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Global Reach?

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If one could actually call the Conejo Valley's small biotech community in 1980 an industry, AMGen was the local industry leader from the moment of its launch that year. In 1983 AMGen became simply Amgen, and was soon recognized the world over as the leader in commercial biotechnology.

With Amgen's ascent also came a small measure of global awareness for a little town called Thousand Oaks.

But a funny thing happened: Amgen remained the region's only homegrown biotech giant.

True, Baxter Biosciences/Baxter Healthcare has also set up shop nearby in Newbury Park and in Westlake Village. But Amgen stands alone as the only blockbuster drug maker that came of age alongside Interstate 101 north of Los Angeles. Meanwhile, America's big biotech centers have grown up in Northern California, San Diego and New England.

But that doesn't mean Amgen is the only biotech firm along the 101 Corridor with global impact. One company that is particularly adept at creating global partnerships and seeking out emerging markets is Camarillo-based AmProtein Inc.

"Currently, our partners in China include the state-run biopharmaceutical company in Harbin, the North China Pharmaceutical Company in Shijiazhuang, and privately owned AmProtein-China in Hangzhou," says the company's founder and chief scientific officer, Dr. Matthew Hui, a former Amgen scientist.

AmProtein has garnered acclaim, attention and praise internationally for having in development promising new ways of delivering chemical therapies via fast-growing cell vectors.

"We will license out this technology and commercialize bioreactors," Dr. Hui said, speaking from China via an Internet connection. He added, "...We have invented two dual-domain drugs which double block two pathological pathways and are good for multiple factor mediated human diseases."

Whereas in past years biotech companies mainly went to China to find production solutions, and Wall Street or the Silicon Valley to find cash, Hui is in China looking for partners and funding sources. While plenty of funding still comes to biotech from domestic venture capital sources, changes in financial markets have some firms looking across the Pacific for investors. (Find a closer examination of funding along the 101 Biotech Corridor in another article in this special report).

"Due to our lack of fundraising capability in the U.S., our strategy is to use the availability of Chinese funding and an educated workforce," Hui says.

Amgen has faced its own financial challenges during its history, and not just those evidenced by the massive layoffs of recent years. It was not until after spending the 1980s methodically sowing seeds for clinical and commercial success, and overcoming financial challenges along the way, that Amgen enjoyed its golden-child adolescence during the 1990s.

Wide reach

That was when Amgen's first homerun drugs, Neupogen and Epogen made the company famous and

very profitable. Today the company's tentacles stretch out from T.O. to places like Kentucky, New York and The Netherlands, to name just three of the dozens of countries where Amgen has facilities.

Still, the hub of Amgen's global biotech empire continues to be its 45-building headquarters in Thousand Oaks. AmProtein hopes to create a similar realm with Camarillo at the center of its worldwide operations.

But there are already as many ways the 101 Biotech Corridor's global influence is manifest as there are products biotechnology has created. An influential trade publication based in the United Kingdom, called Bioenergy Business, recently invited a Thousand Oaks firm that is developing more cost-effective and viable methods of growing so-called "biofuel" crops, to lay out the latest research for its readers. Of course the company took the opportunity for a little plug of its own cutting-edge work in the article.

"Leading energy crop companies such as Ceres are working to address these issues through advanced breeding biotechnology and optimization of crop management practices," said Anna Rath, director of business development at Ceres.

Scientists at Ceres believe biofuels from crops could replace 75 percent of the gasoline used in the U.S. With China and India poised to overtake the U.S. as greater consumers of petroleum products, a lot of eyes from around the globe are watching Ceres.

Further north along Interstate 101 from the Thousand Oaks companies is MannKind Corporation, which is headquartered in Valencia, and has locations in New Jersey and Connecticut. MannKind's global reach is in the promise of the therapeutic products the firm is in advanced stages of developing, as well as in the geographic scope of its clinical trials.

"We're focused on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer," said Hakan S. Edstrom, president and COO of MannKind.

The company's leading investigational product is its Technosphere Insulin System, which is now in Phase 3 of clinical trials in the U.S., Europe and Latin America. MannKind is also working on cancer drugs.

"We have initiated a Phase-1 study on a potential cancer vaccine," Edstrom says. "It is designed to target two tumor-specific antigens...on the basis of their level of expression in commonly occurring adult malignancies, such as ovarian, prostate, renal, pancreatic, breast and colon carcinomas as well as in melanoma."

In other words, MannKind could one day have an effective cancer vaccine. Such an advent would constitute a genuine blockbuster drug and Amgen would gain a hometown peer – a new biotech giant on the block.

Today there is a concerted effort to increase the mark of the 101 Biotech Corridor on the world map in a big way. To that end groups have formed to promote, organize and sell the products of existing commercial entities along the 101, as well as entrepreneurs, investors and scientists who also want to launch companies along the corridor.

The Biotech Forum is one such group, founded by attorney Brent Reinke and venture capitalist John Dilts. It was modeled on another business-incubation group the pair is involved in and includes weekly networking opportunities, educational programs and conferences to help new and established biotech businesspeople grow their operations.

But a more narrowly focused group is actively seeking, and getting, clients from all over the world. The California Biotechnology Research Consortium is a biotech company's biotech company. Established by former Amgen scientists, CBRC helps biotech companies get therapies to market.

Or, as one consortium official put it, "Get your biotechnology product to the patients who need it, rapidly and inexpensively."

Global clientele

The companies that comprise the California Biotechnology Research Consortium are all located in the Conejo Valley, offering a global clientele all of the components needed to commercialize a drug, starting with recombinant protein expression, which is perhaps too simply stated, finding a biological medium for getting therapies where they need to go on a cellular level.

