

BIOSCIENCE ECONOMIC DEVELOPMENT:

LEGISLATIVE PRIORITIES, BEST PRACTICES, AND RETURN ON INVESTMENT

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The Bioscience Industry: An Introduction



he bioscience industry is one of the most innovative and important economic drivers in the United States, accounting for over 1.6 million jobs and an additional 5 million jobs in the U.S. due to the economic multiplier effect. Bioscience jobs require a highly skilled workforce and therefore result in jobs paying on average 79 percent more than the average worker in the United States' private sector. The highly skilled nature and demand for bioscience jobs supports a wage growth that well outpaces that of the private sector, increasing by 13.1 percent in real terms since 2001, compared with just 4.4 percent pay raises among all other industries.

Currently, the United States leads the world in terms of innovation and growth in the bioscience industry. Global competition within the industry, however, has been rapidly increasing. State sponsored programs to encourage investment and assist bioscience companies in leveraging existing resources are vital to the growth of this innovative industry in the U.S.

The Biotechnology Industry Organization (BIO), in partnership with the Council of State Bioscience Associations (CSBA), has developed this updated digest of noteworthy public policy strategies and programs to assist policy leaders and their bioscience industry partners in identifying new and innovative measures to create, nurture, and retain the bioscience industry. "Curing diseases, first and foremost, means saving lives. But it also means reducing health care costs. With science-based regulatory systems, appropriate tax policy and incentives to encourage continued innovation, America's biotechnology sector can help drive substantial job growth in the United States and advance our nation's competitiveness over the long term."

BIO President and CEO James C. Greenwood Press Release 01/25/12

Defining the Biosciences

he bioscience industry is a diverse group of industries and activities with a common link—they apply knowledge of the way in which plants, animals, and humans function with the goal of developing new treatments, therapies and, processes. The industry spans different markets and includes manufacturing, services, and research activities.

Whether we call ourselves biotech, biosciences, or the life science industry, the diversity of the scientific discovery and commercialization efforts are linked by the application of knowledge of the ways plants, animals, and humans function.

In cooperation with BIO, The Battelle Technology Partnering Practice in 2012 identified five major sectors of the biosciences that reflect the size and diversity of this growing technology sector.

• Agricultural Feedstock and Chemicals: Industries that utilize advances in biochemistry and biotechnology for producing products involved in crop protection, advanced seed, agricultural processing, bio-fuels, biodegradable materials from plant-based feedstock, sustainable industrial oils and lubricants and enzymes and bio-based catalysts for industrial processes.

- **Drugs and Pharmaceutical:** Industries that produce vaccines, biopharmaceuticals, tissue and cell culture media.
- *Medical Devices and Equipment:* Industries that produce a variety of biomedical products such as surgical instruments, orthopedic implants, bioimaging equipment, dental instruments and patient care products (such as walkers, wheelchairs and beds).
- Research, Testing and Medical Laboratories: Emerging companies working to develop and commercialize new drug discovery/delivery systems and gene and cell therapies as well as more service-oriented firms involved in pre-clinical drug development, clinical trials, and research/laboratory support services. While primarily focused on human health, many companies also focus on research and testing for agriculture and veterinary uses.
- Bioscience-related Distribution: Industries that specialized in approaches such as cold storage and highly regulated product monitoring, and new technologies for distribution such as automated pharmaceutical distribution systems. These dedicated bioscience-related distribution industries include three unique subgroups one associated with medical equipment and device distribution; another with drug distribution; and a third with agricultural-related chemicals and seed distribution. Each of these bioscience-related industries is becoming integral in the primary production of bioscience goods in an age of advanced logistics and the increasingly specialized nature of bioscience product development.

Capital Formation Initiatives

tate governments and regional economic development organizations have increasingly begun to target the bioscience industry because it is an economic engine that provides highwage, high-skilled jobs across a broad range of occupations.

During the last decade, this understanding of the economic potential of the industry has led to policies and programs that provide supportive tax environments in capital formation, technology transfer, and funding for a workforce to facilitate research, development, and manufacturing.

