

CRITICAL PERSPECTIVE

Biotechnology: What's Ahead for Ohio?

DOROTHY C. BAUNACH, MARGARET P. FURGALUS, AND LYNN K. SHESSER, Edison BioTechnology Center, 11000 Cedar Avenue, Cleveland, OH 44106-3052

INTRODUCTION

Since its founding in 1987, the Edison BioTechnology Center has become the premier advocate for Ohio's biomed/biotech industry. As part of the Ohio Department of Development's Thomas Edison Program, the Center works closely with the state's leading universities and medical institutions, businesses, foundations, and civic and state organizations. Programs and services of EBTC facilitate the growth of the industry, build a supportive infrastructure, and help to create a national identity for Ohio. One of EBTC's key functions is to track the growth of Ohio's biomed/biotech industry. Presented here are findings from EBTC's most recent state survey as well as data from a number of national surveys. The challenges facing Ohio as it takes its place as a key player in this emerging industry are described.

DISCUSSION

EBTC Mission

EBTC has been monitoring, promoting, and contributing to the growth of Ohio's biomedical and biotechnology research and industry base for five years. The center has not actively engaged in biotechnology development involving agriculture, the environment, and animals (other than human) to date. Therefore, the comments offered in this paper are restricted primarily to EBTC's present constituency: the research and industry base in Ohio which focuses on the use of biological processes to create products for human health care and for the more well-established biomedical devices industry which is based on Ohio's strong manufacturing and materials base. EBTC directs its programs to both the biomedical and the biotechnology areas. It counts as members Ohio's major research institutions (Case Western Reserve University, Children's Hospital Research Foundation—Cincinnati, The Cleveland Clinic Foundation, The Metro Health System, The Ohio State University, Ohio University, the University of Cincinnati, and University Hospitals of Cleveland) as well as corporate members from all areas of the state (Fig. 1).

EBTC fills a unique niche between Ohio's academic and research institutions engaged in biomedical research and a growing industry base; it supports this industry through five programs:

1. Centers of Excellence—EBTC pursues multi-institutional, multi-disciplinary consortia which can assemble a critical mass of resources in specific technology focus areas and increase the probability of substantial technological advances.

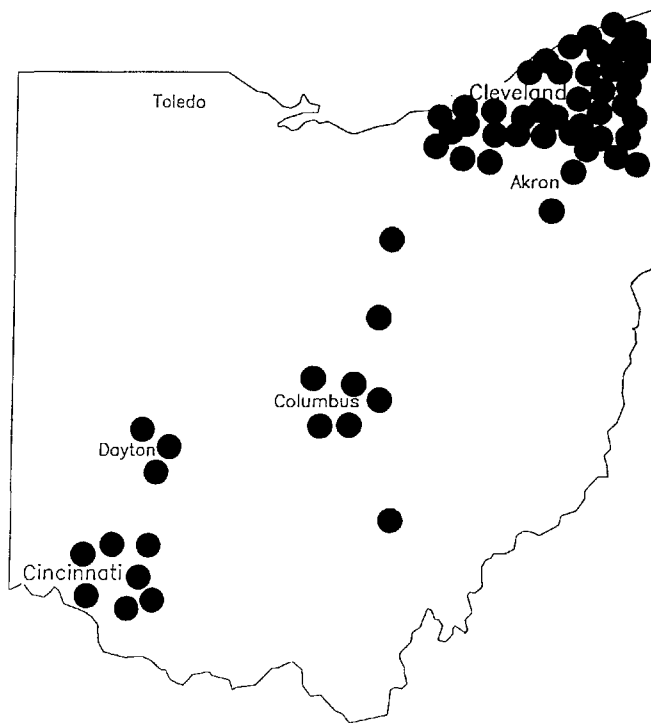


FIGURE 1. EBTC membership (8 Institutions, 60 Companies).

