

## Gastrointestinal drugs focus of local company

BY ANNE KRISHNAN : The Herald-Sun  
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DURHAM -- Tranzyme Pharma has retooled its business plan twice in the past five years, finding new life when its survival was threatened.

Now flush with cash, the Durham biotechnology company is developing medical therapies that will help patients thrive.

Tranzyme focuses on gastrointestinal drugs that either speed up or slow the progress of food through patients' digestive systems, a \$1 billion market, said Chief Executive Vipin Garg.

"Everybody has upset stomachs and we live through it," he said. "The difference is when the episodes become chronic. You cannot live life that way."

Tranzyme's headquarters, its biological discovery program and the program that will prepare the company's first application to the U.S. Food and Drug Administration are in the Triangle. The company has about 35 employees, 15 of them in Durham and at labs in Research Triangle Park and the rest in Canada and Birmingham, Ala.

The company's first drug targets are well known within the scientific community, but they've proven difficult to hit with traditional pharmaceutical products known as small molecules, Garg said.

Tranzyme's expertise can create chemical compounds that are small enough to be given in pill form, yet, like the large molecules produced by many biotechnology companies, still can hit complicated targets, he said.

"There's no question the most convenient drug is a tablet you take once or twice a day, or once a week, with a glass of water and you're done," he said.



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Tranzyme Pharma company members from bottom left are Vincent Parrino, business development associate; Ayyappan Nair, senior scientist; Vipin Garg, CEO and president; Laura Shaughnessy, senior scientist and I.N.D. project manager, and Beth Chamblin, associate scientist.

The company's lead therapy is designed to get a patient's bowels moving again after surgery. Tranzyme expects to file its investigational new drug application with the FDA and begin clinical trials before the end of the year.

Tranzyme also hopes to use a similar compound for treating diabetic gastroparesis, a disorder in which a diabetic patient's stomach empties too slowly. There's currently no treatment, and episodes can result in a trip to the hospital, Garg said.

In addition, the company is working on therapies for irritable bowel syndrome with diarrhea and for functional dyspepsia, which results in abdominal pain.

Treatments for those gastric motility diseases, particularly gastroparesis, are few and far between, said Mary-Angela DeGrazia-DiTucci, president and founder of the Association of Gastrointestinal Motility Disorders Inc. in Lexington, Mass.

"We're always looking for new, better things," she said. "Treatments are currently rather limited, and what works for one patient may not work for another."

She counts about a dozen companies currently developing therapies for gastroparesis, functional dyspepsia, post-operative ileus or IBS.

"Tranzyme certainly is one of the pioneers in this," she said. Two of her organization's advisory board members also sit on the company's scientific advisory board.

DeGrazia-DiTucci, who suffers from a number of GI motility diseases herself, founded AGMD in 1991 to bring patients, researchers and medical caregivers together. The organization has about 500 members.

"It's such a specialized field," she said. "Just when we think we've come so far in finding out about motility, we find that we have so much more to do."

Even Tranzyme's early gastroparesis results have attracted e-mails and other contact from patients wanting to know when the drug will be available and whether they can participate in clinical trials, Garg said.

"That illustrates there's a need for a treatment," he said. "The opportunity is huge to really fix those problems."

A group of scientists and entrepreneurs, including Chapel Hill's David Drutz, general partner with Pacific Rim Ventures, founded Tranzyme in late 2000. They licensed technology out of the University of Alabama-Birmingham, secured \$2 million in startup funding and hired Garg as the company's first chief executive.

The new venture focused on building tools for drug discovery, particularly cell lines on which Tranzyme could test broad libraries of compounds for their therapeutic potential.

Garg and his colleagues expected the \$2 million to last until they could generate enough data to support a larger fundraising round, allowing Tranzyme to shift into its own drug development program.

Then Sept. 11 happened.

"We had to figure out how we were going to survive going forward," Garg said.

The company put its technology on the market and began generating revenue by creating cell lines for other biotech and pharmaceutical companies. At its peak in 2002, the company generated \$2 million a year in fee-for-service work.

Once Tranzyme was self-sustaining, Garg and his colleagues turned again to planning its growth strategy.

"Our goal really was to use this technology in drug discovery and development," he said.

The problem was that Tranzyme had the biology underpinnings to identify potential therapeutic candidates, but not the chemistry to turn those candidates into drugs. In December 2003, Tranzyme merged with Quebec-based Neokimia, which had developed strong, proprietary technology that matched up well with Tranzyme's own strengths.

"It was critical for us that we make it happen," Garg said. "If it didn't take place, there's a good chance neither company would be around today."

Together, the companies were able to do what neither of them had been able to achieve alone -- raise venture capital. Their first \$6 million went toward integrating the two businesses, defining a strategy and choosing a product that they would take into clinical trials as soon as possible. Six months after the merger, Tranzyme began a significant funding round that culminated with the closing of another \$26 million in May.

Meanwhile, Tranzyme continues to generate annual revenue of \$1 million to \$1.5 million through fee-for-service work for its clients, from creating cell lines to helping local biotech firms like Trimeris develop their next drugs.

The company works hard to make the most of its cash by outsourcing a number of functions, Garg said. A South Carolina company is working on manufacturing the company's active ingredients; a company in the United Kingdom will produce the finished products; and CiVentiChem, a Cary company with operations in Hyderabad, India, is conducting research and development for the manufacturing process.

"The idea of looking for the best value for our money is not foreign to us," Garg said. "We thrive on that idea."

That means a lot of traveling for Garg and Chief Financial Officer Rich Eisenstadt, who split their time between Montreal and the Triangle, as well as other sites where Tranzyme's work is being done.

"I feel like I'm one-third Indian, one-third American and one-third Canadian," said Garg, a Cary resident.