The charts on the following pages demonstrate the extent to which state governments are targeting and supporting the industry for economic growth and development.

State Capital Formation Priorities

- Research and
 Development Tax Credits
- NOL Carry-forwards
- Tax Credit Transferability
- Sales and Use Tax
 Exemptions
- Creation of Capital
 Access Funds
- State Pension Fund
 Investment

- Capital Gains Tax
 Reductions
- Investment Tax Credit
- Developing Incubator/ Shared Research & Manufacturing Facilities
- Workforce Development
 Programs

Small Business Innovation Research Matching Grants Specific to Biosciences

Fifteen states match various SBIR phases of development research.

State	SBIR Funding Focus/Bioscience Specific	Legislative Program Title	
CT	Targeted toward manufacturers	Small Business Innovation and Diversification Program	
DE	For SBIR Phase I	Small Business Innovation Research	
FL	Requires a university partnership	Florida High Tech Corridor Phase II SBIR/STTR External Investment Program	
FL	For SBIR Phase I and II	Florida Research Commercialization Matching Grant Program (currently closed)	
HI	For SBIR Phase I	Hawaii Small Business Center	
IN	For SBIR Phase I (unfunded in 2012)	Indiana 21st Century Research and Technology Fund	
KS	Not exclusive to SBIR but still of interest	Kansas Bioscience Matching Fund	
KY	For SBIR Phase I and II	Kentucky SBIR-STTR Matching Funds Program	
MA	For SBIR Phase II	Small Business Matching Grant Program at Mass Life Sciences Center	
MI	Only for commercialization purposes; for Phase I and II	Michigan Emerging Technologies Fund	
MT	For SBIR Phase I		
NC	For SBIR Phase I (no funding for current year)	Phase I Matching Funds Program	
OK	For SBIR Phase I	SBIR Phase II Matching Funds Program	
SC	For SBIR Phase I	SC Launch SBIR/STTR Phase I Matching Grant Program	
VA	For SBIR Phase I and II	Also STTR Phase I and II	

MATCHING BIOSCIENCE COMPANY PHASES OF DEVELOPMENT AND STATE POLICY SUPPORT MECHANISMS

Because of the lengthy commercialization timeline to success, the Biosciences sector has three distinct phases of company creation and expansion. Over the past fifteen years, BIO, with the assistance of its member companies, has identified key enabling types of legislation to support emerging, testing, and manufacturing companies in our technology sector. This chart characterizes those phases of development and essential legislative support mechanisms needed by these companies.

Emerging Companies

Early-Stage Development. It is at this stage that company researchers identify the action mechanisms of the lead compound or diagnostics tool and develop protocols to begin verifying the viability of the discovery with early testing on in vitro media. Many of these companies can focus on developing products for markets that would otherwise not be served by larger organizations. Typically these companies have no products on the market, less than 100 employees, and are funded by Angel and Venture Capital supporters.

Testing Companies

Mid-Stage/Product Development. Once the technical viability of a discovery has been established, the target product must be developed. This stage of company development typically requires significant investment in personnel, equipment and facilities. These companies generally have less than 200 employees and have products on Phase One FDA safety trials.

Late-Stage/Regulatory Review and Approval. Clinical trials are required to show that products are both safe and effective. Clinical research contractors are often retained. In the case of biopharmaceuticals, pilot-scale manufacturing facilities must be built or contract manufacturing capacity must be secured, along with the necessary scientific, engineering, operating, and maintenance personnel. Small quantities of the product must be produced for testing.

Manufacturing Companies

6

Mature/Manufacturing/Marketing and Sales. In this stage, the company manufactures commercial quantities of its approved product, creates a sales force or licenses product to another company. Sale of manufactured products produces revenues and, hopefully, profits. Traditional sources of financing, such as commercial loans and public stock offerings, may become viable.

