



TYRX, Inc.

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“Site Specific Delivery - Global Impact”

A leader in the commercialization of implantable medical-pharmaceutical devices

Mission: TYRX delivers site-specific therapy by commercializing proprietary, implantable medical-pharmaceutical combination devices for the surgical markets.

About TYRX: Since its inception in 1998, TYRX scientists, engineers and marketers have focused on a singular goal — creating unique, cost-effective solutions that address surgical-site infections (SSIs) and inflammatory tissue-reaction associated with implanted medical devices. TYRX is an FDA registered, ISO 9001:2000 and ISO 13485:2003 certified medical device manufacturer of combination medical-pharmaceutical devices utilizing novel polymer technology, including a world-wide license from Rutgers, The State University of New Jersey, covering a broad range of resorbable materials and drug delivery technology. Additionally, TYRX has licensed from Baylor College of Medicine and The University of Texas M. D. Anderson Cancer Center combination drug patents and associated technologies to address the problem of postsurgical infection and fibrosis. TYRX is deploying its capabilities across a broad range of combination products.

Market: The worldwide market for combination products (products incorporating both a drug & a device component) is expected to be the highest growth segment of the medical products industry and TYRX is positioned to be an innovative leader in the space. TYRX has gained market approval for a number of products, and is developing additional product franchises through the application of proprietary technologies in general, cardiovascular, cosmetic and orthopedic surgery. TYRX is targeting the reduction of infection and scar development, common morbidities associated with all medical device implants. It is estimated that medical implant related infections and fibrosis add an estimated \$3.8 billion to annual US healthcare costs.

Intellectual Property: TYRX possesses 2 in-licenses providing far reaching fields of use covered by 20 issued patents. Rutgers, The State University of New Jersey has granted a license covering a broad family of “best-in class” biodegradable polymers (16 patents). Baylor College of Medicine and MD Anderson Cancer Center has granted a broad license covering clinically proven combination antibiotics for use with implant medical devices (4 patents). TYRX has filed 7 patent applications covering proprietary products targeting cardiovascular and cosmetic surgical applications.

Technology: TYRX’s combination medical device platform utilizes a unique family of tyrosine-based resorbable polymers that can be tailored to the appropriate mechanical strength, rate of therapeutic agent release and rate of biological resorption. The polymers have been shown to absorb benignly *in-vivo* and have been used in FDA cleared implantable medical devices.

Product Development:

- **Cardiac Rhythm Management Devices (CRMDs):** Following its FDA clearance, TYRX launched the AIGIS_{Rx}[™] Anti-bacterial Envelope in June 2008—the first FDA-cleared combination medical device-pharmaceutical product designed to
 - stabilize cardiac rhythm management devices (CRMDs), and;

- reduce infections associated with implantable pacemakers and/or implantable cardioverter defibrillators (ICDs), as demonstrated in *in vitro* and *in vivo* studies
- CRM products are currently implanted at the rate of 500,000 units per year in the US and post-surgical infections are estimated to have a \$700M annual economic impact. As of March 31, 2009, TYRX has sold over 2,600 AIGIS_{Rx}[™]. Additional information regarding the AIGIS_{Rx}[™] Anti-bacterial Envelope may be found at www.AIGISRx.com. TYRX is currently developing a third generation, totally resorbable AIGIS.
- **Cardiac Surgery:** Mediastinitis is a dangerous and expensive to treat infection of the sternum, which may occur after a Coronary Artery Bypass Graft (CABG) or other open chest procedure. TYRX has developed an antibiotic eluting bone paste that has the potential to reduce or eliminate this high morbidity/high mortality post-surgical complication. *In vivo* studies are scheduled to begin in 2010.
 - **Interventional Cardiology:** TYRX has developed a proprietary drug-eluting stent (DES) polymer coating that does not cause inflammation, and is fully biocompatible, during resorption. TYRX is presently exploring collaboration with the major players the field of drug eluting stents.
 - **General Surgery:** In July 2006, TYRX received FDA clearance for PIVIT[™] AB, a new surgical mesh coated with a proprietary bioresorbable polymer containing the antimicrobial agents of minocycline and rifampin. In January 2007, TYRX entered a licensing/co-development agreement and strategic alliance with C.R. Bard for the development and marketing of unique hernia repair products incorporating TYRX PIVIT[™] AB technology for the prevention of scarring and infection.
 - **Cosmetic Surgery:** TYRX has completed extensive *in vitro* and *in vivo* studies confirming its ability to reduce the severity of capsular contraction in breast implant recipients via a reduction in bacterial colonization and capsule formation. Capsular contraction is evident in 10 – 17% of all breast augmentations and is the main reason for a re-operation / removal. TYRX anticipates beginning its human clinical studies during 2010.
 - **Orthopedic Implants:** TYRX's proprietary bioresorbable polymer containing the antimicrobial agents of minocycline and rifampin may be used to coat orthopedic implants with the intent of reducing the potential for infection. TYRX expects to enter clinical studies with an orthopedic partner during 2010.

Financing: In February 2008 TYRX raised \$25 million in a venture capital financing led by Clarus Ventures and co-led by Pappas Ventures, anticipated to be the final financing for the company. Use of proceeds includes product development efforts, support of commercialization & distribution, and production scale-up.

For Further Information:

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