

Covalon Technologies Ltd.

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

December 31, 2024



MANAGEMENT'S DISCUSSION & ANALYSIS

For the three months ended December 31, 2024

February 21, 2025

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, 2024, and with our unaudited condensed consolidated interim financial statements for the three months ended December 31, 2024. 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 discussion and analysis document ("MD&A"), financial information for the three months ended December 31, 2024 and 2023 is based on the unaudited condensed consolidated interim financial statements of the Company, which were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS Accounting Standards") and are presented in Canadian dollars unless otherwise specified. The accounting policies adopted are consistent with those of the previous financial year end.

In accordance with its terms of reference, the Audit Committee of the Company's Board of Directors reviews the contents of the MD&A and recommends its approval to the Board of Directors. The Board of Directors approved this MD&A on February 20, 2025. Disclosure contained in this document is current to that date, unless otherwise noted.

Management's Responsibility for Financial Reporting

The unaudited condensed consolidated interim 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 unaudited condensed consolidated interim 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 unaudited condensed consolidated interim financial statements and the MD&A. The Board of Directors of the Company (the "Board of Directors") carries out its responsibility for the unaudited condensed consolidated interim 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 unaudited condensed consolidated interim financial statements and the MD&A.

Non-GAAP Financial Measures

This MD&A refers to certain non-GAAP measures. These measures are not recognized or defined measures under IFRS Accounting Standards, do not have standardized meaning prescribed by IFRS



Accounting Standards 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 Accounting Standards 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 Accounting Standards. The non-GAAP 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 Accounting Standards. We use non-GAAP 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 Accounting Standards measures. We believe that investors, securities analysts, and other interested parties frequently use non-GAAP measures in the evaluation of issuers. Management also uses non-GAAP 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-GAAP measures to the relevant reported measures, please see "Definitions and Reconciliations of Non-GAAP 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 and 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 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 Covalon Technologies Ltd. MD&A Q1 F-2025

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solutions for advanced wound care, infection risk reduction, and medical device coatings, we offer innovative, gentle, and compassionate options for patients. Our solutions are designed for patients but made for those delivering the care. They are designed to improve the standard of care and patient experience in pediatric and acute care hospitals, long-term care settings and home healthcare visits.

For more than 20 years, we have successfully delivered vascular access, advanced wound care, perioperative care, and customized medical device coating solutions to patients throughout the United States, Canada, Latin America and the Middle East. We leverage our patented medical technology platforms and expertise in two ways: (i) by developing products that are sold under Covalon's name; and (ii) by developing and commercializing medical products for other medical companies under development and license contracts. We are becoming the standard of care for major pediatric and acute care hospitals in the United States and around the world because healing shouldn't hurt.

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.

Covalon's products are regulated by various government agencies in the countries in which the products are distributed and/or manufactured. To the extent required under applicable law or to comply with the applicable guidelines in the jurisdictions in which it operates, Covalon will put forward submissions to regulatory bodies for their feedback and/or approval. There are risks associated with such filings - please see in the "Risks and Uncertainties" section below. In the Company's Management Discussion and Analysis dated June 30, 2024 we indicated that we had filed a catch up 510(k) to the US Food and Drug Administration (FDA) for our ColActive® Plus and ColActive® Plus AG products. As was expected, and is typical for these filings, the Company received feedback from the FDA. The Company is incorporating this feedback into additional testing that is currently taking place, and once complete, we will re-submit to the FDA. As previously shared, there are risks and uncertainties associated with any FDA submission and subsequent interaction, and as such there can be no assurances as to the outcome.

The Company has transformed its strategy to focus on growing its United States and international infection control and wound care businesses by building technology and brand awareness with clinicians and customers

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

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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 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 technologies that are branded as CovaCoat, CovaCoat with API, Centaur, CovaGuard, and SD-168. Covalon's patented coating technology underlying CovaCoat, CovaCoat with API, and Centaur are based on a proprietary "grafting from" process which utilizes photo-polymerization to create active grafting sites where new polymer chains are initiated and propagated from the surface of an existing medical device.

Our Products

We have approximately 21 families of medical devices and approximately 150 separate SKUs, many of which are derived from our platform technologies. Availability of the Company's products for sale will differ by country/region. Our full list of products 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	
TV Clear	dressing with chlorhexidine and silver	
CovaClear IV	Clear silicone adhesive vascular access dressing	
VALGuard	Helps protect line-to-line connections, luer locks, &	
VALGuaru	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 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 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 sales force in the United States that sells directly into pediatric and acute care hospitals and associated institutions. The Company has set up distribution relationships with a number of companies in North America, the Middle East, Latin America, 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.



