

# **Covalon Technologies Ltd.**

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

**September 30, 2021**

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

### **For the year ended September 30, 2021**

#### **December 10, 2021**

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, 2021. 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 years ended September 30, 2021, and 2020 is based on the audited consolidated financial statements of the Company, which were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") and are presented in Canadian dollars unless otherwise specified. In accordance with its terms of reference, the Audit Committee of the Company's Board of Directors reviews the contents of the MD&A and recommends its approval to the Board of Directors. The Board of Directors approved this MD&A on December 10, 2021. Disclosure contained in this document is current to that date, unless otherwise noted.

#### **AquaGuard Sale**

The financial information related to the AquaGuard product line is reported in the current period as discontinued operations. Certain prior period financial information on the consolidated statements of operations and comprehensive income (loss), and consolidated statement of cash flows have been updated to present the AquaGuard product line as discontinued operations and has therefore been excluded from continuing operations for all periods presented in this MD&A. This MD&A reflects only the results of continuing operations, unless otherwise noted.

On July 29, 2021, the Company sold the AquaGuard product line to TIDI Products, LLC ("TIDI"), an arm's length party, for \$37,837,852 including post-closing adjustments related to actual amounts of inventory and indebtedness ("AquaGuard Sale"). Under the terms of the purchase agreement, the Company sold all its interest in Covalon Technologies Holdings (USA), Ltd. and Covalon Technologies AG Ltd. ("Former Subsidiaries") to TIDI. The transaction included the sale of moisture barrier products sold under the AquaGuard brand, certain trademarks and intellectual property, related customer contracts, and the manufacturing assets to support the AquaGuard business. Immediately prior to closing, the Company spun-off all its assets in the Former Subsidiaries other than its AquaGuard product line business to an existing subsidiary, which will carry on the Company's ongoing business in the United States and includes the United States sales team. The initial purchase price of \$37,837,852 million includes \$2,548,200 placed in escrow for indemnity claims (which escrow amount will be released 50% on July 29, 2022 and the remaining 50% on September 30, 2022, assuming no claims). The Company used proceeds of \$8,660,529 from the AquaGuard Sale to fully satisfy its indebtedness to its senior lender, HSBC Bank Canada

(“HSBC”), and the Company’s acquisition line credit facility (the “Facility”) with HSBC has now been terminated.

The Company also extinguished US\$7,552,300 (\$9,490,221 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) of secured indebtedness owed to Cenorin, LLC (“Cenorin”) under a promissory note dated as of October 1, 2018, as amended, (the “Acquisition Note”) by making a cash payment of US\$4,000,000 (\$5,026,400 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) to Cenorin and issuing to Cenorin 200,000 warrants for the purchase of common shares in the capital of the Company (the “Warrants”). Each Warrant entitles the holder to acquire a common share of the Company at a price of \$4.00 for a period of five years from the date of issuance. The issuance of the Warrants was approved by the TSX Venture Exchange.

Following the AquaGuard Sale, the Company continues to sell its other products into the United States through distributors and also directly to healthcare facilities.

### **Impact of COVID-19**

In March 2020, the World Health Organization characterized the outbreak of the novel strain of coronavirus, specifically identified as COVID-19, as a global pandemic. In response to the outbreak, governmental authorities in Canada and internationally have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, non-essential business closures, quarantines, self-isolations, shelters-in-place, and social distancing. The governmental responses have caused material disruption to business globally, economic slowdowns, and shifts in economic markets. The ongoing uncertainty related to COVID-19, and the related governmental responses, has and may continue to negatively impact the Company, its suppliers, as well as customers and their demand for our products and services.

During the year ended September 30, 2021, the Company was approved for, and recorded, funding of \$535,275 (2020 - \$520,500) under the Canadian Emergency Wage Subsidy Program (“CEWS”). During the period, the Company also applied for, and received, US\$1,103,860 or CAD\$1,384,581 converted (2020 – US\$1,103,861 or CAD\$1,523,829 converted) in a second draw of the United States Paycheck Protection Program loan (“US PPP Loan”) from the US Small Business Administration (“SBA”) under the US Paycheck Protection Program. The Company also received funds from other subsidy programs in the amount of \$65,631 (2020 - \$102,845). The Company recognizes government grants and subsidies when there is reasonable assurance that it will comply with the conditions required to qualify for the grant, and that the grant will be received. These amounts are recorded as an offset to the corresponding operating expense account.

During the year, the Company’s first draw of the US PPP Loan (US\$1,103,861, CAD\$1,384,581) and second draw of the US PPP Loan (US\$1,103,860, CAD\$1,523,829), and all related interest, was forgiven by the SBA and no repayments were required.

