

Covalon Technologies Ltd.

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

September 30, 2023

MANAGEMENT'S DISCUSSION & ANALYSIS

For the year ended September 30, 2023

January 26, 2024

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, 2023. Additional information on Covalon Technologies Ltd., can be obtained on SEDAR PLUS at www.sedarplus.ca, as well as the Company's website at www.covalon.com. Unless otherwise indicated, all references to the terms "we", "us", "our", "Covalon" and "Company" refer to Covalon Technologies Ltd. and its subsidiaries.

In this management's discussion and analysis document ("MD&A"), financial information for the years ended September 30, 2023, and 2022 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 January 25, 2024. 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 prior period as discontinued operations. Certain prior period financial information on the consolidated statements of operations and comprehensive income (loss), and consolidated statements of cash flows pertain to the AquaGuard product line and are presented as discontinued operations and have 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.

Management's Responsibility for Financial Reporting

The consolidated financial statements and MD&A have been prepared by management of the Company, 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”.

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 and the availability of external financing to fund the Company’s ongoing liabilities and commitments. These forward-looking statements involve risks and uncertainties, including 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 patient-driven medical device company, built on the relentless pursuit to help the most vulnerable patients have a better chance at healing. Through a strong portfolio of patented technologies and solutions, we offer innovative, gentle, and more compassionate solutions in the areas of advanced wound care, and vascular access infection prevention. Our solutions are designed for patients and made for care providers. Our head office, manufacturing facility, 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" and trades on the OTCQX Market under the symbol "CVALF".

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.

Covalon-branded products are sold directly and 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, Asia, Latin America, and a number of other international countries.

Over the past year the Company has transformed its strategy to focus on growing its United States and international infection prevention and wound care business by building technology and brand awareness with clinicians and customers. This is being accomplished through the Company's portfolio of consumable medical device dressings that are sold to hospitals, long-term care facilities, clinics, and home healthcare providers directly by the Company's sales team and through distribution partners.

Covalon currently has two proprietary platform technologies that have the potential to be developed into a number of medical devices and products: (i) Collagen matrix; and (ii) Antimicrobial silicone adhesive. 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.

Antimicrobial Silicone Adhesive Platform: Covalon's patented antimicrobial silicone adhesive platform is the basis for a family of pre-surgical, post-surgical and vascular access product solutions 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.

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

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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.

In 2018, the Company entered into a multi-year license agreement with a large medical device company providing rights to the customer to exploit Covalon’s technology on a portfolio of medical devices. Contributing to the Company’s decision to shift away from the medical coating business is the fact this customer has been unable to meet its internal deadlines over the past several years, which has resulted in unpredictable revenues, unpredictable staffing requirements, and significant increased costs for staff and facilities for Covalon, that has prevented Covalon from scaling its services business. As a result of the negative impacts on Covalon, the Company spent a considerable amount of effort over the past year to renegotiate with the customer so as to be fairly reimbursed by the customer. In response, the Company was notified that this customer has determined to not proceed with its medical coating projects under this license agreement for now and accordingly, Covalon does not anticipate continuing to derive services revenue under the license agreement and, had the decision not been made to transition away from the medical coating business, the Company expects it would have still experienced a material decrease in revenue from medical coatings for the coming periods.

As of the date of this MD&A, it is anticipated that development and consulting services revenues derived from patents and trademarks relating to the medical coating platforms described above will materially decline from current levels (Q4 2023: \$319,307, Q4 2022: \$498,017, and YTD 2023: \$2,451,288, YTD 2022: \$1,484,441) and it is anticipated there will be no material revenues associated with medical coatings beyond October 1, 2023.

Our Products

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

Advanced Wound Care Dressings	
ColActive Plus	Collagen matrix dressing
ColActive Plus Ag	Collagen matrix dressing with silver
ColActive Transfer	Wound contact layer
CovaWound Silicone	Self-adherent soft silicone foam dressing
CovaWound Silicone with Border	Self-adherent soft silicone foam dressing with border
CovaWound Silicone Sacrum	Self-adherent soft silicone foam dressing with border for use on the sacrum

CovaWound Silicone Heel	Self-adherent soft silicone foam dressing with border for use on the heel
CovaWound Foam	Non-adherent foam dressing
CovaWound Foam with Border	Non-adherent foam dressing with adhesive border
CovaWound Alginate	Alginate dressing
CovaWound Alginate Ag	Alginate dressing with silver
CovaWound Super Absorbent	Soft hydrophilic wound contact layer with super absorbent polymer core
CovaWound Hydrocolloid	Absorbent hydrocolloid matrix dressing
CovaView Transparent IV Dressing	Transparent IV vascular access dressing
Surgical and Peri-Operative Products	
SurgiClear	Antimicrobial clear silicone adhesive post-surgical dressing with chlorhexidine and silver
MediClear Pre-Op	Antimicrobial silicone film for pre-operative skin
MediClear Post-Op Absorb	Self-adherent silicone dressing with absorbent pad
MediClear Scar	Self-adherent silicone dressing for scar care

Infection Management Products	
IV Clear	Antimicrobial clear silicone adhesive vascular access dressing with chlorhexidine and silver
CovaClear IV	Clear silicone adhesive vascular access dressing
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, 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 small direct sales force in the United States that sells directly into acute care hospitals and associated institutions. Following the divestiture of the AquaGuard product line, we significantly reduced our sales force in the United States to align with our continuing operations revenue base and to rebuild our direct sales team to leverage digital, virtual, and remote customer engagement in addition to traditional in-person sales engagement. The Company has set up distribution relationships with a number of companies in North America, the Middle East, Latin America, and Asia.

In addition to our direct sales efforts into hospitals and our United States and international distributor networks, Covalon also utilizes 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.

Operational Highlights for the Year Ended September 30, 2023

- On March 9, 2023, the Company announced that Martin Goldfarb was elected as a Director on the Covalon Board.
- On March 9, 2023, the Company announced that the shareholders approved an Omnibus Long-Term Incentive Plan (the "Plan"). The Plan supersedes and replaces a prior stock option plan which was in place previously.
- On September 26, 2023, the Company announced that its Board of Directors has appointed Amir Bolor, Char of the Company's Board, as Interim Chief Executive Officer ("CEO"), effective immediately following the departure of Brian Pedlar. The Board then commenced a search for a permanent CEO.

