Department of Business & Economic Development

Maryland TEDCO

Technology·Development·Corporation

Maryland's Bioscience Strategic Plan
2003-2008

March 26, 2003

CONFIDENTIAL DRAFT

Table of Contents

Executive Summary

In a little more than a decade, the State of Maryland has gone from having roughly two dozen bioscience companies to being recognized as one of the premier locations for bioscience in the world. It is now home to more than 300 companies employing approximately 20,000 people, ranking Maryland third nationally in terms of industry size and second nationally on a per capita basis. This success has not happened by chance. Maryland has an extraordinary array of bioscience assets, particularly in research and development (R&D), and the leadership of the State has had a focused plan to build on those assets and channel industry growth.

According to the Biotechnology Industry Organization (BIO), a trade group based in Washington, D.C., Maryland was the first state to adopt or pass a comprehensive strategic plan for the industry. Developed by the Maryland Department of Business & Economic Development (DBED) at the request of the General Assembly, the first plan was released in 1991. It assessed Maryland's bioscience strengths and weaknesses, evaluated the State's role in bioscience development, and established priorities for moving the industry forward.

Using the plan, the State developed a variety of tools and incentives to commercialize cutting edge R&D and nurture bioscience start-ups. Primarily, these early-stage tools focused on funding assistance, workforce development, regulatory/tax assistance, and facility development.

The rapid growth of bioscience companies in Maryland, and the successful contributions the industry has made in the past decade (that include the mapping of the human genome), attest to the State's growth strategy for the industry. This success has not gone unnoticed.

When other states with emerging bioscience investment programs look for a model, California, Massachusetts and Maryland are the three most often mentioned. Clearly, Maryland's status is an asset in recruiting bioscience companies and the best minds in the industry. However, success breeds competition. Dozens of other states (and, indeed, other countries) are now pursuing aggressive strategies to grow their bioscience industries, threatening Maryland's leadership role in the near term.

Maryland's investment programs and funding initiatives, however innovative, are rapidly becoming modest in comparison to other states. Another concern is a possible declining trend in Maryland's share of NIH extramural funding. Recent data show that Maryland's NIH funding peaked in 2001 and is now flat, whereas competitor states in the region, such as Pennsylvania and North Carolina, continue to increase. If subsequent analyses confirm this trend, Maryland's overall return on investment in R&D will decline.

Beyond competitiveness with other states, Maryland must make sure that its industry support programs, investment vehicles, regulations, and infrastructure keep pace as its industry stands poised to achieve new growth milestones. The effectiveness of strategies that helped nurture early-stage bioscience companies develop products must be re-evaluated and altered, where necessary, to reflect the growing needs of the industry as it now competes in the global marketplace. If not, Maryland's important resources such as innovative companies, a highly skilled workforce, and top scientists, will become susceptible to the aggressive business attraction efforts of other competing jurisdictions.

To ensure that bioscience companies in Maryland continue to grow and prosper, the General Assembly asked DBED and the Maryland Technology Development Corporation (TEDCO) to prepare an updated strategic plan to guide State support of this important industry as we begin the new millennium.

This document will detail the growth and future needs of Maryland's bioscience industry, and make recommendations for the sustained growth and diversification of the industry over the next five years. It will focus on several areas identified as key to the industry:

- Excellence in Academic and Research Institutions
- Technology Transfer Initiatives
- Availability of Venture Capital
- Workforce Development
- Business Infrastructure
- Public Policy
- Industry Advocacy

It is envisioned that if many of the recommendations set forth herein can be implemented over the next five years, Maryland's bioscience industry will reach new milestones characterized by a vibrant and diverse industry of international recognition that will ultimately bring the benefits of commercial success.

Introduction

The following report details the growth and future needs of Maryland's bioscience industry. This continuation in a series of State Bioscience Strategic Plans, dating back to 1991, highlights the accomplishments, but more importantly lays out recommendations for the sustained growth and diversification of Maryland's industry over the next five years.

As a relatively smaller State, Maryland needs to leverage its resources at a higher rate than other states to remain competitive. The report will identify mechanisms for maintaining the State's research base, including greater collaboration among universities, evaluation of programs and targeting of investments, increasing the amount and diversity of industry sponsored research, and stimulating centers of excellence and research institutes utilizing industry-university-federal lab partnerships.

I. Historical Background and Future Challenges

Why is there a need to reexamine the definition of the "biotechnology industry" in 2003? For many, the concept of this industry derives from the early origins of the industry in the United States in the 1980's with such companies as Amgen and Genentech. The U.S. biotechnology industry, however, has experienced marked growth and diversification. In 1993, approximately 79,000 people were employed in the biotechnology industry. By 2001, direct employment had grown to 174,000 with almost another 300,000 in companies supplying inputs, goods or services to the industries or its employees. Total revenues generated in this sector grew from $8 billion to $25 billion during that time, generating almost $10 billion in state and federal tax revenues including personal income tax. Research-and-development expenditures increased from $5 billion to $14 billion.

Within the past decade, the use of existing biotechnology applications and commercial products has penetrated a number of other industries. Similarly, innovation in other technology industries has opened the door for the incorporation of new hybrid biologics-based products and applications. Therefore, it is crucial that we understand the maturation and diversity of the biotechnology industry in order to construct, refine or amend Maryland's biotechnology strategic plan in order to be globally competitive in the 21st century.

A. Broadening the Industry Definition

Biotechnology is operationally defined as 'the incorporation and commercialization of the use of biological molecules, cellular organisms and/or biological processes to solve problems or make useful products.' This defines most of what we understand as the core companies of the biotechnology industry and is incorporated in most analyses that define the industry and its growth metrics. More importantly, the infusion of the use of biotechnology in other larger industrial fields requires consideration of at least three major subdivisions, often referred to as the three "waves" of biotechnology:

- Medical Biotechnology
- Agricultural Biotechnology
- Industrial & Environmental Biotechnology

Medical Biotechnology: In the United States, medical biotechnology, in particular therapeutic development, receives the highest visibility due to those companies' heavy dependence upon investment capital and the associated risk involved in bringing therapeutics to market. This industry sector has captured headlines, entrepreneurs and the imagination of budding researchers every time new, innovative biotherapeutics are introduced as a cure to diseases that have avoided traditional pharmaceutical solutions for years.

Agricultural Biotechnology: Agricultural biotechnology focuses on improved crop performance or composition through the inclusion of value-added characteristics (termed "traits") by genetic transfer methodologies. This field has most recently gained visibility, albeit somewhat negative, from the drift or contamination of some traits back into the natural crop type. The commercialization of agricultural biotechnology, while generally well accepted in the United States, has met resistance in Europe. With European competitors reluctant to advance applications in this field at home, the United States stands to gain substantial opportunities for growth and global leadership in the agricultural biotechnology industry.

Industrial & Environmental Biotechnology: The third wave, industrial and environmental biotechnology, is the most unrecognized by the public, and thus most likely overlooked in consideration of strategic development needs. Implementation of biotechnology applications in these industries offers lower production costs by streamlining process steps using biocatalysts, reduced pollution using embedded bioremediation, or efficient resource (e.g. biofuels) generation. If successful, tremendous near-term and long-term economic savings will be realized as we move away from depleting, resource-based activities to renewable-based or "sustainable" industries. Commercialization of these technologies is predicted to reach substantial market potential by 2010.