Operationally, the Company has been negatively impacted by the COVID-19 pandemic, and the efforts to mitigate the pandemic, as have many of the Company’s employees, customers, and vendors regardless of geographic location. The Company’s direct sales staff have been limited in their ability to call on customers in the United States and the United Kingdom. There have also been increased costs associated with shipping products, and a slow-down in receiving regulatory approvals. As a result of this uncertainty there is a higher

level of estimation uncertainty as it relates to the assessment of impairment for intangibles, provisions for inventory and receivables, and general future cash flows. Our distribution relationships with several companies in North America and internationally have been impacted due to the material disruption to business globally, economic slowdowns, and shifts in economic markets caused by governmental responses to the COVID-19 pandemic. The Company has not experienced material payment delays or defaults from customers as a result of the COVID-19 pandemic and its impact on their respective businesses. Future events related to COVID-19, including, for example, government responses to future COVID-19 variants, may impact both the Company's ability to collect cash and demand for some of the Company's products. While the ongoing negative impacts of the pandemic are uncertain, the Company has taken strides to reduce operating and discretionary expenses to help mitigate these risks. For the year ended September 30, 2021, operating expenses were reduced by \$3,176,638 compared to the year ended September 30, 2020. The prior year comparative period included a non-recurring provision for doubtful accounts of \$1,420,002 related to the change of distribution partners in the Middle East. Overall, operating expense reductions included the reduction of headcount, travel, and tradeshow activities. The Company will also continue to assess subsidies and programs that are ongoing or made available in the future.

### **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 of Directors approves the consolidated financial statements and the MD&A.

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

This MD&A refers to certain non-IFRS measures. These measures are not recognized or defined measures under IFRS, do not have standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional financial information to complement those IFRS measures by providing further understanding of our results of operations from management's perspective. Accordingly, these measures should not be considered in isolation or as a substitute for analysis of our financial information reported under IFRS. The non-IFRS financial measures, adjustments, and reasons for adjustments should be carefully evaluated as these measures have limitations as analytical tools and should not be used in substitution for an analysis of the Company's results under IFRS. We use non-IFRS measures including "Working Capital", "Adjusted Gross Margin" and "Adjusted EBITDA" to provide investors with supplemental measures of our operating performance and thus highlight trends in our core business that may not otherwise be apparent when relying

solely on IFRS measures. We believe that investors, securities analysts, and other interested parties frequently use non-IFRS measures in the evaluation of issuers. Management also uses non-IFRS measures in order to facilitate operating performance comparisons from period to period, to prepare annual operating budgets and forecasts and to determine components of management compensation. For definitions and reconciliations of these non-IFRS measures to the relevant reported measures, please see “Definitions and Reconciliations of Non-IFRS Financial Measures” on page 21 of this MD&A.

### **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. More specifically, this MD&A contains forward-looking statements which include, but are not limited to statements regarding: the Company’s corporate strategy and strategic objectives; the availability of external financing to fund the Company’s ongoing liabilities and commitments; the direct and indirect impact of the COVID-19 pandemic on the Company’s business and operations, including supply chain, manufacturing, research and development costs, contracted service providers and employees, and general business and economic events. These forward-looking statements involve risk and uncertainties, including the impact of the COVID-19 pandemic on the Company, the ability of the Company to maintain operations in the U.S., estimates related to future operating expenses, the volatility of the Company’s stock price, 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 infection management, advanced wound care, and surgical procedures. Our head office and laboratories are located in Mississauga, Ontario, Canada. The Company’s common shares are listed for trading on the TSX Venture Exchange (the “TSX-V”) under the ticker symbol “COV”.

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 other international countries.

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

Covalon currently has three proprietary platform technologies that have the potential to be developed into dozens of medical devices and products: (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:** Covalon has several medical coating platforms, that are branded as CovaCoat, CovaCoat with API, Centaur, CovaGuard and SD-168. Covalon's patented coating technology underlying CovaCoat, CovaCoat with API and Centaur are based on 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. Covalon's patent pending antimicrobial sanitizing technology platform (the CovaGuard™ Platform) incorporates Benzalkonium Chloride (BAC) into a unique lipid delivery system that can be applied to a variety of surfaces (porous and non-porous), and skin, to provide immediate and sustained kill of viruses and bacteria. Covalon's SD-168 is a persistent surface coating that is capable of remaining active for up to 30 days on a non-porous surface.

## **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
VALGuard	Helps protect line-to-line connections, luer locks & access ports from environmental contamination.

### **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. 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 (as described below) 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. As restrictions related to COVID-19 have been put in place on hospitals, and those who are able to enter hospitals, our sales force has had to adapt and modify their approach. This has resulted in limited access for our sales force to service these customers.

The Company has set up distribution relationships with a number of companies in North America, the Middle East, Latin America, Asia, and Europe. The governmental responses to the COVID-19 pandemic have caused material disruption to business globally, economic slowdowns, and shifts in economic markets. The significant uncertainty related to the virus, and the governmental responses, have negatively impacted the Company's suppliers, as well as our customers and their demand for our products and services. A significant number of the Company's products are consumed during elective and other procedures at hospitals, clinics and other medical institutions that were materially impacted by the quarantine measures undertaken at these facilities. As a result, the usage and therefore the demand for the Company's products has been temporarily materially negatively impacted by the global pandemic.

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 year ended September 30, 2021**

- On October 21, 2020, the Company announced that the Board of Directors had initiated a process to explore and evaluate a range of strategic alternatives available to the Company in order to enhance shareholder value. An independent special committee of the Board of Directors (the "Special Committee") was formed to oversee the strategic process.