Operational Highlights Subsequent to the Year Ended September 30, 2023

- On January 4, 2024, the Company announced that its Board of Directors (the “**Board**”) has appointed Mr. Brent Ashton to serve as Chief Executive Officer and a director of the Company, effective immediately.

Financial Highlights for the Three Months Ended September 30, 2023

- Total revenue for the three months ended September 30, 2023 increased 28% to \$6,895,248 compared to \$5,390,205 for the same period of the prior year.
- Product revenue for the three-month period ended September 30, 2023 increased 35% to \$6,535,060 compared to \$4,829,911 for the same period of the prior year. Product revenue increased \$1,705,149 compared to the prior year due substantially to increased customer demand for the Company’s collagen dressing product line in the US market.
- Development and consulting services revenue for the three-month period ended September 30, 2023 decreased to \$319,307, compared to \$498,017 for the same period of the prior year.
- Licensing and royalty fees for the three months ended September 30, 2023 were \$40,881, compared to \$62,277 for the three months ended September 30, 2022. 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, 2023 increased to 42% compared to 24% in the same period for the prior year. During the three months ended September 30, 2023, the Company booked inventory provision expense of \$697,470, as compared to \$1,255,081 during the three months ended September 30, 2022. The gross margin is significantly influenced by source of revenue and by the relative mix of products sold in any given financial period.
- Operating expenses for the three months ended September 30, 2023 increased \$396,593 to \$5,753,759, compared to \$5,357,166 for the prior year’s comparative period, substantially due to termination benefits to a former senior management team member.
- Both net loss and net loss from continuing operations for the three months ended September 30, 2023 was \$2,880,329 or \$0.12 per share, compared to a net loss of \$4,075,801 or \$0.16 per share for the three months ended September 30, 2022.
- Adjusted Gross Margin for the three-month period ended September 30, 2023 was 53% compared to 49% for the same period of the prior year. Gross margin is highly influenced by the mix of collagen-based dressings, silicone-based dressings, medical coating services, passive dressings, 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. For further information about Adjusted Gross Margin, see “*Definitions and Reconciliations of Non-IFRS Financial Measures*” below.
- Adjusted EBITDA loss for the three months ended September 30, 2023 was \$1,829,109, compared to an Adjusted EBITDA loss of \$2,161,553 for the three months ended September 30, 2022. For further information about Adjusted EBITDA, see “*Definitions and Reconciliations of Non-IFRS Financial Measures*” below.

Business outside of direct sales in the United States is primarily comprised of distributing bulk shipments of products, 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.

Financial Highlights for the Year Ended September 30, 2023

- Total revenue for the year ended September 30, 2023 increased 47% to \$26,595,286 compared to \$18,146,390 for the same period of the prior year.
- Product revenue for the year ended September 30, 2023 increased 46% to \$23,920,670 compared to \$16,429,051 for the same period of the prior year. Product revenue increased \$7,491,619 over the prior year due substantially to increased customer demand for collagen dressings in the US market and silicone-based dressings.
- Development and consulting services revenue for the year ended September 30, 2023 increased by 65% to \$2,451,288, compared to \$1,484,441 for the same period of the prior year.
- Licensing and royalty fees for the year ended September 30, 2023 were \$223,328, compared to \$232,898 for the year ended September 30, 2022. 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, 2023 increased to 54% compared to 41% in the same period for the prior year. During the year ended September 30, 2023, the Company recorded an inventory provision expense of \$317,521 as a result of changes in obsolescence estimates, as compared to an inventory provision expense of \$2,264,853 being recorded during the year ended September 30, 2022. The gross margin is significantly influenced by source of revenue and by the relative mix of products sold in any given financial period.
- Operating expenses for the year ended September 30, 2023 increased \$2,254,506 to \$18,890,339, compared to \$16,635,833 for the prior year's comparative period. Approximately \$1,650,652 relates to increased sales and marketing activities primarily due to an increase in sales and marketing staffing levels.
- Net loss from continuing operations for the year ended September 30, 2023 was \$4,460,998 or \$0.18 per share, compared to a net loss of \$9,253,918 or \$0.36 per share for the year ended September 30, 2022.
- Net loss from discontinued operations for the year ended September 30, 2023 was \$nil, compared to a net loss of \$409,295 or \$0.02 per share for the year ended September 30, 2022.
- Net loss for the year ended September 30, 2023 was \$4,460,998 or \$0.18 per share, compared to a net loss of \$9,663,213 or \$0.38 per share for the year ended September 30, 2022.
- Adjusted Gross Margin for the year ended September 30, 2023 was 56% compared to 55% for the same period of the prior year. Gross margin is highly influenced by the mix of collagen-based dressings, silicone-based dressings, medical coating services, passive dressings, 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. For further information about Adjusted Gross Margin, see "*Definitions and Reconciliations of Non-IFRS Financial Measures*" below.
- Adjusted EBITDA loss for the year ended September 30, 2023, was \$2,682,455, compared to an Adjusted EBITDA loss of \$5,633,230 for the year ended September 30, 2022. For further

information about Adjusted EBITDA, see “*Definitions and Reconciliations of Non-IFRS Financial Measures*” below.

Business outside of direct sales in the United States is primarily comprised of distributing bulk shipments of product, 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.