Foundational Legislative Enablers:

- SBIR/STTR Small Business Technology Match Funding
- Angel Investor Tax Credit
- Seed Capital Tax Credit
- Incubator/Accelerator Funding

Foundational Legislative Enablers:

- Net Operating Losses (Carry-Over, Transferability)
- Research and Development Tax Credits
- Capital Investment Tax Incentives
- Innovation Investment Tax Incentives

Foundational Legislative Enablers:

- Site and Infrastructure Grant Funds
- Renewable Energy Tax Credits
- Road Access and Rail Access Programs
- Sales and Use Tax Discounts, Exemptions and Refunds
- Utilities Rebates

State R&D Tax Credits

Thirty-nine states reported offering R&D tax credits, an increasing number of which offer a larger credit if the research is conducted by an in-state university. R&D tax credits are refundable in seven states and transferable in three others.

State	R&D Tax Credit	Transferable	Refundable	Comments
AR				
AZ				
CA				
CO				
CT				
DE				
GA				
HI				
ID				
IL				
IN				
IA				Refundable tax credit is equal to 6.5% of qualified expenditures and it may be increased for bioscience firms participating in the High Quality Jobs Programs
KS				
KY				
LA				
ME				
MD				
MA				
MN				
MS				R&D Jobs Credit
MT				
NE				
NH				
NJ				In FY 2012 the R&D Tax Credit was increased from 50% to 100%
NM				
NC				
ND				
NY				
OH				
OR				
PA				
PR				
RI				The R & D tax credit has a carry forward of 14 years
SC				
UT				
VA				
WA				Washington state has no state income tax. Instead a Business & Operating (B&O) tax is levied against businesses. The R&D tax credit can be taken against the levied B&O tax.
WV				Investment Credit
WI				

State Tax Credits to Encourage Early-stage Investment

States also use tax policies to encourage private investment in early-stage companies and/or in funds that make early-stage investments. Twenty states offer tax credits to angel investors who invest in technology companies, seven of which are targeted specifically to angel investors who invest in bioscience companies. Thirteen states reported providing tax credits to individuals who invest in early-stage venture funds.

	State Tax Credits Provided to:				
State	Angel Investors	Bioscience Angel Investors	Investors in Early-Stage Venture Funds	Investors in Bioscience Early-Stage Venture Funds	
AZ					
CO					
HI					
IN					
IA					
KS					
KY					
LA					
ME					
MD					
MT					
NM					
NY					
NC					
ND					
OH					
OK					
OR					
RI					
VA					
WV					
WI					

"The key to economic recovery, both in our state and nationally, lies in securing economic growth and job creation in innovative industries such as the biotech sector. I'm proud that New Jersey continues to lead the way in this sector-creating the jobs and technology breakthroughs that improve the quality of life for our citizens and people around the world."

New Jersey Governor Chris Christie, Press Release 06/12/12

Funds of Funds to Increase the Availability of Venture Capital

States also use tax credits to increase the availability of venture capital. They can create funds that make investments directly in companies, invest in privately managed funds that agree to invest in state companies; or create a fund that in turn invests in private venture-capital funds, which is referred to as a "fund of funds" if it involves more than one fund. As of 2010, Twelve states reported investing in a fund of funds, eleven states reported investing state dollars in private venture capital firms and fourteen states reported making direct investments in bioscience companies.

State	Invested in Fund of Funds	Invested in Private VC Firms	Invested in Bioscience Companies	Other
DE				
HI				Appropriated funds for contract with private nonprofit to provide funding for companies
IL				
KS				
KY				
MA				Through Massachusetts Technology Development Corporation
MD				
MI				
MT				
NJ				
NM				
NC				
ОН				
OK				
OR				
PA				
RI				
SD				Provides financing for feasibility studies in the form of a forgivable loan
TN				
VA				
WI				

State Sales Tax Exemptions to Support the Growth of Bioscience Companies

Thirty-five states reported exempting sales tax for equipment used in R&D, and thirty-three states reported exempting equipment purchased for biomanufacturing from sales tax. Seven states—Colorado, Missouri, New Jersey, New Mexico, North Carolina, Rhode Island and Wisconsin—have sales tax exemptions specifically targeted to bioscience firms.