- On November 13, 2020, the Company announced the appointment of Amir Bolor as Chair of the Company's Board of Directors. Mr. Bolor is an independent director of the Company, and also Chair of the Special Committee.
- On January 6, 2021, the Company obtained a waiver from HSBC for covenant breaches related to the quarter ended September 30, 2020, under the Company's Facility.
- On February 19, 2021, the Company obtained a waiver from HSBC for covenant breaches related to the quarter ended December 31, 2020, under the Company's Facility.
- On March 5, 2021, the Company drew \$1 million against its facility available through the Business Credit Availability Program ("BCAP") with the Business Development Bank of Canada ("BDC") facilitated through HSBC.
- On March 25, 2021, the Company and Cenorin entered into a call option agreement that allowed the Company to settle, at its option, on or before October 1, 2021, the US\$7.5 million Acquisition Note for a payment of US\$4 million and subject to the approval of the TSX-V, issuance of 200,000 Warrants with an exercise price of CAD\$4.00. The exercise of the call option by the Company under the call option agreement was conditional on approval from HSBC.
- As a conclusion of the strategic review, on July 29, 2021, the Company announced the sale of its AquaGuard product line to TIDI, an arm's length party for US\$30M subject to adjustments for estimated cash, inventory, and working capital amounts.
- On July 29, 2021, the Company used proceeds of the AquaGuard Sale to repay \$8,660,529 of indebtedness under the Facility (including the BCAP amount) and the Facility was terminated.
- On July 29, 2021, the Company also used proceeds of the AquaGuard Sale to extinguish US\$7,552,300 (\$9,490,221 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) of secured indebtedness owed to Cenorin under the Acquisition Note by making a cash payment of approximately US\$4,000,000 (\$5,026,400 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) and issuing 200,000 Warrants to Cenorin.
- On September 24, 2021, the Company announced that Dr. Myrna Francis had retired as a member of the Board of Directors of the Company.

### **Financial Highlights for the Three Months Ended September 30, 2021**

- Total revenue for the three months ended September 30, 2021, increased 125% to \$6,610,580, compared to \$2,940,485 for the same period of the prior year driven by an increase in product sales.
- Product revenue for the three-month period ended September 30, 2021, increased 144% to \$6,027,755, compared to \$2,475,005 for the same period of the prior year. Product revenue increased in the United States by 105% or \$2,063,592, and in the Middle East by 532% or \$1,316,943. The Company had manufacturing delays in the prior year at a third-party location that negatively impacted the revenue and these issues were subsequently resolved.
- Development and consulting services revenue for the three-month period ended September 30, 2021, increased by 23% to \$522,383, compared to \$424,318 for the same period of the prior year. During the quarter, the Company engaged in 14 customer development projects of various sizes with approximately 6 medical product companies that included the various projects underway

associated with the previously announced major contract with one of the world's largest medical device companies that licensed Covalon's proprietary medical coating technologies. Revenue from development and consulting services varies based on opportunities and the length of the sales cycle for given projects.

- Licensing and royalty fees for the three months ended September 30, 2021, were \$60,442, compared to \$41,162 for the three months ended September 30, 2020. The timing of this revenue will vary depending on length and timing of projects and discussions with customers.
- Gross margin for the three-month period ended September 30, 2021, increased to 46% compared to 6% 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. Both periods include inventory allowance provisions (2021 - \$231,618; 2020 - \$1,353,653), and rework costs associated with selling product. These additional expenses are discussed in Adjusted Gross Margin.
- Operating expenses for the three months ended September 30, 2021, decreased 20% or \$467,008 to \$1,921,949, compared to \$2,388,957 for the prior year's comparative period. The Company recorded \$8,668 (2020- \$418,872) of government subsidies which were netted out against the related expenses. These amounts are excluded in the calculation of Adjusted EBITDA (see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" for definition of Non-IFRS measures) below.
- Net income from continuing operations for the three months ended September 30, 2021, was \$1,025,244 or \$0.04 per share, compared to a net loss of \$2,312,302 or \$0.09 per share for the three months ended September 30, 2020.
- Net income from discontinued operations for the three months ended September 30, 2021, was \$21,344,351 or \$0.83 per share, compared to a net income of \$129,265 or \$0.01 per share for the three months ended September 30, 2020.
- Net income for the three months ended September 30, 2021, was \$22,369,595 or \$0.87 per share, compared to a net loss of \$2,183,037 or \$0.08 per share for the three months ended September 30, 2020.
- Adjusted Gross Margin for the three-month period ended September 30, 2021, decreased to 51% compared to 55% for the same period of the prior year. The year over year change was consistent with the factors noted above. For further information about Adjusted Gross Margin, see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" below.
- Adjusted EBITDA from ongoing operations for the three months ended September 30, 2021, was a profit of \$1,775,323, compared to an Adjusted EBITDA loss of \$986,481 for the three months ended September 30, 2020. For further information about Adjusted EBITDA, see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" below.

### **Financial Highlights for the year ended September 30, 2021**

- Total revenue for the year ended September 30, 2021, increased 45% to \$19,561,301 compared to \$13,508,434 for the same period of the prior year driven by an increase in product sales.