	2023	2022	2023	2022
Revenue				
Product	\$6,535,060	\$4,829,911	\$23,920,670	\$16,429,051
Development and consulting services	319,307	498,017	2,451,288	1,484,441
Licensing and royalty fees	40,881	62,277	223,328	232,898
Total revenue	6,895,248	5,390,205	26,595,286	18,146,390
Cost of sales	4,004,706	4,078,868	12,233,447	10,652,885
Gross profit before operating expenses	2,890,542	1,311,337	14,361,839	7,493,505
Operating expenses				
Operations	527,306	592,558	1,904,941	2,064,808
Research and development activities	481,890	385,490	1,413,278	1,365,803
Sales, marketing and agency fees	2,101,152	2,200,727	8,167,894	6,517,242
General and administrative	2,643,411	2,178,390	7,404,226	6,687,980
	5,753,759	5,357,165	18,890,339	16,635,833
Finance expenses (income)	17,112	29,973	(67,502)	111,590
Net loss from continuing operations	(2,880,329)	\$(4,075,801)	(4,460,998)	\$(9,253,918)
Net loss from discontinued operations	-	-	-	(409,295)
Net loss	\$(2,880,329)	\$(4,075,801)	\$(4,460,998)	\$(9,663,213)
Other comprehensive income (loss)				
Amount that may be reclassified to profit or loss				
Foreign currency translation adjustment - continuing operations	437,435	1,275,417	(61,814)	1,906,963
Total comprehensive loss	\$(2,442,894)	\$(2,800,384)	\$(4,522,812)	\$(7,756,250)
Loss per common share of continuing operations				
Basic loss per share	\$(0.12)	\$(0.16)	\$(0.18)	\$(0.36)
Diluted loss per share	\$(0.12)	\$(0.16)	\$(0.18)	\$(0.36)
Loss per common share of discontinued operations				
Basic loss per share	\$0.00	\$0.00	\$(0.00)	\$(0.02)
Diluted loss per share	\$0.00	\$0.00	\$(0.00)	\$(0.02)
Loss per common share				
Basic loss per share	\$(0.12)	\$(0.16)	\$(0.18)	\$(0.38)
Diluted loss per share	\$(0.12)	\$(0.16)	\$(0.18)	\$(0.38)

Revenue and Gross Profit

Total revenue for the three months ended September 30, 2023 increased 28% to \$6,895,248 compared to \$5,390,205 for the same period of the prior year. Product revenue for the three-month period ended September 30, 2023 increased 35% to \$6,535,060 compared to \$4,829,911 for the same period of the prior year. Product revenue increased \$1,705,149 compared to the prior year due substantially to increased customer demand for the Company's collagen dressing product line in the US market. The increase in customer demand is as a result of being designated as a primary vendor by one of our key distributors, as well as increases in the number of customers through Covalon's distribution channels.

Development and consulting services revenue for the three-month period ended September 30, 2023 decreased to \$319,307, compared to \$498,017 for the same period of the prior year.

Licensing and royalty fees for the three months ended September 30, 2023, were \$40,881, compared to \$62,277 for the three months ended September 30, 2022. The timing of this revenue will vary depending on length and timing of projects and discussions with customers. 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 for the three-month period ended September 30, 2023 increased to 42% compared to 24% in the same period for the prior year. During the three months ended September 30, 2023, the Company booked an inventory provision expense of \$697,470, as compared to \$1,255,081 during the three months ended September 30, 2022. Gross margin is highly influenced by the mix of collagen-based dressings, silicone-based dressings, medical coated devices, passive dressings, and related service revenues generated in the periods. Gross margin fluctuates as a result of the mix of products sold in any given quarter, or year, by product type and geography.

Total revenue for the year ended September 30, 2023 increased 47% to \$26,595,286 compared to \$18,146,390 for the same period of the prior year. Product revenue for the year ended September 30, 2023 increased 46% to \$23,920,670 compared to \$16,429,051 for the same period of the prior year. Product revenue increased \$7,491,619 over the prior year due substantially to increased customer demand for collagen dressings in the US market and silicone-based dressings.

Development and consulting services revenue for the year ended September 30, 2023 increased by 65% to \$2,451,288, compared to \$1,484,441 for the same period of the prior year.

Licensing and royalty fees for the year ended September 30, 2023, were \$223,328, compared to \$232,898 for the year ended September 30, 2022. 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, 2023 increased to 54% compared to 41% in the same period for the prior year. During the year ended September 30, 2023, the Company recorded an inventory

provision expense of \$317,521 as a result of changes in obsolescence estimates, as compared to an inventory provision expense of \$2,264,853 being recorded during the year ended September 30, 2022.

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.

	Three months ended		Year ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operations				
Wages, benefits and consulting fees	\$446,050	\$431,775	\$1,503,643	\$1,390,021
Depreciation and amortization	7,627	23,660	67,943	90,773
Facility	15,826	34,986	25,507	114,470
Other	57,803	102,137	307,848	469,544
	527,306	592,558	1,904,941	2,064,808
Research and development activities				
Wages, benefits and consulting fees	246,527	162,187	799,669	916,293
Depreciation and amortization	38,717	9,807	151,838	34,387
Patent and trademark maintenance	102,197	136,924	307,175	270,708
Other	94,449	76,572	154,596	144,415
	481,890	385,490	1,413,278	1,365,803
Sales, and marketing activities				
Wages, benefits and consulting fees	1,710,755	1,857,924	6,503,977	5,557,430
Travel	213,422	151,476	625,273	427,233
Other	176,975	191,327	1,038,644	532,579
	2,101,152	2,200,727	8,167,894	6,517,242
General and administrative				
Wages, benefits and consulting fees	1,369,145	815,157	3,718,102	3,566,558
Directors compensation	29,959	35,976	119,041	129,465
Professional and related costs	634,325	441,618	1,287,235	1,275,017
Facility	(13,431)	169,144	134,902	435,418
Insurance	92,880	97,234	414,427	363,014
Information technology system costs	187,196	135,046	674,700	295,610
Depreciation and amortization	111,938	411,395	524,545	655,991
Other	231,399	72,820	531,274	(33,093)
	2,643,411	2,178,390	7,404,226	6,687,980
Total operating expenses	5,753,759	5,357,166	18,890,339	16,635,833

Operating Expenses

Operating expenses for the three months ended September 30, 2023 increased \$396,593 to \$5,753,759, compared to \$5,357,166 for the prior year's comparative period, substantially due to termination benefits to a former senior management team member.

The Operations department contains expenses related to Quality Control, Quality Assurance, Production, and Regulatory activities. Operations expenses decreased to \$527,306 in the current quarter from

\$592,558 in the comparable period, primarily due to lower other costs of \$44,334 due primarily due to increased manufacturing activity levels, which resulted in higher absorption of costs to inventory in the current quarter compared to the prior year.

