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Zacks Small-Cap Research

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Covalon Technologies Ltd (CVALF-OTC)

AquaGuard More Than Doubles U.S. Sales, Moves Covalon Closer to Sustained Profitability

We forecast Covalon to generate revenue and EPS of C$55.3M and C$0.09 in 2019 and C$65.9M and C$0.27 in 2020. We value Covalon using a combination of P/S and P/E methodologies. Based on analyst's revenue and EPS estimates of publicly traded companies in focused on wound care and medical supplies, infection control and vascular products, we calculate fair value of Covalon at ~C$10.9/share, or US$8.00 based on current exchange rates.

Current Price (05/31/19)	$3.50
Valuation (U.S.$)	**$8.00**

OUTLOOK

Q2 results were both relatively very strong and, in our opinion, very encouraging – particularly as it relates to contribution from AquaGuard, the acquisition (which closed 10/1/18) of which brought a complimentary product portfolio and a U.S. sales force with a client base of 1,500 hospitals.

Q2 total revenue was $13.3M, up 132% yoy, +82% sequentially and well ahead of our $9.5M estimate. Revenue through the first six months was $20.6M, an increase of $8.5M, or 70%, from 1H'18. AquaGuard accounted for $6.6M, or 78% of that revenue growth.

The main goals of the AquaGuard acquisition were to diversify geographical revenue – from Covalon's previous heavy reliance on the Middle East to now a greater contribution from the U.S – as well as to reach a point of sustained and continuously improving profitability. With 60% of revenue coming from the U.S. since the acquisition closed – up from 31% in the comparable prior-year period, geographical revenue diversification has already been accomplished.

Meanwhile, sustained and growing profitability is clearly on the forefront of management's priority list. Excluding acquisition-related expenses, including approximately $1.5M in Q2'19, profitability appears as if it would already be on the way to showing significant improvement.

SUMMARY DATA

52-Week High	**$7.12**
52-Week Low	**$2.55**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**1,480**
Shares Outstanding (mil)	**22**
Market Capitalization ($mil)	**$78**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**35.4**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**67.3**
P/E using 2019 Estimate	**52.2**
P/E using 2020 Estimate	**17.5**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue

(in '000s of C$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	6.4 A	5.7 A	7.9 A	6.7 A	26.7 A
2019	7.3 A	13.3 A	13.6 E	21.2 E	55.3 E
2020					65.9 E
2021					70.7 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.02 A	-$0.02 A	$0.09 A	-$0.03 A	$0.07 A
2019	-$0.09 A	-$0.01 A	$0.07 E	$0.12 E	$0.09 E
2020					$0.27 E
2021					$0.35 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Fiscal Q2 2019 Results

Covalon Technologies (CVALF / COV.V) reported financial results for their fiscal 2019 second quarter ending March 31st and provided a business update. Relative to the financials, results were both relatively very strong and, in our opinion, very encouraging – particularly as it relates to contribution from AquaGuard, the Seattle-based medical technology company that Covalon recently acquired. As a reminder, AquaGuard brought a complimentary product portfolio and a U.S. sales force with a client base of 1,500 hospitals. The acquisition closed on October 1, 2018 and was very rapidly integrated into Covalon's operations.

Q2 total revenue was $13.3M (all referenced currency is Canadian $ unless otherwise noted), up 132% yoy (from $6.4M in Q1'18), +82% sequentially (from $7.3M in Q1'19) and well ahead of our $9.5M estimate. Revenue through the first six months was $20.6M, an increase of $8.5M, or 70%, from 1H'18. AquaGuard accounted for $6.6M, or 78% of that revenue growth.

The main goals of the AquaGuard acquisition were to diversify geographical revenue – from Covalon's previous heavy reliance on the Middle East to now a greater contribution from the U.S – as well as to reach a point of sustained and continuously improving profitability. With 60% of revenue coming from the U.S. since the acquisition closed – up from 31% in the comparable prior-year period, geographical revenue diversification has already been accomplished. For additional context in this regard, AquaGuard-related revenue accounted for 53% of total U.S. sales through the first six months of fiscal 2019 and was responsible for 76% of U.S. revenue growth (as compared to the first six months of fiscal 2018).

Revenue from the U.S. and the Middle East were $6.9M and $6.2M in Q2'19, accounting for 52% and 47% of total sales, respectively. This compares to $1.5M (U.S.) and $4.1M (M-E) in the prior-year periods, which accounted for respective contributions to the total of 26% and 72%. U.S and Middle East revenue were $12.4M and $7.8M in the first six months of the current year, as compared to $3.7M (+235%) and $8.0M (-2.5%) in the year-earlier period.

Management reiterated their previously issued guidance of achieving more than $25M in sales from the U.S. in 2019 – a goal which is nearly already 50% accomplished. And while Covalon did not specifically reiterate their previous guidance of generating approximately $30M of sales from the Middle East in 2019, they did note that they expect much of the deliveries in that territory to happen during Q4. We note that Middle East revenue was well ahead of our $3.9M estimate in Q2 and while we have updated our quarterly cadence, our total 2019 revenue estimate of approximately $29M from the Middle East remains largely unchanged. This reflects a portion of the ~$100M of competitively bid contracts that Covalon recently secured from that part of the world. This total is expected to be recognized as revenue over the next two and one-half to three years.

Meanwhile, sustained and growing profitability is clearly on the forefront of management's priority list. Operating loss was ~$100k and $1.7M in the three and six months ending 3/31/19, which compares to operating income of ~$500k in Q1'18 and break-even operating income through the first half of fiscal 2018. But, excluding acquisition-related expenses, including approximately $1.5M in Q2'19, profitability appears as if it would already be on the way to showing significant improvement since the company acquired AquaGuard.

As it relates to the operational update…

Importantly, management indicated on the Q2 call that the integration of the two companies has gone smoothly and educating the new customer base (of ~1,500 hospitals) of (legacy) Covalon's products (including their flagship IV Clear adhesive antimicrobial used to protect IV access sites) is well underway. While Covalon cautioned that the sales process as it relates to hospital customers can be somewhat lengthy (which we can attest to being the case for most medical technologies), that initial purchasing of the company's products from (legacy) AquaGuard's customer base has already begun.

And in addition to further productivity gains from the complimentary product portfolios and related synergies (such as similar customer call points) from combining of the two companies, we continue to see other near-term growth catalysts as well. This includes product sales contribution from other geographies, namely Europe and Latin America. Adoption of Covalon's advanced wound care products by U.K.-based acute care facilities and Clinical Commissioning Groups, along with expanding the company's reach into other countries, should benefit European sales. And sales in Latin America could accelerate as the company makes a more determined effort to compete for contracts in the seven countries in that part of the world where they currently have a presence. Additional licensing agreements related to the company's medical coating technologies represents another possible near-term growth opportunity.

Financial Model Updates

We have updated our model following the reporting of fiscal Q2 results. We now model fiscal 2019 revenue of $55.3M (revised from $53.4M), which includes $25.4M (revised from $24.0M) and $29.1M (revised from $28.7M) in sales from the U.S. and Middle East, respectively. We continue to anticipate some moderate gross margin benefit from direct sales of AquaGuard products but also believe this will be more than offset by lower margin sales to the Middle East. We currently model gross margin of 68% (revised from 67%) for the full year 2019, down from 74% in 2018. Our operating expense forecasts account for the incremental expenses related to AquaGuard as well as increasing agency fees related to Middle East contract sales. Our current estimates result in an operating margin of 4.9% (revised from 7.4%) and net income and EPS of $2.0M (revised from $3.0M) and $0.09 (revised from $0.13) in fiscal 2019 (versus $1.6M and $0.07 in fiscal 2018). We show significantly greater improvement in profitability and EPS in 2020 as the operating leverage benefits of the new-normal, higher revenue levels become more pronounced.

Valuation

We value Covalon using a combination of price/sales (based one one-year forward sales) and price/earnings (based on two-years forward EPS) methodologies. We use two-years forward EPS as it more fully captures the anticipated operating leverage of the new-normal, higher revenue levels. Based on analyst's revenue and EPS estimates of publicly traded companies focused on wound care and medical supplies, infection control and vascular products (see table near end of report), we calculate fair value of Covalon at approximately $11.0/share in Canadian dollars and, based on the current exchange rate (i.e. US$1/C$1.35), approximately $8.06 in U.S. dollars (which we round to $8.00/share).

BACKGROUND

Covalon's Products and Distribution

Covalon's products fall within three main categories; advanced wound care, infection protection and perioperative care. The company has regulatory clearances on ~25 medical device product families encompassing approximately 150 separate stock keeping units (SKUs). In addition to their suite of currently marketed products, Covalon has (per their fiscal Q1'19 MD&A, filed 2/26/19) several new product candidates under development that they believe could be filed for regulatory clearances within the next two years' time.

Covalon's products are sold in the U.S. and internationally by third-party distributors. The company also sells certain of their products and out-licenses their technologies to large medical companies under OEM arrangements (whereby the purchaser sells the products under their own brand names).

Covalon's acquisition of Seattle-based AquaGuard, which closed on October 1, 2018, brought complementary infection control products as well as a U.S. sales force, which counts as many as 1,500 hospitals and clinics as customers. This direct sales force supplements Covalon's already established U.S. distribution network which we expect will result in margin enhancement as well as product cross-selling opportunities. Similarly, Covalon will look to sell AquaGuard's products internationally through the company's existing distribution network.

Advanced Wound Care dressings

Covalon's advanced wound care product line encompasses a variety of wound dressings including collagen-based dressings (with and without silver), foam dressings, alginate dressings, hydrophilic layered dressings and hydrocolloid dressings. The composition of these dressings has been well established as providing functional utility towards facilitating wound healing of advanced wounds, such as DFUs, venous leg ulcers and severe burns. As we explain later in this report, advanced wound dressings account for a significant portion of sales of the total advanced wound care product market.

Covalon's 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

Source: Covalon's 2018 MD&A, SEDAR

ColActive Plus and ColActive Plus Ag (i.e. with silver) collagen-based dressings are the company's 'flagship' wound care products. These dressings, which actively interact with the wound to promote healing, are used to facilitate closing of chronic, hard-to-heal wounds. These dressings contain three important ingredients which work together to promote wound healing; collagen, ethylenediaminetetraacetic acid (EDTA) and carboxymethyl cellulose (CMC). Before we explain the role that each of these plays in wound healing, we first discuss some of the biology of chronic wounds.

