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Life sciences represent a significant growth engine for our innovation economy. In this report on Medical Frontiers, we take a look at research and clinical work under way from Cambridge to Worcester to Rhode Island that promises to enhance and extend life.

From correspondent Patricia Resends comes the story of a Coventry, R.I. firm that made the staggering leap from fiber manufacturing to supplying the scaffolding used for human tissue engineering. Pioneered by MIT's Robert Langer, bioengineering now gets some of its materials from a factory that opened in 1920.

Wendy Wolfson writes about a collaboration between Genzyme and Midwest firm to work on "autologous cell therapy", which uses a patient's own cells to repair damage caused by a heart attack, or halt progressive heart failure. The venture is recruiting for a 300-person Phase II trial in France, Belgium, the United Kingdom and Germany.

And from UMass Medical Center comes a report from Dr. Stephanie A. Moore on the next wave in cardiac assist devices, known as the artificial heart. Aimed at helping the 5 million Americans with chronic heart failure, the new devices are smaller, more reliable, and less evasive.

Jim Malone
Editor

Textile operation is reshaped to take on biomedical research

Concordia extends its expertise and thrives

By Patricia Resende
Special To Mass High Tech

Harvesting human arteries from scratch could change the way patients receive bypass surgery, and Concordia Manufacturing LLC, a longtime textile mill, is now working to make that and other new medical procedures possible.

Concordia is one of the few textile mills still operating in Rhode Island and has survived, in part, due to its willingness to extend its textile expertise to other areas, particularly the medical and bioscience industries during the past five years.

One of the most promising biomedical products now being manufactured by Concordia is its BioFelt scaffold, which is an absorbable, non-woven 3-D felt on which cells can be grown and form tissue.

Concordia's foothold in tissue engineering scaffolds can be traced back to co-development work that began in the mid-1980s involving the MIT Langer Lab, run by MIT professor Robert Langer, and Mansfield-based Albany International Research Co., from which Concordia acquired the resulting tissue engineering scaffold assets this year.

Now researchers at Duke University, along with more than a dozen other universities, are using the BioFelts for research in tissue engineering.

"You can seed them with cells, grow the cells and then use (BioFelt scaffolds) to replace and enhance cells in the body", said Randal Spencer, chief executive officer of Concordia.

To engineer functioning tissue, Spencer said, it is necessary for the scaffolds to be seeded with a large number of cells that are distributed evenly. Static seeding compared to seeding scaffolds under dynamic conditions results in high seeding densities and even distribution of cells.

And the scaffolds need to be engineered just right. If a scaffold is too soft, for example, it could collapse under the cells' mechanical forces, according to a recent paper co-written by Shulamit Levenberg, an associate researcher at MIT and a lecturer at Technion, the Israel Institute of Technology.

Concordia's BioFelt scaffolds are said to be flexible and soft, with a high porosity factor- greater than 97 percent, according to the company.

Laura Niklason, associate professor at the Duke University Medical Center who began research of vascular arteries in Langer's lab, uses Concordia's scaffolds in a tube-shaped device, made of biodegradable polymer to seed cells in the harvesting of artificial arteries.

"We use the BioFelt and seed them with vascular cells and grow them in a lab to form a completely new artery", she said from her office at Duke. "We work with cells from animals and are doing animal implantations and are also branching out to human cells."

Using Concordia's BioFelt is an attractive sell for Niklason because the polymer in the material is approved by the U.S. Food and Drug Administration. It is also already in use in sutures, so it's likely to be tolerated as a component of tissue that would eventually be placed in humans.

"Secondly, Concordia is basically transforming their production process so that it is neat and clean and meets FDA standards," Niklason said. "It's very bold and innovative of them to try to reinvent themselves in the biomedical sphere."

The textile industry has a tremendous amount of expertise from which the biotech industry can benefit, but historically there has been a disconnect," she said.

"Things (Spencer) finds very easy to do from a manufacturing standpoint is dazzling to us because there is no way we can do that kind of stuff," Niklason said.

The old mill, in operation since 1920, would wind, twist and braid materials for a variety of applications including boat sails, tennis racket frames and apparel and was once the top provider of the fibers used in the hook-and-loop material commonly known as Velcro and developed by Velcro industries.

Overseas outsourcing of textile manufacturing, however, together with economic downturn and volatility in the U.S. textile market nearly forced Concordia to shut down for good.

But by pushing the envelope and finding new applications for its materials, Concordia was able to stay afloat with help from the state of Rhode Island. In late 2003, Concordia received \$1.5 million in funding from different sources including the Rhode Island Economic Development Corp., Sovereign Bank, and the Slater Center for Biomedical Technology.

The Slater Center and (executive director) Rich Horan have played a crucial role, and he has helped us to articulate our story to the biomedical community," Spencer said. "It is a very unusual example of how the state has really helped."

Why would an old yarn mill receive funding from a biotechnology and life sciences group?

Because Concordia easily made the transition to manufacturing biomedical devices and focused on research and development, it wound up securing a number of strategic collaborations.

For Example, Davol, Inc., a Cranston, R.I.-based developer of medical devices used in hernia repairs, laparoscopy and orthopedics and subsidiary of C.R. Bard, Inc., asked Concordia to produce biomedical material to be used in homeostasis.

“That got us excited and we built a clean room,” Spencer said. That clean room, approximately 1,000 square-feet, has new and used equipment and operates as any other clean room would.

Cost of producing the fiber, however, was too high, according to Spencer, and Davol put the project on hold.

Spencer moved quickly in another direction and began discussions with existing customer Albany International Research, which was making the BioFelt Scaffolds.

“We were familiar with the people at Albany but one of our gripes with them is they didn’t do it under clean conditions,” Niklason said.

Spencer didn’t wait long to address Niklason’s concerns. Early this year Concordia purchased the assets of Albany Research International. The opportunity was perfect for him and Albany, which had let the technology lag, according to Spencer.

“We’ve always been looking for ways to take our fiber expertise out to a different level, and that’s why we are still here,” Spencer said.

Niklason said, “When they spun this technology out to Concordia and we heard Concordia; A has a clean facility and; B were willing to develop novel materials, we were very excited.”

Spencer said he also plans for Concordia to be the company to make scaffolds for Niklason, who is in the midst of forming her own start-up.

Niklason said she hasn’t made any supplier decisions for the five-month old company, Humancyte.

“It’s too early to say, but it is certainly possible,” she said.

To keep the company's core business flowing while Concordia makes the transition to the medical field the company still provides yarn that is used in aerospace applications such as high-performance jet planes, and in the auto industry with use in BMW air bags.

Patricia Resende is a freelance writer in Rhode Island