AIDS' Next Frontier

Biotechs try to change how the system works

June 1, 1995 By Paul Wynn

Taken a look at the AIDS-treatment horizon lately? The view has been rather depressing for a while. Kicking up some new dust, however, is a maverick brand of pharmaceutical research called biotechnology that may redefine the "right way" to discover drugs. Biotech companies have an aggressive, Wild West attitude, and they know how to work the AIDS community. But are they working in the name of legitimate progress or just working us over? *POZ* investigates.

Whether it's chasing after golden dreams, starring roles or open space, it seems like all the risk takers move out West. So it shouldn't be surprising that one will find innovative scientists there, particularly in California, challenging the mysteries of AIDS. And it's about time. Mavericks or not, the AIDS community desperately needs researchers who are willing to break the rules. For more than a decade, which seems like an eternity, AIDS activists have been battling stodgy scientists and hidebound procedures at pharmaceutical companies.

A handful of scientists are willing to take some chances, often with a gold-rush mentality. These researchers are in the biotechnology industry. Their companies are scattered across the country but many are clustered on the West Coast. Industry pioneers such as Amgen and Genentech, both of which have developed bioengineered products to fight AIDS-related disorders, are the leaders in this industry.

Amgen, Genentech and the several hundred other biotechnology companies operate very differently from pharmaceutical companies in the way they approach AIDS research. Scientists at pharmaceutical companies, even with the help of computerized drug screening, usually employ hit-or-miss methods to discover drugs.

Once they identify a small molecule that shows activity against HIV, they create a chemically derived drug. This standardized process has churned out drugs such as AZT and the new class of agents called protease inhibitors. But as we know, AZT and its clones have dubious benefits. Protease inhibitors are expected to be merely good alternative therapies, not breakthrough products.

Biotechnology companies (or biotechs), as their name suggests, use *Star Trek*-style biology to treat AIDS. Unlike the pharmaceutical companies that develop chemical drugs that can be quite toxic to the human body, blasting like a shotgun at anything in their path, biotechnology firms

manipulate substances such as genes and proteins already found in the body, focusing like a laser beam precisely on the offending agent.

Biotechs are willing to take risks to develop innovative products, but like their products, biotechs tend to focus narrowly. Martin Delaney, founder of Project Inform in San Francisco, says, “The benefits of this [narrow focus] are that the product gets the company’s full resources and undivided attention. On the downside, they get into positions where there is so much riding on a product that they are much slower to abandon it than a larger drug company would be. They just hang in there past all reasonable hope.”

Biotech research is usually directed by scientists who come from academia or government institutions such as the National Institutes of Health (NIH). These scientists tend to be highly specialized in novel research areas such as gene therapy, protein therapy, immunotherapy and many others. Researchers have pursued many innovative biological approaches that have produced both failures and successes.

Nevertheless, these scientists have already contributed several important products to treat AIDS-related diseases. For the treatment of Kaposi’s sarcoma, San Francisco-based Genentech discovered recombinant interferon alpha, sold as Roferon-A. Amgen, located in Thousand Oaks, California, has developed two breakthrough products, Neupogen and Epogen. Neupogen, or filgrastim, is a granulocyte stimulating factor, which enhances the production of white blood cells when a person develops neutropenia. Epogen, chemically known as epoetin alfa, is an antianemia agent that stimulates red blood cell production.

Research style is a major difference between the pharmaceutical and biotech industries, but the corporate cultures -- and certainly the profit margins -- take very different paths. The biotech industry is young. Most firms were established in the mid-1980s, compared to some pharmaceutical companies that trace their origins to the late 19th century. In addition, next to the giant drug manufacturers, biotechs look like dwarfs. Biotech “giants” Amgen’s and Genentech’s combined sales, for instance, are less than one-quarter the sales of the world’s largest pharmaceutical firm, Merck & Co. Their small size allows them to be more entrepreneurial, more innovative and more likely to take risks than the large drug companies.

To keep their research running, biotechnology companies consume millions of dollars. Without any incoming revenue from products, the companies rely on funding from government research grants, venture capitalists and, increasingly, their pharmaceutical rivals. Only one in 10 companies manages to post annual profits. And a majority of them only have a few years of start-up cash before they will fold. As Delaney points out, biotech CEOs are under enormous pressure to strike a home run very early on.

Companies teeter on the edge of existence until they accomplish the task of developing a safe and effective product. Until that point, CEOs at biotechs are forced to promote their companies to Wall Street to pull in fast cash from stock speculation -- this is where the industry really garnered its fast, wild and even reckless reputation.

High-roller HemaCare helps justify this charge. Since 1990, HemaCare has been studying a product called Immupath, a whole-plasma product for AIDS. The treatment works by taking the plasma component from blood, filtering plasma-suspended antibodies from asymptomatic HIV positive people and then inserting the rarefied plasma into PWAs during the later stages of their disease. As the studies proceeded, officials at the Sherman Oaks, California company hired a public relations firm to coordinate a campaign to spread the news about Immupath. One AIDS activist, who chose to remain anonymous, says the company's intensive promotion was to induce the brokerage community on Wall Street to invest money in the company.

