Facility is secured by a general security interest over the assets of the Company and the wholly owned subsidiaries. The Company is also subject to financial covenants and certain reporting requirements customary with credit facilities of this nature.

### 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.

Covalon acquired AquaGuard, a division of Cenorin LLC, and issued 178,028 common shares as a closing share payment on October 1, 2018 (see Note 3). These shares were valued at \$1,271,901 based on the Company’s closing share price at the acquisition date. Included in this amount is 75,136 common shares (\$647,250) of the Company which were issued pursuant to the terms of a lock-up agreement. For shares issues in escrow, the Black Sholes model was used to determine the average fair value as of \$5.48/share across the three escrow release points (12 months, 18 months, and 24 months).



The following is a summary of the movements in share capital from October 1, 2018 to December 31, 2018:

	<b>Number of Shares (#)</b>	<b>Amount (\$)</b>
Balance at September 30, 2018	22,009,130	39,257,032
Options exercised	8,500	35,524
Shares issued as consideration for acquisition	178,028	1,271,901
Balance at December 31, 2018	22,195,658	40,564,457

During the three months ended December 31, 2017, 23,333 options were exercised for proceeds of \$44,483.

### Sources and Uses of Cash

	<b>Three months ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Cash flows from operating activities	<b>(3,702,541)</b>	(121,423)
Cash flows from investing activities	<b>(4,842,850)</b>	(63,739)
Cash flows from financing activities	<b>5,820,207</b>	223,133

### Operating Activities

Cash used in operating activities for the quarter ended December 31, 2018, was \$3,702,541 compared to \$121,423 used for the prior year's comparative period. Non-cash working capital used \$2,614,877 of cash during the quarter ended December 31, 2018, compared to \$973,037 for the prior year's comparative period. At December 31, 2018, accounts receivable had increased \$2,254,578 over September 30, 2018, 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.

During the period, the Company acquired the assets of AquaGuard and these additions have been reflected in investing activities.

### Financing Activities

During the quarter ended December 31, 2018 the Company had a net draw of approximately \$6 million against the banking facilities to facilitate the initial payment of the AquaGuard acquisition and to fund working capital.

As part of the acquisition, the Company issued 178,028 common shares of the Company with an aggregate, fair value, of \$1,271,901.

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

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

### **Financial Instruments**

The Company is subject to interest rate risk on its cash, cash equivalents and debt. The Company believes that interest rate risk is low due to market based variable interest rate. During fiscal 2019, the Company took on floating rate debt to fund the acquisition described in the financial statements and to fund working capital.

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 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 had a net loss for the quarter ended December 31, 2018, of \$1,909,411 and a net income of \$1,617,648 for the year ended September 30, 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 year Covalon entered tenders to bid on various contracts associated with a significant amount of revenue to Covalon. The certainty of the contracts being awarded to Covalon is uncertain but this would further increase the concentration of revenue associated to individual customers. The loss of any of our significant customers would have a significant negative effect on our overall operations.

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

In general, raw materials essential to our businesses are readily available from multiple sources. However, for reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Covalon works with contract manufacturers, in various capacities, to produce salable products. In order to mitigate any potential negative effects, Covalon works to ensure that inventory levels of both raw materials and finished products are at an adequate level for future forecasts. However, there is no guarantee that our inventory will be sufficient to carry us through any periods of turmoil. Covalon has no direct control over third-party suppliers and therefore interruptions or delays, in the products and services provided, may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs, or quality control problems and all of these would likely have a materially adverse effect on our business and operations.

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

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

There can be no assurance that:

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

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

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

***Covalon competes in a highly competitive industry against large multination competitors, and new market entrants.***

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

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

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

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

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

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

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

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

Failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from

obtaining, or affect the timing of, future regulatory approvals. Meeting regulatory requirements and evolving government standards around the world may delay marketing of our new products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us. We cannot assure you that the FDA, or other regulatory agencies, will approve any products developed by us, on a timely basis, if at all; or, if granted, that approval will not entail limiting the indicated uses for which we may market the product, which could limit the potential market for any of these products.

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

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

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

- pay substantial damages;
- cease the development, manufacture, use, or sale of product candidates or products that infringe upon the intellectual property of others;
- expend significant resources to design around a patent, to develop, or acquire non-infringing intellectual property;
- discontinue processes incorporating infringing technology; and,
- obtain licenses to the infringed intellectual property.

