

Believing in biotech

Though they aren't behemoths like Scripps Research Institute, three local companies are optimistic that Scripp's expansion into Florida will bring untold benefits to their businesses.

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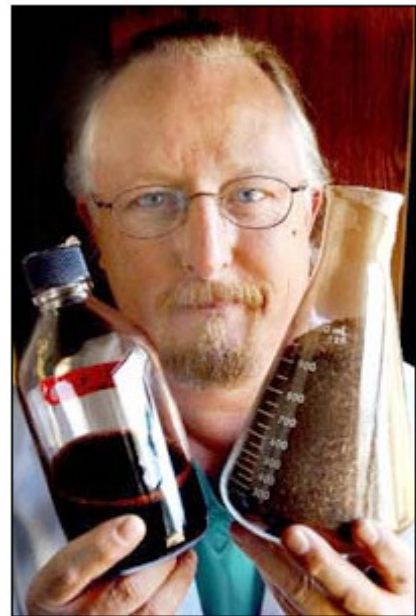
When Gov. Jeb Bush launched his whirlwind - and successful - campaign to bring Scripps Research Institute to Palm Beach last month in exchange for more than \$500-million in public funds, he said it would put the state on the map in the biotechnology industry.

Florida hasn't exactly been a slouch in what has been broadly defined as the life sciences, which includes pharmaceutical manufacturing, medical devices and research and development. According to Enterprise Florida, the industry employs about 37,000 workers throughout the state. One of the largest U.S. biotech companies in terms of revenues, Nabi Biopharmaceuticals, is in Boca Raton, where it has 250 employees.

Most companies involved in the life sciences are considerably smaller, in both sales and work force. Nationwide, a recent study found that only 44 biotech companies have more than 1,000 employees. And most have considerably less glitz than Scripps, which has a sprawling campus overlooking the Pacific Ocean in La Jolla, Calif., and three Nobel Laureates on its faculty.

Following are profiles of three of the dozens of businesses in the Tampa Bay area that fit the broadest definition of biotechnology. Tampa Bay Research Institute, like Scripps, is a nonprofit organization engaged in pure scientific research. Intelligent Micro Patterning makes microdevices used by biotech researchers. Orthopedic Designs Inc. develops technology for repairing joint fractures.

Unlike Scripps, each local biotech is a bare-bones operation, depending on scientific grants, private investors and sales to keep the doors open. They also share an optimism that Florida's generous incentives to Scripps and its expansion to Florida will bring untold benefits to their businesses.



[Times photo: Cherie Diaz]

Guy Bradley of the Tampa Bay Research Institute holds pine cone extract, left, and fine shreds of pine cones, right. The institute is exploring the potential uses of the extract to boost the body's immune system.

Tampa Bay Research Institute

Scripps Research Institute, with its \$400-million in assets, 288 principal investigators and more than 40-year history, makes independent medical research look lucrative.

Tampa Bay Research Institute, which has been on Roosevelt Boulevard N by the landfill since 1981, makes it look like a constant struggle, with little spinoff but unlimited hope.

The institute in St. Petersburg was co-founded by Akiko Tanaka and colleague Dr. Meihan Nonoyama with \$3-million in seed funding from Tanaka's alma mater, Showa University in Japan. Nonoyama, a virologist, served as president until his death in 1995, when Tanaka succeeded him. Today, the facility has four principal investigators, close to \$4-million in assets and 20 employees.

Though the institute's research has focused on finding cures for chronic and infectious diseases, it has not generated a marketable drug or licensed any inventions to a big pharmaceutical company. That does not deter Tanaka, a soft-spoken pharmacist and virologist, who said the institute has received nearly 10 patents for its work and has others pending.

"We have several possibilities of research now that may have drug potential," she said. "The big plus about being independent is that we can do everything based on research results, without being influenced by drug companies or universities. The downside, of course, is that we're constantly seeking funding."

For this fiscal year, the institute received about \$400,000 in grants from the National Institutes of Health out of an operating budget of \$1.75-million. Most of the remainder was raised from community donations, primarily from local individuals including John W. Galbraith, former chairman of the Templeton funds' St. Petersburg business operations, and former Florida Progress Corp. executives Andy Hines and Jack Critchfield.

The nonprofit group is governed by a 15-member board of trustees headed by Mike Williams, a financial planner with Wallace, Welch & Willingham Inc. in St. Petersburg. Its scientific advisory committee includes the University of Chicago's Bernard Roizman, a leading expert on the herpes simplex virus.