Matrix metalloproteases' effects on wound healing…

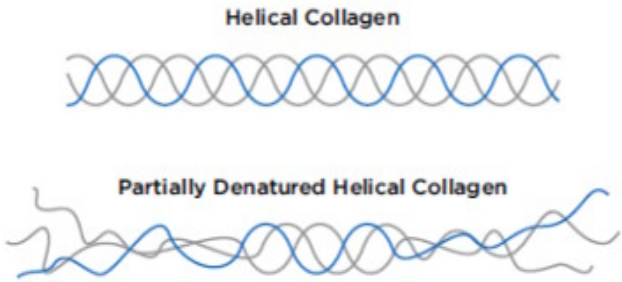
Matrix metalloproteases (MMPs) are specific proteases (i.e. enzymes) found in wound beds. Of the 23 MMPs known to exist, four are believed to play a role in wound healing; MMP-1, MMP-2, MMP-8 and MMP-9. MMPs facilitate wound healing by breaking down foreign material and certain proteins associated with the normal healing process. But, at higher levels, MMPs actually inhibit wound healing by destroying essential proteins such as collagen, growth factors and newly formed extracellular matrices (ECM).

In acute, or normal-healing wounds, proteases initially increase but then reduce, thereby promoting the healing process. But, in chronic wounds, MMPs rise to higher levels and persist for longer periods (called Elevated Protease Activity or EPA), creating an environment in which the wound fails to fully heal. As such, healing of chronic wounds often requires minimizing EPA. In fact, a study has shown that if EPA is present, there is a 90% chance that the wound will become chronic (i.e. non-healing within four weeks).[1] Covalon's ColActive Plus and ColActive Plus Ag use collagen, EDTA and CMC to control MMPs and promote wound healing.

Collagen's role in wound healing…

Collagen (derived from the Greek word for glue), which is the most prevalent protein in humans and the main component of structural tissue, plays an important role in all phases of wound healing, including fibroblast proliferation and re-epithelization. It contains three polypeptide chains which are twisted around each other to form a triple helix. Collagen dressings are one of the most commonly used advanced wound care products. Collagen in these products is typically either native (i.e. 'type I'), in which the triple helix is intact, or denatured, whereby heating is used to uncoil the helix.

Per Covalon's product descriptions of their collagen matrix products (ColActive Plus and ColActive Plus Ag), their patented manufacturing process produces a crosslinked matrix of collagen containing both native and random coil configurations of collagen chains (image below). This partial unwinding of the collagen triple helix, per Covalon, exposes a greater proportion of the polypeptide sequence to potential interactions with wound site components, thereby improving healing capacity.



Source: Covalon

Collagen in wound dressings such as ColActive Plus and ColActive Plus Ag acts as a sacrificial substrate to elevated MMP levels. So, instead of destroying the collagen in the wound bed, MMPs bind to the collagen in the wound dressing, thereby sparing the essential building blocks of the wound healing process.

Ethylenediaminetetraacetic acid's (EDTA) role in wound healing…

MMPs contain a zinc atom, a necessity for them to be active. EDTA has strong binding affinity for metal ions including iron, calcium and zinc. ColActive Plus (Ag) is thereby able to deactivate MMPs through the use of EDTA, which removes the zinc ions.

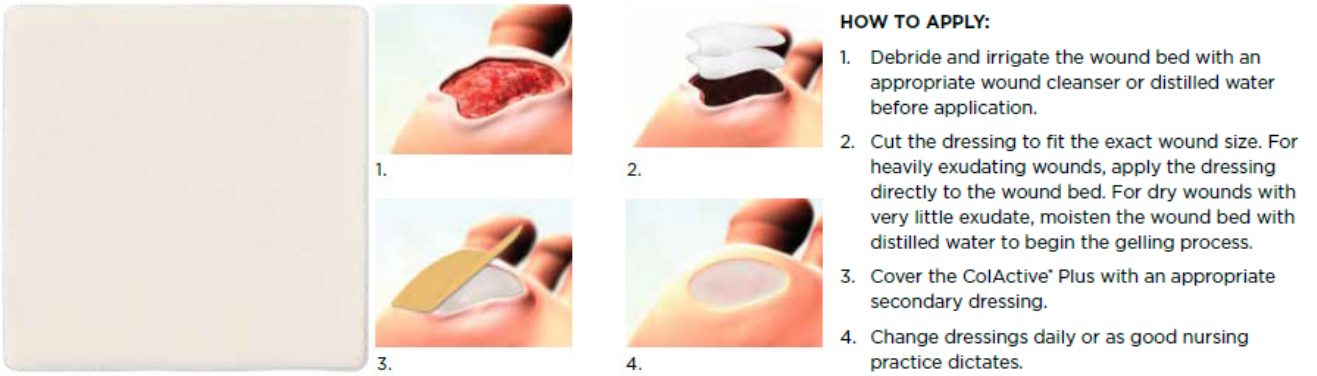
Carboxymethyl cellulose's (CMC) role in wound healing…

Carboxymethyl cellulose is a water-soluble carbohydrate polymer derived from cellulose with highly absorptive and conformable properties. CMC facilitates wound healing by keeping the wound bed moist and absorbing exudate, including inflammatory cells, which has been shown to facilitate wound reepithelization.[2]

ColActive Plus received FDA 510(k) clearance in April 2005. The 510(k) FDA Summary document describes it as "an advanced wound care dressing composed of collagen and sodium alginate provided in a sterile sheet or rope form. ColActive Collagen Wound Dressings are pliable, absorbent dressings that absorb moisture such as wound fluid forming a gel, thus maintaining a moist environment at the wound surface that aids in the formation of granulation tissue and epitheliazation. The dressings can be cut to specific wounds and are to be layered for the management of deeps wounds."

[1] Serena T, Cullen B, Bayliff S, et al. Protease activity levels associated with healing status of chronic wounds. Poster presented at: SAWC, Baltimore, 2012.
[2] Richters, C. et al. Effects of a hydrofiber dressing on inflammatory cells in rat partial-thickness wounds. Wounds 16, 63–70 (2004).

ColActive Plus Dressing and Instructions For Use



Source: Covalon website, Product information

It is indicated "for the management of full and partial thickness wounds including: pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular etiologies, venous ulcers, second degree burns, donor and graft sites, abrasions, dehisced surgical wounds [and] traumatic wounds healing by secondary intention".[3]

Reimbursement: Covalon's product information on their website cites HCPCS (Medicare) codes A6021, A6022 and A6023 for reimbursement of ColActive Plus (as well as for ColActive Plus Ag), which refers to different sizes of collagen dressings. Medicare/CMS "A" codes typically do not require clinical trial data.

ColActive Plus Ag received FDA 510(k) clearance in June 2005. The 510(k) FDA Summary document describes it as "an advanced wound care dressing composed of collagen, sodium alginate and silver chloride provided in a sterile sheet or rope form. ColActive AgTM Collagen with Silver, Antimicrobial Dressings are pliable, absorbent dressings that absorb moisture such as wound fluid forming a gel, thus maintaining a moist environment at the wound surface that aids in the formation of granulation tissue and epithelialization. The dressings act as an effective barrier to bacterial and fungal penetration. The silver content is intended to prevent colonization of the dressing. The dressings can be cut to fit specific wounds and are able to be layered for the management of deep wounds." It is indicated for the same types of wounds and injuries as ColActive Plus.

CovaWound includes ten different types of wound dressings which are designed as highly absorbent, waterproof dressings which act to retain exudate and maintain a moist environment. An example of the CovaWound product line is CovaWound Silicone Self-Adherent Soft Silicone Foam Dressing with Border which, per the description in Covalon's product information literature, is an "atraumatic dressing consisting of a soft silicone adhesive that does not stick to the surface of a wound or cause epidermal stripping or pain upon removal. Its absorbent core consists of a polyurethane foam and a non-woven fabric to lock in exudate and prevent the wound bed from drying out and the surrounding skin from becoming macerated. The outer surface of the product is a vapor-permeable membrane, which acts as a barrier to liquid and microorganisms." FDA premarket notification was not required for Covalon to be able to market the CovaWound product line which, unlike ColActive Plus, does not contain collagen.

[3] FDA 510(k) Summary #K050177. January 24, 2005



Source: Covalon

Reimbursement: Covalon's product information on their website cites HCPCS codes specific to foam dressings, adhesive bandages, alginate dressings (specific to CovaWound Alginate), specialty absorptive dressings and hydrocolloid dressings (specific to CovaWound Hydrocolloid).

Infection Protection products

The company's infection protection segment refers to the their 'IV Clear', 'SilverCoat Foley Catheter' and MediClear Pre-Op antimicrobial products.

Covalon's Infection Protection Products

Infection Management Products	
IV Clear	Antimicrobial clear silicone adhesive vascular access dressing with chlorhexidine and silver
MediClear Pre-Op	Antimicrobial silicone film for pre-operative skin
SilverCoat Foley Catheter	Silicone Foley catheter with silver

Source: Covalon's 2018 MD&A, SEDAR

IV Clear is used to secure, protect and disinfect vascular access catheters' insertion sites, which are notorious for causing catheter related blood stream infections (CRBSIs). CRBSIs are a significant concern for hospitals and serious problem associated with the use of vascular access catheters, which "pose a greater risk of device-related infections than any other types of medical device and are major causes of morbidity and mortality".[4] IV Clear is made of soft silicone, to maximize comfort on the fragile skin surrounding access sites, and embedded with two antimicrobials; chlorhexidine and silver, which per the product's literature, have been proven to kill 99.99% of the microorganisms most commonly associated with CRBSIs.