2. Technology Funding Programs—EBTC directs its funding to projects which have near-term commercial potential and can attract follow-on financing for commercialization; its programs strongly encourage alliances between Ohio companies and research institutions in technology development. Institutional research agenda are not generally market-driven and may not always match Ohio industry needs. The strategic plan of EBTC defines a key role in assisting researchers and companies to cooperatively address recognized market needs.
3. Business Assistance—EBTC focuses on providing services to emerging biomedical and biotechnology companies in ways which will nurture the growth of the industry base in Ohio. One-on-one counselling, focus groups and key introductions to clinical partners, potential investors, etc., enable the entrepreneur to access the extensive network of resources which EBTC has assembled in five years of operation.
4. Education and Outreach Programs, Publications—The programs provided by EBTC serve a variety of education and networking objectives, and

draw more than 1,000 participants annually. Seminars feature topics of immediate interest and utility to emerging companies (e.g., FDA regulatory issues, commercialization strategies, and so forth); topic selection is based on member surveys and input from the industry. The Edison BioTechnology Center offers special programs to meet the needs of its institutional members. Currently in development is a graduate-level training program describing the FDA approval process, scheduled to be offered at The Ohio State University later this year. The center is also involved in the creation of a bioscience education program for high school biology teachers which has drawn industrial, public, and foundation support. Publications provided by EBCT enhance the flow of information to its government, academic, corporate, and community constituencies.

5. Industry Advocacy—A national identity for the Ohio biomed/biotech industry is being built by EBTC. Special surveys, the annual *Directory of Ohio Biomedical & Biotechnology Companies*, and EBTC's participation in national studies, associations, etc., promote Ohio's expanding role in an industry which is becoming increasingly important to the national economy. The center is in a unique position from which to observe the industry and assess Ohio's participation. To monitor industry development, EBTC draws upon

national surveys as well as its own studies.

National Level Outlook

The accounting firm of Ernst & Young annually studies the national biotechnology industry, surveying companies that use biological processes to develop products for human health, animal health, agricultural productivity, food safety and nutrition, energy enhancement, and environmental conservation. The firm has just released its 1993 report (Burrill and Lee 1993), and key observations indicate that the biotech industry is maturing and moving towards the wide-spread launch of products that have been in development for several years.

- Total revenues (\$8.1 billion) are up 28% from the last reporting period.
- Of survey respondents, 89% expect to launch their first product by 1996.
- Ernst & Young predicts industry-wide profitability by the mid-1990s, as a number of products clear the FDA.
- Ohio now ranks 12th in the nation in number of biotech companies, a 20% increase from 1991 (Fig. 2).

The next ten years are projected to be growth years for the biomed/biotech industries. Investment in research and development for human health care is increasing and,