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

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

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



These laws require, among other things:

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

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

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

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

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

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

Covalon cannot determine what effect changes in regulations or legal interpretations by the various regulatory bodies or the courts, when and if promulgated or issued, may have on our business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by a regulatory body could have an adverse effect on the sales of these products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the regulatory bodies and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

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

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

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

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

We also rely on trade secret protection to protect our interests in proprietary know-how and for processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. In addition, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. These agreements may be breached and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access

to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

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

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

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

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

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

from various regulatory bodies for our products, which would be costly and time consuming. Also, we may be unaware of pending patent applications that relate to our technology. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our products or using technology that contains the allegedly infringing intellectual property, which could harm our business.

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

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

Examples of such issues include:

- Outsourced manufacturing production may not be achieved within Covalon's timelines;
- Production quality measures may not be achieved;
- Sales expectations are not achieved; and,
- New products are not launched expeditiously.

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

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

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

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

site could result in product delay, which could adversely affect our business, results of operations, financial condition and cash flow.

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

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

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

Covalon is highly dependent on its senior management, and its scientific and technical personnel for both their domain knowledge and technical expertise. The competition for qualified personnel in the healthcare field is intense and Covalon relies heavily on its ability to attract and retain qualified managerial, scientific, and technical personnel. Covalon's ability to manage growth effectively will require continued implementation and improvement of its management systems and the ability to recruit and train new employees. To obtain and retain the high quality of employee which Covalon desires will also come with potentially large expenditures. Covalon may not be able to successfully attract and retain skilled and experienced personnel which could harm its ability to develop products and generate revenues. If Covalon is unable to retain key employees, or hire quality candidates, this could have a material adverse effect.

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

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

with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

***Leverage, Liquidity and Restrictive Covenants.***

Our ability to meet our debt-services requirements will depend on our ability to generate cash in the future, which depends on many factors, including our financial performance, working capital and future capital-expenditure requirements. The Facility contains restrictive covenants that may limit the discretion of management with respect to certain business matters and capital allocation decisions, including, for example, any prospective return of capital to shareholders through dividends or share repurchases. In addition, our ability to borrow funds in the future may depend on the satisfaction of the covenants contained in the Facility. A failure to comply with any covenants or obligations under the Facility could result in a default, which, if not cured or waived, could result in the acceleration of the relevant indebtedness. If such indebtedness were to be accelerated, there can be no assurance that our assets would be sufficient to repay such indebtedness in full. There can also be no assurance that we will generate cash flow in amounts sufficient to pay outstanding indebtedness or to fund any other liquidity needs. If the amounts become repayable due to an inability to comply with covenants, or if we are unable to extend the terms of the facilities at time of renewal, the loss of the credit facilities could have an adverse effect on our business.

***There are risks associated with any future acquisitions.***

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

Potential difficulties related to our acquisitions include:

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

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

### ***Inability to Successfully Integrate or to Attain the Expected Benefits from AquaGuard Acquisition.***

In October 2018, we completed the acquisition of AquaGuard, a Seattle, Washington-based division of medical technologies company Cenorin, LLC. The benefits we expect to achieve as a result of the acquisition of AquaGuard will depend, in part, on our ability to realize anticipated growth opportunities. There can be no assurance that our management will be able to fully realize the expected benefits of the acquisition of AquaGuard. Even if we are able to integrate the AquaGuard business and operations successfully, this integration may not result in the realization of the full benefits of the growth opportunities we currently expect within the anticipated time frame or at all.

Our ability to realize the anticipated benefits of our recent acquisition depends in part on successfully consolidating functions and integrating operations, procedures, systems, and personnel of our businesses in a timely and efficient manner, as well as on the ability to realize the anticipated growth, cross-selling opportunities and potential synergies from integrating operations. There is no assurance that improved operating results will be achieved as a result of growth or acquisition or that our businesses will be successfully integrated in a timely manner.

## **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 adoption by the Company for the accounting period beginning on October 1, 2019, or later periods. None of these are expected to have a significant effect on the consolidated financial statements, except for the following standard that has been issued but is not yet effective:

#### *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, and the Company intends to adopt in its consolidated financial statements for the annual period beginning October 1, 2019. The Company will recognize assets and liabilities for all leases, except for its low value leases, on the consolidated balance sheet upon adoptions.

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.