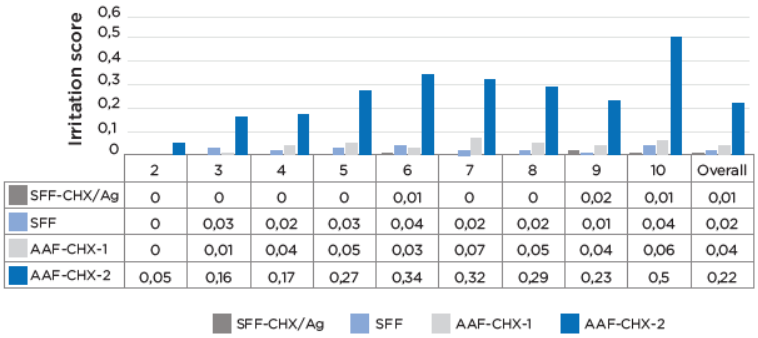
IV Clear is the only adhesive antimicrobial on the market today that uses silicone, the technology around which was developed and patented by Covalon. All competing products use acrylic as their adhesive. The difference can be significant as it relates to patient comfort as well as risk of infection. While both generally sufficiently secure the respective drapes, acrylic is much more difficult to remove from the skin (with bonding strength actually increasing the longer it remains in place) than is silicone. This can lead to Medical Adhesive Related Skin Injuries (MARSI), which are painful and, as a result of damage to the skin, increases susceptibility to infection. As such, MARSI can be more than a small annoyance, particularly when frequent dressing changes are necessary. Studies have shown that MARSI is a relatively common occurrence and complication associated with dressing changes. In fact, Farris et al. found that approximately 13% of admitted patients will experience an occurrence of MARSI on a daily basis.[5]

Another study, sponsored by Covalon, showed that skin irritation among individuals that received an antimicrobial silicone-based film dressing (i.e. IV Clear) was many times less severe than among those that received an acrylic-

[4] Gahlot R., et al. Catheter-related bloodstream infections. Int J Crit Illn Inj Sci. 2014 Apr-Jun; 4(2): 162–167.
[5] Farris MK et al., Medical Adhesive-Related Skin Injury Prevalence Among Adult Acute Care Patients: A Single-Center Observational Study. J Wound Ostomy Continence Nurs. 2015 Nov-Dec;42(6):589-98. doi: 10.1097/WON.0000000000000179.

based dressing.[6] The study included 216 individuals and a total of nine (i.e. repetitive) applications of test dressings over a three week period with the goal of comparing skin irritation and pain associated with the respective adhesive products. Results showed that IV Clear (SFF-CHX/Ag in the charts below) was associated with significantly less irritation ($p<0.05$) as compared to the acrylic adhesive products (AAF-CHX-1 and AAF-CHX-2 in the charts below). IV Clear was also associated with approximately 10x less pain (significantly less, $p<0.05$) upon removal than that of the acrylic adhesive product.

IV Clear's silicone adhesive associated w/ significantly less irritation (L) and pain (R) as compare to acrylic dressings



	2	3	4	5	6	7	8	9	10	Overall
SFF-CHX/Ag	0	0	0	0	0,01	0	0	0,02	0,01	0,01
SFF	0	0,03	0,02	0,03	0,04	0,02	0,02	0,01	0,04	0,02
AAF-CHX-1	0	0,01	0,04	0,05	0,03	0,07	0,05	0,04	0,06	0,04
AAF-CHX-2	0,05	0,16	0,17	0,27	0,34	0,32	0,29	0,23	0,5	0,22

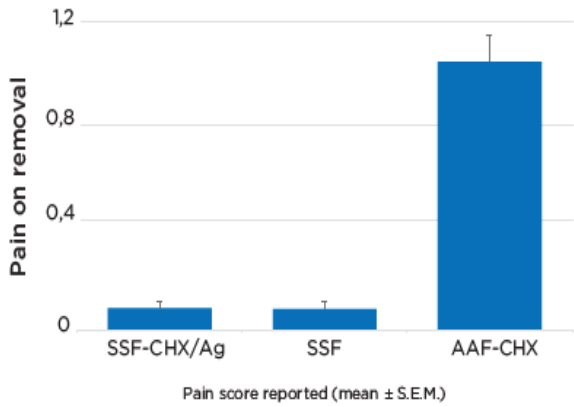
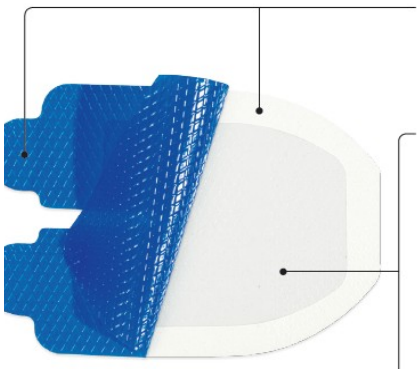


Figure 2: Mean irritation score3 results from each Study Visit and overall. There is a significant difference between SSF-CHX/Ag and SSF versus AAF-CHX-2 at each evaluation and overall. A significant difference is seen between SSF-CHX/Ag and SSF versus AAF-CHX-1 at Study Visit 4 and 7.

Source: Val DiTizio, Covalon

Reports of skin related injuries associated with certain adhesive films, including competitors to IV clear, also appear to be fairly common. FDA's Manufacturer and User Facility Device Experience (MAUDE) database houses incidence reports of medical devices. We queried incidence reports for Covalon's IV Clear product and again for Tegaderm, a competing product made by 3M which uses an acrylic adhesive, for the period June 2012 (the month following IV Clear's FDA clearance) through January 2019. While IV Clear returned zero incident reports, Tegaderm returned 125. While we note that not all 125 reports are related to cases of MARSI, our random perusal found several that were. As a result of less associated pain, irritation and MARSI, we think Covalon's patented silicone adhesive (in addition to its dual antimicrobials; chlorhexidine and silver) provides them and their IV Clear product with a potentially very potent competitive advantage.

IV Clear



CONVENIENT
- 2 piece liner and tabbed paper frame for easy application
- Window delivery for positioning accuracy
- Easy to apply
- All-in-one securement system minimizes training requirements

ANTIMICROBIAL PROTECTION
- Transparent and breathable film with dual antimicrobials – chlorhexidine and silver, embedded in the soft silicone adhesive[4]
- Provides antimicrobial protection throughout the entire surface area for up to 7 days[3,9]
- Kills on average 99.99% of bacteria and yeast commonly associated with CRBSIs[9]

SOFT SILICONE ADHESIVE
- Allows visibility of insertion site
- Reduces pain and trauma at dressing changes[2,5-8]
- Highly breathable, constantly transfers excess moisture[4]

EXTERNAL PROTECTION
- Barrier to external contamination[4]
- Fluid impermeable[4]



Synergystic Antimicrobial Protection

IV Clear™ has the unique advantage of two antimicrobial agents, chlorhexidine and silver. The synergistic effect of chlorhexidine and silver kills 99.99% of microorganisms most commonly associated with CRBSI and prevents regrowth for up to 7 days.[1,2] Furthermore, it serves as a barrier against external contamination, such as exogenous bacteria and fluid.[2]

Source: Covalon

IV Clear, which **received 510(k) FDA clearance in May 2012,** is "intended to cover and protect insertion sites, and secure devices to skin. Common applications include IV catheters, central venous lines, PICCs, suction catheters, epidural catheters, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices. IV Clear inhibits microbial growth within the dressing and prevents external contamination."

Reimbursement: Covalon's product information on their website cites HCPCS codes specific to 'supplies for maintenance of non-insulin drug infusion catheter' and 'transparent film, sterile'.

[6] Val DiTizio, Covalon Technologies. A Human Repeat Patch Test Study

SilverCoat Foley Catheter

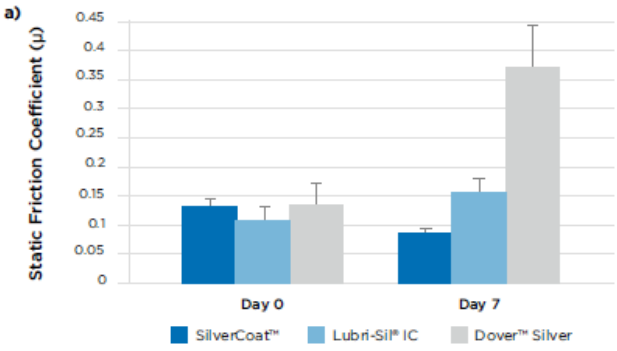


Source: Covalon

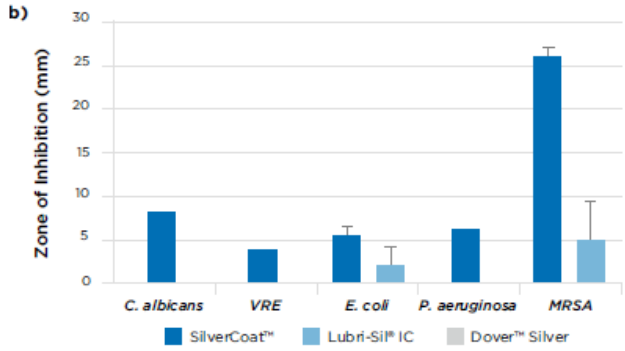
SilverCoat, Covalon's silver-embedded silicone Foley urinary catheter, has a lubricious coating impregnated with silver ions. The SilverCoat technology, per the product literature, "utilizes an advanced, patented surface modification process that permanently binds with the catheter at the monomer level for improved functionality and performance."

Per Covalon's product literature (we do not have access to the detailed study design or results), **SilverCoat outperformed competing silver coated Foley catheters** including Bard's Lubri-Sil IC and Covidien's Dover Silver as measured by lubricity and antimicrobial protection. While SilverCoat maintained its lubricity over seven consecutive days, the competing catheters experienced a reduction in lubricity over the same time period (chart a). In addition, SilverCoat was associated with significantly less ($p<0.05$) CAUTI-related microbes when tested with an antimicrobial assay as compared to both other products (chart b). And finally, adhesion and growth of P. aeruginosa (an organism commonly isolated from CAUTI patients) was almost nil with SilverCoat but substantial on Bard's and Covidien's catheters (Figure 2).

SilverCoat's superior lubricity



SilverCoat's superior antimicrobial properties



Source: Covalon, SilverCoat Product Info

SilverCoat's superiority on biofilm attachment and growth

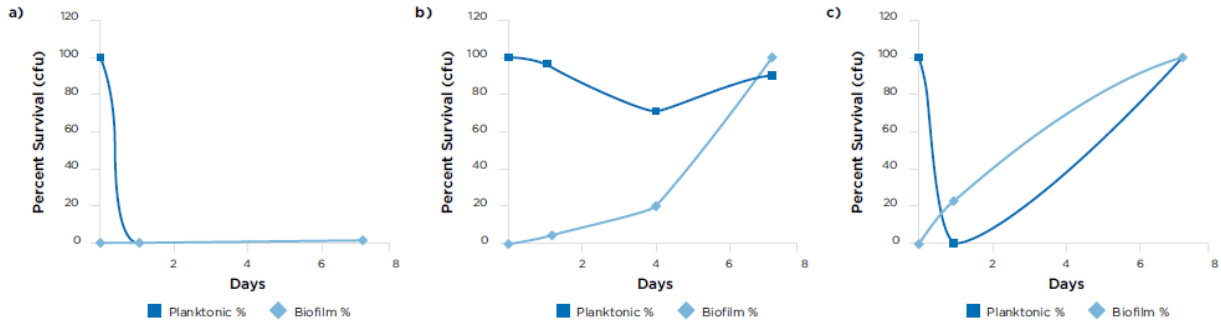


Figure 2: Planktonic and Biofilm percentage measured on **(a)** SilverCoat™ compared to **(b)** Bard's Lubril-Sil' and **(c)** Covidien's Dover™ shows that CovaCoat™ virtually eliminates the attachment and growth of *P. aeruginosa* in this biofilm adhesion assay over a 7-day period.

