

# Early Development Firms Set the Stage for Medical Devices

Early Development Firms Set the Stage for Medical Devices (c) 2007 Windhover Information Inc., Norwalk, CT

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**They say they're not incubators, accelerators, or seed funds, but a new kind of hybrid. The mission of a host of new medical-device development firms is to get very early-stage technologies on the road to commercialization.**

Mary Stuart

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Innovia: Deftter Devices through Chemistry

Leonard Pinchuk is one of the creative geniuses behind the largest product launch in the history of medical devices, Boston Scientific Corp.'s *Taxus* stent. He formed **Innovia LLC** in 2002 to continue to do what he loves best: use his polymer expertise to create innovative products. Pinchuk identified a novel polymer called SIBS, poly(styrene-*block*-isobutylene-*block*-styrene), invented by scientists at the **University of Akron**, and patented its use for implantable medical devices. This polymer helped make *Taxus* a \$3-billion product in its first year. He also invented the nylon angioplasty balloon that is now the world's most popular angioplasty balloon, which propelled **Cordis Corp.**, a Johnson & Johnson company, **Guidant Corp.**, and Pfizer/Schneider into the interventional market and helped enable the balloon—implantable stent industry. He also invented a flexible coronary stent, the family of polycarbonate urethane biomaterials used for implantation, polyurethane-based vascular grafts and stent grafts, and the first modular self-expanding bifurcated stent-graft for treating abdominal aortic aneurysms. In fact, he has more than 80 patents in medical device fields.

Pinchuk found himself working with Boston Scientific by a circuitous route. He began his career as the manager of the applied physics and chemistry group at Cordis but in 1987 joined with its former CEO Norman Weldon, PhD, to form Corvita Corp., a start-up developing vascular grafts. The Innovia story begins here. "Corvita had more than 11 different financings with more than 17 different venture capital firms," says Pinchuk, "and due to multiple serial dilutions, I didn't do as well as I should have," despite the fact that he was the company's lead inventor. "Also, we were a development company, but our administrative group was larger than our development group, mostly to interact with the venture capitalists. These were red flags to me," he adds.

Corvita subsequently changed hands a number of times. It went public in 1995 [W#199430164], was sold to **Pfizer Inc.**'s Schneider division in 1996 [W#199610095], and in 1998, when Pfizer divested Corvita to buy Warner-Lambert, Boston Scientific purchased it.

Pinchuk was offered an executive position at Boston Scientific as VP of corporate research and development, but he preferred to be in a smaller company. So in October 2002, with no specific product in mind, he formed Innovia LLC, along with John Martin, who'd also been a research engineer at Cordis and was a co-founder of Corvita, to develop new applications for the aforementioned SIBS biomaterial.

Pinchuk had developed the SIBS material while at Corvita, and the intellectual property eventually passed to Boston Scientific, which currently owns the Pinchuk patents. SIBS is a novel family of biocompatible, rubbery copolymers that don't degrade in the body and don't elicit a foreign body response. Boston Scientific, which holds the license to SIBS, supplied generous funding to Innovia, and it sublicenses the use of SIBS in certain fields. Innovia--not the spin-offs--will house materials know-how and will manufacture material and parts for the spin-offs.

Innovia is unusual in its funding relationships with corporate investors. Pinchuk says he has been offered venture capital money many times, and he may use that funding route for certain spin-offs in the future, but for now, "I prefer industrial money. They don't want to own more than 20% of your company due to reporting and other fiduciary requirements. They don't necessarily want a board seat, and also, the money comes out of their M&A budget, not the R&D budget, and it's easier to get more funding for new projects this way. Their ultimate goal is to acquire you if your product works."

Because SIBS has many different clinical applications, Innovia operates by forming spin-offs. Research in the spin-offs is funded by the sale of equity and the investing entity in many of Innovia's deals has the option to purchase the remaining equity in the spin-off for a predetermined price. Innovia has created six spin-offs, and Pinchuk says four of them are already financed--none with VC money, although he may seek that option for one of the companies developing a synthetic heart valve, an early-stage, long-term project.

Innovia's first spin-off is **InnFocus LLC**, which is developing an implantable device for glaucoma, the number one cause of irreversible blindness. Glaucoma is a disease in which the aqueous humor, the watery fluid that fills the front of the eye, builds up because a spongy, self-cleaning filter known as the trabecular meshwork clogs and fluid doesn't drain properly through the clogged mesh. Fluid build-up puts pressure on the blood vessels leading to the optic nerve, triggering the death of retinal ganglion cells and causing vision loss. Glaucoma treatments today include the implantation of tubes and relatively large drainage plates that are used to shunt fluid from the inside of the eye to a space created by the plate below the surface of the eye. The large bulky plates and tubes are difficult to implant, they require extensive manipulations to prevent the eye from deflating, which can cause retinal detachment and blood vessels to burst. The bulky plates and tissue capsules that form around them can also restrict motion of the eye causing double vision. Innovia has used SIBS to create an improved drainage shunt that is less than 1/100th the size of conventional devices and that can be easily implanted with less risk.

