



The EpiCard Epic

Intelliject's auto-injection device for treating food allergies is shaping up to be a blockbuster. And it's just the first of many promising products likely to flow from the Richmond lab.

By James A. Bacon

Intelliject, LLC, finds itself in an enviable position right now. Although the fledgling company still needs to file a New Drug Application with federal regulators for its product, the EpiCard, and then await agency approval, it has giant pharmaceutical companies standing in line to do business. The biggest challenge the company faces right now, says CEO Spencer Williamson, is picking the right partner.

That's a lot of due diligence for a 10-person firm. "It's the kind of problem a lot of people would like to have," Williamson says. "But it's still a problem."

Truly, most start-up businesses *would* love to have Intelliject's problems. So vast is the market for the EpiCard -- millions of Americans suffering from severe allergies need a device that can make emergency injections of epinephrine -- that Intelliject is in a position to command up-front payment for rights to license the product before it has even won FDA approval.

Even more enviable, unlike most companies that have developed a new drug or medical device, Intelliject has not struggled to raise capital. The first three rounds -- family & friends, angel, institutional -- will largely

suffice. Instead of raising cash to build a large organization, Intelliject will use royalties from the EpiCard to underwrite development of follow-up products. Says Williamson: "We may put a little more capital in at some point, but we have been blessed from the start with significant interest and access to value-add capital."



CEO
Spencer
Williamson

Richmond has never seen anything quite like Intelliject. Local life sciences ventures have raised tens of millions of dollars in outside capital, and some companies have shown modest success, but no business has come so far, so fast. And none have the seemingly blue-sky potential for limitless growth.

Williamson and the company's two 28-year-old founders, identical twins Evan and Eric Edwards, are looking already to their next projects. The technology developed for the EpiCard, which is tightly protected with more than 50 patents, can be used to deliver medicine for the

treatment of asthma, multiple sclerosis, rheumatoid arthritis and the symptoms of chemotherapy. Also, there are potential applications for biodefense, the military and pandemic preparedness like the avian flu.

"We feel like we were divinely brought together," says Williamson. "There is no challenge we can't get over. Every challenge is meant to be. It's part of the journey."

Evan and Eric both have suffered from severe food allergies -- egg products, seafood, tree nuts, peanuts -- since they were children. Evan has had two close calls. In one incident, he accidentally ingested nuts mixed with hummus at a northern Virginia restaurant. He didn't have an epinephrine auto-injector with him. Within minutes, his lips and throat began to swell as his body slipped into anaphylactic shock. He was saved by being rushed to a local hospital.

Native Richmonders, the Edwards lads decided to devote their lives to developing solutions for people suffering the same infirmity. Evan obtained a masters degree in systems engineering at Virginia Commonwealth University, with a concentration in human factors engineering, while Eric studied clinical disease management at VCU's Medical College of Virginia as a MD/PhD candidate.

At age 26, the Edwardses were far enough along in the development of an EpiCard prototype that they could start building the company. Their key hire was Williamson, a Virginia Military



Eric (left) and Evan Edwards, the 28-year-old inventors of the EpiCard.

Institute grad with an MBA from Chapel Hill who had risen through the ranks at pharmaceutical giant Eli Lilly and medical device manufacturer Guidant Corporation.

For some three decades, people who suffer severe allergies have had the option of only one portable auto-injector: EpiPen, an outgrowth of NASA technology produced by Napa, Cal.-based DEY L.P. While EpiPen has helped patients for 27 years, in Williamson's estimation the product has several drawbacks.

First, it's fairly large: not so bad for an adult, but a major inconvenience for children. (Only a third of severe allergy sufferers consistently carry auto-injectors with them.) Second is safety: once the EpiPen is used, the needle protrudes from the tube, where it can jab someone. Third is the ease of use. It's one thing to pop off the cap, extend the needle and jam it into your thigh when your mind is clear. It's quite another when your blood pressure is plummeting, your throat is constricting and you're losing your cool.

The EpiCard is designed to be more compact than EpiPen, making it easier for a child to carry in a pocket. Furthermore, the needle retracts when it has been used, eliminating the po-

tential for accidental sticks. Most imaginatively, the EpiCard bears a voice chip that walks the patient through the administration of the epinephrine step by step.

"It's small, it's simple, it's safe," says Williamson. "We've put this in the hands of people who've never used it before. They've used it appropriately."

Those differentiators should be sufficient to give EpiCard a big competitive advantage in the marketplace, but the Intelliject team is working on yet another. The shelf life of epinephrine in auto-inject devices is about 18 months. Trouble is, there's no way to tell if the drug has gone bad. "People forget the darn things have expired," Williamson says. Intelliject is working on an epinephrine formulary that will last longer -- and a device that will tell patients when it's time to replace the unit.

The auto-injection market for allergy sufferers is immense. According to Wikipedia, between 1.2 and 16.8 percent of the U.S. population is considered "at risk" for having an anaphylactic reaction. Of those who actually experience anaphylaxis, up to one percent may die as a result. In other words, according to Williamson, on average five Americans die every day from the syndrome. And the problem appears to be getting worse -- perhaps as a result of American society's hyper-sterile environments and children's lack of exposure to germs that would build up their immune systems.

EpiCard is intended to do more than save lives, Williamson says. It will provide peace of mind. "People live in fear when they go to a restaurant or a friend's house. What if the mother is making sandwiches and uses the same knife on peanut butter as the mayonnaise?"

Williamson cites a study that compared the quality of life of diabetics to people with food allergies. Even though diabetics have to inject themselves every day, they enjoy a better quality of life. "He feels in control. The food-allergy person doesn't."

Putting patients in control -- that sums up the company's mission. "Our vision," says Williamson, "is to revolutionize health care by designing patient-centric pharmaceutical products that empower patients to control, and gain freedom from, their medical condition."

A key element of Intelliject's strategy is to run a lean, capital-efficient business. "We're a semi-virtual organization," says Williamson. "We have partners all over the world on the manufacturing side, the drug development side. I was in Eastern Europe last week."

The trick is picking the right partners and executing the plan through them. "It's a lot of work," Williamson says. "You have to manage a lot of partners. I think we do a pretty good job with that, but it's not easy." On the positive side, the strategy allows Intelliject to stay small and focused on what it does best: product development.

To excel at its core mission, Intelliject is recruiting top people from around the world to staff the company. "Our philosophy on people is this: If you're going

to build a world-class company, you have to have world-class talent," Williamson says. That means persuading people, who could live anywhere they want, to pick up and live in Richmond, Va. Fortunately, that has not been a problem.

The firm's downtown location, in the First Market Bank building, is "dynamite." It's right off the canal, with lots of sights, sounds and tastes all around. The company flies in the recruit, puts him in a hotel on Shockoe Slip and sells the city's quality of life. The most recent hire, says Williamson, just moved here from Zurich, Switzerland. "He's bought a house in Glen Allen and has two kids at Steward School. He's fired up."

"We love being here," he says. We are an hour and a half from the FDA and some of the best regulatory consultants in the world. We're two-and-a-half hours from the Research Triangle," where Intelliject interacts with companies and consultants.

Everything seems to be going Intelliject's way at the moment and Williamson could hardly be more up beat. "This thing is smelling like it's going to be pretty valuable," he says. "We openly talk about it, if this business is wildly successful, we want to stay together and do things that impact, and help, people."

What could be more fulfilling?

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