Source: Covalon, SilverCoat Product Info

SilverCoat, which received FDA 510(k) clearance in November 2015, is "to be used as a urological catheter inserted through the urethra to pass urine from the urinary tract by individuals that are ≥ 30kg and over 12 years of age. SilverCoat Silicone Foley Catheters should not be used on patients with known hypersensitivity or allergy to silver or silver-containing organics or inorganics."

Reimbursement: Covalon's product information on their website cites an HCPCS code specific to 'indwelling catheter, foley type, two-way, all silicone'.

MediClear Pre-Op is a clear polyurethane film which is coated with an antimicrobial silicone adhesive containing the disinfectant chlorhexidine and antimicrobial silver salts. FDA 510(k) cleared in September 2017, it is indicated "for use as a pre-operative (incision/insertion) drape that provides continuous antimicrobial activity to reduce the risk of contamination of the skin site by acting as an external barrier to microbial and other contamination. MediClearPreOp can be left on the preoperative incision site for up to 7 days. MediClear PreOp is intended to be used on intact skin and for external use only."[7]

MediClear Pre-Op



Source: Covalon

Acting as a physical barrier against external bacteria and other infectious threats, the chlorhexidine and silver salts incorporated into MediClear Pre-Op have been shown to eliminate 99.99% of application-related microorganisms within 10 minutes of exposure. This is Covalon's first product that directly addresses the multibillion-dollar pre-surgical skin antisepsis market.

It is the only OTC product currently available that has dual antimicrobial protection and the only adhesive pre-surgical antimicrobial on the market (and, similar to Covalon's other products, uses a silicone adhesive). It is cleared for sale directly to patients (i.e. over the counter) as well as to institutional accounts, such as hospitals and clinics.

Surgical and Perioperative Care products

Covalon's surgical and perioperative care products includes 'SurgiClear', 'MediClear Post-Op Absorb' and 'MediClear Scar'. As the product category name implies, these products are generally used during and/or after surgery. These products also use a silicone adhesive.

Covalon's Surgical and Perioperative Care products

Surgical and Peri-Operative Products	
SurgiClear	Antimicrobial clear silicone adhesive post-surgical dressing with chlorhexidine and silver
MediClear Post-Op Absorb	Self-adherent silicone dressing with absorbent pad
MediClear Scar	Self -adherent silicone dressing for scar care

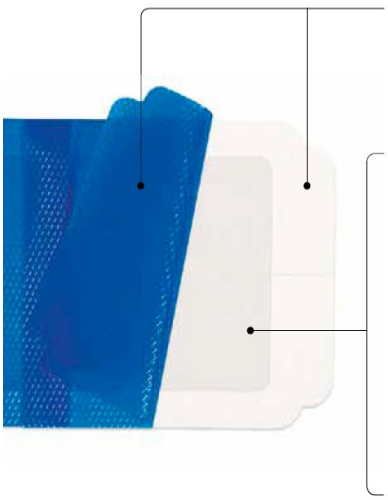
Source: Covalon's 2018 MD&A, SEDAR

SurgiClear contains the disinfectant chlorhexidine and antimicrobial silver. It is the only antimicrobial post-surgical dressing that allows for surgical site visibility – a potentially significant competitive advantage as it does not require removal of the dressing in order to monitor the wound for possible complications.

SurgiClear has been proven to kill 99.99% of the microorganisms most commonly associated with surgical site infections (SSIs) and prevent their regrowth for up to seven days. FDA 510(k) cleared in August 2012, SurgiClear is intended to be used "to cover and protect a wound caused by percutaneous medical devices such as drains, chest tubes, orthopedic pins, fixtures, and wires. SurgiClear may also be used to cover and secure primary dressing. SurgiClear inhibits microbial growth within the dressing and prevents external contamination."[8]

[7] FDA 510(k) Summary. Sept 14, 2017
[8] FDA 510(k) Summary. Aug 13, 2012

SurgiClear



CONVENIENT
- 2 piece liner and tabbed paper frame for easy application
- Window delivery for increased positioning accuracy
- Transparency allows for continuous visualization of the area
- Easy to apply and use, conforms well to body contours of multiple site areas

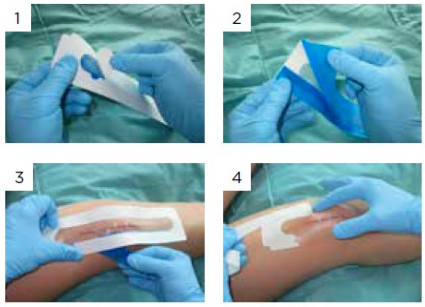
ANTIMICROBIAL PROTECTION
- Transparent and breathable film with dual antimicrobials – chlorhexidine and silver, embedded in the soft silicone adhesive
- Provides antimicrobial protection throughout the entire surface area for up to seven days[2]
- Dual antimicrobials kill 99.99% of bacteria and yeast commonly associated with SSIs[2]

SOFT SILICONE ADHESIVE
- Allows visibility of the incision site
- Highly flexible over joints
- Non-sensitizing, reduces pain and trauma at dressing change[2, 4-11]
- Leaves no residue and is easy to remove
- Highly breathable, constantly transfers excess moisture[13]

EXTERNAL PROTECTION
- Barrier to external contamination[2]
- Fluid impermeable and waterproof[13]

HOW TO APPLY:

1. Remove the centre window of the paper backing.
2. Hold the flap of the top blue liner and peel off. Place the exposed adhesive on the skin and smooth the dressing over the skin.
3. Hold the flap of the remaining blue liner and peel off and smooth the dressing over the skin towards the edges.
4. To remove frame; start from the pre-cut line, peel off in a circular motion and smooth the dressing towards the edges to ensure good adhesion.

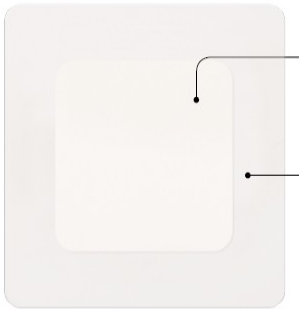


Source: Covalon. SurgiClear Product Info.

Reimbursement: Covalon's product information on their website cites HCPCS codes specific to 'transparent film, sterile'.

MediClear Post-Op Absorb is an absorbent, bacteria proof, self-adherent silicone border dressing which can be used for a variety of exuding wounds, including those following surgery. **MediClear Scar** is a thin, discreet, clear medical self-adherent silicone dressing of polyurethane film coated with solt silicone adhesive gel that adheres to the contours of scars. It is used to help prevent hypertrophic and keloid scars.[9] FDA premarket notification was not required for either MediClear Post-Op Absorb or for MediClear Scar. Covalon notes that MediClear is the only pre-surgical drape that fully protects patients before surgery.

MediClear Post-Op Absorb



HYDROPHILIC FOAM PAD
- Fast and effective absorption of wound fluid.
- Flexible over joints (hips, knees, etc).

TRANSPARENT POLYURETHANE BACKING FILM
- Barrier against external contamination.[3]
- Highly breathable.
- Waterproof, can be worn in the shower.[3]
- Allows visibility of wound fluid.

SOFT SILICONE ADHESIVE
- Gentle but secure adhesion.
- Can be worn for up to 7 days.

MediClear Scar

POLYURETHANE FILM BACKING
- Thin and discreet.
- Conformable.
- Breathable with good moisture vapour exchange.
- Effective barrier against external contamination.
- Waterproof.

SOFT SILICONE CONTACT LAYER
- Adheres gently but securely to scar tissue and skin.
- Ensures removal with minimal pain and trauma.
- No extra fixation required.

Source: Covalon. Product Information documents

AquaGuard Acquisition Brings Complementary Products, U.S. Sales Force: *Expected to Significantly Steepen Revenue, Earnings Growth*

In fiscal Q2 2018 (ending March 30, 2018) Covalon formed a Special Committee of the Board to evaluate certain potential growth initiatives, potentially including acquisitions, strategic alliances and partnerships aimed at maximizing shareholder value. Less than six months after that committee was formed, Covalon pulled the trigger on a major acquisition.

[9] MediClear Post-Op Absorb, MediClear Scar product information

Covalon's acquisition of AquaGuard, a Seattle-based business of medical technology company, Cenorin, closed on October 1, 2018. AquaGuard brings complementary infection control products as well as a U.S. sales force, which counts as many as 1,500 hospitals and clinics as customers. Their products are sold through a 25-person, experienced direct sales team as well as through a specialty distributor network. AquaGuard's product line of infection protection products aimed at both the professional healthcare setting as well as the consumer market, looks to be a seamless fit with Covalon's existing product portfolio, which is also targeted to the hospital segment and with similar call points. And while Covalon had previously relied on third-party distribution to detail their products in the U.S., AquaGuard's sales force should mean margin enhancement as well as substantial product cross-selling opportunities related to Covalon's infection control products (such as IV Clear). Similarly, we expect Covalon will look to sell AquaGuard's products internationally through the company's existing distribution network.

Per Covalon's press release in September 2018 announcing the definitive acquisition agreement, AquaGuard generated $11.1M (US ~$8.5M) in revenue and $683k (US $526k) in profit before taxes in their 2017 fiscal year ending 12/31/17.

The $16.1M (US $12.375M) purchase price will be paid in cash and stock and allocated as follows (subject to working capital adjustments);

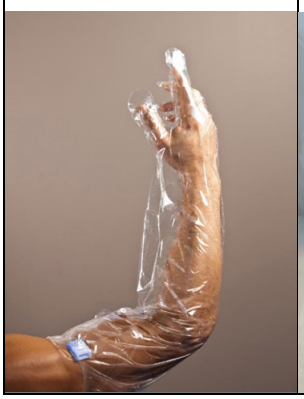
- $4.7M (US $3.612M) in cash at closing
- $0.65M (US $500k) worth of shares of Covalon common stock at closing, which will be held in escrow (i.e. locked up) for up to two years
- $3.32M (US $2.552M) in cash payable within 12 months of closing (i.e. by 9/30/19)
- $6.5M (US $5M) in cash payable within 24 months of closing (i.e. by 9/30/20)
- $0.92M (US $705k) payable at closing by issuance of shares to management and key staff related to certain liabilities

…in addition, AquaGuard shareholders were eligible to receive up to $1.17M (US $900k) upon the achievement of certain (undisclosed) revenue targets by 12/31/18. This was achieved and Covalon made the payment in fiscal Q2 2019.