As with the definition of biotechnology in general, the distinction among these waves of biotechnology can and will likely blur. Evidence of this occurrence can be seen in the marked increase, in just the past few years, of research and development efforts to produce human and animal therapeutics (e.g. edible vaccines) in common crops.

"Bioscience": Another term that has gained popularity of late is the "bioscience" industry – a more general definition that includes a number of the ancillary businesses that in some way or another incorporate the use of biotechnology to assist the pharmaceutical industry as well as core biotechnology companies. Examples of this would be companies that perform contract research services ("CROs or CSOs") such as toxicology and other pre-clinical evaluations of potential therapeutic molecules, research (tools development, etc.) or the contract manufacturing of biologics ("CMOs") that include biotherapeutics and industrial enzymes.

As various bioscience disciplines integrate with each other, Maryland is likely to address a broader corporate base, more diverse business models and in certain cases, different needs' assessments. For example, an exponential increase in biological data has required the development of new computing algorithms and database management. Arising from this industry demand, genomics information has spawned a hybrid area of specialty – the information technology (IT) based industry called "bioinformatics." Another example of the integration of bioscience fields is the migration and incorporation of novel biological molecules/processes into the traditional diagnostics or medical devices industries.

It is with this understanding and within this total context that a comprehensive 2003 State Bioscience Strategic Plan must be viewed. While the largest common denominator within the diverse "bioscience" industry is research and development (R&D), business models and needs vary.

Just as R&D-based corporations invest heavily in intellectual, financial and human capital with clear short-term and long-term goals that carry certain associated risks, the active participation of State government and dedication of public resources to the bioscience industry must be viewed in that same context—as a *strategic investment* in the future economic development of the State. ***Those states most creative in ways to invest, with clear goals and mitigated risk concerns, will be those most likely to succeed in transforming their economies to derive maximal benefits from all advances in technology and in the bioscience industry in particular.***

B. Maryland's Biotechnology Strategic Plans

Maryland recognized the need for guidance in assisting the growth of its nascent biotechnology industry in the late 1980's. For more than a decade, the State of Maryland has implemented a strategy to grow its bioscience industry. This strategy grew out of recognition by leaders of the General Assembly that the State is rich with life sciences assets, including the National Institutes of Health; Johns Hopkins University and the University System of Maryland; and more than 40 federal agencies involved in R&D in the life sciences. According to the Biotechnology Industry Organization (BIO), a trade group based in Washington, D.C. that represents more than 1,000 biotechnology companies worldwide, Maryland was the first State to adopt or pass a comprehensive strategic plan for its industry.

At the request of the General Assembly, the Maryland Department of Business & Economic Development (then MD-EED) convened a committee of State economic development experts, industry members, and academic faculty. This first plan, released in 1991, was entitled *Commercial Biotechnology Development in Maryland: a Strategy for the 1990's.* A separate, more focused study entitled *Maryland's Biotechnology Manufacturing Strategy for the 1990's* was also issued in 1991 by the then Maryland Business Planning & Economic Analysis Committee and the Bioprocess Facility Steering Committee. These plans assessed Maryland's biotechnology strengths and weaknesses, evaluated the State's role in biotechnology development, and established priorities for moving the industry forward.

Under the initial plan, the State used a variety of tools and incentives to commercialize cutting edge R&D and nurture biotechnology start-ups. Primarily, these tools focused on funding assistance, workforce development, regulatory & tax assistance, and facility development. Additional vision to the original 1991 plan appeared in 1993 in a report entitled *Five-Year Biotechnology Strategic Plan*, which was a part of the University of Maryland's Biotechnology Institute FY 1994-1998 Plan issued by MD-EED. Lastly, another assessment was undertaken in 1996 by the Bioscience Industry Advisory Committee issued as the *Strategic Review and Recommendations* in which elements were included in the 1997 Maryland Economic Development Commission report *Strategic Directions for Increasing the Competitiveness of Maryland's Growth Industry Sectors*.

Key milestones were achieved as a direct result of the implementation of the 1991 and subsequent plans:

- Maryland has one of the earliest state biotechnology institutes, the University of Maryland Biotechnology Institute, now having grown to five specialized centers conducting world-class research in medical, agricultural, industrial and environmental biotechnology.

- National recognition of Maryland's university programs in the life sciences, computer science and engineering has climbed markedly.

- Public, technology sector-specific grant and investment funds (DBED's Challenge and Enterprise Funds) were created to provide seed capital for startup companies. Other monies were directed to seed-stage venture capital programs.

- A state-supported network of technology incubators – one of the largest in the U.S. – nurtures young startup companies to ensure their success.

- Technology transfer to the commercial sector from federal and academic research labs is facilitated by grants from the Maryland Technology Development Corporation (TEDCO), created by the State of Maryland in 1998 in part with monies derived from the return on investment from DBED's technology funds.

- Multiple research park initiatives are underway in addition to the original and now expanding Montgomery County Shady Grove Life Sciences Center.

- The state has more than the original, state-supported certified contract biomanufacturing organization in place to assist in the process and production needs of Maryland's bioscience industry.

- In-state workforce quality and availability for the bioscience industry now hold the highest national rankings.

While the implementation of some strategic plan elements has proven more successful than others, overall the State strategy over the past decade has paid off. As a result, the State of Maryland is now one of the leading biotechnology centers in the world.

C. Maryland's Metrics & Its Bioscience Industry

Although 41st in geographical size and 19th in population, Maryland's success in the development of its high technology industries and the bioscience industry in particular has been noteworthy. Maryland is one of the ten states selected as a 2001 Honor Roll State by the Corporation for Enterprise Development in its annual Development Report Card for the States. The Report Card provides an annual assessment of each state's economy and potential for future growth. Maryland received A's in two major categories, performance and development capacity, and a B rating in business vitality *(Corporation for Enterprise Development, 2001).*

Maryland enjoys a reputation as a leader in bioscience, based largely upon its research and development infrastructure. The State of Maryland is richly endowed with R&D institutions – its universities, federal laboratories, and private companies receive over $8.6 billion annually in federal R&D obligations and the State is ranked #1 on a per capita basis (2nd overall) in the nation. Federal laboratories in Maryland – led by the National Institutes of Health (NIH) but also including NASA and the Army Research Laboratories—conduct over $4.9 billion in intramural research, nearly three times as much as in any other State. Johns Hopkins University receives nearly $1 billion in federal R&D annually, more than any other university in the nation, and the University System of Maryland's research institutions conducted over $800 million in externally research in FY02 alone. The City of Baltimore was among the top five cities supported by NIH for biotechnology research, receiving $618 million in 2001, and the top city for R&D contracts.

Recently, the Brookings Institution has ranked the Washington-Baltimore metropolitan area among the nation's nine leading biotechnology clusters. These areas were designated because they possess the key ingredients needed for biotechnology growth: strong research and the ability to convert that research into commercial activity. (*The Brookings Institution, June 2002*). This view was reiterated by a recent study from the Milken Institute that ranks states based on criteria critical to future high-tech growth. The states ranked highest in this index are those that are most capable of turning their research capabilities into commercial products – Maryland was 5th in the nation. *(The Milken Institute's New Economy Index, October 2001).*

Maryland's workforce quality and availability is the result of more than two decades of funding initiatives on education for a 21st century high technology economy. The results have achieved national attention: Maryland was rated #1 in the nation in workforce education by the Progressive Policy Institute's recently released *2002 New Economy Index* of the 50 states. Nationally, Maryland is ranked 1st in Health Sciences as well as in doctorates in the Biological and Agricultural Sciences per capita. In addition, Maryland is ranked 1st in percentage of workforce in professional and technical positions (23.0%) and 4th in the percentage of workforce with a BA degree or higher. This environment assures the potential for Maryland to become an entrepreneurial R&D powerhouse.