Financial Performance During the Three Months Ended December 31, 2024: (all figures are in \$CAD)

	Three months ended December 31,	
	2024	2023
Revenue		
Product	\$8,077,940	\$4,575,767
Development and consulting services	5,826	56,640
Licensing and royalty fees	82,214	30,650
	8,165,980	4,663,057
Total revenue		
Cost of sales	3,171,514	1,814,520
Gross profit	4,994,466	2,848,537
Operating expenses Operations Research and development activities Sales, marketing, and agency fees General and administrative	371,069 373,339 1,209,820 1,725,570 3,679,798	630,713 311,411 1,646,303 1,731,625 4,320,052
Finance income Loss/(gain) on finance lease receivable	(41,068) 149,690	(9,964) (610,008)
Net income (loss)	1,206,046	\$(851,543)
Other comprehensive income (loss) Amount that may be reclassified to profit or loss		
Foreign currency translation adjustment	1,850,454	(387,273)
Total comprehensive income (loss)	\$3,056,500	\$(1,238,816)
Earnings (loss) per common share		
Basic earnings (loss) per share	\$0.04	\$(0.03)
Diluted earnings (loss) per share	\$0.04	\$(0.03)



Revenue, Gross Margin and Operating Expenses

Total revenue increased 75% to \$8,165,980 compared to \$4,663,057 in the same period of the prior year. Product revenue grew by 77% to \$8,077,940 compared to \$4,575,767, driven by stronger customer demand for the Company's collagen dressing and the expansion of its product offerings within US hospitals.

Development and consulting services revenue amounted to \$5,826 compared to \$56,640 in the same period last year, reflecting the Company's strategic decision to prioritize its United States product business. Licensing and royalty fees were \$82,214 compared to \$30,650, with timing variations dependent on the duration and progress of customer projects. Revenue may fluctuate quarterly due to variations in contractual arrangements, product shipment timing, and service completion.

The company maintained a gross margin of 61% consistent with the same period in the prior year. During the three months ended December 31, 2024, the company recorded a \$114,645 release in inventory provision due to revised obsolescence estimates, compared to a \$192,771 release in the same period of 2023. Gross margin fluctuations are primarily influenced by product mix by type and geography.

Total operating expenses decreased by 15% to \$3,679,798, compared to \$4,320,052 for the same period of the prior year. A significant portion of this decrease is related to the restructuring of the sales and marketing teams, which was completed in the first quarter of the prior fiscal year.

The operations department covers expenses related to quality control, quality assurance, production, and regulatory activities. Operations expenses decreased to \$371,069 compared to \$630,713 in the same period of the prior year, due to higher costs related to sustaining engineering costs in the prior period.

Research and development expenses increased to \$373,339 compared to \$311,411 in the same period of the prior year primarily due to higher patent & trademark costs as the costs can vary by quarter and fiscal year due to the timing and region of the renewals.

Sales and marketing expenses decreased 27% to \$1,209,820, compared to \$1,646,303 in the same period of the prior year. This decrease is attributed to the restructuring of the sales and marketing teams, which was completed in the first quarter of the prior fiscal year.

General and administrative expenses remained flat, decreasing by \$6,055 to \$1,725,570 compared to \$1,731,625 in the same period of the prior year. Wages, benefits, and consulting fees included non-cash share-based compensation expenses of \$90,523, down from \$115,929 in the prior year. These costs reflect outstanding stock options and deferred share units (DSUs) and their respective fair values.



Related Party Transactions

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

	Three months ended December 31	
	2024	2023
Compensation and short-term employee benefits	\$395,293	\$315,035
Share based payment expense	73,343	56,191
	468,636	371,226

The Company had previously accrued \$667,969 for termination benefits related to a former senior management team member during the last fiscal year. The amount continues to represent management's best estimate of the termination benefits owed. On April 5, 2024, this former senior executive filed a claim for wrongful dismissal. An additional amount of \$1,832,031 has been claimed, which the Company has not accrued for and believes to be unwarranted. There can be no assurance as to the final outcome of the claim and termination benefits owed.

During the year end September 30, 2013, a non-interest-bearing loan of \$50,000 was made to a key employee. As of December 31, 2024, \$10,000 of this loan remained outstanding.

Gain / Loss on Finance Lease Receivable

During the first quarter of 2024, the Company entered into two sublease agreements for a total of 10,451 square feet out of a total of 18,246 square feet that comprises its Seattle facility. Both subleases are considered finance leases as it was reasonably certain that the sublease term will match that of the Company's existing lease agreements to April 2026. As a result of these transactions the company recognized a finance lease receivable at the inception of the subleases in the amount of \$610,088 with an offsetting gain recognized in the condensed consolidated interim statements of operations and comprehensive income (loss).