Another drug-development component, provided by member firm Alliance Protein Laboratories, is protein purification and characterization, which, among other things, ensures product stability.

Camarillo-based APL says it is the only U.S. contract lab offering specific kinds of protein characterization services.

"If a biotech company wants the prestige of saying they have received American laboratory analysis using the biophysical techniques we pioneered such as analytical ultracentrifugation, they have to come to us for characterization services," said Tsutomu Arakawa, Ph.D., president and director of protein chemistry at Alliance Protein Laboratories.

Foreign biotech companies who see U.S. laboratory validation as having a beneficial impact on the marketing of their drugs, as in "Analyzed in the U.S.A.," will only find it in Camarillo, according to APL.

Another consortium member is iGORi Method Development of Thousand Oaks. IGORi can literally take an idea for a biopharmaceutical product and develop a drug that can then be tested for safety and efficacy. IGORi works with other California Biotechnology Research Consortium members to provide some of the analysis, characterization and delivery components along the way.

The consortium's end user delivery-systems member is Integrity Biosolutions, of Camarillo. Integrity offers clients products and services ranging from manufacturing and advanced drug stabilization to injection devices.

For biotechnology firms, the consortium's attraction is based on access to experienced, former-Amgen scientists on a contract basis, and one-stop shopping for the services member companies offer.

But it is CBRC member AmProtein which may be most likely to take its place next to Amgen as a worldwide leader in biotechnology. In fact, Hui hopes one of his company's discoveries will soon merit consideration for a Nobel Prize in scientific discovery.

"This discovery has been confirmed in mammalian cells," he said. "In brief, we can express antibody or protein at commercial levels in one step with gene number amplification."

AmProtein's first-ever DNA physical structure-based mammalian expression mechanism, which may be common for all eukaryotic cells, represents a second revolution after Dr. L. A. Chasen's landmark discovery of gene amplification in 1982. Eukaryotic cells are a cell type upon which all complex organisms are based.

AmProtein also has a new type of bioreactor, a device used for transferring oxygen in cells, a procedure that is elemental to the development of gene therapies.

But Hui won't say if he thinks AmProtein will be the next Amgen.

"I worked at Amgen for many years," he says. "Amgen was the best company in the U.S...(but) they have become a huge company...more bureaucratic and less efficient."

Whether or not Amgen has become too bureaucratic is a subjective question, but no one can dispute its massive size. The company has facilities in at least 35 countries, including Australia, France, Latvia, Russia, Austria, Germany, Lithuania, Slovakia, Belgium, Greece, Luxembourg, Slovenia, Canada, Hong Kong, Mexico, Spain, Czech Republic, Hungary, The Netherlands, Sweden, Denmark, India, New Zealand, Switzerland, England, Ireland, Norway, United Arab Emirates, Estonia, Italy, Poland, Finland, Japan, Portugal, and seven of the United States, as well as Puerto Rico (source:

Amgen).

AmProtein has facilities in China and Camarillo – for now.

“Camarillo was originally selected due to its affordability,” says Hui. “In the past few years, almost all of our discoveries took place in Camarillo in simple conditions.”

Trouble with funding

But that affordability was ultimately negated by a lack of financial resources in the U.S. for AmProtein’s first product, Current, which will be released in summer.

“Due to the difficulty of funding in U.S, the second stage commercial refinement activities took place in China with our partners there,” Hui says. “The production is currently handled in China due to favorable government policies and cheaper labor force.”

AmProtein also sees a ripe customer base for high-output gene-expression product “Current” abroad, not just cheap labor for its production.

“Current is badly needed by Chinese vaccine manufacturers and antibody manufacturers as well as the Indian, Russian and Mexican biotech industry,” Hui says.

“The release of Current will also help small companies and university labs in the U.S. to quickly transform their research success into commercial success due to its affordability.”

In fact, Current could accelerate discoveries at university laboratories around the world by simple virtue of the increase in the volume of research the product will allow them to do.

“At its peak, Columbia University got \$1 billion per year for licensing fees (for Dr. L.A. Chasin’s dihydrofolate reductase discovery),” says Hui.

So, are large U.S. firms asleep at the wheel these days when it comes to potential biotech revolutions bubbling under the surface at small domestic companies and those abroad (or in the case of AmProtein visa-vie Amgen, just up the road)?

“Our progress has been well received by most of the Chinese companies, the Chinese Government, plus some Mexican and Indian Companies,” Hui says. “In the U.S, many people know of our progress but only two medium size companies have taken us seriously, Fibrogen and Geron.”

Of large U.S. biotechnology firms, Hui reports, only one – Novartis – has been interested in AmProtein’s work to date.

“Amgen and Genentech are more snobbish in their dealings and take a more cautious approach to our progress,” he says.

Biotech giant Genentech, a name that at various points in time has meant: the big bully from the North Country (South San Francisco is Genentech’s world headquarters), the on-par competitor, the courtroom opponent and the licensing partner.

From a global standpoint, Amgen may arguably be seen as the stronger of the two. From a regional or corporate-headquarters perspective, Genentech is the big fish in a big pond, while Amgen is one of two big fish in a tiny puddle of biotech companies.

Reinke of the Biotech Forum believes that could change in the not-too-distant future.

“Our goal is to make this area a major global biotech cluster,” he says. “We have a lot of work to do, but don’t be surprised if it happens sooner rather than later.”

If that is the case, drivers may one day see a lot more of those squat corporate monikers on the manicured lawns of sweeping campuses joining the ranks of Baxter and Amgen with names such as

MannKind and AmProtein.

MannKind's potential cancer vaccine and AmProtein's cell-vector revolution (not to mention its already debt-free status and expected \$100 million revenues in five years) are just the kind of companies that give the 101 Biotech Corridor growing global reach.

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