- Product revenue for the year ended September 30, 2021, was \$17,650,865, compared to \$11,329,716 for the same period of the prior year. Product revenue increased in the United States by 61% or \$4,108,210, and in the Middle East by 91% or \$2,130,644. In the prior year the Company appointed a new distribution partner in the Middle East which temporarily reduced orders in the region during the transition periods.
- Development and consulting services revenue for the year ended September 30, 2021, decreased by 15% to \$1,691,380 compared to \$1,979,282 for the same period of the prior year. Revenue from development and consulting services varies based on opportunities and the length of the sales cycle for given projects.
- Licensing and royalty fees for the year ended September 30, 2021, were \$219,056 compared to \$199,436 for the year ended September 30, 2020. The timing of this revenue will vary depending on length and timing of projects and discussions with customers.
- Gross margin for the year ended September 30, 2021, increased to 50% compared to 34% 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. Both periods include inventory allowance provisions, and rework costs associated with selling product. These additional expenses are discussed in Adjusted Gross Margin.
- Operating expenses for the year ended September 30, 2021, decreased 26% or \$3,176,638 to \$8,857,988 compared to \$12,034,626 for the prior year's comparative period. The Company has made strides to reduce operating expenses as it relates to headcount and discretionary spending.
- Net income from continuing operations for the year ended September 30, 2021, was \$418,964 or \$0.02 per share, compared to a net loss of \$7,822,790 or \$0.30 per share for the year ended September 30, 2020.
- Net income from discontinued operations for the year ended September 30, 2021, was \$23,057,942 or \$0.89 per share, compared to a net income of \$870,566 or \$0.03 per share for the year ended September 30, 2020.
- Net income for the year ended September 30, 2021, was \$23,476,906 or \$0.91 per share, compared to a net loss of \$6,952,224 or \$0.27 per share for the year ended September 30, 2020.
- Adjusted Gross Margin for the year ended September 30, 2021 increased to 53% compared to 52% for both the year ended September 30, 2021, and the same period of the prior year. For further information about Adjusted Gross Margin, see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" below.
- Adjusted EBITDA for the year ended September 30, 2021, was \$1,262,313, compared to an Adjusted EBITDA loss of \$3,543,700 for the year ended September 30, 2020. For further information about Adjusted EBITDA, see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" below.

Ongoing business is primarily comprised of distributing bulk shipments, which result in 'lumpy' or uneven revenue recognition quarter-to-quarter, depending on when bulk orders are placed, shipped to distributors, and delivered to hospitals. As is typical with many companies, including many in the healthcare field,

Covalon's lumpy revenue model makes it difficult to accurately estimate revenue recognition in any given quarter or quarter-to-quarter.

### **Selected Annual Information**

The following table sets forth selected consolidated financial information for the years ended September 30, 2021, 2020, and 2019. The information has been derived from our audited consolidated financial statements and accompanying notes, in each case prepared in accordance with IFRS. The current year figures include only continuing operations and the comparative periods include both continuing and discontinued operations.

	<b><u>For the year ended September 30,</u></b>		
	<b><u>2021</u></b>	<b><u>2020</u></b>	<b><u>2019</u></b>
Total revenue	19,561,301	25,800,106	34,004,622
Net income (loss)	418,964	(6,952,224)	(9,137,773)
Net income per share	0.02	(0.27)	(0.41)
Net income per share (diluted)	0.02	(0.27)	(0.41)
Total assets	40,582,104	34,696,974	39,606,933
Total non-current liabilities	2,211,943	2,953,469	6,733,108
Cash Dividends declared	Nil	Nil	Nil

During the year ended September 30, 2021 the Company completed the AquaGuard Sale, as discussed above. The 2021 figures include only results from continuing operations. The fiscal 2020 and 2019 results are as reported in the respective annual financial statements and include AquaGuard related revenue and expenses that would have been classified as discontinued operations in the current fiscal year.

	Three months ended September 30,		Year ended September 30,	
	2021	2020	2021	2020
<b>Revenue</b>				
Product	\$6,027,755	2,475,005	\$17,650,865	11,329,716
Development and consulting services	522,383	424,318	1,691,380	1,979,282
Licensing and royalty fees	60,442	41,162	219,056	199,436
<b>Total revenue</b>	<b>6,610,580</b>	2,940,485	<b>19,561,301</b>	13,508,434
<b>Cost of sales</b>	<b>3,545,483</b>	2,754,604	<b>9,864,970</b>	8,861,011
<b>Gross profit before operating expenses</b>	<b>3,065,097</b>	185,881	<b>9,696,331</b>	4,647,423
<b>Operating expenses</b>				
Operations	340,887	140,471	995,158	1,040,499
Research and development activities	299,625	140,457	1,140,517	794,241
Sales, marketing and agency fees	305,293	649,458	1,927,181	2,916,571
General and administrative	976,144	1,458,571	4,795,132	7,283,315
	<b>1,921,949</b>	2,388,957	<b>8,857,988</b>	12,034,626
<b>Finance expenses</b>	<b>117,904</b>	109,226	<b>419,379</b>	435,587
<b>Net income (loss) from continuing operations</b>	<b>1,025,244</b>	(2,312,302)	<b>418,964</b>	(7,822,790)
<b>Net income from discontinued operations</b>	<b>21,344,351</b>	129,265	<b>23,057,942</b>	870,566
<b>Net income (loss)</b>	<b>\$22,369,595</b>	\$(2,183,037)	<b>\$23,476,906</b>	\$(6,952,224)
<b>Income (loss) per common share of continuing operations</b>				
Basic earnings (loss) per share	<b>\$0.04</b>	\$(0.09)	<b>\$0.02</b>	\$(0.30)
Diluted earnings (loss) per share	<b>\$0.04</b>	\$(0.09)	<b>\$0.02</b>	\$(0.30)
<b>Income per common share of discontinued operations</b>				
Basic earnings per share	<b>\$0.83</b>	\$0.01	<b>\$0.89</b>	\$0.03
Diluted earnings per share	<b>\$0.83</b>	\$0.00	<b>\$0.89</b>	\$0.03
<b>Income (loss) per common share</b>				
Basic earnings (loss) per share	<b>\$0.87</b>	\$(0.08)	<b>\$0.91</b>	\$(0.27)
Diluted earnings (loss) per share	<b>\$0.86</b>	\$(0.08)	<b>\$0.91</b>	\$(0.27)