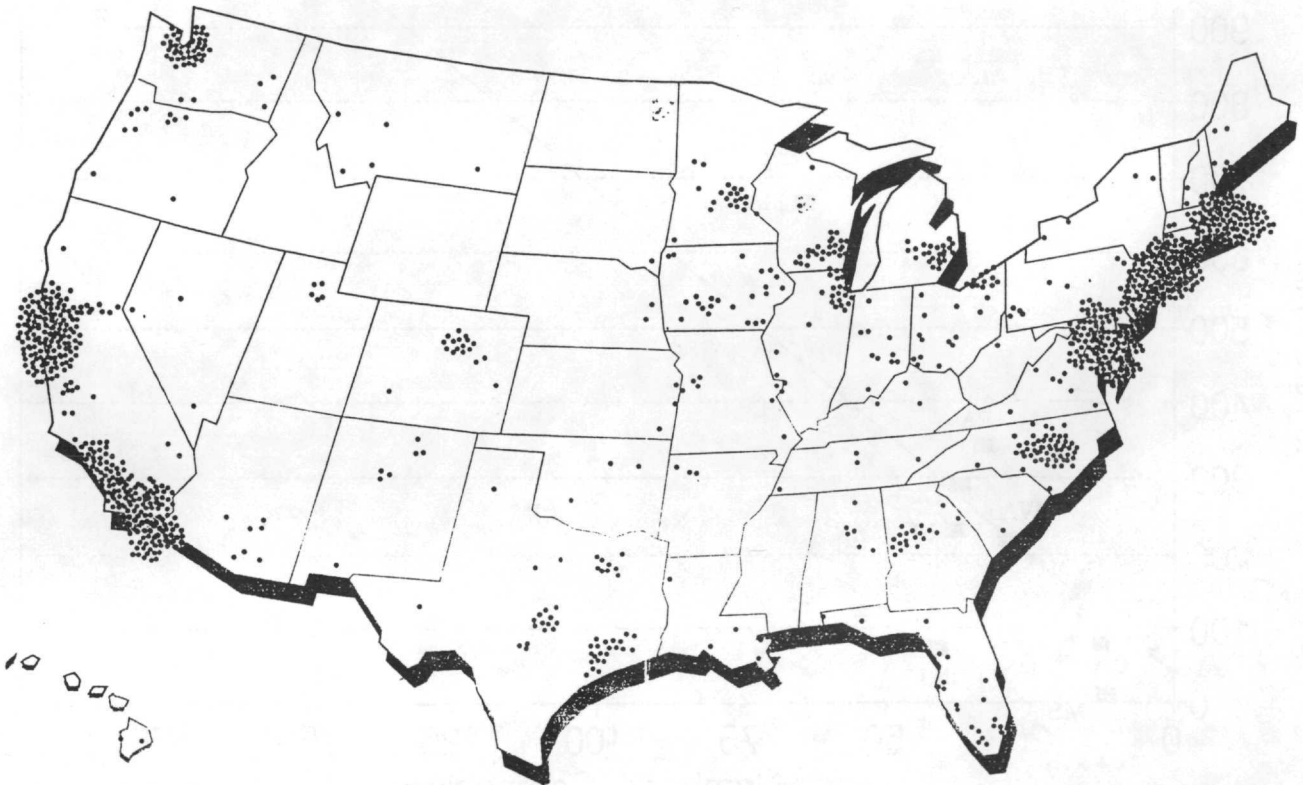


FIGURE 2. Location of biotech companies in the United States as reported by Ernst & Young (1993).

as more products obtain FDA approval and reach the marketplace, industry-wide profitability is anticipated. This optimistic outlook points to a promising future for Ohio as it takes its place in the industry.

Outlook for Ohio's Industry

Competition among states for a key position in the biomed/biotech industry is intensifying. Many states, notably California, North Carolina, Maryland, New York, Massachusetts, and Pennsylvania, have achieved national prominence with well-established programs to support the industry. In 1992, more than 80 biotechnology centers were located across the United States, each with various research, technology development, education, and business support programs. Most are affiliated with major academic research institutions and many are part of larger research park and business incubation programs. All receive state support through universities or regional development programs. Advantages for Ohio in this competition are significant and, if further developed, can make the state a major player.

The biomed/biotech research and industry base in Ohio is notable and should be a continued source of economic growth for the state. Human health care will remain a primary focus of investment for research and development. A direct relationship between the level of research funding provided by the National Institutes of Health (NIH) and the number of biomed/biotech start-ups

has been demonstrated by EBTC. In 1990, Ohio ranked tenth in the receipt of research dollars from NIH (Fig. 3); continued NIH funding at present or greater levels should have a positive effect on industry in the state.

This optimistic outlook is confirmed by EBTC's own survey (Edison BioTechnology Center 1992) of the biomed/biotech industry in Ohio, released in July 1992. A key finding is that small to medium size companies (annual sales less than \$200 million) have experienced significant growth over the last five years, with average annual increases of 14.2% in employees and 17.8% in sales (Fig. 4).

Furthermore, the rate of new company formation, historically five starts per year, has been accelerating since 1985. Based on survey findings, EBTC predicts the formation of at least 14 new companies by 1994; Ohio's small to medium size biomed/biotech companies (in actual number of companies, the largest segment of the industry) could have aggregate sales as high as \$650 million and an employment level as high as 7,000 by that time.

Challenges to Ohio's Industry

Ohio faces several challenges in developing its biomed/biotech industry.