Over the past 12 years, Maryland's bioscience industry has grown from some two-dozen companies to over 300 diverse companies, employing almost 20,000 people. These corporations, largely in the medical biotechnology sector, conduct innovative pharmaceutical discovery, medical diagnostics and device development, research tools development, biomanufacturing and core research activities in genomics and bioinformatics. In addition, our industry cluster contains an extensive network of highly skilled contract research organizations, serving basic research, pre-clinical and clinical trials needs.

Over forty Maryland companies are conducting clinical trials with new and innovative biotherapeutics. Others are creating gene-based diagnostics and innovative technology platforms. Maryland's bioscience industry recently achieved international recognition with the completion of the sequencing of the human genome in 2000, a combined effort of one of our industry leaders, Celera, Inc., and one of our strategic scientific assets, the National Institutes of Health's *Human Genome Project*.

Eighteen publicly traded bioscience companies have their headquarters in Maryland, representing a total market capitalization of nearly $10 billion USD. Our industry contains the third largest state cluster (2nd per capita) of core biotechnology companies in the United States following California and Massachusetts, as well as one of the fastest growing, according to an independent analysis by Ernst & Young *(E&Y Biotechnology Report: 15th Annual Review, October 2001).* Our industry is beginning to see second-generation companies spinning out from our more established corporations. Mid-sized foreign biotechnology and pharmaceutical companies have chosen Maryland for their U.S. headquarters or subsidiary R&D operations.

Significant to Maryland's success is the proximity of many of our companies to one another, our universities, and the federal regulatory agencies relevant to the diverse needs of the bioscience industry. As a result, many Maryland bioscience companies have found in-state solutions to outsourcing requirements, partners for enhanced technology development, and expediency in regulatory review.

D. Competition & The Challenges Ahead

When other states with emerging biotechnology investment programs look for a model, California, Massachusetts and Maryland are the three most often mentioned. In the past few years, Maryland has become recognized as having put into place programs containing specific funding vehicles and corporate incentives that address the needs of startup and expanding bioscience enterprises. Surrounding Maryland's efforts are the requisite clusters of scientific excellence in its research and academic institutions.

Clearly, this status of Maryland is an asset in recruitment of bioscience companies both nationally and internationally. ***Maryland's investment in programs and funding initiatives, however innovative, are rapidly becoming "modest" in comparison to other states.*** Recent aggressive economic initiatives by other states (and indeed other countries) to stimulate growth in their bioscience industry will threaten Maryland's leadership role in the near term. Maryland's leadership in R&D funding is challenged by investments by other States in R&D infrastructure. *State Government Initiatives In Biotechnology 2001*, prepared for the Biotechnology Industry Organization, found that 41 States have initiatives underway to support and grow the industry, including "substantially increased state funding for bioscience-related research centers, building modern facilities and fully equipped labs with state-of-the-art instrumentation …designed to secure federal NIH and other research funding support."

A survey of *State Investments in Technology-Based Economic Development* (October 2002), prepared by Battelle Technology Partnership Practice, provided an overview of recent and proposed investments in technology-based economic development being made by a number of competitor States. Highlights include:

<u>California</u>

- State's employee retirement fund to invest $500M (to augment fund's existing $100M investment) in the biotechnology sector.
- State funding $100 million established the *Institute for Bioengineering, Biotechnology, and Qualitative Biomedical Research*

<u>Georgia</u>

- Georgia Research Alliance (GRA) created to turn university research into economic growth for the state. Since 1992, the State of Georgia has invested more than $300 million in GRA programs.
- Newly announced $1 billion long-term initiative to make state a national leader in cancer prevention, treatment and research.

<u>Michigan</u>

- 1999 launched *Life Sciences Corridor*, $1 billion initiative over 20 yrs. Initiative funded at $50 Million annually from state's tobacco settlement.
- Life Sciences Corridor has awarded $1M to the *Sloan Ventures Catalyst Fund* to establish a seed fund and $2M over 3 years to create the *Michigan State Universities Commercialization Initiative*.

North Carolina

- Golden LEAF – Foundation created by N.C.'s tobacco settlement will invest $85M into economic stimulus package devoted to further biotechnology industry development.

Pennsylvania

- $1.6 billion long-term for health-related research projects.
- Created *Life Science Greenhouses*—$100M investment in each Greenhouse.
- Launched $120M venture fund for technology investments.

A disturbing trend is Maryland's decreasing share of NIH extramural funding. Recent data show that Maryland's NIH funding peaked in 2001 and is now flat, whereas competitor States in the region, such as Pennsylvania and North Carolina, continue to grow. As recently as 1996 Maryland's NIH funding exceeded that of Pennsylvania, but over the past five years Pennsylvania's NIH funding has surpassed Maryland. As the major investments in faculty and facilities are realized, it is expected that other states will become even more competitive for NIH and other federal funding, although it should be noted that university programs in other states as well as Maryland are being greatly constrained under the present economic strictures, related both to state fiscal problems and weak performance of investments. This competition will only intensify as the major increases in NIH funding – a doubling over the past five years – plateaus. Maryland appears to be positioned to compete for new defense-related funding, especially for bioterrorism-related initiatives; however, the large Congressional delegations in states such as California, New York, and Texas can be expected to exercise influence over federal resource allocation decisions.

Although Maryland was the first, seven other states besides MD, CA and MA have since formally adopted biotechnology or life sciences strategic plans with dedicated staff. ***In fact, the very model that Maryland provides could become the template to accelerate the growth of these bioscience initiatives in other states.*** As such, Maryland needs to continue to expand and refine its commitment to its bioscience industry and the supporting academic and research institutions. This strategic position is even more important to meet new demands as Maryland's bioscience companies mature beyond their entrepreneurial phase to become future leaders in the global bioscience marketplace.

In view of this mounting competition, as the bioscience industry in Maryland matures, so also must the State's support of this valuable industry. The effectiveness of strategies that helped nurture early-stage biotechnology companies to develop products must be re-evaluated and added upon to sustain growth, diversify and expand the commercialization potential within all areas of the bioscience industry to more effectively enter the global marketplace. If not, Maryland will be viewed as an attractive target and resource for others to lure away resident companies, educated workforce, and world-class faculty.

II. Strategic Plan Elements and Recommendations

DBED and the Maryland Technology Development Corporation (TEDCO) were asked by the General Assembly to prepare an updated strategic plan to guide State support of the bioscience industry in the next decade and beyond. As part of this re-evaluation process, the State met with 38 top representatives from Maryland's bioscience community over the past year to discuss challenges to the industry.

This industry dialogue illustrated the unique and expanding needs of the maturing bioscience industry in the State. Several action steps were identified to address these needs. Action work groups, convened under the direction of the Department of Business & Economic Development, have held meetings or conference calls to develop recommendations related to these topics.

In addition to these workgroups, a number of key industry reports, referenced at the end of this document, were reviewed and a series of "best practices" both general and Maryland-specific were identified. Recommendations were generated for specific categories relevant to the bioscience industry.

