

# TyRx Pharma Inc.

## Enhancing Medical Devices

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**Contact:** William Edelman, CEO  
**Industry Segments:** Supplies, Equipment & Devices; Drug/Device Convergence  
**Business:** Coated, biodegradable polymer devices  
**Founded:** 1998  
**Founder:** Arikha Moses, PhD, CSO  
**Employees:** 19  
**Financing to date:** \$9.8 million  
**Investors:** Boston Scientific Corp.; Cahn Medical Technologies LLC; AH/AMD Investors LLC; Palm Venture Partners LTD; Tailwind LLC

**Board of Directors:** Charles Cahn, Chairman (Cahn Medical Technologies LLC); William Edelman; Michael Heffernan (Collegium Pharmaceuticals); Arthur Lieberman (Dickstein, Shapiro, Morin & Oshinsky LLP); Arikha Moses, PhD; Burton Joel Ahrens (Edgehill Corp.); Thomas M. Tully; Brian M. Gallagher, PhD  
**Medical Advisers:** Paul Belsky, MD (New York University School of Medicine); Joachim Kohn, PhD (Rutgers University and New Jersey Center for Biomaterials); Peter Fitzgerald, MD, PhD (Stanford University Medical Center); Robert Fitzgibbons, MD; Jonathan Freudman, MD (Freudman Healthcare Consulting LLC); Enrico Nicolo, MD (American Hernia Society)

Every year in the US, some 500,000 pacemakers and defibrillators are implanted and about one in 25 patients gets infections from these procedures. That almost always means that the device must be entirely removed, the patient treated with two to six weeks of antibiotics, and a new device reinserted. Until the next implant, patients and doctors struggle to maintain heart rhythm with temporary pacemakers, an external defibrillator vest, or medications. Costs range from about \$30,000 to \$50,000 per infection.

Next year **TyRx Pharma Inc.** hopes to start selling a solution: implantable devices that will fit around pacemakers and ICDs, coated with an antibiotic-loaded polymer. TyRx is hoping that the economics associated with infection management will enable it to buy raw parts and assemble each device, coat it with the polymer, package it, sterilize it, and sell it to heart surgery centers at an average selling price approaching \$500 per device. Another product, a defect-

reinforcing surgical mesh for hernia operations that elutes anesthesia, should hit the market a few months later, selling at a 10-15% premium over existing uncoated devices.

TyRx's core technology is a versatile biodegradable polymer based on the natural amino acid tyrosine, explains CEO William Edelman, who joined the company in 2004. The material can be spray-coated, dip-coated, or extruded, and it can be fabricated as an injectible liquid, microsphere, load-bearing plastic, or a porous scaffold. Further, the various physical forms of the polymer can be engineered to degrade on schedule, from a few days to 18 months. So far, TyRx has made some 120 tyrosine polyarylates, as this class of polymers is known. Unlike other degradable polymers on the market, says Edelman, these polyarylates break down into components that are found in the body either as synthesized molecules, nutrients or as metabolites of nutrients. Small-molecule drugs are simply mixed

in with the polymer to form a solid solution; the chemical composition of the drug molecule itself is not changed. Preliminary evidence indicates that the polymer could even dispense peptides and proteins.

At the end of this year, the company plans to file a 510(k) application for its first product, a polymer-coated mesh for hernia operations. Meshes are designed to reinforce the tissue defects that result in hernias. "Our ongoing *in vivo* studies have shown that the polymer promotes rapid tissue ingrowth to allow capture of the mesh very efficiently," says Edelman. More importantly, the polymer-coated barrier seems to reduce the inflammatory response often associated with such tissue implants. TyRx is working on devices coated with the polymer alone and also with antibiotics, but anticipates that the main market will be for mesh used to repair hernias (abdominal muscle breaks, through which organs protrude). As these can be extremely painful, TyRx has devised the device that elutes an anesthetizing agent.

This will be shortly followed by a 510(k) submission for the antibiotic-coated hernia mesh and a 510(k) submission for the pacemaker device. Because similar products are already on the market, the FDA would not require TyRx to perform clinical trials, says Edelman, who anticipates conducting post-marketing registry trials. Instead, the company must demonstrate to the FDA that the polymer-coated and antibiotic-polymer coated meshes are substantially equivalent to currently approved hernia meshes. In addition, TyRx will have to provide evidence that the antibiotic-coated device can prevent bacterial growth.