Research and development activities increased to \$481,890 in the current quarter from \$385,490 in the comparable period mainly as a result of \$84,340 in increased wages, benefits, and consulting fees as a result of less wages and benefits being allocated to cost of goods sold in relation to development and consulting services revenue.

Sales and marketing costs decreased 5% to \$2,101,152 in the current quarter from \$2,200,727 in the comparable period, due primarily to \$147,169 in decreased wages, benefits in the current quarter compared to the comparable period, primarily due to changes in the commission structure of the Company.

General and administrative expenses increased to \$2,643,411 in the current quarter from \$2,178,390 in the comparable period. Wages, benefits and consulting fees increased \$553,988 in the current period as compared to the prior period primarily due to termination benefits to a former senior management team member. Professional and related costs increased \$192,707 in the current quarter over the comparable period due primarily due to increased recruiting fees.

Wages, benefits, and consulting fees (for all departments) include a non-cash expense related to stock options that the Company had previously granted. During the three months ended September 30, 2023, shared based payment expense was \$121,872 compared to \$84,450 in the prior year. This expense is a reflection of the number of options outstanding and their respective fair values for accounting purposes.

Operating expenses for the year ended September 30, 2023 increased \$2,254,506 to \$18,890,339, compared to \$16,635,833 for the prior year's comparative period. Approximately \$1,650,652 relates to increased sales and marketing staffing levels.

The Operations department contains expenses related to Quality Control, Quality Assurance, Production, and Regulatory activities. Operations expenses decreased to \$1,904,941 during the year ended September 30, 2023 from \$2,064,808 in the comparable period, primarily due to a decrease in other expense of \$161,696 as a result of lower information technology expenses in this department, and lower facility expenses of \$88,963 as a result of credits received in respect of prior year property tax reassessments, partially offset by higher wages, benefits and consulting fees of \$113,622 as a result of increased staffing levels in this department.

Research and development activities increased to \$1,413,278 for the year ended September 30, 2023 from \$1,365,803 in the comparable period mainly as a result of higher depreciation and amortization of \$117,451 due to higher additions of property, plant and equipment during the year than the comparable period.

Sales and marketing costs increased 25% to \$8,167,894 during the year ended September 30, 2023 from \$6,517,242 in the comparable period, due primarily to increased sales and marketing staffing levels which resulted in higher wages, benefits and consulting fees of \$946,547 as compared to the prior year. Other expenses increased \$506,065 over the prior year due primarily to increased participation in tradeshow

and website enhancements, and travel expenses increased \$198,040 due to increased sales activities compared to the prior year.

General and administrative expenses during the year ended September 30, 2023 were \$7,404,226 which increased compared to \$6,687,980 in the prior period. Other expenses increased \$564,367 in the current period as compared to the prior period and this was substantially due to higher foreign exchange gains which occurred in the comparable period compared to the current period. Also, information technology system costs increased \$379,090 compared to the prior period due to higher information technology system costs as compared to the comparable period due to enhancements to the Company's information technology systems. Further, wages, benefits and consulting fees increased \$151,544 compared to the prior period due to termination benefits to a former senior management team member.

Wages, benefits, and consulting fees (for all departments) include a non-cash expense related to stock options that the Company had previously granted. During the year ended September 30, 2023, shared based payment expense was \$559,154 compared to \$211,438 in the prior year. This expense is a reflection of the number of options outstanding and their respective fair values for accounting purposes.

Related Party Transactions

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

	Year ended September 30,	
	2023	2022
Compensation and short-term employee benefits	\$1,203,822	\$1,107,805
Termination benefits	667,969	-
Share based payment expense	65,668	64,360
	1,937,459	1,172,165

Termination benefits relate to a former senior management team member and are included in accounts payable and accrued liabilities at September 30, 2023 and represents management's best estimate of the termination benefit owing. The final settlement of the termination benefit amount owing remains unresolved, and an additional amount of \$1,440,000 has been claimed, which the Company has not accrued for and believes is unwarranted.

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, 2023, \$10,000 of this loan remained outstanding.

Critical Accounting Estimates and Judgements

The preparation of audited consolidated 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.

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. 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.

Inventory Obsolescence

Management applies judgement when estimating the inventory provision related to obsolescence based on the consideration of a variety of factors, including expiry dates and the timing of forecasted revenue by product. In many cases, product manufactured or purchased by the Company turns quickly and inventory on-hand values are low, thus reducing the risk of inventory obsolescence. However, expiry dates are important in the determination of net realizable value of inventory.

Management ensures that systems are in place to highlight and properly value inventory that has an expiry date within six months of period end. To the extent that actual losses on inventory obsolescence differ from those estimated, inventory, net loss, and comprehensive income (loss) will be affected in future periods.

Accounting Standards Issued But Not Yet Adopted

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 will be adopted by the Company on October 1, 2023. The Company has assessed that there will be no impact of applying the new standard on the consolidated financial statements.

Definition of Accounting Estimates (Amendments to IAS 8)

On February 12, 2021, the IASB issued Definition of Accounting Estimates (Amendments to IAS 8). The amendments will require the disclosure of material accounting policy information rather than disclosing significant accounting policies and clarifies how to distinguish changes in accounting policies from changes in accounting estimates. The amendments are effective for annual periods beginning on or after January 1, 2023. The Company intends to adopt this amendment in its Consolidated Financial Statements for the annual period beginning October 1, 2023. The adoption of this amendment is not expected to have a material 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.