Moving forward, the State has identified key areas or plan elements that will require attention if Maryland is to help sustain the growth of its bioscience industry. They are:

- Excellence in Academic and Research Institutions
- Technology Transfer Initiatives
- Availability of Venture Capital
- Workforce Development
- Business Infrastructure
- Public Policy
- Industry Advocacy

A. Excellence in Academic and Research Institutions

Maryland's continued basis for growth and diversification of its bioscience industry is based largely upon its research and development infrastructure including over 40 federal research institutes and agencies involved in life sciences research and academic institutions including Johns Hopkins University, and institutions of the University System of Maryland actively engaged in biosciences research: the University of Maryland, Baltimore, the University of Maryland College Park, the University of Maryland Biotechnology Institute, and the University of Maryland, Baltimore County. These institutes, directly or indirectly due to associated faculty, have accounted for over 100 of Maryland's bioscience companies *(Founders of Maryland's Bioscience and Medical Instrument Companies, TEDCO, August 2002).*

1) Despite this, Maryland is only in the middle rank of states in terms of technology commercialization, e.g., patents, university spin-outs, venture capital investments. The Brookings Institution *Signs of Life: The Growth of Biotechnology Centers in the U.S.*, which identified the Washington-Baltimore metropolitan area as one of the top tier biotechnology centers in the country, noted as well that the region lags other state leaders in commercialization. Moreover, these institutions are key players in workforce development and connectivity to industry strategic partners that play a major role in the economic viability of the bioscience industry. Yet, state support for higher education dropped precipitously in FY 2003 and 2004. Increased reliance on tuition in lieu of state funds makes it very difficult for universities to support advanced research or technology transfer activities.

Recommendations

2) Maryland universities and colleges should support the expansion of research and educational programs accordingly to meet the ever-growing needs of the bioscience industry for strategic partnering and a well-educated, knowledge-diverse workforce, respectively.

3) Maryland universities and colleges should seek and retain the best of talent to discover new knowledge and disciplines and create new technologies, maintaining an increase in the number of related programs rising in national prominence and rank.

4) Maryland universities and colleges should nurture an entrepreneurial environment on and adjacent to campuses, in particular to support associated technology incubators by providing not only core (facility) assistance, but additionally by providing added-value resources such as business management and legal assistance through the leveraging of existing academic programs and talent.

5) Maryland universities and colleges should increase the number of collaborations and strategic partnerships with national laboratories, leading bioscience corporations both nationally and globally, and be recognized as a major contributor to technology enterprise.

6) To accomplish the above the State should provide competitive (based on national peer-group funding guidelines) support for the operations of its institutions of higher education to meet the needs for both advanced research and development (recruitment of top researchers, laboratory facilities, etc.) and the growing number of students.

7) The State should encourage and support core bioscience and related initiatives from Maryland universities and colleges, including but not limited to research parks and new cutting-edge technology development facilities. Such projects include the Ehrlich Administration's proposed investments in a new Biosciences Research Building at UMCP ($65 million) and an expansion of the UMBI Center for Advanced Research in Biotechnology (CARB II) in Montgomery County ($60 million) as well as joint university-industry facility initiatives.

8) The State must foster focused discussions among institutional leaders, research scientists, and public and private policy makers to raise the level of inter-institutional collaboration.

B. Technology Transfer Initiatives

Commercialization R&D is the critical component of the success of technology based economic development. The Brookings Institution's comprehensive study of the bioscience industry (June 2002) concluded that strong research institutions and commercialization vehicles are essential to the creation of a biotechnology industry. However, Maryland's universities as a whole commercialize their technology at a lower rate than other institutions across the nation. *The Maryland Innovation and Technology Index 2001*, prepared by Johns Hopkins Institute for Policy Studies, compared Maryland with competitor States in the mid-Atlantic region, and found that Maryland's institutions overall capitalize on their R&D assets at a lower rate than those in competitor states.

Similarly, a detailed analysis of invention rates conducted by TEDCO found that *as a whole* the University System of Maryland's institutions fall below the national average in disclosures, patents, and licensing revenue. (It is important to note that this analysis encompasses all technologies, not just bioscience, where invention rates might be higher.). At least in part, this may be because funding for technology development activities lags in Maryland. For example, Pennsylvania's Ben Franklin Partnership Program regularly receives $28+ million a year from the State general fund; the comparable Maryland program receives $5 million

Recommendations

1) Identify new initiatives that could increase the number of high quality patent applications and spinout companies from university technologies.

2) Examine the technology transfer process from the federal laboratories and formulate efforts to connect Maryland's entrepreneurs with the resources of these institutions.

3) Provide increased funding to programs and agencies that facilitate the transfer of technology from federal and academic research entities.

4) Provide forums that connect federal and academic research entities to private bioscience companies to facilitate the commercialization potential for innovative discoveries.

C. Availability of Venture Capital

Building a concentration of bioscience firms in the State requires venture capital (VC) throughout the growth of biotechnology companies as they attain product marketability and profitability. In cultivating a healthy environment for newly emerging bioscience companies, early stage funding, or start up/seed funding, is a crucial component. Few private venture capital groups in Maryland invest in early stage bioscience companies, partially due to the perception that investments in bioscience companies are capital intensive and experience long return on investment (ROI) periods.

As Maryland bioscience companies emerge from the seed funding stage, they typically move directly to Series A or 1st round financing, generally characterized in the $1-10 million range. These companies are being met by a relatively lean venture capital market, and what appears to be a gap between early rounds of financing and later stage financing focus on more mature bioscience companies. Ironically, investor interest and the financial success of expanding VC funds (some having over $400 million to invest within two years) make the portfolio management of investments under $5 million inefficient. Younger companies are left with very limited sources of private funding and increase demand for State sponsored programs. Current market conditions have led to an overall fall of 44% in venture investment in the U.S. for 2002 (*Ernst & Young and VentureOne, 2003*). This has resulted in an increased pressure to invest in sustainable companies that can reach profitability quickly – not the profile of many young bioscience enterprises.

In a separate study by Ernst & Young regarding the state of venture capital investment in Maryland specifically for the bioscience industry (*Venture Capital Climate for Bioscience in Maryland: A Comparative Study of Biotechnology Venture Capital Funding and State Funding Initiatives in Maryland and Selected Other States, 12/2001)* it was found that Maryland's bioscience industry has a private venture capital funding gap of approximately $50 to 100 million per year, as compared to private venture capital financings of biotechnology companies in other selected states (CA, MA, NC, NJ, NY, PA, WA, TX, FL, GA, and CT). In spite of the presence of a large number of companies, Maryland ranks last in venture capital relative to the number of biotechnology companies in each state. The funding gap appears to exist for all funding amounts, though the gap appears most prominent in situations where companies are seeking larger financing amounts, such as those in excess of $3 million.

The funding gap in private venture capital raised by Maryland biotechnology companies is not being closed by current State government funding programs – there is a funding gap even after including investments made by State programs. It should be noted that the estimated venture-funding gap was based on a conservative definition of biotechnology companies, focusing only on Maryland companies that are appropriate candidates for venture capital funding.