Edelman anticipates that the market for anti-infective implantable devices—both the company's pacemaker and hernia product lines—is around \$500 million annually. Details of TyRx's sales and marketing plan are still being worked out, but it won't require a large direct force, Edelman says. Instead, the company will target surgeons at high-volume, standalone

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medical centers, first on the coasts, then in the rest of the country.

"The projects are all moving roughly parallel to each other," says Edelman. "The material composition of our devices are roughly equivalent. So all the production methodology and quality control methods are leveraged across all the products simultaneously." Unlike the heart devices, the anti-pain hernia mesh will require a pilot clinical trial to show safety and then another to show efficacy. TyRx is consulting with the FDA on all of its programs and anticipates that an 8-month, 100-person trial should be enough to show efficacy. These trials should run for most of 2006, with premarket approval anticipated in 2007.

TyRx, which was originally called Advanced Material Design, has gone through several iterations based on different potential uses of its technology, starting with tissue scaffolding, then moving to controlled drug delivery. The company's founder and current CSO, Arikha Moses, learned about the technology as an analyst with Athena Ventures, LLC, a seed-stage venture capital firm focused on life science and biotechnology companies. Moses obtained an exclusive license to 14 patents and patent applications for the polyarylates from **Rutgers University**. These were discovered by Joachim Kohn, a professor of chemistry at Rutgers, an associate of the New Jersey Center for Biomaterials, and a TyRx adviser. TyRx's director of polymer research and development, Satish Pulapura, PhD, is Kohn's former graduate student and co-inventor of the polyarylate polymer that TyRx employs. He left his academic position with Rutgers to join TyRx at its inception.

Founding members are still with the company, but TyRx has a new focus on combination medical products. "When I

came aboard in 2004," says Edelman, "one of the charters I had was 'please look at what we've got and tell us what makes sense.'"

Edelman—who has led numerous device start-ups including MicroSense International LLC, Fibra Sonics Inc., and NeuroMod Inc., and earlier in his career held executive positions at St. Jude Medical Inc., Pfizer Inc., and Baxter International Inc.—took stock of



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TyRx hopes its polymer can repeat this phenomena for other medical devices.

ongoing projects. The company had some positive results using the polymer for controlled-release of drugs, but Edelman thought there were better options. "The economics were rendering drug delivery of generics more a commodity capability than a unique high value capability," he recalls. Meanwhile, **Boston Scientific Corp.** had been evaluating TyRx's polymers for its drug-eluting stents and had paid TyRx a \$1.5 million milestone payment in 2002 as part of a license agreement. That gave Edelman an idea.

Drug-eluting technology has taken a plain stent priced at about \$500 and made it worth \$3,000. Subsequent

competition has lowered prices only somewhat, to \$2200. Edelman thinks TyRx's polymer can repeat that phenomenon with other devices. Executives at Boston Scientific seem to think so as well. Following an internal investor round in August last year of \$1.5 million in exchange for convertible notes, it invested \$4 million in a series D round, which closed in January 2005.

Edelman anticipates that the company will raise an additional institutional round of financing at the end of this year. "If our models hold up," he says, "that may be the last round we go for. If these products hit and stick the way we think they will, we should be cash positive about 24 months post-launch." In May this year, TyRx added two senior positions to navigate the transition. William McJames, VP of product development, was formerly director of R&D for the Cardioventions division of Ethicon Inc., a subsidiary of Johnson & Johnson. Mason Diamond, VP of clinical and regulatory affairs, has worked at a number of companies in the pharmaceutical, medical device and biologics industries, including USBiomaterials Corp. and Quintiles Transnational Corp., and has designed clinical trials in pain, arthritis, cardiovascular, oncology, orthopedics, diabetes, wound healing, infectious diseases, and dermatology.

While the trajectory for TyRx's initial products seems clear, says Edelman, it's too early to know what the company's path will be. Edelman oversaw the sale of MicroSense to Beckton Dickinson & Co. as well as Fibra Sonics to **Misonix Inc.**, but doesn't rule out an IPO for TyRx. The best route will be becoming a fully integrated medical device company, and for that, he says, there's no better model than what Boston Scientific, TyRx's biggest investor, did in stents: "They took a market that was nice and made it unbelievable."—Monya Baker