1. Retaining the Benefits of New Technologies in Ohio—In developing Ohio's technology base, it is important to allow for alternative com-

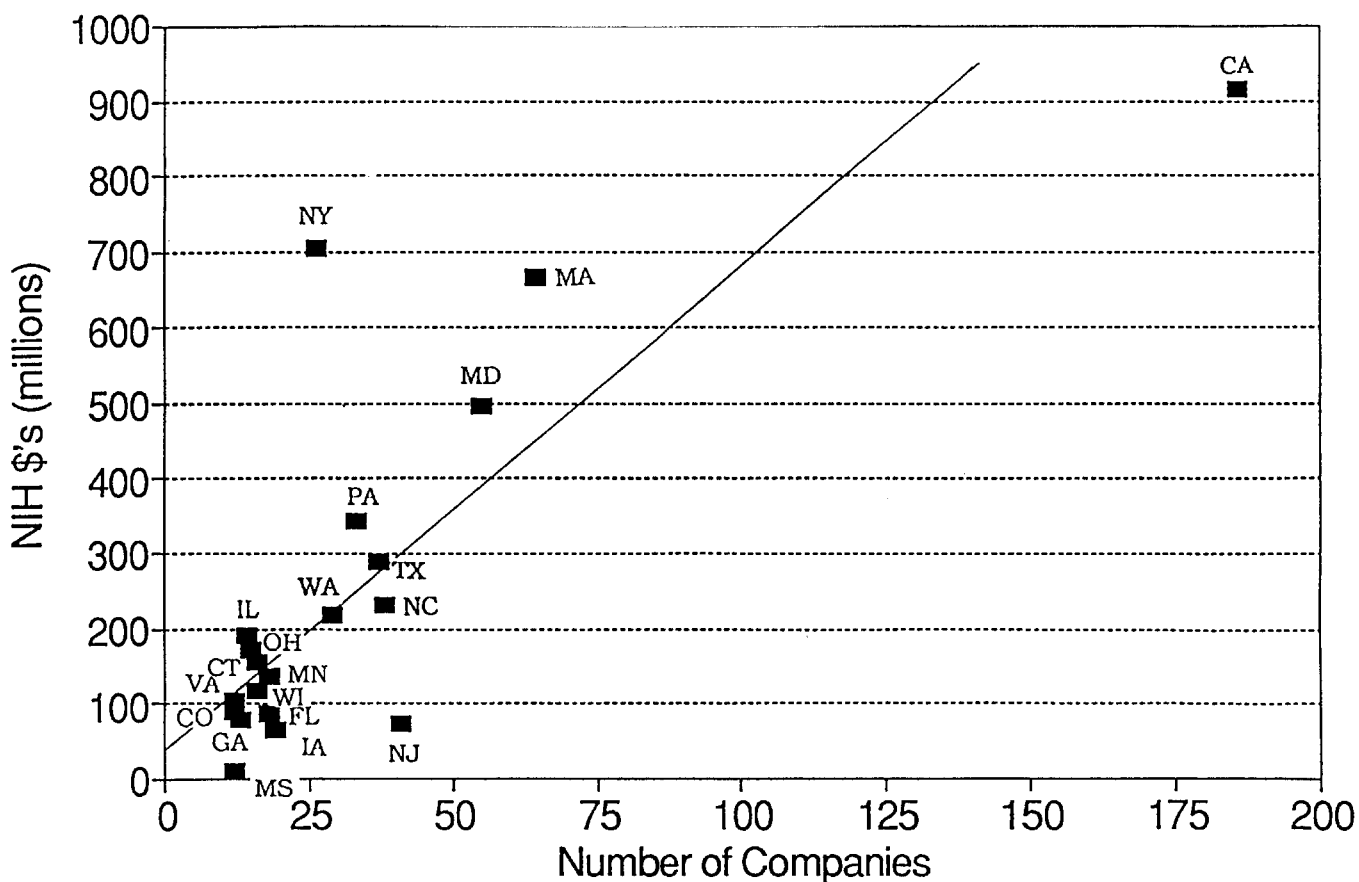


FIGURE 3. Company formation and NIH dollars.

mercialization strategies. Wherever appropriate, the technology itself should remain within the state, either by transferring it to an Ohio company or by forming a new Ohio-based company to develop and market it. However, it must be recognized that biotechnology is developed within the context of a global market and depends to a large extent on strategic alliances which can underwrite the large research and development efforts typical of many biotech products. In some cases, it is more advantageous to the state to recognize a particular technology as a product, and market it to maximize the revenue return to the state. Exploiting the full potential of technological strength in Ohio thus challenges the traditional cultures of both institutional technology transfer offices, which have a bias towards out-licensing, and state funding departments, which define successful technology transfer in terms of job creation or retention.