Recommendations

1) Finance Process

- Formalize and expand DBED's program of investing into venture capital limited partnerships, requiring a commitment of best efforts to invest in local companies. (Cost estimate: $3 million in FY04, increasing to $10 million in FY06)

- Increase funding for DBED's technology grant and venture capital programs: Challenge & Enterprise Funds. (Cost estimate: $8 million in FY04, increasing to $*XX* million by FY08)

- Take leadership and sponsorship roles at events/ maintain active relationships. (Cost estimate: $50,000 annually/ $300,000 for BIO2003)

- Actively promote the benefits of directing investment opportunities into funds in Maryland. (Cost estimate: $5,000 annually)

- Expand efforts to sponsor seminars, training opportunities and consulting assistance for securing federal Small Business Innovation Research (SBIR) funding and/or attracting venture capital funding.

- Request the Comptroller of the Treasury to develop a certification document that companies can present to vendors to allow companies to take advantage of sales tax exemptions for R&D equipment.
(Cost estimate: None)

2) State Pension Funds

- Propose to the Maryland State Pension Board that a small percentage of total assets (approximately 0.5%) be dedicated to equity investments in the bioscience industry specifically or the technology sector in general, particularly in Maryland. (Cost estimate: $150M in fund commitment)

- Propose to the Maryland State Pension Board that the compensation structure in place for its equity managers provide additional incentive for Maryland-based biotechnology investments.
(Cost estimate: None)

D. Workforce Development

A consistent hallmark of thriving bioscience communities throughout the nation is the active participation of industry and institutions of higher education in contributing to a well-trained workforce. In June 2002, the Brookings Institution released *Signs of Life: Growth of Biotechnology Centers in the U.S.*, which identified the Washington-Baltimore metropolitan area as one of the top tier bioscience employment centers in the country.

A number of State and private partners are actively involved in workforce development and meeting the needs of our future economy. Some of these include the Maryland Business Roundtable for Education, the Maryland Higher Education Commission, the Governor's Workforce Investment Board, the University System of Maryland, Maryland Department of Labor, Licensing and Regulation, and the Maryland Association of Community Colleges.

Maryland's higher education institutions have long recognized the importance of bioscience to the Maryland economy, and have developed a full range of science-related programs throughout the State's institutions of higher education. Other programs, such as the Howard Hughes Medical Institute Fellowships at UMCP and UMBC, Career Connections—Maryland's School-to-Work initiative – and the "MdBioLab", a mobile bioscience laboratory that visits high schools throughout the State, are stimulating students' interest into bioscience careers. Clearly, the challenge educational institutions face is to keep pace with advances in technology and industry innovations.

Recommendations

1) Complete a comprehensive survey of Maryland's bioscience industry workforce needs. A partnership of relevant agencies and organizations can undertake this assessment. (Cost estimate: $30,000)

2) Create a Bioscience Industry - Education Advisory Board to keep the content and curricula of programs current. Establish an advisory board with representatives of industry, K-12 education, higher education, economic and workforce development.

3) Establish a comprehensive bioscience internship program for both teachers and students. Establish a central coordinating Internship Office to match interns with employers. Create sponsored minority opportunity internships. (Cost estimate: $250,000 for Internship Office, $500,000 for incentives).

4) The Maryland Higher Education Commission should foster the entrepreneurial development of Associate, certificate, Masters and Ph.D. programs in biomanufacturing, bioengineering, bioinformatics, biomedical informatics, biophotonics, etc. in Maryland's community colleges and universities.

E. Business Infrastructure

The bioscience industry has both unique and non-unique needs that facilitate growth and diversification within the State.

Non-Unique

Examples of non-unique issues are the promotion of highway and transportation initiatives to foster interconnectivity within State to promote and enhance opportunities for Maryland companies to develop business relationships. Provision of areas of affordable housing for all levels of employment in technology enterprises and a high quality of life are also key.

Recommendations

1) Reduce tax rates and costs that are out of line with key competitor states by expanding targeted, fiscally responsible tax credits and abatements that increase economic growth and entrepreneurial investment. Maryland's longer-term goal should be not to exceed national average rates of taxation. Spending affordability targets should reflect this goal and progress should be measured and reported.

2) Consider a reduction of Maryland's personal income tax. Interim measures to reduce the impact on individuals relocating to Maryland as part of a business expansion should be developed.

3) The impact of business personal property taxes on high technology and R&D companies should be reduced further or eliminated; prior legislation making this optional for Counties should be amended to make this mandatory. Not only are property taxes (which are not present in all states) a disincentive to locate or expand in Maryland, but additional time and effort is required to calculate the State tax, which differs from Federal calculations.

4) The development and construction of the Inter-County Connector that would bring Maryland's two largest bioscience clusters within reasonable travel proximity for partnerships and workforce availability should be highly supported.

5) Community developments adjacent to university and bioscience clusters should be promoted that provide for affordable housing alternatives for industry workforce.

Unique:

a) Industry Diversification: Attention to one sector with the bioscience industry can stifle growth and innovation, and thus the potential for economic development opportunities, in others. Maryland has developed a recognized strength in medical biotechnology and associated enterprises. Less represented, however, are companies that conduct research and product development in agricultural, industrial and environmental biotechnology. These areas offer economic opportunity and potential for diversification and growth of Maryland's bioscience industry in the 21st century. Maryland must aggressively seek opportunity to expand these sectors.

In agricultural bioscience, a unique opportunity exists particularly for Southern Maryland as one example, for the conversion of farmland presently or formerly engaged in tobacco plant production. Maryland has enforced a State-mandated phase out of tobacco production by 2004. A majority of farms (more than 70%) have already converted to low cash crop alternatives taking advantage of the federal tobacco subsidy. This situation is temporary and a return to high cash value crops will be necessary in order to sustain these farms economically. Thus, this knowledgeable workforce could be brought together with innovative agricultural bioscience initiatives for the production of value-added, high cash genetically modified crops. Although the USDA Agricultural Research Center is located in Beltsville, university research in agricultural bioscience is less extensive in Maryland than in other states with a larger agricultural base. The UMCP College of Agriculture and Natural Resources and UMBI's Center for Biosystems Research are active in agricultural biotechnology research. Enhancing these research programs may serve as a magnet to establish stronger industry presence as exists in North Carolina as one example.

A similar situation exists for the potential economic development of new bioscience industries focused on industrial and environmental biotechnology, in particular with applications to improve the quality of the Chesapeake Bay estuary. Also, numerous brownfield sites in the State have even greater economic ramifications beyond the applications of any one company's technology thus far.

<u>Recommendations</u>

1) The State and universities should partner to prioritize initiatives of potentially significant economic development and ramifications to the State, its citizens, and business community. Fostering of agricultural, industrial and environmental biotechnology applications, whether resident in State research institutions or accessible through the recruitment of industry partners, could address current unmet needs.

2) The State and the universities and any associated private industry partners should, as a consortium, enter into pilot programs of application of innovative biotechnology solutions to the above initiatives, applying any and all applicable State programs.

3) The universities should assist the State in its business development efforts with the identification and recruitment of key industry partners necessary for successful implementation of such potentially innovative programs

b) Wet Lab Space & Biomanufacturing Capacity: The confluence of a strong bioscience research presence with the infrastructure to convert such research into commercial product and production remains a benchmark for success in cultivating a thriving bioscience community. While a leader in incubating bioscience companies, Maryland must now be able to provide companies the infrastructure to grow and eventually expand to reach manufacturing capabilities. This challenge to retain discovery and production at the same geographical location remains industry-wide. Since part of the FDA's lengthy approval process includes approval of the manufacturing process and physical site, once approval is given, biomanufacturing tends to be geographically stable. Arguably then, as Maryland's bioscience companies progress from the research and development phases, product commercialization and manufacturing will become a future source for economic value and employment.