"They had some sort of fax news-release service that they used every time the president blew his nose, it seemed," the activist says. "So it looked like there was a steady stream of news coming out [about the product], but each time they had any clinical data to report, the information was really twisted. You would look at their actual material and then compare it to their press release and you would think you were talking about two entirely different products."

After completing Phase II studies, the company sent out another press release in mid-January, this time announcing the research was terminated. HemaCare officials say the company abandoned the project due to limited cash and to regulatory delays at the Food and Drug Administration (FDA). What the press release didn't say was that the product never reached the FDA's statistical endpoint of increasing T-cell count. When asked if the company ever misled anyone, HemaCare President and CEO Hal L. Lieberman says, "I write press releases and I don't intend to mislead anyone; I'm saying that press releases are written specifically not to mislead anyone."

Biotechnology companies rely on Wall Street more than the deep-pocketed pharmaceuticals do because, when brokers notice small companies like HemaCare and spread the news about so-called wonder treatments, CEOs can more easily find investors. Martin Delaney says many companies that are dependent upon stock market revenue need a steady stream of good news and the appearance of progress going out to the brokerage community.

Delaney explains that most small biotechnology firms cannot afford to pay expensive public relations firms to coordinate promotion, which means their amateur efforts create a lot of mistakes. "Some of them have been embarrassing in their self-promotion to the point that nobody believes what they say after a while," says Delaney. Understandably, then, biotechs have created their share of skeptics. So even when the industry does attempt to take some positive steps, they still act -- depending on who you listen to -- like novices.

In one area, however, some biotechs are very much ahead of their larger and older cousins: They're aggressively reaching out to the AIDS community.

Public relations veteran David Nathanson works with biotechs every day. At Edelman Public Relations in San Francisco, Nathanson is the "bridge," as he calls himself, between biotechs and the AIDS community. He says he is determined to get effective treatments to HIV positive people, many of whom he counts among his friends. "For a long time, I've been an advocate of companies working with the AIDS community so they can really use them as a partner as they go through the

FDA approval process and get important feedback on the trial design of these drugs," Nathanson says.

One of his newer clients is the Florida-based SunPharm. The five-year-old biotech is working with the University of Florida in Gainesville on a product for AIDS-related chronic diarrhea, which is a major problem for up to 30 percent of all PWAs. Nathanson coordinated one meeting between SunPharm and seven AIDS organizations to review data from the Phase I study. The two parties met again to discuss the trial design for the Phase II study.

SunPharm President and CEO Stefan Borg sees the relationship between his company and AIDS activists as being ultimately beneficial to both groups. But prominent West Coast activist Jeff Getty believes SunPharm's motives are not so virtuous. The longtime ACT UP/Golden Gate member says he has been lied to by so many pharmaceutical and biotech companies concerning their AIDS drug development that he's become deeply skeptical about the altruistic motives claimed by companies like SunPharm who want to work with the AIDS community. He sees more practical motivations. "SunPharm needs the community to punch the product through the [regulatory] system," Getty says. "So of course they want to meet with the community. We have a capitalist system that's developing therapies for AIDS, is what it's boiling down to: Whether its biotechnology or pharmaceutical, it's still the same thing. The bottom line is money and survival of the company, not our lives. And if they tell you that their bottom line is saving our lives, they are bullshitting you."

Stefan Borg readily agrees that meeting with the AIDS community makes good business sense. But in the meantime, he thinks getting input from the AIDS community is crucial to the success of the diarrhea product. "I think the AIDS groups provide a tremendous experience base from their daily contact with people who suffer from AIDS," says Borg. "That exposure and their interaction with other companies can be a tremendous resource in pointing out what would be a product with desirable benefits."

One area in which biotechs have graduated from the freshman class is their ability to squeeze money out of the pharmaceuticals. Without it, biotechs would be hard-pressed to pursue their innovative (read "expensive") research. At some point, most biotechs receive money from the pharmaceutical industry in the form of research collaborations or marketing agreements. Some pharmaceutical companies go one step further and buy controlling interests in biotechs. Genentech, for instance, is majority-owned by Hoffmann-La Roche, the Swiss-based drug company that developed ddC.

Ownership by pharmaceutical companies might seem to jeopardize biotechnology's entrepreneurial environment, but so far those fears have been unrealized. From every indicator, pharmaceuticals that have large stakes in biotechnology firms have not disturbed their creative research programs. Hoffmann-La Roche officials insist they will not interfere with Genentech's innovative high-tech research efforts.

Most activists see these partnerships as a reflection of the realities of the marketplace. "Many of

the biotechs are forced to partner with larger pharmaceutical companies to get access to capital and marketing expertise," says David Nathanson. "And we are seeing more of that, and my philosophy is whatever needs to be done to get a therapy out to people is what needs to be done."

That's something even the average street-corner AIDS activist can't possibly disagree with.

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