On December 19, 2024, one sublease tenant notified us of their intention to terminate their sublease early, providing a 60-day notice. The tenant will be vacating the premises on February 28, 2025. This has resulted in a loss on the finance lease receivable of \$149,690 for the three months ended December 31, 2024.

Share-based Payments

The Company operates a long-term incentive plan under which the Company issues equity instruments of the Company as consideration in exchange for employee or director services (the "Plan"). The Plan is open to eligible directors and employees of the Company. The Plan regulates the issuance of the following equity instruments: stock options, deferred share units ("DSUs") and restricted share units ("RSUs").

Stock options currently outstanding vest over three or four years and have a contractual life of between five and ten years. Each tranche in an award is considered a separate award with its own vesting period and grant date fair value. The fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. Compensation expense is recognized over the tranche's vesting period



using the graded vesting method by increasing the contributed surplus based on the number of awards expected to vest. For performance-based stock options these are measured at the grant date fair value of the awards and are recognized over the vesting period of four years on a straight-line basis. The Company employs the Monte Carlo simulation model to determine the fair value of performance-based stock options, due to the model's ability to incorporate the complexities and specific conditions of these awards.

For each DSU or RSU granted under the Plan, the Company recognizes an expense equal to the market value of a common share of the Company (the "Common Shares") at the date of grant based on the number of DSUs or RSUs expected to vest, recognized over the term of the vesting period, with a corresponding credit to contributed surplus for share-based compensation anticipated to be equity settled or a corresponding credit to a liability for those anticipated to be cash settled. Share-based compensation expense is adjusted for subsequent changes in management's estimate of the number of DSUs or RSUs that are expected to vest, for DSUs or RSUs anticipated to be cash settled and changes in the market value of common shares. The effect of these changes are recognized in the period of the change. Vested DSUs or RSUs are settled either in common shares or in cash or a combination thereof at the discretion of the Company.

Potential Impact of Tariffs on Operations

On February 1, 2025, President Trump signed an executive order imposing a 25% tariff on goods imported from Canada and Mexico, effective February 4, 2025. In response, the Government of Canada announced retaliatory tariffs on certain US goods, which will be implemented in phases starting February 4, 2025. Mexico has also indicated it may impose retaliatory tariffs but has not yet announced specific measures. Additionally, the US has imposed a separate 10% tariff on imports from China. To allow time for negotiations, all three North American governments have agreed to a temporary 30-day pause on the tariffs.

The Company's operations may be impacted by tariffs, potentially affecting pricing and demand dynamics. The overall economic impact remains uncertain and will depend on the severity and duration of the tariffs. The Company is actively monitoring the situation and has identified strategies to mitigate risks, with several options available to minimize the impact of any potential future tariffs.

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 audited consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from estimates and such differences could be material.

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. If the recoverable amount of the respective non-financial asset is less than its carrying value, 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 for a variety of factors, including expiry dates and the timing of forecasted revenue by product. In many cases, produce 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 with six months of period end. To the extent that actual losses on inventory obsolescence differ from those estimated, inventory, net income (loss), and comprehensive income (loss) will be affected in future periods.

Accounting pronouncements issued but not yet effective

The IASB has issued classification, measurement and disclosure amendments to IFRS 9, Financial Instruments and IFRS 7, Financial Instruments: Disclosures with an effective date for annual reporting periods beginning on or after January 1, 2026. The amendments clarify the date of recognition and derecognition of some financial assets and liabilities and introduce a new exception for some financial liabilities settled through an electronic payment system. Other changes include a clarification of the requirements when assessing whether a financial asset meets the solely payments of principal and interest criteria and new disclosures for certain instruments with contractual terms that can change cash flows (including instruments where cash flows changes are linked to environment, social or governance targets).

IFRS 18, Presentation and Disclosure in Financial Statements (IFRS 18) is a new standard that will provide new presentation and disclosure requirements and which will replace IAS 1, Presentation of Financial Statements (IAS 1). IFRS 18 introduces changes to the structure of the income statement; provides required disclosures in financial statements for certain profit or loss performance measures that are reported outside an entity's financial statements; and provides enhanced principles on aggregation and disaggregation in financial statements. Many other existing principles in IAS 1 have been maintained. IFRS 18 is effective for years beginning on or after January 1, 2027.

IFRS Accounting Standards and amendments issued but not yet effective have not yet been assessed.



