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**BIO 2008**

## Funding gap threatens San Diego, U.S. biotech prominence

By Ivor Royston

June 15, 2008

The 2008 BIO International Convention at the San Diego Convention Center this week symbolizes our region's prominent role in life-sciences research and development, and marks the 30th anniversary of our biotechnology industry, which began with the founding of Hybritech in 1978.

Over the past three decades, San Diego has come to lead the nation in this arena, according to the Milken Institute's Biotech Index, which ranks San Diego as the number-one biotech/life-science cluster in terms of innovation and impact on the marketplace.

However, this leading role is being threatened by other regions of the country, as well as other countries that are challenging not only San Diego but our nation's superiority in the research and development of new medicines.

In Texas, for example, voters approved the Texas Technology Initiative and the Texas Enterprise Fund, earmarking \$55 million to attract technology and biotechnology businesses to the state. Baylor University and the M. D. Anderson Cancer Center in Houston both have well-established venture philanthropy programs focused on early-stage investment in translational research, which moves discoveries from the laboratory bench top to clinic bedsides.

On the global landscape, the United States' dominant role is threatened by other countries, such as China. Foreign governments are funding early-stage development of promising biotechnologies. One only needs to witness the phenomenal growth of Shanghai's "Medical Valley" to grasp where things are headed. Scientists from foreign countries trained in the U.S. are no longer staying here to commercialize and profit from their discoveries. They are taking what they learned back to their native countries and developing the products there.



Associated Press  
Joe Panetta, center, CEO of Biocom, San Diego's umbrella biotechnology industry organization, on the exhibit floor of the 2007 BIO International Convention in Boston.

Why is this happening? Follow the money. Or the lack thereof.

The situation is this: The traditional model for funding early-stage drug development has evaporated. Venture capitalists by and large are no longer willing to risk investing in the pre-clinical phases that would lead to the acceptance by the Federal Drug Administration of an application of an investigational new drug for clinical trials in man. Venture capitalists today are primarily interested in technologies and molecules that are ready for human trials. But in California and other regions in the U.S., government agencies, philanthropists and drug manufacturers have not stepped in sufficiently to fill this translational medicine funding gap – known to insiders as the “valley of death” – to the degree needed to fund more than a small percentage of emerging technologies.



JIM BAIRD / Union-Tribune  
Biosite research associate purifies antigens in Sorrento Valley.

Don't get me wrong. San Diego has a thriving life-sciences community. The scientific research being done at our research institutes is world-renown. Medicines and diagnostic tools to combat life-threatening and degenerative diseases have been developed here, including Biogen Idec's blockbuster cancer drug Rituxan, Agouron's novel drugs for AIDS, Hybritech's early-detection tests for prostate cancer, Gen-Probe's diagnostics for infectious diseases, and Amylin Pharmaceuticals' diabetes medications. Dozens of companies are involved in developing cancer therapeutics alone. Our region's biotech industry, represented by BIOCOM, boasts more than 700 companies employing roughly 40,000 employees, with an annual economic impact of \$8.5 billion.

But this could change dramatically in the coming years if new sources of early-stage funding for translational research are not found. New technologies are essential for sustaining a growing and prosperous life-sciences industry. Existing patents are expiring and we need new products to fill the pipeline. Unless we bridge that chasm between the end of the research grant and clinical development, we stand to lose out, not just in San Diego, but throughout the United States.

That's not to say nothing is being done. Drug giant Pfizer launched its Pfizer Incubator in 2004 to help turn innovative ideas from scientist-entrepreneurs into marketable products. The Burnham Institute for Medical Research is raising funds for a venture philanthropy program to promote early-stage and preclinical innovations. The Cystic Fibrosis Foundation and other patient advocacy groups are now funding translational research. And CONNECT has initiated the concept of an Actively Managed Venture Company, or AMVC.

Teams of business professionals will fund and manage the early-stage development of promising technologies, then sell the assets to pharmaceutical companies or venture capitalists once the technologies demonstrate their potential for commercial viability.

These programs are an excellent start, but we need more of these novel approaches to solve the early-stage funding problem, combined with increased government funding of translational research. California should examine the Texas model and could enact legislation to fund translational research similar to how Proposition 71 set aside \$3 billion for stem-cell research. In addition, Congress should expand the mandate of the National Institutes of Health to fund more pre-clinical studies required to nominate a drug for the clinic and complete the investigational new drug-enabling studies.

We cannot rest on our laurels. We need to act now to remain competitive not only with other regions in this country, but with other countries where government support and a thriving entrepreneurial spirit are threatening the pre-eminence of our life-sciences/biotechnology industry.

It takes more than \$1 million to move a new technology through the investigational drug studies, but the payback can be hundreds of millions, if not billions, of dollars. Let's not be penny-wise and dollar-foolish. We risk losing our dominance and future economic growth by failing to invest a nominal amount now to fund the most promising emerging technologies and drugs.

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■ Royston, a medical doctor, is the co-founder of Hybritech, San Diego's first biotechnology company, as well as IDEC Pharmaceuticals and the Sidney Kimmel Cancer Center, and he is a founding managing partner of Forward Ventures, which invests in life-science companies.

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