### Revenue and Gross Profit

Total revenue increased \$6,052,867 or 45% to \$19,561,301 for the year ended September 30, 2021, compared to \$13,508,434 in the prior year. Product revenue was \$17,650,865 for the year ended September 30, 2021, compared to \$11,329,716 in the prior year. Product revenue increased in the United States by 61% or \$4,108,210 and in the Middle East by 91% or \$2,130,644.

Development and consulting services revenue for the year ended September 30, 2021, was \$1,691,380 which represents revenue earned from the Company's work on development and consulting projects; a decrease from prior year's services revenue of \$1,979,282. During the quarter ended September 30, 2021, we engaged in 14 customer development projects of various sizes with approximately 6 medical product companies that included the various projects underway associated with the previously announced major contract with one of the world's largest medical device companies that licensed Covalon's proprietary medical coating technologies. Licensing revenue was \$219,056 for the year ended September 30, 2021, compared to \$199,436 for the year ended September 30, 2020.

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.

Gross margin was 50% for the year ended September 30, 2021, compared to 34% for the prior year. Adjusted Gross Margin was 53% for the year ended September 30, 2021, compared to 52% for the prior year. 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. Gross margin fluctuates as a result of the mix of products sold in any given quarter, or year, by product type and geography.

**Operating Expenses**

	Three months ended		Year ended	
	September 31,		September 31,	
	2021	2020	2021	2020
<b>Operations</b>				
Wages, benefits and consulting fees	\$293,833	\$182,504	\$1,131,846	\$1,104,879
Depreciation and amortization	737	843	2,748	3,408
Government subsidies	-	(47,363)	(173,844)	(198,598)
Other	46,317	4,487	34,408	130,810
	<b>340,887</b>	140,471	<b>995,158</b>	1,040,499
<b>Research and development activities</b>				
Wages, benefits and consulting fees	242,844	197,338	1,113,437	839,624
Depreciation and amortization	7,528	9,523	29,848	36,363
Government subsidies	-	(27,902)	(132,341)	(108,129)
Other	49,253	(38,502)	129,573	26,383
	<b>299,625</b>	140,457	<b>1,140,517</b>	794,241
<b>Sales, and marketing activities</b>				
Wages, benefits and consulting fees	203,270	651,311	1,226,697	2,478,703
Travel	-	4,446	283,850	145,609
Government subsidies	-	(278,963)	(314,992)	(601,369)
Other	102,023	272,664	731,626	893,628
	<b>305,293</b>	649,458	<b>1,927,181</b>	2,916,571
<b>General and administrative</b>				
Wages, benefits and consulting fees	666,677	509,315	2,040,090	2,292,503
Directors' compensation	53,013	55,633	228,771	218,043
Professional and related costs	88,325	510,776	1,296,181	1,663,553
Facility	135,646	105,062	542,833	564,625
Depreciation and amortization	153,217	184,195	385,027	457,870
Accounts receivable write-off	-	-	-	1,420,002
Government subsidies	(8,668)	(64,644)	(180,644)	(224,383)
Other	(112,066)	158,234	482,874	891,102
	<b>976,144</b>	1,458,571	<b>4,795,132</b>	7,283,315
<b>Total operating expenses</b>	<b>\$1,921,949</b>	\$2,388,957	<b>\$8,857,988</b>	\$12,034,626

The Operations department contains expenses related to Quality Control, Quality Assurance, Production, and Regulatory activities.

Operating expenses for the three months ended September 30, 2021, decreased \$467,008 to \$1,921,949 compared to \$2,388,957 for the prior year's comparative period. The Company also recorded \$8,668 (2020-\$418,872) of government subsidies which were netted out against the related expenses. There was a decrease in personnel costs of \$133,844 compared to the same period in the prior year.



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 September 30, 2021, had stock option related expenses of \$9,697 related to continuing operations compared to \$91,463 in the prior year. This expense reflects the number of options outstanding and the fair value of the expense over the vesting period for accounting purposes. If an employee leaves the Company before the end of the vesting period, the expenses will be reversed.

Operating expenses for the year ended September 30, 2021, decreased \$3,176,638 to \$8,857,988 compared to \$12,034,626 for the prior year's comparative period. The Company has made strides to reduce operating expenses as it relates to headcount and discretionary spending. The decrease in operating expenses is primarily related to a decrease in wages, benefits, and consulting costs of \$1,203,639 and government subsidies relating to COVID-19 relief that reduced operating expenses by \$801,821 (2020 - \$1,132,479).

Wages, benefits, and consulting fees (for all departments) include a non-cash expense related to stock options that the Company had previously granted. The year ended September 30, 2021, had stock option related expenses of \$163,769 related to continuing operations compared to \$715,428 in the prior year. This expense reflects the number of options outstanding and the fair value of the expense over the vesting period for accounting purposes. If an employee leaves the Company and does not exercise their options, the expenses will be reversed.

### **Related Party Transactions**

The following is a summary of the Company's compensation to key management personnel.