Summary of Quarterly Results and Financial Position

	2025 First Quarter	2024 Fourth Quarter	2024 Third Quarter	2024 Second Quarter	2024 First Quarter	2023 Fourth Quarter	2023 Third Quarter	2023 Second Quarter	2023 First Quarter
Revenue	\$ 8,165,980	\$ 8,867,558	\$ 9,224,307	\$ 8,413,610	\$ 4,663,057	\$ 6,895,248	\$ 6,270,039	\$ 7,244,594	\$ 6,185,405
Net income (loss))								
before amortization and depreciation	1,463,171	864,959	1,694,466	1,708,174	(611,349)	(2,665,562)	(230,583)	(464,757)	(130,736)
Net income (loss)	1,206,046	612,867	1,448,050	1,460,418	(851,543)	(2,880,329)	(501,767)	(698,081)	(380,821)
Net earnings (los per share	s) 0.04	0.02	0.06	0.06	(0.03)	(0.12)	(0.02)	(0.03)	(0.02)
Cash	17,497,607	16,746,781	9,406,600	7,259,953	8,292,480	8,794,650	9,190,108	10,766,955	14,062,520
Net working capital	28,098,110	25,042,594	18,814,985	16,869,077	14,760,153	16,102,617	18,638,806	20,038,162	21,609,848
Current ratio	8.1	7.3	5.2	6.8	4.8	4.1	5.4	5.4	5.2

Revenue of the Company continues to be inherently unpredictable due to our business model and fluctuates from quarter to quarter.

Liquidity & Capital Resources

	December 31, 2024	September 30, 2024
Cash and cash equivalents	\$17,497,607	\$16,746,781
Total assets	\$34,816,921	\$31,806,574
Deferred revenue	\$ -	\$72,082

On December 31, 2024, cash and cash equivalents totaled \$17,497,607 compared to \$16,746,781 at September 30, 2024. During the three-months ended December 31, 2024, the Company generated a total of \$750,826 in cash compared to a cash outflow of \$502,170 in the prior year.

Accounts receivable on December 31, 2024, increased by \$1,711,344 from September 30, 2024. The timing of cash flows from customers remains variable due to payment terms, which may include upfront advances, payments on shipment, as well as standard and extended credit terms. The Company also mitigates credit risk by utilizing Export Development Canada ("EDC") insurance and accepting letters of credit for larger transactions to ensure collection certainty.

Inventories as of December 31, 2024, increased by \$874,830 compared to September 30, 2024, driven by fluctuations in sales timing, customer order patterns, and adjustments to the supply network.



Prepaid expenses decreased by \$234,703 from September 30, 2024, primarily due to reduced advance payments for inventory purchases. These fluctuations reflect standard operational adjustments to meet customer demand and ensure supply continuity.

Accounts payable and accrued liabilities increased by \$52,405 from September 30, 2024, primarily due to the timing of sales, customer orders, and adjustments to the supply chain.

Total assets as of December 31, 2024, were \$34,816,921, up from \$31,806,573 on September 30, 2024, with cash and cash equivalents comprising 50% of total assets. Accounts receivable and inventories are considered liquid assets, with collection periods and turnover ratios generally within the 30- to 90-day range. Other assets include property, plant, equipment, and intangible assets, which represent key intellectual property that supports the Company's revenue-generating activities, albeit with lower liquidity.

The Company actively monitors its working capital to ensure sufficient cash and cash equivalents are available to meet operational needs and capital expenditure commitments. Contractual obligations, including lease liabilities and accounts payable and accrued liabilities, are due within one year and are 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	3,380,618	3,380,618	3,380,618	-	-
Lease liabilities	784,672	653,287	434,715	218,572	-
Total	4,165,290	4,033,905	3,815,333	218,572	-

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 of December 31, 2024, the Company had a total of 27,398,077 Common Shares issued and outstanding.

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

Security Type	Number Outstanding
Common Shares	27,418,077
Options	1,302,500
Warrants	200,000
Deferred Shared Units	280,000



Sources and Uses of Cash and Cash Equivalents

	Three months ended December 31,	
	2024	
		_
Cash flows generated by (used in) operating activities	124,531	95,041
Cash flows used in investing activities	(192,122)	(89,639)
Cash flows from financing activities	(116,045)	(150,047)

Operating Activities

Cash generated in operating activities for the three months ended December 31, 2024, was \$124,531, compared to cash generated of \$95,041 in the prior period. Non-cash working capital used \$1,588,593 during the three months ended December 31, 2024, compared to \$1,100,240 generated in the prior year. At December 31, 2024, accounts receivable used cash of \$1,500,680 compared to cash generated of \$2,707,881 primarily due to the timing of sales relative to the period end and customer payment patterns.