2. Ensuring Adequate Financing Mechanisms—Research can be funded in the early stages through a combination of foundation grants and federal and state programs, but the entrepreneur faces a funding gap when forming his/her company to commercialize a product. He/she may no longer qualify for continued support

from these early stage sources, most of which direct funds through institutions rather than into businesses, and the product is not yet sufficiently developed to attract venture capital or bank investment. In many cases, at this stage, the entrepreneur must devote time and energy to seeking private investors, at great cost to the management of the business. The cost to the economy is high when these growth-oriented businesses fail. Projects with good commercial potential may die before they can attract traditional investment funds. At the very least, the commercialization process will be slowed and product introduction delayed.

Absence of seed funding is not the only financial challenge. EBTC's survey found that over the past five years, Ohio biomed/biotech companies attracted only 10% of the venture capital investments made in Ohio and accounted for only 1% of all venture capital invested in biomed/biotech ventures in the U.S

Growth in the biomed/biotech industry in general will be tempered by the U.S. health care policy decisions and FDA and other regulatory postures, but the availability of capital, both seed funding and venture capital investment, will be critical to



FIGURE 4. Employee and sales growth in small to medium Ohio biotech companies. $n = 61$ of 111.

the future of Ohio's industry.

3. Ensuring a Pool of Technically-trained Labor—A scientifically literate pool of employees is important for expansion or retention of emerging biomed/biotech businesses in Ohio. The life sciences have seen an explosion of knowledge and the translation of that new knowledge into technology in the past two decades. Unfortunately, many primary and secondary school teachers have not had the opportunity to become familiar with advances in the life sciences and are unprepared to incorporate this new and exciting knowledge into the curriculum. Studies have shown that students make career choices as early as the seventh grade; it is imperative that efforts be directed toward both teachers and students to enhance the effectiveness of science education and to encourage students in the pursuit of careers in the life sciences.

Entrepreneurial Issues

In its national survey (Burrill and Lee 1992), Ernst & Young identified four key factors in developing the biotechnology industry:

1. Proximity to world-class research institutions.
2. Access to venture capital and other forms of financing.
3. A climate which supports and nurtures the entrepreneurial culture.

4. High quality of life/low cost of living factors.

Ohio has the basis for providing all four of these elements, but further development is needed in each area.

Institutional researchers must be encouraged to see the commercial potential of their work and to explore that potential; institutional barriers which discourage researchers from commercializing their work must be eliminated.

Ohio is home to several large venture capital groups; these firms must be encouraged to invest in Ohio-based ventures and to assist in bringing venture capital to bear from other regions of the country. In addition, innovative ways of providing seed capital funding to assist early-stage companies must be explored.

Ohio's incubator program provides a nurturing environment for emerging businesses but on a small scale. Supporting the entrepreneur/promoter who can envision the commercial possibilities of an idea and, more importantly, provide the push to translate that idea into a marketable product, is a vital part of business development. Finding new ways of providing that support will be critical to the future of Ohio's industry.

Finally, quality of life factors can be related to the need to develop locally, and to attract and retain the talented labor pool which will be needed as the Ohio's biomed/biotech industry matures.

LITERATURE CITED

- Burrill, G. S. and K. B. Lee, Jr. 1992 Biotech '92: Promise to reality, an industry annual report. Ernst & Young, San Francisco, CA.
- ____ and K. B. Lee, Jr. 1993 Biotech '93: Accelerating commercialization. Ernst & Young, San Francisco, CA.
- Edison BioTechnology Center 1992 Ohio's biomedical and biotechnology industry: An analysis of the state's activities and progress. EBTC, Cleveland, OH.