Bioscience companies, particularly in the medical bioscience field, first must have the highly specialized infrastructure, such as wet labs, necessary to begin conducting research and development. Wet labs have been analogized to the bioscience industry as fiber optics are to the information technology industry. For start-up bioscience companies, wet lab facilities can allow multiple companies to divide the high cost of outfitting a lab with sophisticated pieces of equipment, such as fume hoods, that are necessary for conducting the first crucial steps of research and development up to the initial stages of manufacturing. Due to the specialized nature of wet labs and the unique requirements for individualized products under development, cost often makes it impractical to retrofit an existing structure or office space.

Currently, approximately one-third of Maryland bioscience companies are engaged in therapeutic research and development. As a product progresses into later phases of testing, companies must decide whether to rely on contract manufacturing or construct their own biomanufacturing facility. The cost outlay for such a facility ranges between $25-200 million, depending on the nature of the product, and could have a prolonged return on capital expenditures of 5 years or longer. With over 350 biotherapeutic candidates in the United States alone, there is a predicted global shortage of biomanufacturing capacity as these potential products enter final testing and market levels of production.

While Maryland has certain limited pilot scale facilities for biomanufacturing, and even some large-scale contract manufacturing facilities, Maryland is in need of additional biomanufacturing capacity as well as "wet lab" space. Scheer Partners has estimated as recently as mid-2002 that there is approximately one million square feet of need in the State, compared to an availability of approximately 250,000 square feet. Projects, such as the University of Maryland, Baltimore (UMB) biotech park, are moving ahead to address the needs of burgeoning, young bioscience companies in the State. In the past, about three-dozen companies have come out of UMB, but most relocated elsewhere as they grew ("UMB president says biotech park on track," *Baltimore Business Journal – March 24, 2003*). Johns Hopkins University as well will be developing a sizeable biotech park in East Baltimore to cultivate new bioscience discoveries while quelling the egress of maturing bioscience companies to manufacturing operations outside of the State.

An evaluation of existing wet lab space and biomanufacturing capabilities present and planned is crucial in being able to assess the need for future facilities and their infrastructure attributes.

Recommendations

1) Maryland should undertake or partner in the undertaking of analyses of the availability of wet lab facility space and the current and anticipated needs for increased biomanufacturing capacity and facilities. A preliminary study of wet lab needs is underway.

2) Maryland should provide additional financing and incentives to companies that wish to build their own biomanufacturing facilities.

3) Maryland should support, through applicable programs, the expansion of pilot-scale (e.g. university or institute associated) and contract manufacturing facilities in the State.

4) Besides loan guarantee programs, Maryland could guarantee "time of lease" payments on facilities to help companies bridge financial dry periods between raising venture capital rounds.

5) Maryland could explore financing partnerships on shared facility alternatives, including 2-3 smaller bioscience companies. Facility infrastructure, regulatory certification issues and management need to be addressed. Maryland could work with county economic development agencies to identify/prepare "shovel-ready" building sites or shell facilities with incentives for redirected use.

6) Maryland needs provide increased support for academic and corporate workforce development in this dedicated industry sector to meet future in-state demand.

c) Clinical Trials: In Maryland alone, over 40 bioscience companies have therapeutic products in clinical trials. Clinical trials represent one of the most costly, time consuming and high-risk aspects of the drug discovery process. Since all aspects of the process are regulated by the Food and Drug Administration (FDA), clinical trials are subject to specific timelines and milestones. Inherently, this process is known to incorporate delays due to FDA backlog, poorly designed trial protocols or the inexperience of bioscience company staff, which may possess strong scientific credentials, but have little or no active knowledge of the complexities of the clinical trial process.

In order to mitigate the costly and time-consuming federal regulatory process, many U.S. companies are taking their business and clinical trials to Europe. In fact, a startling seventy percent of Phase I trials of U.S. companies are conducted in Europe. This trend hit close to home in January 2003, when Rockville-based Human Genome Services, Inc. announced that it was launching a new subsidiary company, Human Genome Sciences Europe GmbH in Dusseldorf, Germany, to administer testing and development of its new pharmaceuticals.

Another hurdle for the biotechnology and pharmaceutical companies with drugs in clinical trials phase is the ability to recruit sufficient numbers of patients who qualify for specific clinical studies. In response to this problem, the University of Maryland, Baltimore (UMB) has created a Clinical Trials Center to better connect in-state patients with appropriate protocols. While removed from this process, there are some steps the State and its university-associated health care institutions can consider to facilitate this growing need.

Recommendations

1) Subsidize training courses on clinical trials for bioscience managers.

2) Assist in the development of a registry listing where specific patient populations can be found in-state and a registry of resources that are available in Maryland to companies doing clinical research.

3) Increase the State's emphasis on recruiting world-class physician researchers to Maryland institutions, who would then act as magnets for specific patient pools.

4) Expand the scope of current law regarding insurance coverage for participants in clinical trials.

5) Actively market the clinical trial capabilities of Maryland medical institutions to the pharmaceutical and bioscience industries in their promotional materials.

6) Make training for clinical trials a specialty area in the curricula of the medical institutions. Build on the training already conducted for pharmacists, nurses, and physicians at UMB and JHU.

7) Create a network of research coordinators to work with community hospitals and physicians throughout Maryland. Extend the UMB clinical trials center by linking with Maryland's Oncology Network.

F. Public Policy

The impact and ever-increasing relevance of bioscience research and innovations in our daily lives emphasizes the crucial, growing role bioscience plays in our evolving society. Here in Maryland, the landmark accomplishment of mapping of the human genome, has opened the door to a new era of medicine with the possibilities of everything from developing vaccines that work at the molecular level of a disease to personalizing medication to one's own DNA signature. Particularly as our baby-boomer population begins to retire, the need for such products and pharmaceuticals will rise.

The tragic assaults on our nation's air transportation system and on New York City on September 11, 2001, and the ensuing deliberate Anthrax contamination of the U.S. postal system, has increased public attention to the clear potential for additional bioterrorist threats not only in the United States but throughout the world. Subsequently, the demand for pre-emptive diagnostic and therapeutic solutions has increased precipitously, from both consumers and government agencies that are charged public safety. Recognizing the value of the bioscience industry, not just in terms of job and revenue creation, policy makers acknowledge the bioscience industry's life improving, life saving and perhaps life-extending advances that may be provided to their constituencies.

As states recognize the long and short term growing value of the bioscience industry, many states are making a conscience effort to create an environment to foster bioscience companies. The *State Government Initiatives in Biotechnology 2001* report, prepared for the Biotechnology Industry Organization (BIO), indicates that a key element in nurturing a productive bioscience climate is a "stable and supportive public policy structure."

Along with tax benefits that assist companies in attaining financial footing, bioscience companies seek an encouraging regulatory climate and government policies that reflect an understanding of the industry's challenges. Policies that restrict certain types of research or place arbitrary price controls on products may often times negatively impact a company's ability to raise necessary capital.

Recognizing the importance of industry concentration in a specific geographical area, States leverage economic incentives to attract companies to locate within their borders. In addition to traditional economic incentives, the perception of a welcoming public policy environment also may be inviting to businesses in a particular discipline.

