

Entrepreneurial Dominion



Jay Bua

Thin Skinned

Ascend Therapeutics specializes in delivering pharmaceuticals through the epidermis. Its TamoGel product could provide relief to millions of women who suffer from chronic breast pain.

One of the greatest challenges in pharmaceutical research is figuring out how to deliver a drug to the location in the human body where it's needed. Compounds taken in pill form must run a veritable gauntlet. First, the large organic molecules must make it past the acidic cauldron of the stomach. Then, once they're absorbed into the bloodstream, they must fight their way through the liver, which metabolizes foreign compounds and expels the residue.

In theory, you can crash through these natural barriers if you deliver massive enough doses. But that's tricky. Too much of a compound can create negative side effects.

Such problems create a business opportunity for Ascend Therapeutics, a Herndon company that has licensed technology from a Belgian firm for delivering drugs "transdermally," or through the skin. "There are a number of molecules that would benefit from an alternative route of administering a product," explains Ascend CEO Jay Bua. "Our technology is a gel system. It absorbs into the skin. It avoids the stomach, and avoids the liver."

Ascend's business strategy is to identify known pharmaceuticals that would benefit from transdermal delivery and then conduct clinical trials to prove to the federal Food and Drug Administration that the new delivery mechanism is safe and efficacious. Though founded only two years ago, the company already has two products in Phase Two of clinical trials. If results are positive, one of them, TamoGel, could move to a Phase Three trial -- large-scale testing in multiple locations -- by the end of the year.

TamoGel targets the five or six million women in North America who suffer from severe breast pain due to an excess of estrogen. "There's nothing else on the market that can treat it," says Bua. "Women get referred around from physician to physician. But other than telling them to avoid caffeine, there's really not much a doctor can do."

Treating chronic breast pain may not offer the blockbuster potential of a Viagra or a Lipitor, but it could transform Ascend into a serious player in the pharmaceutical industry in an incredibly short time on the basis of a modest investment. So far, Ascend has needed to raise only \$19 million, though it does expect to seek another funding round in 2005 to finance the Phase Three trials. The company has a slew of other products in the investigative pipeline, including one in Phase Two that would offset the use of estrogen, which can cause men to grow breasts, in the treatment of prostate cancer.

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If TamoGel receives FDA approval, Ascend will have the breast-treatment niche all to itself. Says Bua: "There are no other developed products in this field right now, nothing that doctors can turn to. There is no competition in the drug-development cycle." The company still faces years of clinical trials before generating significant income, he adds, but "so far, all signs are encouraging."

A 20-year veteran of the drug business, Bua helped pioneer the development of transdermal drug delivery in North America. From 1988 to 2002, he worked for Laboratoire Besins, the Belgian firm that invented Enhanced Hydroalcoholic Gel (EHG), which enables the absorption of drugs through the skin. The skin, like the liver, is an effective barrier to outside chemicals – that's why so few pharmaceuticals are delivered through ointments or creams. But Besins' gel separates the outer skin cells enough for the drug to penetrate to the lower layers.

Besides bypassing the stomach and liver, EHG enjoys another potential advantage as a drug delivery mechanism. "Think of the skin as a sponge," Bua says. "If we create the gel right, the drug will leach into the blood stream." In contrast to drugs that are ingested orally, which peak rapidly in the blood, transdermal delivery allows the active ingredients to leak slowly. "When you're talking about a chronic condition that exists day in and day out, steady-state delivery is what you want."

While working for Besins, Bua recognized the potential for a testosterone gel, Androgel, to stimulate demand for testosterone replacement therapy, and nursed the product through the commercialization process. Today, Androgel is the leading product in what is now a \$400 million-a-year market.

By the early 2000s, Besins' EHG technology was generating \$400 to \$500 million in sales in North America – with many new potential applications on the horizon. The trouble with licensing the technology and collecting royalties is that other people capture most of the economic value added. Bua dreamed of creating a business that would reap a larger share from the successful launch of new products. In 2002, he formed Ascend Therapeutics.

Financed initially by his old bosses at Besins and later by a European investor, Bua obtained the license for the EHG gel in the North American market. He assembled an R&D team under Dr. Dana C. Hilt, the chief medical officer; Suzanne Richardson, CFO in charge of business development; and Andrew Palumbo, in charge of running clinical trials. With a staff of 10, the company is in a "holding pattern" until the TamoGel results come in, Bua says. But assuming

everything goes as expected, he expects to double employment by year's end, and grow even more in 2005.

The firm's location in Herndon, a center of the information technology industry, is a bit off-beat for a biotech company but it has worked out nicely, Bua says. Besins set up shop in the Washington area in the late 1980s to be close to its Washington, D.C., law firm, which assisted in drug development. Bua, who had experience in drug development at Ciba-Geigy, didn't mind relocating to the area – his wife's family is from Northern Virginia.

Ascend's office is located near Washington Dulles International Airport, a convenience for international business partners, and the company has had no difficulty recruiting senior management talent. Hilt, the chief medical officer, commutes to work from Maryland every day. Richardson, the CFO, is a University of Virginia grad who had worked extensively in Northern Virginia's financial sector.

Ascend brings to the table a prestigious advisory committee including top scientists in drug development strategy, alternate delivery systems and benign conditions of the breast. Also, notes Richardson, the company has strong hands-on experience registering compounds based on alternative delivery methods. "Jay has been involved in most of the transdermal delivery drugs in the United States. He knows what needs to be done to get a drug through the FDA."

Meanwhile, Ascend continues to enjoy a strong relationship with Besins, the world's largest manufacturer of prescription gels. Says Bua, "They will manufacture the gels for us going forward."

Looking ahead, the biggest business challenge – aside from shepherding TamoGel and kindred products through the FDA approval process – will be negotiating the partnerships and contracts that give Ascend a bigger piece of the product-development pie. "We don't want to just be an R&D company," says Bua. "But we're not naïve. We know you can't build a pharmaceutical company overnight. We see biting this off in small pieces." One intermediate step might be participating in a product's revenue stream based on sales and profitability.

"In three or four years, we hope to be sharing in commercialization," he says, "with a plan to step up with greater involvement as we go forward."

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