

Business North Carolina

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Pilot Therapeutics' odyssey leads a scientist to discover there's more — and less — to business than he thought.

By Irwin Speizer



Staring out from a Web page in a tight T-shirt with his muscular arms crossed, Floyd "Ski" Chilton might pass for a biker but for the lack of menace in his eyes. In fact, he is a 49-year-old biochemist, an authority on the effects of fatty acids on human health. A scientist with some 60 patents who runs a National Institutes of Health research project from his base at Wake Forest University Medical School, he is a crusader for his vision of how to fix the American diet, with an advice book in print and another in the works.

But around Winston-Salem, he is best known — not always fondly — as a businessman. Nine years ago, he used his research to start Pilot Therapeutics Inc., a company that promised to launch the Twin City into the forefront of biotechnology. He envisioned hundreds of workers developing, perfecting, manufacturing and distributing what are called medical foods. The scheme touched off a bidding war between the Carolinas. Chilton followed the money to Charleston, only to burn through millions in seed capital from public and private sources. He ran out of cash before he got a product to market. In late 2003, he shuttered the business and, early the next year, limped back to Winston-Salem and Wake Forest, adopting a profile so low that many of his backers had no idea what had become of him.

It was the end of Pilot Therapeutics — or so many thought. But Chilton had only induced a coma, with the company retaining rights to key patents and products under development. In November, he shocked the business back to life with an announcement that Pilot had inked a deal with a Boulder, Colo.-based company that would make and market its medical foods to treat allergies, asthma and eczema. Efficas Inc. has started selling products based on Chilton's science on its Web site. If they catch on, it hopes to sell them in stores.

Pilot now has its first operating cash flow, and Chilton is cautiously trying to reconstitute the company. Whether Pilot will have better luck this time is another question. He plans to concentrate on the science and leave the business to managers. Looking back on its disastrous first run, he says, "I was simply an entrepreneur trying to survive."

That he became a scientist and author is itself a testament to his perseverance. Chilton grew up in Pilot Mountain, the dyslexic son of a tobacco farmer, forced to cope in an age when few understood his malady. In sixth grade, teachers put him in special-education classes. Through will and effort, he worked his way back into the mainstream. "That type of thing can either destroy you or do something else. For me it did something else. I have spent my whole life trying not to be put back into that class again, driven by fear of that."

He had a knack for science and a basic understanding of business, thanks to his father. When he was in high school, his dad gave him a small stake to trade stock. They would compete for best gains. Later, his father turned over a two-acre plot of tobacco, which Chilton worked and harvested to pay for college. The irony is not lost on a man whose career is based on promoting health. "I see nothing good about tobacco. But we are born where we are born."

After graduating from Western Carolina in 1980 with a bachelor's in biology and chemistry, he enrolled at Wake Forest, completing his doctorate in biochemistry in 1984. His thesis was on the inflammatory response, the biological defense the body uses to fight infection and other assaults. A little inflammation at the right time is a good thing. But when the body doesn't know when to turn it off, bad things happen, such as arthritis, asthma and allergies.

His thesis proposed a unified theory of inflammation, which he has been developing ever since. "In the human genome," he says, "there are 25,000 to 30,000 functional genes. Of those, 1,500 to 2,000 control inflammation. How we goose these genes by environment and food plays a critical role in which genes are being overproduced, which underproduced." Chilton spent a year at the University of Colorado doing post-doctorate training in pharmacology, then landed as an assistant professor at Johns Hopkins School of Medicine in 1986. In short order, he became a respected research scientist with several NIH grant projects.

While he was in Baltimore, one of his three sisters, Tammy, called him, desperate. At 12, she had been diagnosed with juvenile rheumatoid arthritis. Having struggled through treatments trying to control the pain and inflammation, she wanted some answers: Should she try some of the natural remedies promoted by alternative health sources? Was there anything he had run across that might help? "Most great journeys in life happen because you desperately love and want to help someone," he says. "She was my inspiration and driver."

Using NIH money and grants from drug companies, Chilton began studying fatty acids to see if they could control inflammation. He had started clinical tests of combinations of fatty acids by the time Wake Forest recruited him in 1991 as a biochemistry professor. He became the director of a new molecular-medicine program, and his work led to a series of patents. Five years later, he stumbled onto a combination he was convinced could help not only his sister but others suffering from inflammatory afflictions.

He was seeking a new way to block leukotrienes, substances that the body uses to sustain inflammation. Leukotriene blockers are a \$3 billion-to-\$4 billion industry worldwide and include such blockbuster drugs as Merck's Singulair, which treats asthma and allergies. Chilton came up with a natural alternative derived from borage, a bristly herb Germans use in soups and salads. Its oil contains gamma-linolenic acid, a compound that can block leukotrienes but is rarely found in nature.