Two areas in which Maryland can affirm its commitment to advancing the bioscience industry in the State are:

- strategically using the tax structure to encourage bioscience companies to grow and increase private investment in biotechnology firms, and

- expand Maryland state laws and policy to reflect an understanding of what the bioscience industry needs to thrive in the State.

a) Tax Policy: Maryland offers some generous tax credits. Many bioscience companies cannot take advantage of several tax credits because they have no corporate income tax liability. Net operating loss, or NOL, legislation is a technology business tax certificate program providing for the sale of unused net operating losses (NOL). This proposal establishes a tax benefit transfer program whereby bioscience corporations can sell unused net operating losses to other corporate taxpayers in the State, raising critical capital needed to flourish. For example, Connecticut businesses with $70 million or less in gross sales may exchange unused R&D tax credits with the state for a cash payment equal to 65 percent of the value of the credit.

Legislation seeking to create an NOL tax transfer program failed in the Virginia and Maryland legislatures in 2001 and 2002. The Maryland legislation was met with opposition to the relative complexity of administering a program that would have to track and allow NOLs as well as R&D credits to be sold. In addition, the cap of $20 million per year placed on the amount of NOLs that could be sold was seen as cost prohibitive in a slowing economy.

The goal is to improve Maryland's competitiveness in the bioscience industry sector and demonstrate the State's leadership in this arena by being among the first states to implement a program of this type. This initiative would signal Maryland's interest in supporting and encouraging the growth of these companies by recognizing the long lead time that many experience prior to profitability and their need for capital now to continue research and development work.

Recommendations

1) Improve the regulatory environment by streamlining the permitting process, reforming or eliminating unnecessary regulations, especially those exceeding Federal mandates, and achieving a customer orientation among enforcement and regulatory officials. Regulatory processes should be re-engineered to reduce cycle times and reduce the costs of the compliance process to affected businesses.

2) Support and maintain tax incentives, in particular R&D related credits. Modify proposals to restrict eligible purchases to in-state vendors or defer sales taxes only until the company's product has reached marketability.
3) Support Investment Tax Credits (ITCs). ITCs can help reduce the steep costs bioscience companies face when purchasing necessary specialized equipment (for instance, outfitting a wet lab) needed to conduct research and development with a particular pharmaceutical product. ITCs can include provisions such as credit for manufacturing modernization/upgrade, sales tax exemptions for computer and R&D equipment, and property tax exemptions on specialized equipment.

4) Support Specific Bioscience Industry Incentives. In order to attract targeted business sectors, states craft incentives for specific industries. For example in 1997, Arkansas produced a biotechnology tax incentives package that included "a 30% tax credit on the cooperative research with state universities, a 5% credit on the cost of construction, expansion, improvement, renovation or purchase of a biotechnology facility, a 30% credit on the cost of training employees in biotechnology and a 20% credit on the amount that the cost of qualified research exceeds the cost of such research in the base year."

5) Review available data on NOL legislation and its success or failure in other states. New Jersey, Connecticut and Hawaii have implemented the program or a portion of the initiative. Focus only on net operating loss tax transfer; not the sale of unused R&D credits. It is too cumbersome to have more than one type of tax credit transferred/sold.

6) Support legislation for bioscience companies to transfer their unused net operating losses (NOL) to other Maryland corporations. The amount of tax benefits that could be transferred would be capped at $10 million annually, as well as there would be a lifetime cap of $10 million for each participating company. This cap would represent the maximum amount that would not be paid to the State treasury. The appropriate level of this annual maximum, balancing the needs of the industry against fiscal issues of the state, is an important policy consideration.

7) As to the criteria of who can sell their NOL, a "new and emerging bioscience corporation" would be defined as one with less than 225 employees, of which 75% are Maryland-based. "Bioscience" would be defined as any activity that substantially involves research, development or manufacture of biologically active molecules; devices that employ or affect biological processes; or devices and software for production or management of specific biological information.

8) Proposed legislation should further define eligible buyers to be unaffiliated corporations in traditional economic industry sectors such as manufacturing and should set up criteria by which applications from sellers would be evaluated.

9) Applications from sellers would be evaluated on the following criteria: the viability of the company's technology; whether the technology is sufficiently innovative to provide a competitive advantage; whether the development of the technology will likely result in growth in full-time employment in the State; whether the company has insufficient resources from other sources; and whether the infusion of this financial assistance will materially and positively affect the company's financial situation. Financial institutions or DBED's Investment Financing Group could facilitate the transfer between buyers and sellers.

10) Create tax credits for individuals and corporations who invest in small, start-up companies requiring "seed capital."

11) Achieve capital gains tax relief that encourages investors who put their money into long-term equity holdings, particularly in start-up technology firms that need patient capital to see them though research and development phases.

12) Continue to enhance the State's research and development tax credits, consider applying the credit against not only income tax, but also insurance premiums and franchise taxes.

13) Pursue legislation that provides provisions for exemption of taxation on royalties for high tech products and gains from stock options.

b) Maryland Bioscience Legislative Policy: When seeking an area to locate and to expand, bioscience companies look for evidence of an encouraging regulatory climate and policy makers that understand and are sympathetic to the challenges of the bioscience industry. States acknowledge this and send messages back to the industry by the policy they promulgate. For instance, last year, California passed a new law that while vague in operational details, the state hopes will carry the general message that California welcomes bioscience companies to engage in private stem cell research. It is too soon to assess the success of the California legislation and message since the bill was signed into law only five months ago, but it sends a clear message to other states that competition for bioscience business has increased. Similar legislation was introduced in the Maryland House of Delegates this 2003 legislative session.

Policy makers and key leaders in the State must affirm Maryland's commitment to the bioscience industry by producing thoughtful and comprehensive proposals that will advance the growth of the industry and be cognizant of unnecessarily restrictive State regulations that will have a damaging effect on the State's competitive posture, particularly in the area of human subject research.

Recommendations

1) Discourage legislative initiatives that restrict or unduly regulate private bioscience corporations over and above that which is mandated by federal regulations.

2) Actively pursue legislative initiatives that support Maryland's bioscience industry and are generally in line with those promoted by the Biotechnology Industry Organization (BIO).

G. Industry Advocacy

The bioscience industry is particularly dependent upon federal budgetary and regulatory policies, from the level of funding for research sponsored or performed by the National Institutes of Health, to the capacity of the U.S. Patent and Trademark Office to promptly and accurately review patent applications, to the approval procedures of the

Federal Drug Administration. Due to their proximity to Washington, D.C., Maryland firms are well positioned to influence and take advantage of policy actions that affect the industry. Issues of interest to the industry include federal tech transfer policies, funding for the Patent Office, and procedures regulating clinical trials.

Through representation by organizations such as the Maryland Bioscience Alliance, and through the attention of the Congressional delegation, the State's emergent bioscience industry has been represented on policy issues at the federal level. However, the State government has not taken an active role in promoting the interests of the industry at the national level.

Similar opportunities for the promotion of Maryland's bioscience industry <u>in state</u> must be sought. For an industry so dependent on strategic partnering, aggressive implementation of programs should be pursued that connect existing Maryland companies and institutes likely to benefit from sustained industry growth.

<u>Recommendations: Federal</u>

1. Be a national spokesperson for the industry. Take leadership roles in national and international events (such as BIO2003), lead trade missions, speak at events, etc. to increase global awareness of the depth and breadth of Maryland's bioscience industry.