"The institute has never borrowed any money," Williams said of the low-budget operation, where the decor is stuck in the 1980s, but the labs boast up-to-date equipment. "We have to have research results good enough to attract additional government funding and get the rest from the community. We're competing with everyone else out there for money."

Current research projects at the institute include investigator Amy Sears' work on antiviral drugs to be used against the herpes virus. Another investigator, Ted Prigozy, is developing vaccine technologies and has applied for government funding under biodefense initiatives.

But a major, long-term focus at Tampa Bay Research Institute is on the potential uses of pine cone extract as an oral botanical drug to boost the immune system.

Guy Bradley, who worked at the institute as an undergraduate, rejoined the staff five years ago to identify how the pine cone extract, made from mulched cones that are byproducts of papermaking, works.

"It's like tracing a long-distance phone call," Bradley said. "It's clear the extract, taken orally, is a powerful stimulative to the immune system. Now we have to figure out what are the messages it sends and how does it get the ball rolling?"

An international scientific journal published the institute's latest paper on its findings about the pine cone extract in the spring, generating feedback and collaborative opportunities with researchers around the world, Bradley said. Last month, the institute applied for a five-year, \$1.2-million NIH grant that should allow the researchers to move the extract to human clinical trials.

"We have a lot of work to do," said Bradley, who is now testing the pine cone extract on mice injected with cancerous tumors. Bradley, who previously was a tenured professor at Eckerd College, said the decision to join Tampa Bay Research Institute was easy after seeing the X-rays of a 12-year-old boy whose softball-size lung tumor shrank to the size of a golf ball after two months of taking pine cone extract. "There was no way I could not do this," he said.

Working in virtual anonymity, Tanaka and her colleagues try to be positive about the Scripps expansion, which has received more publicity and government funds than they could ever dream of.

"It could be an opportunity for collaboration," said Williams, the institute's chairman. "At the same time, Scripps has a worldwide reputation, so it could be a bit of overshadowing."

Prigozy, who previously worked for a biotech company in Northern California and before that for the Institute for Allergy and Immunology in La Jolla, already is collaborating with a Scripps' researcher on his vaccine work. He expects the spillover from Scripps' expansion to help ease a sense of isolation biotech researchers have in Florida.

"There will be more biotech conferences here and they'll recruit some famous people," said Prigozy, who also collaborates with scientists in Europe and Japan. "It's been a little bit of an adjustment to come to Florida. You have to be a little more assertive and aggressive. Scripps will bring tremendous clout. In terms of life sciences, Scripps has as much brand recognition as Harvard."

Orthopedic Designs Inc.

It took Scripps Research Institute, promising countless spinoffs and potentially life-saving drugs, less than a week to get state approval for \$369-million in public money.

It took John Schaber, with an FDA-approved product and proven market, 18 months to raise \$6.3-million from investors for the medical technology startup he runs in St. Petersburg.

Unlike Scripps, which focuses on scientific research, ODI develops devices to repair joint fractures. The company was started in 1995 by Dr. Dale Bramlet, a St. Petersburg orthopedic

surgeon and president of All Florida Orthopedics, who thought he had a better way to fix hip fractures.

After seeing traditional surgical screws work loose in the joints and require a second operation, Bramlet tinkered with a way to make the screw anchor in the bone, rather than just the marrow. His fix: four retractable talons that are deployed by the surgeon after the screw has been inserted. With the talons, the device works much like a molly bolt used to hang planters from ceilings.

Using \$1-million of his own money and tapping family and friends, Bramlet got a patent for his invention, found a manufacturer, had the talon screw tested at the University of Florida's biomechanics lab and received approval for its use from the Food and Drug Administration. The final product was ready to market by late 2000.

Recognizing that it took more money and time than he had to move his invention to the next stage, Bramlet hired Schaber to run the company in March 2000. Bramlet remains the company's largest shareholder. Schaber had worked for orthopedic device manufacturers for 20 years and knew the network of independent agents who sell the products to doctors.

Schaber said it has been an uphill battle trying to convince surgeons to try a new product, especially when there are more than a dozen variations on the hip screw already on the market.

"But now we've got doctors using about 100 a month and they're seeing better results," Schaber claimed.

The complication rate with ODI's screw is 0.5 percent, compared with 6 to 19 percent for competitors, he said. More than 2,100 of the company's screws have been used to repair hip fractures.

ODI's screw, made of stainless steel and in an assortment of sizes, sells for about \$800, which Schaber said is similar to competitors' prices. This year, the company expects about \$1-million in sales, but it is at least two years away from profitability.