	<b>Year ended September 30,</b>	
	<b>2021</b>	2020
Compensation and short-term employee benefits	<b>\$1,003,055</b>	\$1,173,661
Share based payment expense	<b>90,247</b>	441,990
	<b>1,093,302</b>	1,615,651

During the year end September 30, 2013, a non-interest-bearing loan of \$50,000 was made to a key employee. As of September 30, 2021, \$10,000 of this loan remained outstanding.

### **Critical Accounting Estimates and Judgements**

The preparation of financial statements requires that management make 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 could be material.

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management

makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

#### i) Impairment of Non-Financial Assets

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

### Accounting Standards Adopted

On October 31, 2018, amendments to IAS 1 and IAS 8 to clarify and align the definition of material information and provide guidance to help improve consistency in the application of materiality when used in other IFRS standards. These amendments were effective for years beginning on or after January 1, 2020 and are to be applied prospectively. The Company adopted the amendments on October 1, 2020 and there was no impact on the consolidated financial statements.

### Summary of Quarterly Results and Financial Position

The below table has been adjusted to reflect the income and cash flow items that relate to continuing operations only.

	2021 Fourth Quarter	2021 Third Quarter	2021 Second Quarter	2021 First Quarter	2020 Fourth Quarter	2020 Third Quarter	2020 Second Quarter	2020 First Quarter
Revenue	\$ 6,610,580	\$ 6,034,374	\$ 4,316,648	\$ 2,599,699	\$ 2,940,485	\$ 4,388,601	\$ 1,759,622	\$ 4,419,726
Net income (loss) before amortization and depreciation	1,424,771	783,006	(199,875)	(888,472)	(2,121,951)	(354,368)	(3,968,297)	(621,554)
Net income (loss)	1,025,244	756,047	(303,571)	(1,058,756)	(2,312,302)	(431,084)	(4,088,858)	(990,546)
Net income (loss) per share	0.04	0.03	(0.01)	(0.04)	(0.09)	(0.02)	(0.16)	(0.04)
Cash	22,946,923	3,529,136	3,794,509	2,533,891	3,506,991	4,200,135	3,850,062	4,115,806
Net working capital	32,442,688	(6,313,584)	(7,430,778)	(7,998,634)	(7,787,221)	(5,818,351)	(6,454,096)	(3,101,402)
Current ratio	7.5	0.7	0.7	0.6	0.7	0.8	0.7	0.9

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 milestones in any period.

**Liquidity & Capital Resources**

	<b>September 30, 2021</b>	September 30, 2020
Cash	<b>\$22,946,923</b>	\$3,506,991
Total assets	<b>\$40,582,104</b>	\$34,696,974
Deferred revenue	<b>\$577,097</b>	\$788,272

On September 30, 2021, cash totaled \$22,946,923 compared to \$3,506,991 at September 30, 2020. During the year ended September 30, 2021, the Company had positive total cash flow of \$19,439,932. The positive cash flow for the year ended September 30, 2021 was largely driven by the AquaGuard Sale. The Company had positive \$621,366 from continuing operating activities compared to cash used of \$6,001,264 in the prior year. The Company also has an additional \$2,548,200 held in escrow related to the AquaGuard Sale. Assuming no claims are made, this amount is expected to be released from escrow: 50% on July 29, 2022; and 50% on September 30, 2022.

Accounts receivable at September 30, 2021 increased \$3,062,110 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 \$137,061 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. As at December 10, 2021, cash totaled approximately \$24 million.

Total assets at September 30, 2021 were \$40,582,104 compared to \$34,696,974 at September 30, 2020. Cash comprised 57% of total assets at September 30, 2021. The Company's accounts receivable are liquid, and the balance of the Company's assets are comprised of property, plant and equipment and 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 \$211,175 to \$577,097 at September 30, 2021, compared to \$788,272 at September 30, 2020.

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 lease liabilities and accounts payable and accrued liabilities that are due within a year, as reflected in the following table:

	<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	4,039,607	4,039,607	4,039,607	-	-
Lease liabilities	2,590,873	2,867,653	651,407	2,216,246	-
<b>Total</b>	<b>6,630,480</b>	<b>6,907,260</b>	<b>4,691,014</b>	<b>2,216,246</b>	-

Using the proceeds of AquaGuard Sale, on July 29, 2021 the Company repaid all outstanding debt owed under the Facility with HSBC that was used to fund the Company's October 1, 2018 purchase of the

AquaGuard business. As a result, the Facility was terminated. Proceeds from the AquaGuard Sale were also used to extinguish US\$7,552,300 (\$9,490,221 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) \$9,490,221 of secured indebtedness owed to Cenorin under the Acquisition Note by making a cash payment of approximately US\$4,000,000 (\$5,026,400 based on the USD:CAD Bank of Canada exchange rate on July 29, 2021) \$5,026,400 to Cenorin and issuing to Cenorin 200,000 Warrants to Cenorin. Each Warrant entitles Cenorin to acquire a common share of the Company at a price of \$4.00 for a period of five years.

During the year ended September 30, 2021, the Company drew \$1 million against the BCAP facility through HSBC and subsequently repaid this facility in full.

## Shareholders' Equity

### Common Shares

The Company is authorized to issue an unlimited number of common shares with no par value (the "Common Shares"). As at September 30, 2021, the Company had a total of 25,868,677 Common Shares issued and outstanding.