Covalon expects the bolt-on sales from AquaGuard to more than double their U.S. revenue, which accounted for ~48% of the company's total sales in 2018. Management is guiding for U.S. sales, which were $12.8M in 2018, to grow to more than $25M in fiscal 2019. Additional upside related to AquaGuard could come from organic and/or synergistic growth from that business.

AquaGuard's products

AquaGuard's product lines consist of waterproof disposable moisture barriers for infection protection of; surgical incisions, intravenous sites, catheters, peripherally inserted central catheter (PICC) lines, dialysis catheters, orthopedic casts, transdermal patches and other wounds and dressings. Most of their products can be used in both the professional healthcare setting as well as in a patient's own home.

AquaGuard Glove: designed with the assistance of clinicians in hospitals to protect IV, surgical and wound sites when patients shower.	**AquaGuard Boot:** disposable waterproof barrier which is simple to apply with no assistance needed, allowing for patient independence while showering.	**AquaGuard sheet (4"x4"):** a waterproof disposable moisture barrier for small surgery sites, transdermal patches, Broviac catheters, tube thoracostomies, pediatrics.	**AquaGuard sheet (5"x5"):** a waterproof disposable moisture barrier for small surgery sites, pediatrics, Hickman catheters, ports, stomas.	**AquaGuard sheet (7"x7"):** a waterproof disposable moisture barrier for peripheral lines, small surgery sites, transdermal patches, pediatrics.
				

AquaGuard sheet (9"x9"): a waterproof disposable moisture barrier for PICC lines, Hickman catheters, ports, stomas, dialysis lines, IJ catheters	**AquaGuard sheet (10"x12"):** a waterproof disposable moisture barrier for PICC lines, stomas, Knee/hip or shoulder incisions, dialysis catheters, ostomies.	**AquaGuard sheet (12"x14"):** a waterproof disposable moisture barrier for knee/hip or shoulder incisions, ostomies, large dressings or surgery sites.	**AquaGuard sheet (7"x22"):** a waterproof disposable moisture barrier for back surgery sites, long narrow surgery sites, sternotomies.	**AquaGuard sheet (12"x24"):** a waterproof disposable moisture barrier for abdominal incisions, large dressings or surgery sites, mastectomies, orthopedic incisions, ostomies.
				

Source: product descriptions and images from aqua-guard.com

MARKETS

Advanced Wound Care: DFU particularly problematic in Saudi Arabia and other Arab countries

The chronic, advanced wound care market is big and growing. While it also includes venous and pressure ulcers, the vast majority of the chronic wound market is represented by diabetic foot ulcers. Approximately 30M Americans and 415M people worldwide have diabetes and prevalence is on the rise, with almost 2M new cases diagnosed each year in the U.S. An estimated 9.5% of Americans currently have diabetes – this is expected to grow to as much as 33% by the year 2050.

Diabetic foot ulcers afflict roughly 15% - 25% of all diabetics within their lifetimes. Approximately 1.5 million diabetic foot ulcers occur every year in the United States, with an estimated 6.5M Americans suffering from the condition at any given time. And while problematic in the U.S., incidence in the Middle East, where Covalon has experienced particularly strong demand for its advanced wound care (and infection protection) products, is even higher. Of the top ten countries with the highest prevalence of diabetes, six are in the Middle East. Moreover, among all Arab countries, prevalence of DFU was found to be the highest in Saudi Arabia (i.e. a particularly significant territory for Covalon). In fact, prevalence of DFU in Saudi Arabia (~11.9%) is nearly three times as high as that of Egypt, the Arab country with the second highest prevalence (4.2%).[10]

DFU is usually a progressive condition and can worsen very rapidly over time. If the wound is not controlled within a short period (~ 4 weeks), the risk of infection, hospitalization, amputation and death escalates. This not only puts the patients' health at risk, it can also dramatically increase the cost of treatment. As such, effective and timely therapy that closes the wound and facilitates complete healing is critical in order to avoid long-term complications, potentially including amputation. DFU precedes over 80% of all non-traumatic lower-limb amputations among diabetics, leading to more than 80k amputations annually. Clinical studies have shown that comprehensive foot programs (including advanced therapies) can reduce amputation rates by 45% to 85%.

Diabetic foot ulcer



Source: Medscape

The cost of addressing diabetic foot ulcers can also be very costly. Depending on the source, the cost of care of diabetic foot ulcers can vary significantly, but generally falls somewhere between $7k and $60k per ulcer (the discrepancy largely due to whether amputation is required) and $25B in aggregate in the U.S. The annual direct cost of care of DFU to Medicare alone could be as much as $2.2B. When considering private payers and ancillary costs such as lost work time, the total cost of DFU in the U.S. is likely in the many tens of billions of dollars. As such, payers

[10] Mairghani M. et al. The prevalence and incidence of diabetic foot ulcers among five countries in the Arab world: a systematic review. J Wound Care. 2017 Sep 1;26(Sup9):S27-S34.

and providers, in addition to patients, have an economic interest in effective DFU therapy.

Standard of care for treating advanced wounds, which typically includes dressing the wound and possibly the use of a walking boot, remains the most commonly prescribed first-line therapy and has been shown to be effective for early-onset (i.e. - acute) ulcers. However, a considerable amount of clinical trial data from over the last 20 years has proven that standard of care is significantly less effective in healing more severe (i.e. older, larger) wounds and earlier intervention is positively correlated with improved patient outcomes.

The body of evidence strongly supports the use of more effective (i.e. advanced) therapies at an earlier stage of treatment in order to reduce the risk of acute wounds becoming chronic and increase the likelihood of chronic wounds fully healing. A retrospective analysis of clinical trial data of 622 patients with chronic DFUs prescribed standard of care showed 31% (139 of 450) of patients achieved complete healing after 12 weeks. This fell to 24% (41 of 172) of patients where standard of care was continued for 20 weeks.[11]

Advanced wound dressings, such as collagen and hydrocolloid matrices and those incorporating hydrogels, hydrophilic foam, alginates and silver are generally considered second-line therapy after standard of care. Advanced wound dressings account for a significant portion of the overall advanced wound care market, global sales of which totaled $2.6B (US) in 2015 and are expected to expand at a CAGR of 9% over the next decade.[12]

Advanced dressings have a variety of advantages over conventional wound bandages including providing a moist environment, superior absorbency, can be left on the wound for longer duration, easier removal and antimicrobial properties.

Infection Protection

Approximately 1B peripheral intravenous (PIV) and central venous catheters (CVC) are used worldwide each year, including ~300M in the U.S. In addition, 100M indwelling urinary catheters are sold globally each year, including 25M sold in the U.S. The large size of these markets coupled with the high risk of infection of both types of catheters make these attractive growth opportunities for Covalon in our opinion.

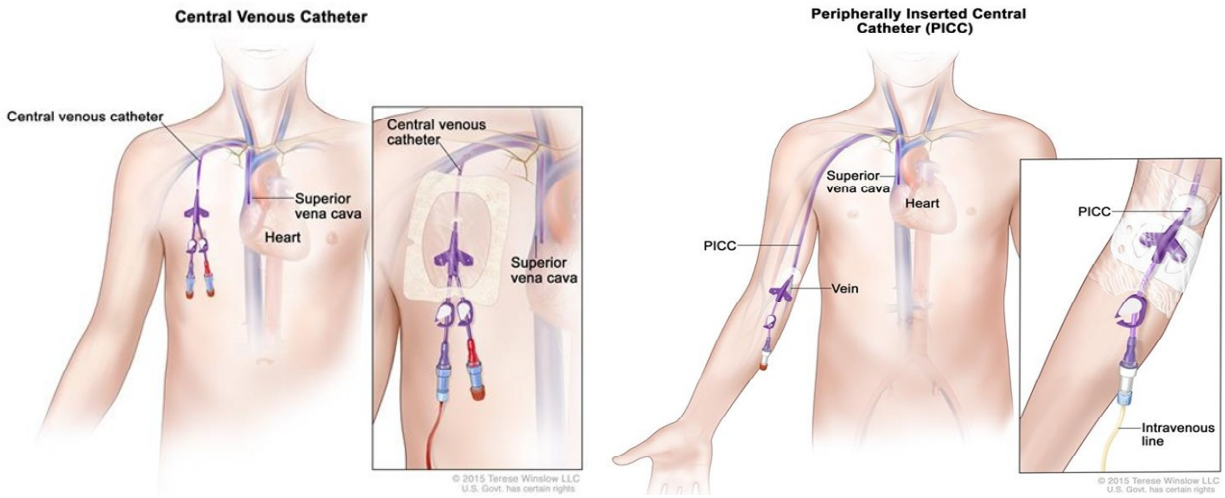
Venous lines consist of a flexible plastic tube which is inserted into a vein for the purpose of delivering fluids or drugs. The other end, where the fluids or drugs are administered, remains outside of the body. As these catheters can remain in place for extended periods of time (particularly as it relates to CVCs), their point of entry into the body is highly susceptible to infection. This risk of infection can be further exacerbated if the adjacent skin becomes irritated as a result of removal of film dressings which, as we explained earlier, is a relatively common occurrence when acrylic adhesive dressings are used.

Cather-related infections, particularly those associated with central venous catheters, are relatively common. Of the approximately 7M central venous lines used in the U.S. (~30M WW) each year, approximately 500k (~2M WW) will become infected. While the rate of infection of PIVs is substantially lower than that of CVCs, the relatively massive number of peripheral intravenous catheters inserted each year (for context, ~50% - 80% of all inpatients receive a PIV) means that the total number of PIV infections is about the same as that of CVCs. Of the 300M PIVs used in the U.S. (700M WW) each year, approximately 530k (~1.1M WW) will become infected.

Catheter-borne infections, including catheter-related bloodstream infections (CRBSI), are a significant problem associated with the use of catheters. In fact, Gahlot et al. found that central venous lines "pose a greater risk of device-related infections than any other type of medical device and are major causes of morbidity and mortality."[13] Approximately 12% - 15% of central line-associated bloodstream infections (CLABSI) result in death. A separate (8 year) study found that skin flora migrating down the PIV catheter tract accounted for the greatest number of hospital-acquired S. aureus bloodstream infections.[14]

Catheter-associated infections are also costly to treat, adding as much as $50k per occurrence, on average, of incremental cost to the healthcare system.[15] Catheter-related infections are the most costly, per incident, of all hospital-acquired infections and add nearly $2B of cost to the U.S. healthcare system each year.