	2023 Fourth Quarter	2023 Third Quarter	2023 Second Quarter	2023 First Quarter	2022 Fourth Quarter	2022 Third Quarter	2022 Second Quarter	2022 First Quarter
Revenue	\$ 6,895,248	\$ 6,270,039	\$ 7,244,594	\$ 6,185,405	\$ 5,390,205	\$ 4,526,007	\$ 3,293,834	\$ 4,936,345
Net loss before amortization and depreciation	(2,665,562)	(230,583)	(464,757)	(130,736)	(3,531,057)	(1,437,150)	(2,369,655)	(940,215)
Net loss	(2,880,329)	(501,767)	(698,081)	(380,821)	(4,075,801)	(1,608,600)	(2,462,015)	(1,107,502)
Net loss per share	(0.12)	(0.02)	(0.03)	(0.02)	(0.16)	(0.06)	(0.09)	(0.04)
Cash	8,794,650	9,190,108	10,766,955	14,062,520	14,061,631	14,035,183	19,578,464	22,371,357
Net working capital	16,102,617	18,638,806	20,038,162	21,609,848	22,689,201	25,890,645	27,998,821	30,515,094
Current ratio	4.1	5.4	5.4	5.2	6.0	10.0	9.1	8.5

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

	September 30, 2023	September 30, 2022
Cash and cash equivalents	\$8,794,650	\$14,061,631
Total assets	\$24,900,593	\$30,378,081
Deferred revenue	\$80,702	\$260,471

On September 30, 2023, cash and cash equivalents totaled \$8,794,650 compared to \$14,061,631 at September 30, 2022. During the year ended September 30, 2023, the Company had total use of cash of \$5,266,981 as compared to a use of cash of \$8,885,292 in the prior year. The Company used \$6,637,681 in total cash flows of continuing operations compared to \$9,573,814 in the prior year. The Company also generated \$1,370,700 of total cash flows of discontinued operations due to the release of cash held in escrow related to the AquaGuard Sale during the period, as compared to generating \$688,522 of total cash flows from discontinued operations in the prior year.

Accounts receivable at September 30, 2023 increased \$1,429,639 from September 30, 2022. 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.

Inventories at September 30, 2023 increased \$978,866 from September 30, 2022. Inventory levels will fluctuate as a result of the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations.

Prepaid expenses at September 30, 2023 decreased \$1,707,568 from September 30, 2022. Prepaid expenses for the Company are primarily attributable to advance payments for inventory purchases and will fluctuate as a result of the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations.

Accounts payable and accrued liabilities increased \$744,401 from September 30, 2022. Accounts payable and accrued liabilities will fluctuate primarily as a result of the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations.

The Company had an additional \$135,200 assigned as collateral to secure the Company's credit cards. These funds are expected to be restricted for more than one year and are included as restricted cash.

Total assets at September 30, 2023 were \$24,900,593 compared to \$30,378,081 at September 30, 2022. Cash and cash equivalents comprised 35% of total assets at September 30, 2023. The Company's accounts receivable and inventories are liquid, with collection periods and turnover ratios generally in the 30 to 90 day range. 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 \$179,769 to \$80,702 at September 30, 2023, compared to \$260,471 at September 30, 2022.

The Company continually monitors working capital to ensure sufficient cash and cash equivalents are 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:

	Carrying amount (\$)	Future cash flows (\$)	Less than 1 year (\$)	Between 1 and 5 years (\$)	Greater than 5 years (\$)
Accounts payable and accrued liabilities	4,464,609	4,464,609	4,464,609	-	-
Lease liabilities	1,562,465	1,616,118	696,008	920,110	-
Total	6,027,074	6,080,727	5,160,617	920,110	-

Shareholder's 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, 2023, the Company had a total of 24,669,577 Common Shares issued and outstanding.

On May 25, 2022, the Company announced that it had filed its intention to make a normal course issuer bid (“NCIB”) for its common shares with the TSX Venture Exchange for up to 1,296,433 shares, representing 5% of the issued and outstanding common shares. Repurchases under the NCIB program were approved by the TSX Venture Exchange, commenced on June 2, 2022, and were authorized to continue until the earlier of: (a) May 31, 2023; and (b) the date in which the maximum number of common shares purchasable under the NCIB have been acquired by the Company. The NCIB ended on May 31, 2023. All common shares that were repurchased by the Company under the NCIB program were cancelled, with any excess or deficiency as compared to the weighted average cost of common shares being charged to contributed surplus.

On June 29, 2022, in connection with the NCIB, the Company entered into an automatic share purchase plan (“ASPP”) with a designated broker. The ASPP was intended to allow for the purchase of the Company’s common shares under the NCIB at times when the Company would ordinarily not be permitted to purchase its common shares due to regulatory restrictions and customary self-imposed blackout periods. Pursuant to the ASPP, prior to entering into a blackout period, the Company could instruct the designated broker to make purchases under the NCIB in accordance with the terms of the ASPP. Such purchases could be made by the designated broker in its sole discretion based on parameters established by the Company prior to the blackout period in accordance with the rules of the TSX Venture Exchange, applicable securities laws and the terms of the ASPP. In accordance with the terms of the ASPP, the Company was able to terminate any instructions given to the designated broker with minimal notice. The Company continued with the ASPP from June 29, 2022 through to May 31, 2023.

For the twelve months ended September 30, 2023, the Company has repurchased 618,200 (September 30, 2022 – 640,900) of its common shares under the NCIB.

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

Security Type	Number Outstanding
Common Shares	24,669,577
Options	890,000
Warrants	2,920,000

Sources and Uses of Cash of Cash and Cash Equivalents

	Year ended September 30,	
	2023	2022
Cash flows used in operating activities	(3,184,008)	(7,993,570)
Cash flows used in investing activities	(1,451,717)	(843,023)
Cash flows from financing activities	(2,156,054)	(2,186,138)
Discontinued Operations	1,370,700	688,522

Operating Activities

Cash used in operating activities for the year ended September 30, 2023 was \$3,184,008, compared to cash used of \$7,993,570 in the prior period. Non-cash working capital used \$317,748 during the year ended September 30, 2023, compared to \$83,384 used in the prior year. At September 30, 2023, accounts receivable increased leading to cash used of \$1,470,010 as compared to cash generated of \$1,842,085 in the prior year due mostly to timing of sales relative to the period end as well as customer payment patterns. Inventories can also be affected by the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations. At September 30, 2023, inventories increased leading to cash used of \$1,043,597 as compared to cash used of \$63,367 in the prior year due mostly to offsetting drawdowns of advance deposits included in prepaid expenses and accommodating customer order requirements for future periods. Inventories can also be affected by the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations. At September 30, 2023, prepaid expenses decreased primarily due to increased inventories, leading to cash generated of \$1,687,013 as compared to cash used of \$1,169,683 in the prior year. Prepaid expenses can also be affected by the timing of making advance payments with suppliers as a result of fluctuations in the timing of sales, customer order patterns, and changes in supply chains which the Company monitors and adjusts for in the normal course of operations.

