Covalon Technologies: “You know you’re doing something right when the world leaders come to you.”

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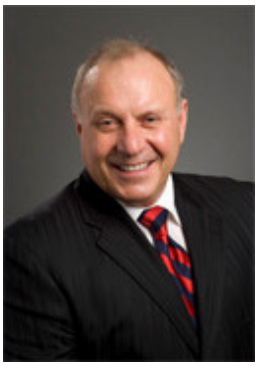

Dr. Frank DiCosmo
President and CEO
Covalon Technologies

By Rachel Barsky

Getting an infection is no walk in the park for patients or hospitals, but Dr. Frank DiCosmo and his team at Covalon Technologies are making things a little easier these days. DiCosmo, president and CEO of the advanced biomedical systems company, is so enthusiastic about Covalon’s products that it is difficult not to catch onto his excitement.

His company’s goal is to be the leader in coatings ventures for medical devices; producing antimicrobial and drug delivery coverings, soft tissue coverings, advanced tissue coatings, tissue regeneration and more. Talkin to DiCosmo and CFO Peter Hobbes, it seems Covalon might achieve its goal even sooner than hoped.

Covalon, one of the Top 50 TSX Venture companies for 2007 and 2008, has its roots at the University of Toronto, where DiCosmo was a professor for 22 years. The company was established in 1999 under the name “UroTeq,” after collaboration between biochemists, physicians and microbiologists there (including a number o DiCosmo’s students, who are still with the group), developed technologies relating to anti-infections, surface coatings, cellular growth and wound healing systems. DiCosmo and the other co-founders, including Covalon’s chief business officer William Jackson, wanted to bring those technologies from the university’s labs to the public marketplace.

In 2004, UroTeq changed its name to Covalon, or “covalent technology on surfaces,” to better reflect its technologies, as the company had expanded from working solely in urology. Covalon began trading on the TSXV on December 24, 2004, and hasn’t looked back since.

In hospital, patients are routinely subject to the insertion of medical devices such as urinary catheters and venous access catheters. The devices are critical, allowing for the delivery of drugs, nutrition and fluids, for instance, but the insertion of such devices can lead to infection which is not only painful for the patients, but can be very costly for hospitals. In the case of urinary tract infections (UTI), explains DiCosmo, single bout of infection in one patient can cost the hospital from $700 to approximately $3,000. “Now you have to put the patient in the hospital, give them antibiotics, remove the device, wait for the antibiotics to let the infection clear, then insert a new device with the possibili of it happening again!”

UTIs account for 40 percent of hospital acquired infections, and 15 to 50 percent of hospitalized patients with urinary catheters are afflicted with UTIs. The risk of getting an infection increases five percent with each day of catheterization. In the case of patients with central venous line infections, there is a 30 to 40 percent chance of infection with use of the device, and the cost of a single infection can be $27,000 or higher.

To complicate things further, says DiCosmo, in the United States—Covalon’s target market—the Centers for Medicare and Medicaid Services ruled that as of October 1, 2008, it will no longer reimburse hospitals for infections that patients acquire while under their care. “Thi bodes very well for Covalon because three of our biggest products that we already have in the market address those areas, and that was by design,” says the CEO. He expects Covalon will further expand, perhaps doubling its production and square footage because of the increas (and expected future increase) in sales of its products.

Covalon’s innovative medical coatings technology is helping to reduce and even eliminate infections. And they say they can coat anything: “ you can stick it in your body, we like to coat it,” says DiCosmo with a laugh. Covalon applies a covalently bonded, high quality hydrophilic polymer substance with silver ion as an anti-infective agent to the devices. Its scientists coat both the outside and inside to ensure that the matter flowing through the tubes (such as blood or urine), also does not get infected. The company’s lubricious Foley catheter—the “Silvertouch”—is marketed by Medline, a $3 billion American company, which does not have a Canadian arm, so Covalon may find a Canadian distributor as well. Silvertouch is still currently available in Canada, however.

Silvertouch, launched in 2006, has shown impressive results. One study on the catheters by St. Vincent Rehabilitation Hospital in Arkansas compared infection rates using Silvertouch catheters and uncoated Foley catheters. Over six months, the Arkansas study, published in the April 2008 issue of the Society of Urological Nurses and Associates, found that the Silvertouch completely eliminated all UTIs, bringing the infection rate to zero from two to four percent. As well, using Silvertouch catheters saves a great deal of money, explains DiCosmo. His company’s devices may be more expensive than regular silicon catheters, selling for $7-$10 while regular catheters might go for $3-$6, but

thousands of dollars are saved in the long term. This is particularly true in the litigious United States, where if a patient gets an infection and there is an anti-infection device proven to work, the hospital will be sued.

