Commentary

Biotech 101: Sorting it Out

New Life Sciences Ecosystem Developing as Commercialization Shifts From Large Companies to Smaller, More Efficient Startups

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From an economic perspective, the Biotechnology industry utilizes biological systems, living organisms, or their derivatives to solve challenging problems and increase productivity within the agricultural, food science, medical, and energy industries. It is a knowledge based industry that integrates techniques, subject matter, and other innovations developed in university and private laboratories with interdisciplinary efforts in genetics, molecular biology, biochemistry, embryology, cell biology, chemical engineering, and information technology. The results are new products and services that extend and improve the quality of human life, bio-remediate toxic spills, reduce the use of harmful pesticides, impart disease and drought resistance to food crops, and enable production of 2nd generation biofuels from biomass waste and environmentally benign energy crops grown on degraded land.

Los Angeles and Ventura Counties are fortunate to be home to three leading universities in biotechnology research, [UCLA, USC, and Caltech]; four world renowned medical research Centers [City of Hope, Cedars Sinai Medical Center, Huntington Medical Research Institute, and Children's Hospital]; the world's largest biotechnology company [Amgen]; and Ceres, a leader in plant breeding and plant genetics for energy crops. These institutions and their research collaborators scattered across the state, nation, and world, form a neural network that combines the creativity of the best human minds with the power of supercomputers – to create a pipeline of innovation and discoveries that both startups and large companies are translating into new products. However, this engine of biotechnology innovation has its challenges.

Between 1998 and 2003, the National Institute of Health's annual Research and Development (R&D) budget increased from $13 billion to $26 billion with the Los Angeles Basin receiving nearly a $1 billion in 2004. R&D spending by pharmaceutical and biotechnology companies' has also been growing at a real 8% annual rate, reaching about $40 billion in 2004. However, the rapid growth of research spending has had little effect on the pace at which new drugs are developed. For instance, annual approvals of innovative new drugs by the Food and Drug Administration increased over the 1980s and peaked sharply in the mid-1990s but then experienced a pronounced six-year decline. Overall, the total number of new drug approvals each year declined from a high of 53 in 1996 to only 20 in 2005. As a result, the average cost of developing an innovative new drug, including expenditures on failed projects and the value of foregone alternative investments has grown significantly, and now exceeds $800 million. Given the apparent declining productivity of both government and private R&D, it may be surprising to learn that in 2007, biotechnology was the second most active area of venture capital investment nationally ($5.3 billion), as well as in southern California ($1.2 billion), and Los Angeles County ($151 million).

So how does one reconcile the appearance of a declining return on investment in biotechnology R&D with rising investment by presumably sophisticated financial investors? The explanation may lie in a change in the structure of the biotechnology industry, whereby the burden of commercializing rapid advances in basic research from universities and other nonprofit research institutions is shifting from large vertically integrated life sciences companies to smaller, more efficient and flexible venture backed (and other) startups. In this new life sciences ecosystem, the larger companies with the expertise and capital to navigate a costly regulatory process, leverage a global supply chain, and manage a more price sensitive healthcare distribution channel, effectively outsource their R&D to small companies. This outsourcing manifests itself through corporate venture capital investments (e.g., Amgen, Dow, and P&G's corporate venture capital funds that are active in southern California), collaborations (e.g., Ceres and Monsanto), and merger and acquisition transactions where large life sciences companies pay for performance and success (e.g.., Amgen's 2006 acquisition of privately held Avidia, and $90 million in potential milestone payments).

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Giving this evolving biotechnology industry landscape, Federal and state government leaders often ask the question, how can we accelerate the processes of innovation and commercialization to create more products and higher paying jobs from the tens of billions of dollars that the federal and state governments invest in university research and SBIR grants to private companies?

As an advisor to the Larta Institute, that designs and manages national commercialization programs for the U.S. Department of Agriculture and National Institutes of Health, I think about this question often, and advise small companies on how they can get maximum commercial bang out of each dollar, whether sourced from the government or private investors. I believe the recipe for success involves uniting the genius of our university or private research scientists with the product and customer focus of a marketing analyst, and the business acumen of a professional manager with the embedded knowledge and commercialization experience of an industry. On very rare occasions, all three talents reside in a single entrepreneur, like Irwin Jacobs who created Qualcomm from human capital spun out of the UC San Diego, or LINKABIT, or in a dynamic duo like Henry Nicholas and Henry Samueli, who built Broadcom after completing graduate work in the Electrical Engineering department at UCLA. However, god creates very few Irwin Jacobs so most early stage startups would benefit by sharing leadership and ownership among a tri- or multipartite founding team (e.g., Rathman, Johnson, Bowes, Wallace, Salser, and Caruthers of Amgen fame) that successfully combine science, marketing, and management.

Another key strategy often required to build a successful biotechnology startup is a determined pursuit of collaborations with large companies. Just as it may in some cases takes a village to raise a healthy child, industry-leading companies can play an important role in fostering the development of startups that commercialize new technologies and products, boost an industry's productivity growth, and stimulate more productive research efforts by internal development teams. A successful partnership requires that small companies master the strategy of cooperative competition or "co-opetition," and the associated art of protecting, sharing, and monetizing intellectual property. Managing the proper balance between competition and cooperation in a partnership with a large company can be the key difference between a small biotechnology company that remains small or fails, versus a small company that grows into a large company, and/or attracts a high acquisition price.

Government research managers and agencies that want to accelerate commercialization and job creation in knowledge-based industries by awarding tens of billions of dollars in SBIR grants to small businesses can improve the government's return on investment by:

(i) recognizing the early foundation of a successful startup, and differentiating in their screening process between lifestyle companies that are destined to become grant mills and wards of the state, versus a rising star that is well positioned to attract private investment, and generate commercially successful products;

(ii) supporting commercialization assistance programs like Larta's CAP that trains first-time entrepreneurs, provides guidance in strategy, and fosters business relationships with industry partners; and

(iii) providing grant funding to startups that are utilizing bioinformatics, computation biology, and the mapping of the Human Genome to identify and screen for certain genes or pathways in a patient population that may be responsible for isolated, but harmful side effects from new drug candidates.

There are also viable strategies for local government and business leaders that want to attract biotechnology companies and other knowledge based industries to their metropolitan statistical areas. Just as physical capital seeks the highest rate of return, biotechnology entrepreneurs seek communities that are home to other biotechnology companies, provide a plethora of networking opportunities, and underwrite facilities for incubating early stage companies. They also favor communities in close proximity to leading universities offering a high quality of life including excellent schools, safe neighborhoods, clean air, affordable housing, and adequate transportation infrastructure. The 101 Life Sciences Corridor has strengths in some of these areas, and serious challenges in others, so there is plenty of work for local governments in addressing the weaknesses, which will ultimately benefit everyone in the region while promoting growth in the local biotechnology industry.

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