[11] Margolis D, et al. Healing of neuropathic ulcers receiving standard treatment: a meta-analysis. Diabetes Care 1999;22(5):692-695
[12] Meddevicetracker
[13] Gahlot R. et al. Catheter-related bloodstream infections. Int J Crit Illn Inj Sci. 2014 Apr-Jun; 4(2): 162–167.
[14] Mestre G, Berbel C, Tortajada P, et al. Successful multifaceted intervention aimed to reduce short peripheral venous catheter-related adverse events: A quasiexperimental study. Am J Infect Control. 2013;41: 520-526.
[15] O'Grady, N. et al. Guidelines for the Prevention of Intravascular Catheter-Related Infections. U.S. Centers for Disease Control and Prevention. Aug 9, 2002

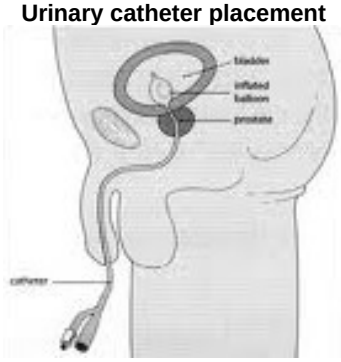


Source: NCI

The market for Covalon's SilverCoat silver-embedded silicone Foley urinary catheter is represented by the 100M indwelling catheters sold each year, 25M of which are sold in the U.S. Foley catheters consist of two channels that run the length of a flexible tube, which is inserted into the urethra (or, in some cases, through an incision directly into the bladder). One channel drains urine from the bladder while the other is used to inflate a balloon (via sterile water pumped through the channel) at the end of the tube, which helps to anchor the catheter inside the bladder.

These catheters can relatively easily become infected from bacteria moving along both the inside and outside of the tube and into the urinary tract and bladder. These infections, called 'catheter associated urinary tract infections' (CAUTI), can result in severe pain and eventual damage to the bladder and kidneys. Bladder and kidney damage can have very serious consequences, including resulting in death. As of 2002 (the most recent year of available statistics), catheter induced infections were believed to have caused more than 10k deaths in the U.S.

Urinary catheter placement



Source: UroToday

One of the most common ways to address the risk of CAUTI is through the use of antiseptic and antimicrobial coated catheters, including those impregnated with silver. However, some studies have indicated that these anti-infective catheters provide no significant benefit[16] while others have shown that they were actually associated with higher rates of serious infections versus standard coated catheters.[17] Note, however, that these referenced studies, which were published in December 2012 and April 1995, did not use Covalon's SilverCoat catheter, which received FDA 510(k) clearance in November 2015.

As we noted earlier, per Covalon's product literature, SilverCoat outperformed competing silver coated Foley catheters, including Bard's Lubri-Sil IC and Covidien's Dover Silver, as measured by lubricity and antimicrobial protection. The relatively novel nature of Covalon's silver catheter, its superiority to competing products (based on the company's evaluation) and significant unmet need to better address risk of CAUTI provides the company with a potentially potent opportunity to take significant share of the sizeable Foley urinary catheter market.

Healthcare facilities have financial incentive to prevent HAIs, most of which are addressed by Covalon's products…
Approximately 1.7M cases of hospital-acquired infections occur each year in the U.S. and studies have shown that about 70% of these are preventable. Moreover, cost of readmissions due to hospital-acquired infections is nearly triple that of readmission unrelated to HAIs. Approximately $9.8B is spent every year in the U.S. to address hospital-acquired infections. **Recent changes in Medicare and private insurers' reimbursement policies related to hospital-acquired infections means that healthcare providers have an even greater incentive to minimize their associated risk.** In 2015 the Centers for Medicare and Medicaid Services (CMS) implemented a program whereby hospitals are financially penalized for adverse patient outcomes – key metrics are rates of

[16] Pickard, R. et al. Types of urethral catheter for reducing symptomatic urinary tract infections in hospitalised adults requiring short-term catheterisation: Multicentre randomised controlled trial and economic evaluation of antimicrobial- and antiseptic-impregnated urethral catheters (the CATHETER trial). Health Technol Assess 2012;16(47)
[17] Riley, DK. et al. A large randomized clinical trial of a silver-impregnated urinary catheter: Lack of efficacy and staphylococcal superinfection. The American Journal of Medicine, April 1995Volume 98, Issue 4, Pages 349–356

CRBSI, catheter-associated urinary tract infections and CLABSI. Most private insurers implemented their own policy changes and, generally, will now also not reimburse providers for hospital-acquired infections.

In addition to catheter-associated infections, surgical site and ventilator-associated infections are other relatively common and costly hospital-acquired infections, costing approximately $21k and $40k per incidence, respectively, on average to treat. In aggregate, catheter-associated (CVC, PIV and UT), surgical site and ventilator-associated infections account for 85%, or $8.3B, of the total cost of all hospital-acquired infections, all of which are addressed by Covalon's products. C**oupled with healthcare facilities' incentive to prevent these, we think this provides an enormous opportunity for Covalon.**

OUTLOOK, MODEL ASSUMPTIONS and VALUATION

A look back…

Covalon generated sales of just $6.6M and incurred a net loss of $3.2M, or $0.27/share, in fiscal 2016. But, catalyzed by new product launches and securing of large international tenders, the company saw revenue jump 315% to $27.3M and net income spike to $1.8M, equal to $0.09/share in 2017. Those contract wins included a tender (announced May 2016) for IV Clear and SurgiClear from a large, ~1,500-bed hospital located in Mecca, Saudi Arabia, a $3.5M contract (announced August 2016) to supply IV Clear to Saudi Arabia's Ministry of Health (announced August 2016) and a $7.6M 12-month contract (also announced in August 2016) to supply ColActive Plus and ColActive Plus Ag, also to Saudi Arabia's Ministry of Health. In September 2017 Covalon announced they had received $14M of new orders under exclusive contracts from the Middle East.

Interest in Covalon's products has apparently been driven in large part by demand from some of Saudi Arabia's most influential hospitals and key opinion leaders (KOLs). Covalon noted at the time that their IV Clear, SurgiClear and ColActive Plus products had achieved "top brand recognition" in their respective product categories in major hospitals in that country, including leading centers for the treatment of diabetic foot ulcers. Along with hospitals associated with Saudi Arabia's Ministry of Health (i.e. national healthcare system), Covalon noted that they were also winning new and additional business in the private sector.

But the growth experienced in 2017 stalled with revenue contracting 2% in 2018 and net income falling 11% to $1.6M, or $0.07/share. While U.S. revenue jumped 175% from $4.7M in 2017 to $12.8M in 2018, revenue from the Middle East dropped by about 40%, from approximately $22M in 2017 to $13M in 2018. Despite contraction in the topline, Covalon still managed to generate significant positive cash flow. Excluding changes in working capital, which included a $3.1M increase in inventories and $2.4M increase in A/R (both associated with filling contract wins), Covalon generated $3.2M in cash from operations in fiscal 2018, which was actually 20% higher than that of 2017.

Our 2019 Projections…

Management's general guidance implies full year 2019 revenue of at least $55M from the Middle East and U.S. Europe and Latin America could bolster that and soon begin to make a material contribution. Adoption of Covalon's advanced wound care products by U.K.-based acute care facilities and Clinical Commissioning Groups, along with expanding the company's reach into other countries, should benefit European sales. And sales in Latin America could accelerate as the company makes a more determined effort to compete for contracts in the seven countries in that part of the world where they currently have a presence.

Licensing, which generated $5.0M of revenue in 2018 and included the first payment of $3.5M (U.S. or ~C$4.6M) under a licensing agreement with a 'large global medical company', represents potential additional incremental top-line growth. While Covalon did not disclose terms of this agreement, given that they characterized the $3.5M as "the first payment", it implies additional revenue is expected to follow. Moreover, as this agreement relates to the company's patented antimicrobial medical coating technology which is being used in the licensee's medical devices, that may suggest that this could result in a long-term revenue stream for Covalon.

We currently model fiscal 2019 revenue of $55.3M (implying growth of 107%), which includes $25.4M and $29.1M in sales from the U.S. and Middle East, respectively. Our Middle East projection is heavily weighted to Q4, reflective of management's comments (on the Q2'19 call in late-May) relative to the currently anticipated delivery schedule.

While we anticipate some moderate gross margin benefit from direct sales of AquaGuard products, we think this is more than offset by lower margin sales to the Middle East. We currently model gross margin of 68% for the full

year 2019, down from 74% in 2018. Our operating expense forecasts account for the incremental expenses related to AquaGuard as well as increasing agency fees related to Middle East contract sales. **Our current estimates result in an operating margin of 4.9% and net income and EPS of $2.0M and $0.09 in fiscal 2019 (versus $1.6M and $0.07 in fiscal 2018). We show significantly greater improvement in profitability and EPS in 2020 as the operating leverage benefits of the new-normal, higher revenue levels become more pronounced.**

Longer-term: *we see several other potential additional catalysts that could drive long-term growth*

In addition to further maturation of the recently onboarded growth drivers that we detailed above and which we think account for much of the company's incremental revenue over at least the next one to two years, we see several other possible catalysts potentially coming online (or making a more significant impact) and helping to fuel longer-term growth. Included among these are;