Pinchuk began looking at ophthalmology when Professor Jean-Marie Parel of the **University of Miami's Miller School of Medicine's Bascom Palmer Eye Institute** in Miami asked him to apply for a government Small Business Innovation Research grant to develop a prosthetic eye for babies born without one eye. As a baby grows, the eyeless eye socket does not, whereas the good eye socket grows normally. This causes the face to deform, so surgeons implant rigid spheres in increasing sizes every few months to stimulate the growth of the empty eye socket. This removal and reimplantation of rigid spheres is very traumatic for the child. Pinchuk's company produced an inflatable eye, invented by David Tse, MD from the Bascom Palmer Eye Institute, that could be implanted and inflated gradually over time by the addition of fluid through a needle, thereby avoiding painful surgery.

Having gained some familiarity and credibility with the Eye Institute, Pinchuk's colleagues there began to study SIBS in animal ocular models, where, unlike other implantable materials, they discovered that it didn't encapsulate. "Just about all materials currently used in medical devices degrade slowly, and as small molecules or particles come off, the shedding debris attracts scavenger cells that try to destroy it and wall it off by forming a tissue capsule around it. The SIBS material is unique because it doesn't degrade; therefore it doesn't attract significant scavenger cells or scar-producing cells and there is virtually no capsule that forms

around it." That property enabled InnFocus to create a glaucoma drainage shunt that is a hundred times smaller than conventional devices as the draining fluid does not have to make its way through a capsule that otherwise would require a large surface area. The InnFocus/Bascom Palmer device is so small that it can be injected through a needle in a procedure that takes less than 10 minutes, Pinchuk says. Further, the device is implanted in an area where there is very little risk of doing further damage to the eye. This is in contrast to other experimental devices where delicate surgery is required to implant devices that drain into Schlemm's canal or the subchoroidal space, where if the surgeon is off by a few micrometers, the eye can be permanently damaged. The InnFocus product is designed to be delivered by cataract surgeons accustomed to short procedures in less risky parts of the eye, and there are 10 times as many of these clinicians as compared with 1,700 highly skilled and specialized glaucoma surgeons. The company has completed animal studies in the US of its first-generation product, and a clinical trial is in progress in France. Innovia is now in funding/acquisition discussions with the three major ophthalmic companies, Pinchuk says.

InnFocus's foray into ophthalmology includes another potentially large product, an accommodating intraocular lens. "SIBS is a rubbery material that magnifies more than most other polymers and can be made into an intraocular lens that you can roll and insert through a needle instead of a large incision. We also speculate that the muscles in the eye may allow it to change its curvature or focal position sufficiently to allow some focusing or accommodation," Pinchuk says. This product will address one of the largest markets to emerge in ophthalmology in recent years—presbyopia, or the loss of accommodation that accompanies aging.

The uniqueness and versatility of this polymer has captured the interest of an unnamed Australian company, where a joint venture called InnVision LLC is being formed to investigate the use of this chemistry to develop an injectable gel that can be used to refill the lens capsule after cataract surgery. This readily deformable, optically clear gel will allow patients to focus their lens to the same extent that they were able to focus when they were teenagers, Pinchuk believes.

The other spin-offs to date include **InnoGraft** LLC, which is developing new sealants for vascular grafts; spine company **InnJect** LLC, for which Innovia and its associated chemists have created an injectable spinal disc nucleus replacement that should be more stable and less inflammatory than any currently available materials; **InnCardia** LLC, the developer of a synthetic aortic heart valve made from the SIBS material that can be delivered conventionally by suturing in place or either minimally invasively or percutaneously and which is designed to make obsolete both tissue and mechanical valves; and **InnSulin** LLC, a company developing a cell encapsulation therapy for the treatment of diabetes.

In this last spin—off, Innovia is working with a consortium of scientists from several universities and institutes in the Ohio area that have developed very unique biomaterials that can be used to encapsulate islet cells from other animals for implantation into humans. Pinchuk believes that these cell encapsulation materials will enable more oxygen transport and will have much better biostability than materials that have been investigated for this purpose in the past, and thus they will encourage the long-term survival of islet cells. "If this technology works as we all expect it will, it will quickly become the treatment of choice for millions of patients who suffer from diabetes," says Pinchuk. It's still early, however, and many cell therapies for diabetes have failed in the past. That program is at the R&D stage, and the consortium members haven't been publicly announced yet.

At this early stage, Pinchuk is president and CEO of each of the spin-offs. Innovia will keep the infrastructure lean to get to an exit. "We don't intend to go into sales and marketing," he says. "Our expertise is in creating the chemistry to enable the product." At Innovia, Pinchuk is able to freely explore the widespread potential of a platform technology. "You can't normally get a vascular graft company to invest in an ophthalmology company," he says.