2. Create a permanent working group on federal biotechnology policy. Establish a working group of industry, academia, advocates, and economic development official.

3. Make specific recommendations to the Congressional delegation on biotechnology policy in the annual package of priorities. Use the working group to develop industry-specific priority positions.

4. With the Congressional delegation, make specific statements on issues under national debate, e.g. prepare issue papers, testify at Congressional hearings, write letters urging action, and coordinate these activities with the Biotechnology Industry Organization (BIO). Include specific recommendations to the Congressional delegation on bioscience policy in the Governor's annual package of federal legislative recommendations, creating a permanent working group to monitor federal actions, and identifying national leadership opportunities for the Governor.

<u>Recommendations: In-State</u>

1. Make support for the growth of the bioscience industry, a visible State priority from the highest levels of government, on parity with other traditionally important economic sectors.

2. Expand number of knowledgeable industry liaisons at DBED with sufficient visibility to effectively advocate Bioscience Industry needs and sufficient authority to address those needs. These persons must be capable of facilitating communication and coordination among universities, community colleges, Federal laboratories, DBED, the State legislature and private industry.

3. Focus State business development efforts to include an emphasis on attracting major pharmaceutical and medical, agricultural, industrial and environmental biotechnology companies to locate in Maryland.

4. Create a central information source at DBED (or other appropriate resource entities) for technology companies to facilitate access to capital resources and improve likelihood of success for new ventures (information on State programs, SBIR's, CRADA's, University resources, GMP training, education, skills development, etc.). A State-wide database that provides information on research and development activities in the public and private sectors could facilitate collegial communications and research in common disciplines.

5. Explore the creation of an industry-led commercial biotechnology intermediary to focus on strategic commercial needs in Maryland that foster a stronger biotech industry in the State. A key role of this new industry-led biotech intermediary might be to serve as a business development liaison to TEDCO's efforts focused on bringing the results of university and federal lab research to the market.

6. Strengthen DBED's bioscience industry point of contact related to the development of a strong commercial biotechnology industry in Maryland.

7. Develop a communications plan for disseminating information to Bioscience executives. Educate the bio-community about the State's activities so that they know the state is active and an industry advocate.

8. Improve communication resources to the Bioscience community in order to ensure access, encourage new venture creation and provide an equitable distribution of resources.

9. Enhance networking activities for biotech companies. (Increase funding for entities such as TCM, GBTC, MdBio, etc.)

10. Convene an annual conference to provide a forum for the state's bioscience industry to communicate its needs to the State's universities and federal facilities. A periodic independent assessment of the degree of compatibility between industries needs and university response should be conducted by the State.

SUMMARY

In the twelve years since the first strategic plan was developed for Maryland's bioscience industry, the number of companies that conduct bioscience-related business in State has increased more than ten-fold. Some of these businesses have gained international recognition, while others are still in gestation. The challenges of supporting this rapid growth and maturation of Maryland's industry are numerous. In addition, aggressive competition by other states and countries for limited resources that are requisite for this industry make timely assessment and corrective implementation of needed programs and initiatives imperative.

Maryland's strategic efforts to nurture early-stage bioscience companies and entrepreneurs have proven successful to date and there is clear evidence that continued government involvement can have a profound, positive influence as the industry matures. Focused State support forged in partnership with the industry and academia is critical to both industry growth and Maryland's continued competitiveness as an industry hub. It is also the best way to ensure limited State resources are used to maximum advantage.

This report was developed by DBED and TEDCO in coordination with industry and academic leaders, and take into consideration a range of factors including the unique circumstances of Maryland's bioscience industry as well as the challenges Maryland faces to retaining and growing its industry given increasing competition. **The recommendations contained in this report are just that; recommendations. They should be viewed as broad guidelines for future bioscience support by the State of Maryland and should be taken into account as the Ehrlich administration refines its agenda for technology in general, and for bioscience specifically.**

Cited and Reference Studies

Studies sponsored by TEDCO (* co-funded with DBED)

"Trends in State Technology-Based Economic Development Programs: Biotechnology and Life Sciences" – Prepared by the Technology Partnership Practice, Battelle Memorial Institute (November, 2000)

"Maryland Innovation and Technology Index 2001" – Prepared by Johns Hopkins Institute for Policy Studies (January 2001)

"Maryland's Technology Development Investments: FY1991 – FY2001" – Prepared by Battelle Memorial Institute, Technology Partnership Practice (March 2001)

"Review of the University System of Maryland Report on Collaboration in Biotechnology" - Prepared by TEDCO (October 2001)

"Maryland Incubator Impact Analysis" – Prepared by RESI Research and Consulting, Towson University, in collaboration with the Maryland Business Incubation Association (October 2001)

"Venture Capital Climate for Bioscience in Maryland" – Prepared by Ernst & Young (December 2001)*

"Review of the University System of Maryland Draft Intellectual Property Policy" – Prepared by TEDCO (January 2002)

"Assessment of the Maryland Health Care Product Development Corporation" – Prepared by TEDCO in collaboration with DBED and the Tech Council of Maryland (February 2002)

"Assessment of the Maryland Bioprocessing Facility" – Prepared by TEDCO in collaboration with DBED and MDBio, Inc. (February 2002)

"Founders of Maryland Bioscience and Medical Instrument Companies" – Prepared by Johns Hopkins Institute of Policy Studies (August 2002)*

"State Investments in Technology Based Economic Development" – Prepared by the Technology Partnership Practice, Battelle Memorial Research (October 2002)

"Maryland Innovation and Technology Index 2003" – Prepared by Johns Hopkins Institute for Policy Studies (February 2003)

“Demand for Commercial Wet Lab Space” – Prepared by Hammer Siler George (forthcoming, Spring, 2003) *

Independent Studies

“The Genome Zone: Life Sciences Real Estate in Washington-Baltimore” – Prepared by Medical Office Properties Inc., Trammell Crow Company (June 2002)

“State Technology and Science Index” – Prepared by the Milken Institute (September 2002)

“Sings of Life: The Growth of Biotechnology Centers in the U.S.” – The Brookings Institution (June 2002)

“The State New Economy Institute 2002” – Progressive Policy Institute

“2003 Development Report Card for the States” – Corporation for Enterprise Development

“State Government Initiatives in Biotechnology 2001” – Prepared for the Biotechnology Industry Organization (September, 2001)

“Report of the University System of Maryland Biosciences Work Group” – (August 2001)

“Financing Maryland Biotechnology” – Prepared by the Greater Baltimore Committee by Merrick School of Business, University of Baltimore (February 1991)

“An Economic Plan for the State of Maryland” – Prepared by the Maryland Economic Growth Task Force (November 1994)

“Strategic Review and Recommendations” – Prepared by the Bioscience Industry Advisory Committee (August 1996)

“Commercial Biotechnology Development in Maryland: A Strategy for the 1990’s” – Prepared by the Maryland Department of Economic and Employment Development (October 1991)

“A Strategic Statement for Technology Development: Strengthening Maryland’s Economy through Commercialization and Modernization” – Prepared by Maryland DEED (November 1992)

“Maryland’s Biotechnology Manufacturing Strategy for 1990’s” – (January 1991)

"Developing a Workforce Strategy for the Life Sciences" - Commissioned by Maryland DEED (January 1992)

"Baltimore Bioscience Initiative" – Prepared for the Baltimore Workforce Investment Board (August 2002)