Investing Activities

Cash used in investing activities for the year ended September 30, 2023 was \$1,451,717, compared to cash used of \$843,023 in the prior period. Investing activities comprise expenditures on general office furniture, lab equipment, restricted cash, and expenditures on intangible assets related to information technology investments and the filing and maintaining patents and trademarks. For the year ended September 30, 2023, the Company made investments of \$494,635 in property, plant and equipment, as compared to \$599,844 in the comparable period, mainly due to enhancements to production capacity of in-house collagen manufacturing. Also, for the year ended September 30, 2023, the Company made investments in intangible assets of \$821,882 as compared to \$481,908 in the comparable period, due to continued investment in enhancing the Company's information systems. In addition, for the year ended September 30, 2023, the Company provided \$135,200 as cash collateral for continued usage of credit cards in the normal course of operations, as compared to cash generated of \$137,061 in the comparable period, which was a result of a release of cash collateral for usage of credit cards.

Financing Activities

During the year ended September 30, 2023, total cash flow used for financing activities was \$2,156,054 as compared to a use of \$2,186,138 in the prior year. For the year ended September 30, 2023, cash flow used for financing activities was mostly due to the repurchase of shares in the amount of \$1,472,286 as a result of the NCIB, as compared to \$1,726,954 in the prior year.

Financial Instruments

The Company is subject to interest rate risk on its cash and cash equivalents. The Company believes that interest rate risk is low due to market based variable interest rate.

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 gross 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 and twelve months ended September 30, 2023. 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>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Gross profit before operating expenses	2,890,542	1,311,337	14,361,839	7,493,505
Add: Depreciation and amortization	56,484	99,882	225,044	251,656
Add: Inventory provisions	697,470	1,255,081	317,521	2,264,853
Adjusted Gross Margin	3,644,496	2,666,300	14,904,404	10,010,014
Adjusted Gross Margin (%)	53%	49%	56%	55%

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 share based compensation, 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 and twelve months ended September 30, 2023. 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>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net income (loss)	(2,880,329)	(4,075,801)	(4,460,998)	(9,253,918)
Add: Interest expense	17,112	29,973	(67,502)	111,590
Add: Depreciation and amortization	214,766	544,744	969,370	1,032,807
Add: Share based compensation	121,872	84,450	559,154	211,438
Less: Government subsidies	-	-	-	-
Add: Inventory provisions	697,470	1,255,081	317,521	2,264,853
Add: Accounts receivable write-off	-	-	-	-
Adjusted EBITDA	(1,829,109)	(2,161,553)	(2,682,455)	(5,633,230)

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 and the consolidated financial statements, together with all other information set forth in the Company's public filings on SEDAR+ which can be accessed at www.sedarplus.com. 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, cash flows, prospects, results of operations, 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:

Macroeconomic trends including inflation and rising interest rates may adversely affect our financial condition and results of operations.

Macroeconomic trends, including increases in inflation and rising interest rates, may adversely impact our business, financial condition, and results of operations. Inflation in Canada and the United States ("U.S.") has recently accelerated and is currently expected to continue to accelerate at an elevated level in the near-term. Rising inflation could have an adverse impact on our operating expenses. There is no guarantee that we will be able to mitigate the impact of rising inflation. Any form of borrowing could be at risk of high interest rates, which would result in higher debt service costs and adversely affect our cash flow. We are unable to guarantee that our access to capital and other sources of funding will not become constrained, which could adversely affect the availability and terms of future borrowings. Such future constraints could increase our borrowing costs, which would make it more difficult or expensive to obtain additional financing or refinance the then existing obligations and commitments, which could slow or deter future growth.

Such macroeconomic trends, including those arising from geopolitical events, are causing economic uncertainty and have resulted in a deterioration of global economic conditions, raising the prospect of a global recession which may negatively impact our business.

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 may have a significant negative effect on our business, results of operations, and financial condition.

Covalon's share price may be volatile, which could result in substantial losses for investors.

The market price of the Common Shares may be highly volatile and could experience wide fluctuations that are not necessarily related to the operating performance, underlying asset values or prospects of the Company. Price fluctuations may occur in response to a variety of 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 the Common Shares, 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;
- pursuit of regulatory approval and implementation of normal course issuer bids and/or automatic share purchase plans (during blackout periods) from time to time;
- 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 the Common Shares.

Covalon has not yet achieved consistent profitability year to year.

Covalon had a net loss for the three months ended September 30, 2023 of \$2,880,329, and a net loss for the year ended September 30, 2023 of \$4,460,998. 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 (approximately 33% 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 (approximately 17% 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 share price and trading volume could decline.

The trading market for the Common Shares will depend in part on the research and reports that securities and 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 the Common Shares in anticipation that we will increase such coverage. If one or more analysts covering us at any given time downgrades our shares, or publishes inaccurate or unfavorable research about our business, our share price would likely decline. If analysts cease coverage of us or fail to publish reports on us regularly, demand for our shares could decrease, which could cause our share price and trading volume to decline.

Offers or availability for sale of a substantial number of Common Shares may cause the price of our Common Shares 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 Common Shares become available for resale in the public market, the supply of our Common Shares will increase, which could decrease the price of the Common Shares. In addition, if our shareholders sell substantial amounts of our Common Shares 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 the 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’s ability to generate revenue is dependent on significant customers.

The loss of one or more significant customers would likely have a negative impact on Covalon’s business. 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, however, portions of the Company’s revenue remain dependent on certain significant customers. If one or more significant customers were to cease to do business with Covalon it would likely negatively impact the Company’s ability to generate revenue. 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 unclear, 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.

Covalon's dependence on third-party suppliers may negatively impact the Company's business if such suppliers are unable to supply materials in a timely manner or to the continued standards of Covalon.