"We plow all our money back into research and development," Schaber said. "We've got three engineers who are developing the adaptation of talons to devices used in total joint and knee replacements and other trauma products. Our product is just a new way of securing implants to bone."

By the end of the month, the company hopes to introduce its next product, a stainless steel nail that fits inside the bone, rather than attaches to the outside. Price for the nail, which requires less invasive surgery than existing implants, is about \$1,600. The market is also less crowded, with only about a half-dozen competitors.

But building up inventory, developing new products and hiring salespeople doesn't come cheap. ODI, which has a dozen employees and 30 commission-based agents, is gearing up for another investment round, this time hoping to raise \$7-million.

Early backers, such as Jabil Circuit chairman William Morean who owns 26 percent of the company, are expected to continue their support of ODI. Schaber thinks the improving economy and maybe even the Scripps' deal may help him close deals faster this time.

"I'm hoping maybe Scripps will bring a focus to Florida and to other companies like us," he said. "Whether you're tech or biotech, it doesn't seem to be the focus here. Last time, I heard lots of investors say, 'It's too bad you're not in California or Boston.' "

Intelligent Micro Patterning

In a cramped, second-floor office across from Williams Park in downtown St. Petersburg, Jay Sasserath and his three partners are building a biotech business.

Intelligent Micro Patterning LLC, started in July 2001, has all the ingredients for the kind of successful spinoff that politicians have been predicting will occur once Scripps Research Institute opens in Palm Beach.

It has patented technology, an experienced management team and customers in the biotech as well as the defense industry. But unlike Scripps, with its half-billion-dollar public funding, Intelligent Micro Patterning has been financed by its owners and has reached cash-flow positive without government or venture capital help.

The low-budget, bootstraps operation at Intelligent Micro is much more representative of how scientific research and development typically translates into a marketable product: with little glitz, lots of long-distance sales calls and plenty of long hours in the lab.

Intelligent Micro's focus is making microdevices, like minicircuit boards and sensors, with features as tiny as 1/20th the diameter of a human hair. The devices can be created on a variety of surfaces, from a glass microscope slide to the inside of a curved surface. Intelligent Micro's products are used by university biotech researchers to allow them to manipulate cells and DNA on microscopic levels. Other uses are as underwater sensors (hence their application to a curved, enclosed surface like a pingpong ball) and as microlenses in fiber optic networks. Cost to develop and fabricate the devices ranges from \$2,000 to more than six figures, Sasserath said.

Sasserath's partner, David Fries, developed the machine that uses a unique process to make the microdevices as a faculty member at the University of South Florida's Center for Ocean Technology in St. Petersburg. Though USF retains the patent on the machine, the company has exclusive global rights to sell microdevices made using the machine, as well as the machine itself.

Though sales of microdevices generated early revenue, equipment sales are becoming a bigger part of the business, Sasserath said. Eight have been sold and two systems are being constructed, one for a researcher at the University of North Carolina Medical School and the second for an unidentified defense contractor. The units, which are about two feet square and use a Windows-based computer and a special patented filter to produce the micro pattern, cost from \$80,000 to \$400,000 each.

Sasserath, former vice president of business development at Plasma-Therm, now Unaxis, in St. Petersburg, is the company's chief executive. His wife, Addys, is in charge of marketing. Carolyn Fries, David's wife, is an engineer who is vice president of engineering and operations. The four partners, equal co-owners, are Intelligent Micro's only full-time staffers. The company also has 10 contract engineers, most of them affiliated with USF, as well as 10 sales reps in the United States, Europe and Asia.

Intelligent Micro has been profitable since January 2002 and has a positive cash flow, Sasserath said. "The two biggest surprises in running my own business are learning how difficult it is to collect on receivables and the importance of good sales people," he said.

Sasserath said most government incentives he has explored seem geared to much bigger businesses than his. One thing his company needs, but can't afford, is wet lab space, complete with sinks, exhaust hoods and ventilation so acids and flammable chemicals can be used.

"A nice lab would cost \$70,000 to \$80,000 to equip and that's high-risk bank financing," Sasserath said. "But if we had one, we could develop more devices. Right now, there are limits on what we can do."

Though Scripps is getting a wet lab, staff salaries and more in Palm Beach, all on the public tab, Sasserath doesn't waste energy being envious.

"They're a potential customer for both our machines and our devices," he said. "I've already got a guy in Southern California chasing them."

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