Covalon is also able to use its coating as a drug delivery system. “Antimicrobial is just the beginning,” says DiCosmo. The company’s wound dressing products, such as Biostep and Colactive, also uses the coating. Wounds are another serious and expensive issue for hospitals and other care centres, particularly geriatric homes. Bed sores, for instance, can cost a hospital up to $47,000 to treat one patient. With patients generally being elderly, the skin is thin and tender, says the CEO, their diets and blood flow are usually poor; thus, closing wounds can take a substantial amount of time.

Patients respond very well to Covalon’s wound dressings, says DiCosmo. The products have healed wounds such as foot ulcers that haven closed with any other company’s products. “One particular patient had wounds that had not closed in over two years and within six to eight weeks of use of our products, the wounds had closed,” he says. “It is absolutely fantastic.” In fact, DiCosmo’s grandmother was the first patient to receive Colactive, which healed an ulcer on her ankle.

The wound dressings utilize covalently-linked denatured porcine collagen platforms. When placed on a bleeding wound, the dressing hydrates, taking in approximately thirty times its weight in fluid and sucking about “all that nasty stuff,” explains DiCosmo. But the product also allows for the binding of important platelets, which allows for clotting and the depositing of growth factors in the wound to help the wound heal itself. “It can stay in the wound up to seven days, better than products out there that have ratings of three days, so that means it’s cheaper to the health care system,” the CEO continues. Normally, creating collagen-based dressings takes about two to three days with multiple steps, but Covalon’s patented technology allows for only one step and 22 hours. Medical devices giant Smith and Nephew approached Covalon to distribute its dressings products. “You know you’re doing something right when the world leaders come to you,” DiCosmo exclaims.

The company is currently working on new wound products, such as hemostatic dressings which would have military applications, as well as ocular dressings. One of their most exciting projects is in the stem cell area, however. Covalon is designed to take into effect increases in diseases such as diabetes, says DiCosmo. The disease is rampant in the United States, not only in the elderly but in young people as well, and the rate is growing. Diabetes alone can lead to cardiovascular disease, ischemic disease, and congestive heart failure, says the CEO.

In these conditions, blood flow is compromised, and if there is no blood flow, tissue dies. “And it doesn’t regenerate. Your heart muscle doesn’t regenerate—ultimately this dead tissue can lead to heart failure.” To help prevent this, Covalon is taking patients’ own stem cells, using bone-derived stem cells from the hip, and genetically engineering the cells with its patented technology Endothelial PAS Domain Protein, or EPAS1. With EPAS1, cells can differentiate into the cells the scientists want them to be. They can grow new blood vessels, for instance, which migrate to where scientists have deposited cells, maturing and feeding newly formed tissue. “New blood vessel formation means that you’re now delivering oxygen and nutrition to that scar tissue, and that scar tissue can now start repopulating with new cells.”

Covalon is currently undergoing EPAS1 experiments in pigs, and has already proven its technology successful in mice. DiCosmo expects the first human trial is perhaps five years away, though the company’s business model is to align itself within the next two to three years with one of the multinationals in the area, such as Boston Scientific or Genzyme.

Because of the highly regulated industry the company works in, change doesn’t happen overnight, says DiCosmo. From conception to launch, the product release process generally takes about 13 or 14 months, save for the company’s long term stem cell projects. The new product then must be accepted in the medical community, so financial rewards are not automatic. Like so many other companies operating in the current economic environment, Covalon’s stock has decreased—it reached a 52-week high on Nov. 6, 2007 at $3.59; approximately one year later on Oct. 27, 2008, the stock reached a 52-week low at $0.40—but the executives’ outlook is positive. “We have cash in the bank,” says Hobbes, $13.3 million to be exact.

Covalon raised capital in 2004, with a second injection in 2007 allowing for a cash burn of approximately $400,000 per month. “We’re pretty happy to be where we are,” says DiCosmo. “We took a hit in the marketplace—everybody else did—but I believe we’ll bounce back stronger than ever.” For now, the Covalon team is focusing on its products. “We’re not a one trick pony show,” concludes the CEO. “We want to be real. We want to build a strong company.”

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