- **Additional acquisitions:** Covalon has repeatedly expressed their desire to grow both organically and through acquisitions. In May 2017 they engaged MPA Morrison Park Advisors Inc. to help with their strategic acquisition strategy. Then, in May 2018, Covalon announced the formation of a Special Committee of the Board of Directors to evaluate certain potential growth initiatives, including possible strategic alliances and acquisitions. Their new banking line, through HSBC, includes $9M for an 'acquisition demand line, a substantial portion of which remains unused following closing of the AquaGuard purchase. So, while AquaGuard was the company's most recent, we think it may not be their last and expect the company will remain diligent in evaluating further potential acquisitions.
- **AquaGuard Synergies:** AquaGuard synergies, including cross-selling of their products to Covalon's existing distribution channels and vice versa, provides for another potential growth opportunity. Success in this regard would represent incremental upside to our existing 2019 (and beyond) revenue projections.
- **New Products, Regulatory Approvals and Commercialization Territories:** recent product regulatory approvals and launches include IV Clear (improved version) and several branded MediClear products, the latter which includes U.S. FDA clearance to market to both healthcare clinics and directly to patients (i.e. OTC). Covalon also recently launched their new Centaur Coating technology. In addition to their suite of currently marketed products, Covalon has (per their fiscal Q2'19 MD&A, filed 5/28/19) several new product candidates under development that they believe could be filed for regulatory clearances within the next two years' time. The company is also expanding their geographic footprint. In addition to the U.S. and the Middle East, they recently made investments to expand their presence in Europe and are now in seven countries in Latin America. Covalon has also recently indicated that entry into and contribution from Brazil and Japan could happen by 2020.
- **Licensing agreements:** a licensing agreement signed in August 2018 paid Covalon $4.5M in upfront fees and is expected to provide incremental revenue this fiscal year. While we have no insight, additional licensing deals, if consummated could provide upside to our current forecasts.
- **Halo Effect from Middle East Demand:** we think that there is potential for a halo effect from the sizeable contracts from the Middle East, which is the single most DFU-afflicted part of the world. Key opinion leaders and influential wound care hospitals in Saudi Arabia, which leads the Arab states in DFU prevalence, are significant customers of Covalon's which we think speaks to the quality, performance and overall attractiveness of their advanced wound care product line. Also noteworthy as it relates to this topic is that Covalon won these contracts through what they have described as a "highly competitive bidding process that involved the clinical evaluation of each product."[18] We think these are strong votes of confidence in Covalon's offerings, from presumably highly discerning healthcare practitioners, and as such, believe that they have the potential to drive interest and adoption for their wound care and infection protection products from other parts of the world.
- **Unmet Needs in Sizeable Markets:** the advanced wound care, surgical and infection protection markets are very large and, particularly as it relates to DFUs, intravenous catheters and urinary catheters, are ripe for the adoption of more effective, innovative products. Given the high cost to treat chronic wounds and catheter-related infections and unmet need for products and therapies that can speed healing, reduce amputation rates, minimize risk of CRBSIs and do so more cost-effectively, Covalon's upside market opportunity is enormous.
- **Exploit Products' Cost-Effectiveness:** Covalon's product are almost certainly more cost-effective than many of their competitors'. While we do not have insight into specific cost or pricing data of their products, we are confident that, at least as it relates to their advanced wound care offerings, that they are significantly less expensive than some of their competitors'. For example, ColActive Plus and ColActive Plus Ag, while not considered 'skin substitutes', conventional advanced wound treatment protocol may consider them similar (at

[18] Covalon February 2019 Investor Presentation

least for less severe wounds). Reimbursement for skin substitutes, such as Apligraf (Organogenesis) and Dermagraft (Organogenesis) averages between ~$1,600 and $2,700 – which we think is likely many multiples of the cost of Covalon's products. We think this cost benefit may be particularly beneficial outside of the U.S. and may provide the company with an exploitable advantage.

- **Costly Hospital-Acquired Infections**: another exploitable opportunity, in our opinion, is hospital-acquired infections which cost the U.S. healthcare system nearly $10B each year. Approximately 70% of these are preventable and insurers no longer reimburse healthcare facilities for their cost. Covalon's infection protection products address infections that account ~85% of the total cost of HAI's. We think this presents an opportunity to exploit their products' advantages, including their dual antimicrobials and silicone adhesive, and take market share from competitors.
- **Cash Flow Provides Investment Opportunities:** positive cash flow should provide the company with additional opportunity to reinvest in growth initiatives. Along with new product development and the possibility of one or more additional acquisitions, we could see expansion of their direct sales force.

Valuation

We forecast Covalon to generate revenue and EPS of $55.3M and $0.09 in 2019. We forecast sales to grow another 19% in 2020 to $65.9M and, given expectations that operating leverage becomes more pronounced at these higher revenue levels, model EPS to triple $0.27 that same year.

We value Covalon using a combination of price/sales (based one one-year forward sales) and price/earnings (based on two-years forward EPS) methodologies. We use two-years forward EPS as it more fully captures the anticipated operating leverage of the new-normal, higher revenue levels. Based on analyst's revenue and EPS estimates of publicly traded companies focused on wound care and medical supplies, infection control and vascular products, we calculate fair value of Covalon at approximately $11.0/share in Canadian dollars and, based on the current exchange rate (i.e. US$1/C$1.35), approximately $8.06 in U.S. dollars (which we round to $8.00/share).

	Wound care comps			Medical sup/infection/vascular	
	P/E	P/S		P/E	P/S
			ANGO	21.0	2.1
ANIK	30.0	5.3	BSX	21.1	5.0
MDWD	NA	11.3	CSII	NA	5.5
MDXG	NA	NA	LMAT	27.5	4.5
ORGO	NA	2.5	MDT	17.0	4.1
OSIR	37.6	3.9	MLAB	60.3	9.1
SNN	23.4	3.9	PFN	NA	9.7
SNWV	NA	5.8	TFX	22.5	5.2
Avg.	**30.3x**	**5.4x**		**28.2x**	**5.7x**

Implied CVALF current fair value based on:			
P/S	C$13.9		
P/E	C$7.8		
Avg	**C$10.9**	**=**	**US$8.06**

Covalon Technologies Ltd

In Canadian dollars	2017 A	Q1A	Q2A	Q3A	Q4A	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
Product Revenue	24.7	6.0	5.1	3.1	5.9	20.0	6.4	12.1	12.3	19.8	50.6	57.7	59.9
YOY Growth	330.8%	8.2%	-9.7%	-23.7%	-38.3%	-19.0%	6.4%	138.4%	300.9%	238.5%	153.3%	13.9%	3.9%
% of total revenue	90.4%	93.3%	88.7%	38.8%	88.1%	74.8%	87.5%	91.0%	90.9%	93.7%	91.5%	87.5%	84.7%
Development & consulting fees	$0.9	$0.4	$0.3	$0.3	$0.8	$1.8	$0.8	$0.8	$0.9	$0.8	$3.3	$3.8	$4.6
YOY Growth	1655.5%	5305.7%	199.2%	-42.3%	218.8%	105.8%	107.6%	151.3%	188.0%	6.1%	85.6%	15.1%	22.0%
% of total revenue	3.2%	6.2%	5.7%	3.7%	11.4%	6.7%	11.4%	6.2%	6.3%	3.8%	6.0%	5.8%	6.6%
Licensing & royalty fees	$1.8	$0.0	$0.3	$4.6	$0.0	$5.0	$0.1	$0.4	$0.4	$0.5	$1.4	$4.4	$6.2
YOY Growth	119.5%	-61.5%	18.7%	235.8%	-36.4%	180.9%	152.1%	18.9%	-91.6%	1405.0%	-72.3%	222.0%	40.5%
% of total revenue	6.5%	0.5%	5.6%	57.5%	0.5%	18.5%	1.0%	2.9%	2.8%	2.5%	2.5%	6.7%	8.8%
Total Revenues	$27.3	$6.4	$5.7	$7.9	$6.7	$26.7	7.3	$13.3	$13.6	$21.2	$55.3	$65.9	$70.7
YOY Growth	315.0%	14.2%	-4.6%	34.4%	-32.0%	-2.1%	13.4%	132.4%	70.9%	218.1%	107.0%	19.1%	7.4%
Cost of Goods Sold	$6.3	$1.9	$1.4	$1.4	$2.4	$7.1	$2.7	$4.1	$4.2	$6.7	$17.7	$20.7	$21.9
Gross Income	$21.0	$4.5	$4.3	$6.5	$4.3	$19.7	$4.6	$9.2	$9.3	$14.4	$37.6	$45.1	$48.9
Gross Margin	76.9%	70.9%	75.7%	82.0%	64.3%	73.6%	63.4%	69.4%	68.9%	68.2%	68.0%	68.5%	69.1%
Operations	$1.4	$0.4	$0.5	$0.6	$0.5	$2.0	$0.3	$0.6	$0.6	$0.8	$2.4	$2.7	$2.8
% Ops	5.3%	6.1%	9.0%	7.4%	7.5%	7.4%	4.3%	4.5%	4.5%	4.0%	4.3%	4.1%	3.9%
R&D	$1.1	$0.4	$0.4	$0.4	$0.3	$1.4	$0.4	$0.4	$0.5	$0.6	$1.9	$2.2	$2.4
% R&D	4.1%	5.6%	6.7%	4.6%	4.6%	5.3%	5.2%	3.0%	3.4%	3.0%	3.4%	3.4%	3.4%
Sales, Mktg & Agency fees	$11.5	$2.2	$2.5	$1.5	$2.0	$8.2	$3.3	$5.7	$4.4	$7.2	$20.5	$21.2	$22.3
% SM&A	42.1%	33.7%	43.5%	19.0%	30.5%	30.6%	44.9%	42.5%	32.5%	34.1%	37.2%	32.2%	31.5%
G&A	$5.2	$1.1	$1.4	$1.8	$2.1	$6.5	$2.2	$2.7	$2.2	$3.0	$10.1	$11.9	$12.4
% G&A	18.9%	17.4%	24.8%	23.3%	31.1%	24.1%	30.7%	20.3%	16.2%	14.1%	18.3%	18.0%	17.5%
Operating Income	$1.8	$0.5	($0.5)	$2.2	($0.6)	$1.6	($1.6)	($0.1)	$1.7	$2.8	$2.7	$7.1	$9.1
Operating Margin	6.6%	8.1%	-8.4%	27.7%	-9.3%	6.1%	-21.6%	-0.9%	12.3%	13.0%	4.9%	10.8%	12.8%
Total Other Income (Expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	($0.3)	($0.1)	($0.2)	($0.1)	($0.7)	($0.8)	($0.7)
Pre-Tax Income	$1.8	$0.5	($0.5)	$2.2	($0.6)	$1.6	($1.9)	($0.2)	$1.5	$2.7	$2.0	$6.3	$8.4
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	$1.8	$0.5	($0.5)	$2.2	($0.6)	$1.6	($1.9)	($0.2)	$1.5	$2.7	$2.0	$6.3	$8.4
YOY Growth	-156.7%	-116.3%	-188.2%	364.3%	-214.8%	-10.7%	-467.4%	-51.5%	-33.2%	-531.8%	24.2%	214.2%	32.3%
Net Margin	-	-	-	-	-	-					3.6%	9.6%	11.8%
Diluted EPS	$0.09	$0.02	($0.02)	$0.09	($0.03)	$0.07	($0.09)	($0.01)	$0.07	$0.12	$0.09	$0.27	$0.35
YOY Growth	-132.3%	-89.0%	-186.5%	784.5%	-43.4%	-20.2%	-480.9%	-53.1%	-30.7%	-514.5%	29.5%	199.0%	29.5%

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Diluted Shares O/S	20.8	23.0	21.5	23.2	21.5	23.2	22.2	22.2	22.3	22.4	22.3	23.4	23.9

Brian Marckx, CFA

LEADERSHIP[19]

Management –

Brian Pedlar
Chief Executive Officer
Mr. Pedlar has been President and Chief Executive Officer of Covalon since April 3, 2010 and a member of the Board of Directors since January 14, 2010. Previously, Mr. Pedlar was President of Pedlar Ventures Limited, a private venture investment and consulting firm based in Oakville, Ontario. He has served in senior executive positions with public companies including temporary Chief Financial Officer, Cygnal Technologies Corp., October 2007; President, Cedara Software Corp., 2005 to 2006; Chief Financial Officer, Cedara Software Corp., 2004 to 2005; and Director of Finance, Cedara Software Corp., 2000 to 2004. Mr. Pedlar has also held senior executive positions with Merge Healthcare and IMAX Corporation. Mr. Pedlar holds a Bachelor of Science degree from Mount Allison University, a post-graduate diploma in Accounting from Wilfrid Laurier University and is a Canadian Chartered Accountant.