By 1998, his work had whetted the interest of investors. He got a call from Academy Venture Fund in Research Triangle Park, and principals Glenn Kline and John Ciannamea met with him. "They worked with Wake Forest to put a license agreement in place," Chilton says. "Wake Forest became an equity owner, and the company was formed." Ciannamea, who is on Pilot's board, declined to comment for this story, except to say that Academy remains an investor — it is Pilot's largest shareholder — and still believes in Chilton. The company hasn't filed an annual report with the U.S. Securities and Exchange Commission in years — an oversight Pilot is working to remedy — but Chilton estimates his own stake at 10% to 15%.

He launched Pilot Biotechnologies in October 1998. Early the next year, Academy and Triad Venture Management teamed to invest \$750,000, and the company changed its name to Pilot Therapeutics. Chilton moved it downtown and hired Sara Brooks Creagh, a vice president of Durham contract-research organization Quintiles Transnational Corp., as president and CEO. It was an interim position, he says, and when she departed in December 2000, he left Wake Forest to run the company.

By then, Pilot had raised more than \$2.5 million in venture capital and started clinical trials on a gel that could be eaten from the package or combined with food. Because it was a dietary treatment rather than a drug, it fell under the classification of medical foods, which meant less-rigorous testing and review by the U.S. Food and Drug Administration at a fraction of the cost. Plans called for products to reach the market in 2001, generating \$14 million of revenue that year and \$143 million by 2003. Through Creagh's connection, Quintiles had become a backer. As part of the deal, Quintiles provided a \$6 million line of credit. A secured creditor, it would be able to turn its debt into equity. It's still waiting to recover its investment.

The next step was to go public. Through a deal arranged by Kline and Ciannamea, the company merged in 2001 with an inactive shell corporation, New York-based InterAllied Group. Pilot became a public corporation cheaply and quickly — but without the new money that comes with an initial public offering of stock. That summer, InterAllied began trading as Pilot Therapeutics Holdings. Then came 9/11. The terrorist attacks hastened the stock market dive and collapse of the tech boom. "We were a public company without any of the advantages of a public company," Chilton says. "We had not been able to raise the promised money. We didn't have an institutional investor. We didn't have an investment bank. We didn't have the promised analyst coverage." Pilot burned through its private financing as it raced to perfect its product. In August 2002, it announced completion of its fifth clinical trial of the asthma and arthritis treatment it now calls Airozin and prepared to test-market it.

Chilton wanted a bigger headquarters, staffed by highly paid scientists and executives to handle research and marketing, plus a factory to make the products. Because his formula relied on borage, which was not available in large quantities in the U.S., production depended on partnerships with farmers. That had political appeal: Borage might replace tobacco on idled acres throughout the Carolinas.

News that Pilot was close to launching a product reached South Carolina Gov. Jim Hodges' administration. Within days, Chilton got a call from economic-development officials trying to bolster biotechnology in Charleston. Their pitch: The state would provide generous incentives if he moved the company to South Carolina. He had stumbled on a new source of funding. As a rule, government provides scant support to startups, focusing on established businesses looking for locations for factories or offices. Most incentives at the time were tax breaks — little help to a company such as Pilot, which might not have taxable income for years. South Carolina was offering cash.

Chilton told his contacts in the Winston-Salem business community about South Carolina's interest. When the information got to Raleigh, North Carolina joined what quickly became a bidding war for a company that had not earned a dime and had barely \$150,000 in the bank. "The whole process just snowballed," Chilton recalls. "It was the strangest thing I ever experienced." North Carolina's Golden LEAF, a nonprofit created to distribute proceeds from half the state's estimated \$4.6 billion share of the national tobacco settlement, jumped in. In August, it established a \$42 million venture fund for biopharmaceutical companies and began talking about investing in Pilot.

News accounts pegged South Carolina's offer at \$10 million in tax credits and incentives, plus \$6 million in working capital; North Carolina's offer, initially reported at \$8 million, apparently was about \$2.5 million.

No one got it right, Chilton says, but he declines to discuss actual figures. In October 2002, Pilot moved to Charleston, where state officials said it would occupy a new \$2 million headquarters and build an \$8 million plant in Orangeburg. Pilot began a small marketing test of Airozin. One of the first to try it was Chilton's sister, though the plan was to sell Airozin initially as an asthma treatment.

While Pilot pushed toward commercial production, its relocation played into politics in both states. Though he wouldn't face re-election until 2004, North Carolina Gov. Mike Easley caught flak in the Triad for letting a homegrown biotech slip away. Defending the state's effort, Commerce Secretary Jim Fain wrote a lengthy Op-Ed piece for the *Winston-Salem Journal*. Golden LEAF had come up with \$2 million of equity financing; the state upped the ante with a \$500,000 grant payable after Pilot created 160 jobs. It would have been eligible for tax breaks for new jobs, plus there were local efforts to sweeten the pot. South Carolina apparently included more upfront cash than Tar Heel officials deemed appropriate, Fain noted. "We believe that private investors, with their own risk tolerance and assessment of the market, should be the ones to provide venture capital in this instance."