As of December 31, 2024, the company's cash used for inventories increased to \$490,795, compared to \$110,936 in the prior year, reflecting fluctuations driven by the timing of sales, customer order patterns, and adjustments in the supply network. Inventories can also be affected by the timing of sales, customer order patterns, and changes in the supply network which the Company monitors and adjusts for in the normal course of operations. Prepaid expenses resulted in cash generation of \$262,005 during the three months ended December 31,2024, compared to cash used of \$197,091 in the prior year, primarily due to decreased advance payments for inventory purchases. The timing of such payments to suppliers can impact prepaid expense balances, which the Company monitors and adjusts as part of its routine operations.

Investing Activities

Cash used in investing activities for the three months ended December 31, 2024, was \$192,122, compared to cash used of \$89,639 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 of patents and trademarks. For the three months ended December 31, 2024, the Company made investments of \$108,947 in property, plant and equipment, as compared to \$74,215 in the comparable period. This reflects continued efforts to enhance the production capacity of the in-house manufacturing operations. Additionally, the Company invested \$83,175 in intangible assets during the year, compared to \$18,364 in the prior year, as part of its ongoing commitment to improving its information systems infrastructure

Financing Activities

During the three months ended December 31, 2024, total cash flow used for financing activities was \$116,045, compared to \$150,047 in the prior year. In the current year, cash outflows for financing activities included \$181,745 in lease liability payments, partially offset by \$65,700 generated from finance lease receivables. In the prior year, financing activities included \$179,144 in lease liability payments, offset by \$29,097 generated from finance lease receivables.



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-GAAP Financial Measures

In this MD&A, we refer to terms that are not specifically defined under IFRS Accounting Standards 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 Accounting Standards measures. The non-GAAP 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 Accounting Standards. 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-GAAP measures used by other companies thereby diminishing their utility.

i) Working Capital

The Company's working capital is a non-GAAP 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-GAAP metric used by management to evaluate business performance 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 Accounting Standards in the consolidated financial statements to Adjusted Gross Margin for the three months ended December 31, 2024 and 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	Three months ended		
		December 31,		
	2024	<u>2024</u> <u>2023</u>		
Gross profit before operating expenses	\$4,994,466	\$2,848,537		
Add: Depreciation and amortization	69,625	52,548		
Add: Inventory provisions (reversals)	(114,645)	(192,771)		
Adjusted Gross Margin	4,949,446	2,708,314		
Adjusted Gross Margin (%)	61%	58%		

iii) Adjusted EBITDA

The Company's Adjusted EBITDA is a non-GAAP metric used by management to evaluate the Company's earnings or loss. We define Adjusted EBITDA as net income (loss) before finance expense (income), depreciation and amortization, share-based payment expenses, inventory provisions (reversals), accounts receivable write-offs, gain (loss) on finance lease receivable and loss (gain) on disposal of property and equipment.

The table below provides a reconciliation of net income (loss) under IFRS Accounting Standards in the unaudited condensed consolidated interim financial statements to Adjusted EBITDA for the three months ended December 31, 2024. Management believes that these non-GAAP 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	
		December 31,
	<u>2024</u>	<u>2023</u>
Net income (loss)	1,206,046	(851,543)
Add: Net finance income	(41,068)	(9,964)
Add: Depreciation and amortization	257,125	240,194
Add: Share based compensation	90,523	115,929
Add: Inventory provision reversals	(114,645)	(192,771)
Add: Impairment of intangible assets	-	74,448
Add: (Gain)/loss on finance lease receivable	149,690	(610,008)
Adjusted EBITDA	1,547,671	(1,233,715)

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.

A number of broad geopolitical and/or economic elements could have a negative impact on our Company. These include trade protection measures such as the imposition or increase in tariffs, changes in global trade laws and policies, import and export licensing, shifts in exchange rates and/or interest rates, inflationary pressures, changes in tax laws (both foreign and domestic), difficulties associated with transacting business with parties in a foreign jurisdiction including increased costs and uncertainties associated with enforcing contractual obligations, and unexpected or unfavorable changes in other regulations.

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 has been at an elevated level in the past few years. 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 income for the three months ended December 31, 2024 of \$1,206,046, and a net income for the year ended September 30, 2024 of \$2,669,792. 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 30% of the presently issued and outstanding Common Shares). The Goldfarb Corporation and its affiliates collectively beneficially own, control, or direct 4,601,563 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.



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 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;
- 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. From time to time, additional modifications to our products may be made after they have received FDA clearance or approval, in circumstances where the Company believes 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 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.

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 timeconsuming, 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 Accounting Standards. 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.