As of the date of this MD&A, the Company had the following securities outstanding:

<u>Security Type</u>	<u>Number Outstanding</u>
Common Shares	25,868,677
Options	1,138,436
Warrants	2,950,000

## Sources and Uses of Cash

	<u>Year ended September 30,</u>	
	<u>2021</u>	<u>2020</u>
Cash flows used in operating activities	<b>621,366</b>	(6,001,264)
Cash flows used in investing activities	<b>(278,529)</b>	(205,362)
Cash flows from financing activities	<b>(8,252,167)</b>	(1,413,359)
Discontinued Operations	<b>26,617,360</b>	1,471,369

## Operating Activities

Cash generated in operating activities for the year ended September 30, 2021 was \$621,366, compared to \$6,001,264 used for the prior year's comparative period. Non-cash working capital used \$1,081,212 of cash during the year ended September 30, 2021, compared to \$75,092 used in the prior year. At September 30, 2021, accounts receivable increased by \$3,062,110 over September 30, 2020, 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 related to filing and maintaining patents and trademarks.

### **Financing Activities**

During the year ended September 30, 2021, the Company drew \$1 million against the BCAP facility with BDC and facilitated by HSBC.

During the year ended September 30, 2021, the Company paid off all outstanding debt, including the BCAP facility, and terminated the Facility with HSBC.

On July 29, 2021, the Company sold its AquaGuard product line and all its interest in two subsidiaries. As part of the transaction the Company repaid all outstanding debt to HSBC, and the Acquisition Note. See AquaGuard Sale above.

### **Financial Instruments**

The Company is subject to interest rate risk on its cash. The Company believes that interest rate risk is low as the Facility with HSBC was terminated during the year ended September 30, 2021 and there are no material interest bearing instruments remaining.

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.

### **Definitions and Reconciliations of Non-IFRS Financial Measures**

In this MD&A, we refer to terms that are not specifically defined under IFRS and have no standardized meanings. Accordingly, these measures may not be comparable to similar measures presented by other companies. These measures are used to provide additional financial information to complement the IFRS measures. The non-IFRS financial measures, adjustments, and reasons for adjustments should be carefully evaluated as these measures have limitations as analytical tools and should not be used in substitution for an analysis of the Company's results under IFRS. Adjusting items that are the same, or similar to, the adjusting items below may recur in the future and may not be included in similar non-IFRS measures used by other companies thereby diminishing their utility.

#### **i) Working Capital**

The Company's working capital is a non-IFRS metric and is calculated as: Current Assets less Current Liabilities as of the reporting date.

#### **ii) Adjusted Gross Margin**

The Company's Adjusted Gross Margin is a non-IFRS metric used by management to evaluate financial margins on revenue in a given period. We define Adjusted Gross Margin as gross profit before operating expenses, plus depreciation and amortization included in cost of sales, plus inventory provision amounts.

The table below provides a reconciliation of gross profit before operating expenses under IFRS in the consolidated financial statements to Adjusted Gross Margin for the three months and year ended September 30, 2021. Management believes that Adjusted Gross Margin is useful in assessing the performance of the Company's ongoing operations and its ability to generate cash flows from period to period. The adjusting items below are considered to be outside of the Company's core operating

results, and these items can distort the trends associated with the Company's ongoing performance, even though some of those expenses may recur.

	Three months ended September 30,		Year ended September 30,	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Gross profit before operating expenses	<b>3,065,097</b>	185,881	<b>9,696,331</b>	4,647,423
Add: Depreciation and amortization	<b>49,470</b>	82,081	<b>282,843</b>	258,979
Add: Inventory provisions	<b>231,618</b>	1,353,653	<b>361,556</b>	2,083,932
Adjusted Gross Margin	<b>3,346,185</b>	1,621,615	<b>10,340,730</b>	6,990,334
Adjusted Gross Margin (%)	<b>51%</b>	55%	<b>53%</b>	52%

### iii) Adjusted EBITDA

The Company's Adjusted EBITDA is a non-IFRS metric used by management to evaluate the Company's earnings or loss. We define Adjusted EBITDA as net loss, plus interest expense, plus depreciation and amortization, plus stock-based compensation, less government subsidies, plus inventory provisions, plus transaction costs, plus accounts receivable write-off expenses.

The table below provides a reconciliation of net loss under IFRS in the consolidated financial statements to Adjusted EBITDA for the three months and year ended September 30, 2021. Management believes that these non-IFRS measures are useful in assessing the performance of the Company's ongoing operations and its ability to generate cash flows to fund its cash requirements from period to period. The adjusting items below are considered to be outside of the Company's core operating results, and these items can distort the trends associated with the Company's ongoing performance, even though some of those expenses may recur.