In South Carolina, Republican Mark Sanford used the deal to flog the Democratic incumbent in the 2002 campaign for governor. In one debate, he noted that Pilot had lost \$2.5 million the previous year and had arrived with only 15 jobs. Hodges argued he was not only bringing biotech but a company that would help farmers, a point Scott Derks, marketing director of the S.C. Department of Commerce, amplified.

Hodges lost, which didn't help Pilot. When Sanford took office, he put the grants under review, creating a series of delays that effectively shut off the money pipeline without having to make a formal decision to stiff the company. "There was a new level of scrutiny that made it more difficult," Chilton says. "This company was the example that everyone knew about. It had achieved rock star status. And it was very uncomfortable." Even making payroll was a challenge. In 2002, Pilot had spent \$412,000 on salaries for its top three executives, including \$176,000 for Chilton. By September 2003, the company, which had received about \$3.5 million from South Carolina, was down to its last \$100,000. Employment had dropped to 10.

Chilton's family had stayed in Winston-Salem, and while his company teetered on the brink, his marriage fell apart. Things got worse. On Nov. 28, 2003, one of his four children, Josh, lost control of his car. The crash paralyzed the high-school linebacker below the waist. Dismissing his remaining employees and closing the Charleston office, Chilton retreated to Winston-Salem. The building that was to be the factory was sold to another company. "I simply couldn't function in this role any more."

Wake Forest took him back as a research scientist. He stayed in touch with some major investors but avoided others. Creditors were left wondering if they would get their money back. "I honestly told [the university] to keep it quiet. I didn't want to be found for six months." Since 1998, Pilot had spent about \$18 million, with little to show except a prototype for a supplement Chilton felt was ready for market. "A lot of people wrote them off," says Michael Batalia, Wake Forest's director of technology asset management. "But Pilot never really went away. They were just trying to find opportunities to partner the technology, to get products out on the market."

In early 2005, Chilton landed a \$7.5 million NIH grant to study dietary supplements and wrote a book aimed at nonscientists. Published by Simon & Schuster, *Inflammation Nation: The First Clinically Proven Eating Plan to End Our Nation's Secret Epidemic* covers the topic and recommends some dietary supplements. In one reference, he mentions Airozin as a type of product that might prove useful. The book — reissued last year by Rodale as *Win the War Within: The Eating Plan That's Clinically Proven to Fight Inflammation* — revived Chilton's sagging reputation and boosted his bruised ego.

Meanwhile, he was quietly hatching a plan to bring Pilot back to life. Burrill & Co., a San Francisco venture fund that specializes in life sciences, had invested in a biotech startup in 2002 and two years later put Chilton in touch with its CEO. Mark Braman spent more than a year mulling Pilot, Airozin and Chilton, who hadn't lost his touch. "He was part of the reason I wanted to do the deal," Efficas' chief executive says. "He is very talented and very passionate about what he's done." In spring 2006, Braman struck a licensing deal with Pilot and Wake Forest, still a partner. Efficas then spent \$1.5 million on product and market research, preparing for a launch.

Pilot stock, which had hit a high of \$9.25 a share in 2002, was rarely traded and almost worthless. On Oct. 24, 5,000 shares changed hands at 3 cents, followed by 1,300 more at the same price the next day. On Nov. 8, Pilot issued an open letter to stockholders — its first communication to them in three years — informing them of the Efficas deal. The letter was signed by Derks, Pilot's new president, who had left South Carolina's Commerce Department after Sanford's election but stayed in touch with Chilton. When

the Efficas deal began taking shape, Chilton brought him on board. On Nov. 13, about 330,000 shares traded, closing at 8 cents. The next day, 570,000 shares changed hands, closing at 23 cents. The stock reached 91 cents Nov. 15, when 380,000 shares traded, though it retreated to close at 60 cents. In mid-March, the price had dropped to 26 cents.

By year-end, Efficas' Web site was selling three medical foods based on Chilton's research, one each for allergy care, asthma and eczema. Like Airozin, each is a gel that can be eaten alone or mixed with food. Cost: \$39.95 for a month's supply. Braman hopes to have the products available at specialty stores by summer and eventually into mass-market outlets. He won't disclose financial details of the arrangement with Pilot but says it is a typical licensing agreement with an upfront payment and royalties on sales.

The deal will create Pilot's first revenue stream, but where the company goes next is unclear. Chilton remains on its board but says his role will be mostly as a science adviser. He is working on his next book, tentatively titled *The Gene Smart Diet*. His sister Tammy works in his lab while pursuing a doctorate in microbiology from Wake Forest. He says her pain has eased and mobility improved since she started taking Airozin.

This, Chilton says, helped him get back to what he does best. "The thing I have come to realize is that a lot of folks can run a company, but very few people can come up with the creative ideas to better humanity. That is where I need to focus for the rest of my life."