Dr. Val Ditizio
Chief Scientific Officer
Dr. DiTizio is a co-inventor of Covalon technologies and a co-founder of the company. He has degrees in science from the University of Toronto as a Biochemistry Specialist. Dr. DiTizio completed his Master's degree in liposome drug delivery. His graduate research involved the application of polymer chemistry and drug delivery in pursuit of novel materials and processes that currently comprise the core of Covalon's intellectual property. Dr. DiTizio holds several US and European patents.

Danny Brannagan
Chief Financial Officer
Mr. Brannagan has been managing Covalon's finance team since joining the Company in November 2014. Mr. Brannagan is a Chartered Accountant and Certified Professional Accountant and holds a Bachelors of Commerce degree from Queen's University. Prior to joining Covalon, Danny spent several years with PriceWaterhouse Coopers LLP in the tax and assurance groups advising public and private companies on taxation and financial accounting matters. Prior to joining PriceWaterhouse Coopers LLP Mr. Brannagan was a professional football player with the Toronto Argonauts where he became the first Canadian-born quarterback to play for the Argonauts since 1969.

Kim Crooks
Vice President of Operations
Kim has over 20 years' cross-disciplinary experience in the pharmaceutical and Medical device industries with international and Canadian companies including Baxter, Bristol-Myers Squibb and Vasogen. Kim has extensive Quality Assurance, Quality Control, Regulatory and Clinical Affairs experience in the US, Canada and the EU. Kim joined Covalon Technologies in 2008 and has been improving internal communications and promoting customer relationships. Kim has built up and led cross functional teams to ensure projects meet Customer expectations as well as streamlining the work flow to improve the efficiency and productivity. Kim holds a Bachelor of Science degree from Carlton University.

Hamed Abbasian
Vice President Business Development
Mr. Abbasian is a founding member of Covalon and has been with the Company since its inception. Prior to that he was involved in research with Covalon's core scientific group at the University of Toronto. Mr. Abbasian has degrees in Biology from the University of Toronto and conducted graduate research the University of Toronto, prior to the founding of Covalon. Mr. Abbasian has held multiple roles at the Company and was closely involved in the development and production of Covalon's wound care and infection management platform technologies. He was also involved in the transfer of lab-based prototypes to commercially manufactured products from 2000 until 2011. Since 2011, Mr. Abbasian has been leading business development activities of Covalon aimed at expanding international sales of Covalon's products, including multiple distribution opportunities in the Middle East, United States, and other international jurisdictions.

Greg Leszczynski
Vice President of Human Resources
Joining Covalon in 2018, Mr. Leszczynski brings with him over 20 years of experience in Human Resources within the technology, healthcare, and financial industries. He has broad experience in all key HR areas, has experience managing global Human Resources and practices, and has a passion for developing leadership within organizations. Throughout his career, Mr. Leszczynski has held various progressive HR positions, including Vice President of Human Resources at Merge Healthcare. Mr. Leszczynski holds an Honours Bachelor of Science from the University of Toronto and is a Certified Human Resources Leader (CHRL).

[19] Per Covalon's website

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Board of Directors –

Abe Schwartz
Chairman
Abe Schwartz is the founder and president of Schwartz Technologies Corporation and has been an advisor to Covalon Technologies Ltd. since March 7, 2008. Mr. Schwartz has been actively building and managing companies, from start-up to maturity since his first start-up, Polaris Technology Corporation, a computer software firm which he founded in 1977. In 1993, Mr. Schwartz co-founded The Workflow Automation Corporation. He was involved with Inter-Citic Minerals Inc. in 2001 as an advisor on a mining-related computer project in China. Mr. Schwartz serves as a Member of the Advisory Board at RedHill Biopharma Ltd. Mr. Schwartz has also held executive positions in various public and private companies including, among others, President, CEO and Director of Cedara Software Corp. In addition, Mr. Schwartz is the chairman of the board of Mitec. Mr. Schwartz has over 35 years of experience in launching products, R&D, international distribution agreements, re-organization in large-scale corporations, venture capital financing, and negotiating mergers and acquisitions.

Joseph Cordiano
Principal, Cityzen Development Group
Joseph Cordiano joined Cityzen Development Group, a real estate development company, as a principal in 2006, where he is responsible for the sales and marketing as well as new business development of its Greater Toronto Area projects. During his 21 years of public service as a Member of the Ontario Provincial Legislature, Mr. Cordiano served as the Minister of Economic Development and Trade, GTA Regional Minister, and as a member of the Priorities and Planning Committee of Cabinet. A graduate of the University of Toronto and The University of Toledo, Ohio, Mr. Cordiano holds an MBA with a specialty in marketing.

Brian Pedlar
Chief Executive Officer
(bio above)

Jeffrey Mandel
President and CEO, Mitec Technologies Inc.
Jeffrey Mandel is currently President and Chief Executive Officer of Mitec Technologies Inc., formerly Mitec Telecom Inc. (MTM.h, TSXV). Mitec exited the telecom and satellite and communications area in 2012. From 2013 to 2015, Mitec was involved in development of technology that addresses certain security and privacy risks associated with electronic data transfer. Mr. Mandel has been involved in the high-tech, communications, healthcare and retail industries over his 30-year career and has led capital development activities as well as identified and executed various successful commercialization strategies for companies for which he has been active. Mr. Mandel has broad experience in corporate finance, mergers and acquisitions and investor relationship management throughout his career, having progressed through a number of senior positions at various firms in the Canadian securities industry.

Dr. Ian Brindle
Professor Emeritus at Brock University
Dr. Ian Brindle is currently a Professor Emeritus at Brock University. Dr. Brindle is also the former Vice President of Research, former Dean of Chemistry and has held other academic postings at Brock University since 1968. Dr. Brindle is a professor of Chemistry, holds a Chancellor's Chair in Research Excellence, is a fellow of the Royal Society of Chemistry (UK) and is author of more than 70 publications in analytical chemistry. The University of Manchester awarded Dr. Brindle the degree of Doctor of Science for belonging to that group of scientists who "have distinguished themselves as authorities in the field by their substantial and original contributions to the advancement of knowledge." He also holds a Bachelor of Science from Manchester University and a Masters of Science from Brock University.

Major General Gale Pollock
Army Nurse Corps, CRNA, FACHE, FAAN
Before retiring from the U.S. Army in 2008, Maj. Gen. Gale Pollock served as Commander, US Army Medical Command, and Acting Surgeon General of the Army. In the latter role, she was the first woman or non-physician to hold this role in any of the military services, and managed a $9.7B annual budget. Maj. Gen. Pollock is an adjunct clinical professor of Yonsei University Graduate School of Nursing, owner of Pollock Associates, an LLC doing healthcare consulting, and serves on several scientific advisory boards. Maj. Gen. Pollock was the founding Executive Director of the Louis J. Fox Center for Vision Restoration in Pittsburgh, PA, served as an associate professor at the University of Pittsburgh School of Medicine and School of Nursing, and was an Advanced Leadership Fellow in Harvard University's Advanced Leadership Initiative.

Dr. Myrna Francis
President, Mfran Healthcare Advisory Services
Dr. Myrna Francis is currently the President of Mfran Healthcare Advisory Services. She has an extensive background in healthcare and is well-known in both private and public sectors; her experience spans the international marketplace – Canada, the US, and Europe. She Dr. Francis has previously held positions as the President and CEO of Canada Health Infoway, Vice President, Global Healthcare Sector, at CGI Group Inc., Partner at CSC Healthcare Group, and numerous executive positions with the Ontario Ministry of Health. She has also served as a Board Director for a variety of companies and organizations,

including RxCanada, Allstate Insurance Company of Canada, and Cedara Software Corp. She currently provides strategic advisory services in the public sector and to multinational private sector companies regarding health information technology, business transformation, business and product growth strategies, and innovation as an independent consultant. Dr. Francis holds a Master's Degree in Bio-Psychology and Ph.D. in Medical Sciences, both from McMaster University, and a Multi-Party Negotiations Certification from Harvard Law School.

John Suk

Owner, Altmax Consulting

Mr. John Suk is currently the owner of Altmax Consulting, a Canadian healthcare consulting company. After holding senior executive roles at McNeil Labs (Johnson & Johnson), GlaxoSmithKline plc, and Hoffman La Roche, in 1997, Mr. Suk founded Byk Canada (later known as Nycomed), a subsidiary of German company Byk Gulden. In the fourteen years Mr. Suk served as President and CEO of Nycomed, the company's sales volume blossomed to over $300 million. From 2006 to 2017, Mr. Suk served on the Board of Directors of Brock University and was Chair of Brock's Board of Trustees from 2013 through 2016. He has also served on the Board of Canada's Research-Based Pharmaceutical Companies (Rx&D), a national association representing the voice of Canada's innovative pharmaceutical industry. He has also served on the Boards of the Health Research Foundation, Innovate Niagara, IIX Technologies, Medical Futures, and Exciton Technologies. Mr. Suk holds an Advanced Management Certificate from Insead, the professional ICD.D designation from Rotman School of Management at the University of Toronto, and an H.B.Sc from Brock University.

HISTORICAL STOCK PRICE



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