In general, raw materials essential to our business 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 instability. 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 the event of the inability of third-party suppliers to supply such materials in a timely manner or to supply materials that continue to meet Covalon's quality, quantity or cost requirements, the Company may be required to purchase these materials from other suppliers, if at all possible. In addition, the Company may be unable to redesign or adapt our technology to work without such raw materials or products. 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. Further, any of these events could harm our reputation or subject us to significant liability.

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. Despite the Company's efforts to protect its trade secrets, these agreements are limited in duration, could be breached and may not provide meaningful protection of trade secrets. 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. Adequate remedies may not be available if there is any unauthorized use of Covalon's trade secrets.

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 impair the Company's competitive position and have a material adverse effect on its business and financial condition.

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, enforce its rights against others, and operate without infringing the exclusive rights of other parties. Covalon has filed and is actively pursuing patent applications in Canada, the U.S., 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 and that additional proprietary products developed by the Company will be suitably protected from infringement. The Company's inability to obtain a patent may limit its ability to protect the intellectual property rights its pending patent applications were intended to cover. In addition, there is no guarantee that any patent issued to the Company will provide adequate protection or bring any competitive advantage to the Company. There can be no assurance that patents will not be successfully challenged by third parties, or that the patents of competitors will not impede Covalon's ability to commercialize its technology.

The Company may be unable to prevent third parties from using its intellectual property without its authorization. There can be no guarantee that competitors will not independently develop products similar to Covalon's products. The unauthorized use of the Company's intellectual property could reduce any competitive advantage that it has developed, reduce its market share, or otherwise harm its business. In the event of such unauthorized use, litigation to protect and enforce Covalon's rights could be costly, and the Company may not prevail. Although Covalon does not believe that its products infringe the proprietary rights of third parties, there can be no guarantee that infringement or invalidity claims (or claims for indemnification resulting from infringement claims) will not be asserted and prosecuted against the Company, or that such actions would not materially adversely affect the Company's business, financial conditions, operations or reputation. Further, the Company could incur significant costs with respect to the defense of any assertions or litigation, which could negatively impact the Company's financial conditions.

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 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 due to the fact that they have significantly greater resources. Uncertainties resulting from the initiation and continuation of any litigation could affect Covalon's ability to continue its operations.

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

- pay substantial damages;
- cease the development, manufacture, use, or sale of product candidates or products that infringe upon the intellectual property of others;
- expend significant resources to design around a patent, or to develop or acquire non-infringing intellectual property;
- discontinue processes incorporating infringing technology; 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 U.S. Patent and Trademark Office (or other proceedings outside the U.S.). The proceedings may include oppositions to determine priority of invention or patentability, which could result in substantial costs to Covalon even if the eventual outcome were favourable.

Engaging in any type of litigation may be costly and time-consuming and may distract management and materially adversely affect our relationships with our partners, suppliers, or potential partners or suppliers. Any negative outcome from such proceedings could materially adversely affect our results of operations.

Covalon operates in a highly competitive industry with 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, which 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:

- i) large and established distribution networks;
- ii) greater financial, sales, marketing, managerial, scientific, technical, and other resources for products research and development, sales and marketing efforts, and protecting and enforcing intellectual property rights;
- iii) greater name and brand recognition;
- iv) more expansive portfolios of intellectual property rights;
- v) established relations with physicians, hospitals, other healthcare providers, and third party payors;
- vi) products which have been approved by regulatory authorities for use in the U.S. or Europe, supported by long-term clinical data; and
- vii) 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. Increased competition may result in reduced operating margins, as well as loss of market share. Our failure to compete effectively could have a material and adverse effect on our business, results of operations, and financial condition.

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.

Covalon's development programs and products subject the Company to the risk of product liability claims, which could be costly and negatively impact business.

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. Covalon may not be able to obtain or maintain adequate insurance coverage to protect the Company against such claims at acceptable costs or at all. Without sufficient coverage any claim, any threat of such a claim, or any product withdrawal could seriously harm Covalon's business.

Any claim made against the Company that is not fully covered by insurance could be costly to defend, result in a substantial damage award against us and divert the attention of our management from operations, all of which could have an adverse effect on our financial performance. In addition, successful claims against the Company may adversely affect our business or reputation.

Some of Covalon’s existing and potential future products may require regulatory approval.

As a developer of medical products, Covalon is subjected to an expansive regulatory regime and accordingly, may need to obtain regulatory approvals for the sale and distribution of certain of its products or future products. Furthermore, 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 U.S. Food and Drug Administration (“FDA”) 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, 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, and 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 and Covalon may be required to dedicate substantial resources in order to comply with any changes in regulations, which could have a material impact on Covalon’s business. Meeting regulatory requirements and evolving government standards around the world may also 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’s products are subject to regulatory oversights and there is no guarantee that the required regulatory approvals will be obtained.

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 U.S., and internationally is governed by a variety of statutes and regulations. These laws require, among other things:

- i) approval of manufacturing facilities and practices;
- ii) adequate and well-controlled research and testing of products in pre-clinical and clinical trials;
- iii) 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,
- iv) 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.

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 or force Covalon to cease selling certain of its products for any period of time or indefinitely. 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.

The regulatory framework in which Covalon operates is uncertain and evolving.

There may be significant changes to healthcare laws and regulations in the future. Covalon continuously monitors these developments and modifies operations when necessary. We cannot guarantee that we will be able to adapt our operations to address new regulations or that new regulations will not adversely impact our business. Although we believe that we are operating in compliance with applicable laws, we cannot guarantee that a review of our business by courts or regulatory authorities will not change in a way that restricts our operations. Further, the implementation of additional regulations or compliance requirements could result in substantial costs to Covalon.

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 and 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, we believe 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 take certain actions against the Company including, among other actions, requiring us to obtain clearance or approval for modifications to our products, impose fines or recall the Company's 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 and/or face additional litigation risks. If any of the foregoing were to occur, our financial condition and results of operations could be negatively impacted.

Covalon's products may contain design defects, which may negatively impact the Company's reputation and operations.