	Three months ended September 30,		Year ended September 30,	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net income (loss)	<b>1,025,244</b>	(2,312,302)	<b>418,964</b>	(7,822,790)
Add: Interest expense	<b>117,904</b>	109,226	<b>419,379</b>	435,587
Add: Depreciation and amortization	<b>399,527</b>	190,351	<b>700,466</b>	756,620
Add: Share based compensation	<b>9,698</b>	91,463	<b>163,769</b>	715,428
Less: Government subsidies	<b>(8,668)</b>	(418,872)	<b>(801,821)</b>	(1,132,479)
Add: Inventory provisions	<b>231,618</b>	1,353,653	<b>361,556</b>	2,083,932
Add: Accounts receivable write-off	-	-	-	1,420,002
Adjusted EBITDA	<b>1,775,323</b>	(986,481)	<b>1,262,313</b>	(3,543,700)

### 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 faces risks related to the COVID-19 pandemic and related government responses.***

The Company's business and its financial condition may be adversely impacted by the effects of COVID-19 and other infectious diseases. The extent to which COVID-19 and other infectious diseases have and may continue to impact the Company's business, operations, financial condition and the market for its securities will depend on future developments and government responses, which remain highly uncertain and cannot be predicted. These include the duration, severity and scope of the outbreak and the actions taken by governmental entities to address and mitigate the pandemic.

Operationally, the Company has been and continues to be negatively impacted by the COVID-19 pandemic, and the efforts to mitigate the pandemic, as have many of the Company's employees, customers, and vendors regardless of geographic location. The Company's direct sale staff have been limited in their ability to call on customers in the United States and the United Kingdom. There have also been increased costs associated with shipping products, and a slow-down in receiving regulatory approvals. Our distribution relationships with a number of companies in North America and internationally have been impacted due to the material disruption to business globally, economic slowdowns, and shifts in economic markets caused by governmental responses to the COVID-19 pandemic. This has also negatively impacted the Company's suppliers.

The Company has seen volatility in demand for both products and services due to a significant number of the Company's products being consumed during elective and other procedures at hospitals, clinics and other medical institutions that were materially impacted by measures undertaken at these facilities to mitigate the impact of COVID-19. In many facilities, these measures remain in place and it is unclear how long these measures will be effect and will continue to impact the demand for our products and services at this time.

Other areas that may, or will continue to, impact our business include, without limitation, workforce productivity and health, disruptions to supply chains, limitations on travel, and the inability of our sales force, and distribution partners, to access hospitals, health care institutions, or facilities which may have a material negative impact on our ability to sell and market products.

Additionally, the COVID-19 pandemic has resulted in a widespread health crisis and social unrest that has adversely affect the economies and financial markets of many regions and countries. There can be no assurance that any continued disruption in financial markets, regional economies and the world economy would not negatively affect the Company's access to capital or its financial performance.

While the effects of COVID-19 are expected to be temporary, the duration of any current or future potential business disruptions and related financial impact cannot be reasonably estimated at this time. The extent to which COVID-19 will continue to impact the Company will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and actions or government mandated directives to contain COVID-19 or treat its impact, among others.

***Following the AquaGuard Sale, there can be no assurance as to how expansive Covalon's U.S. operations will be or whether Covalon will continue its operations in the U.S.***

Immediately prior to the closing of the AquaGuard Sale, the Company spun-off all of its assets in the Former Subsidiaries other than its AquaGuard product line of business to an existing subsidiary which will carry on the Company's ongoing business in the United States. Given the AquaGuard Sale, the Company's U.S. operations have been reduced and there can be no assurance as to how expansive these operations may continue to be or whether the Company will continue to operate in the United States.

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

The market price of our common stock may 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 above or 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 income from continuing operations for the year ended September 30, 2021, of \$418,964 and a net loss of \$6,973,650 for the year ended September 30, 2020. 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.

***Control of our principal shareholders may impact Covalon's business and other matters.***

Abe Schwartz, beneficially owns, controls, or directs an aggregate of 8,160,912 Common Shares (approx. 32% of the presently issued and outstanding Common Shares). The Goldfarb Corporation and its affiliates collectively beneficially own, control, or direct 4,111,563 Common Shares (approx. 16% of the presently issued and outstanding Common Shares). The principal shareholders own a sufficient number of Common Shares that they can effectively control substantially all of the actions taken by shareholders of the Company, including the election of directors and declaration of dividends. Such concentration of ownership could have the effect of delaying, deterring or preventing a change of control of the Company that might otherwise be beneficial to its shareholders and may discourage acquisition bids for the Company or limit the amount certain investors may be willing to pay for the Common Shares.

***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 fail 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'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 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.

***There can be no assurance that the US\$2 million of proceeds from the AquaGuard Sale that are currently in escrow will revert back to the Company.***

As part of the AquaGuard Sale, the Company received a purchase price of \$37,837,852 including \$2,513,200 placed in escrow for indemnity claims which escrow amount will be released 50% in 12 months following closing and the remaining 50% on September 30, 2022, assuming no claims. While the Company anticipates that it will receive the escrowed funds as scheduled, there can be no assurance that an indemnity claim will not arise during the escrow period and further that such funds will revert back to the Company.

***Covalon competes in a highly competitive industry against large multinational 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 license, 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 does not continue 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.***

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 any 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.

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

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 may 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 strategies, 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. 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.

***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.

***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. These strategies may be subject to the availability of funds to the Company through operating cash flows, debt facilities, or equity raises. 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.

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

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

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

*There are risks associated with 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.

## **International Financial Reporting Standards**

### **Standards, Amendments and Interpretations Not Yet Effective**

#### IAS 1 – Presentation of Financial Statements

On January 23, 2020, the IASB issued an amendment to IAS 1 to clarify that liabilities are classified as either current or non-current, depending on the rights that exist at the end of the reporting period. The standard is effective for periods beginning on or after January 1, 2023, and the Company continues to evaluate the impact of applying the new standard.