The Company's products are highly complex and sophisticated, and from time to time, may contain design defects. If such defects are discovered, the Company may not be able to successfully correct the errors in a timely manner. The occurrence of errors and failure in the Company's products could result in the delay or the denial of market acceptance of its product. Moreover, as the Company's products provide patients with care, such errors may result in care delivery errors resulting in patient safety risks. Alleviating such errors may require the Company to make significant expenditure of its resources. The harm to the Company's reputation resulting from product errors may be materially damaging.

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 our 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 expenses 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’ intellectual property, which 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's success is partially reliant on the strategic partnerships it has in place and its partners' ability 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:

- i) outsourced manufacturing production is not achieved within Covalon's timelines;
- ii) production quality measures are not achieved;
- iii) sales expectations are not achieved; and
- iv) new products are not launched expeditiously.

Covalon's success will be dependent on the Company's ability to maintain its strategic partnership and its ability to seek out and establish new strategic alliances and working relationships. There can be no assurance that existing strategic partnerships will not be terminated or adversely modified in the future, nor can there be any assurances that new strategic partnerships, if any, will provide the Company with the same benefits as the relationships currently in place.

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. There is no guarantee that third parties will 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 their 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 U.S. 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 regulations will have on us. However, the implementation of new legislation and regulations 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. There is no guarantee that additional financing will be available to Covalon when needed or on terms that are acceptable, and the failure to obtain financing could result in the delay of our growth objectives. 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 on the Company's operations.

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. In addition, there can be no assurance that Covalon will be able to raise the additional funding that it may require to carry out its growth strategy and to complete acquisitions. 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 or cause downgrades in our future debt ratings leading to higher borrowing costs. This could in turn negatively affect our ability to access public debt or equity markets for capital.

Ineffective internal controls over financial reporting could be harmful to Covalon's results of operations.

Covalon's internal controls over financial reporting are designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. With this said, internal controls over financial reporting are not guaranteed to provide absolute assurance with regard to the reliability of financial reporting and financial statements. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation could harm Covalon's results of operations or cause Covalon to fail to meet its reporting obligations and may result in a restatement of its financial statements for prior periods. Ineffective disclosure controls and procedures and internal controls over financial reporting could also cause investors to lose confidence in the Company's reported financial and other information, which would likely have a negative effect on the price of the Common Shares.

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 U.S. hospital market and 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.

Future changes in environmental regulation could adversely impact Covalon's operations.

Environmental legislation is rapidly evolving in a manner that involves stricter standards and enforcement, increased fines and penalties for non-compliance, and a heightened degree of responsibilities for companies. Environmental legislation, regulations, or other measures could entail costs, restrictions, and delays in the Company's activities. There can be no assurance that future changes in environmental regulations, if any, will not adversely affect Covalon's operations.

Covalon may be adversely impacted due to foreign currency risk.

Covalon reports its results in the Canadian dollar. Fluctuations in the exchange rates between the Canadian dollar, the U.S. Dollar, the European Euro, and other various currencies used in jurisdictions in which Covalon does business may have a material adverse effect on the business, financial condition, and operating results of the Company.

If Covalon fails to comply with applicable data privacy and security laws, rules and regulations, the Company's reputation, business, and operating results could be negatively affected.

There are numerous laws and regulations governing the collection, dissemination, access, use, security and privacy of personally identifiable information and protected health information, as well as consumer protection laws and regulations and other data protection laws. New privacy legislation may create additional rights for consumers and impose additional requirements on the Company. If we fail to comply with applicable privacy and security laws, regulations and standards, properly maintain the integrity of our data, protect our proprietary rights, or defend against cybersecurity attacks, our business, reputation and results of operations could be materially and adversely affected.

In addition, compliance with applicable data privacy and security laws, rules, and regulations could require the Company to engage in costly compliance exercises or limit our ability to collect, use, and disclose data. Failure to comply with such laws, rules, and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity. Any of the foregoing could negatively affect our operating results, business, and reputation.

Covalon's informational technology systems are at risk to cyberattacks, which could negatively affect the Company's operations and reputation.

Covalon's operations depend on the reliability and security of the Company's information technology ("IT") systems. Information security risks have significantly increased in recent years as a result of new technologies, the use of the internet and telecommunications technologies, and the increase in activities of organized crime, hackers, terrorists, and other external parties. Our operations rely on the secure processing, transmission, and storage of confidential, proprietary, and other information in our computer systems and networks.

Although Covalon has established and continues to enhance security controls intended to protect the Company's IT systems and infrastructure, there can be no guarantee that such security measures would be effective in preventing the following:

- unauthorized access, use or disclosure of sensitive or confidential information;
- cyberattacks;
- theft, misplaced, lost, destroyed, or corrupted data;
- operational disruption from system impairment;
- computer viruses and emerging cybersecurity risks; and
- programming and human errors or malfeasance.

A significant breach of the Company's IT systems could cause disruptions in our operations, lead to the loss, destruction, corruption or inappropriate use of sensitive data including employee information or intellectual property, or result in lost revenues due to theft of funds or disruption of activities, which could result in a material disruption of our business operations. In addition, if any of the foregoing events occurs, the Company may be subject to a number of consequences, including reputational damage and a diminished competitive advantage. The Company may also be required to notify governmental agencies, the media, or individuals pursuant to various privacy and security laws.

Covalon’s reputation could be negatively impacted if our independent suppliers or manufacturers fail to promote ethical business practices in a manner beyond our knowledge or control.

There is an increasing expectation by stakeholders to address social and environmental challenges (including climate change, human rights, forced labour, child labour, racism, and inequality) and to demonstrate exemplary governance in managing environmental, social and governance (“ESG”) risk. An inability to manage this risk can result in higher cost of capital, regulatory compliance, and disclosures. In order to manage ESG risk, Covalon operates its business responsibly and ethically, and remains in compliance with laws and regulations that are reflected in several key policies. If our independent suppliers or manufacturers fail to use ethical business practices and comply with applicable laws and regulations, our reputation and business could be harmed. While our operating guidelines promote ethical business practices, we do not control our independent suppliers or manufacturers or their business practices.