	Sales tax exemption for equipment		Sales tax on equipment purchased for
State	used in R&D	Specifically targeted to bioscience	biomanufacturing
CO			
CT			
DE			
FL			
GA			
HI			
IL			
IN			
IA			
KS			
KY			
LA			
ME			
MD			
MA			
MI			
MN			
MS			
MO			
NE			
NV			
NJ			
NM			
NY			
NC			
ND			
OH			
PA			
PR			
RI			
SC			
SD			
VA			
WA			
WI			

Return on Investment Success Stories

S tate public officials continually consider the balance between funding innovative programs and assuring that those funds will provide benefits to state taxpayers. The following examples of recent reports on Return on Investment (ROI) illustrate the positive job creation benefits of the industry in the states where companies are located and provides a glimpse into the continued potential of the industry as it grows in size and diversity of commercial applications in health, agriculture, and industrial biotechnology marketplaces.

CALIFORNIA

The **California Institute for Regenerative Medicine (CIRM)** was oreated in 2004 through a ballot initiative (Proposition 71) which authorized \$3 billion dollars from bond sales over ten years to fund stem cell research in California. CIRM funds awards in three areas: Training, Facilities, and Research. Presently, almost 70 percent of all awards go towards stem cell discovery and clinical research and new therapy development. CIRM has funded research into forty diseases including Alzheimer's, Amyotrophic Lateral Sclerosis, Autism, Cancer, Diabetes, Heart Disease, HIV/AIDS, Huntington's disease, Multiple Sclerosis, Sickle Cell Disease, and Stroke. Many of these areas do not have effective therapies and CIRM's projects focus on generating proof of concept, finding a candidate drug, or beginning clinical trials with the Food and Drug Administration.

The CIRM's Economic Impact Report showed that the one-time economic impact from the **\$1.1 billion dollars of CIRM grants** committed as of July 2012 and the **\$884.3 million in matching funds** will have created **24,654 new full time jobs** and payments of over **\$201 million in state and local taxes**.

Case Study: Progenitor Cells Secreting GDNF for the Treatment of ALS, Cedars-Sinai Medical Center

Summary:

Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's Disease) is a devastating disease for which there is no treatment or cure. Progression from early muscle twitches to complete paralysis and death usually happens within 4 years. Every 90 minutes someone is diagnosed with ALS in the USA, and every 90 minutes someone dies from ALS. Human neural progenitor cells found early in brain development can be isolated and expanded in culture to large banks of billions of cell. When transplanted into animal models of ALS they have been shown to mature into support cells for dying motor neurons called astrocytes. In other studies, growth factors such as glial cell line-derived growth factor (or GDNF) have been shown to protect motor neurons from damage in a number of different animal models including ALS. The idea behind the current proposal is to modify human neural progenitor cells to produce GDNF and then transplant these cells into patients. As the first trial in the world to combine progenitor cell and gene transfer of a growth factor, it will make California a center of excellence for these types of studies.

http://www.cirm.ca.gov/

http://www.cirm.ca.gov/sites/default/files/files/about_cirm/ Economic_Impact_March_2011.pdf

The biomedical industry alone is a vital component of California's economy. The 2013 PricewaterhouseCoopers California Biomedical Industry Report found that California's public policy over the past decade has generated considerable Return on Investment that includes:

- 2,321 biomedical companies in California with \$69.2 billion in annual revenue
- Total estimated employment: 152,806
- Average Salary: \$101,658
- http://www.californiabiomedreport.com/

- Total NIH grants awarded: \$3.33 billion
- Total venture capital investment: \$1.98 billion
- Total biomedical exports: Approximately \$20 billion annually

KANSAS

In passing the Kansas Economic Growth Act of 2004, the Kansas state legislature established the **Kansas Bioscience Authority (KBA)** to grow and invest in the in the state's bioscience industry. KBA investments cover research and development in start-up businesses to the expansion and attraction of well-established bioscience companies with investments made with both near-term goals including the creation of new jobs with high wages, and longerterm goals to make economic gains sustainable. State funding is based on a percentage of the growth in state income taxes paid by existing bioscience workers over 2003 levels and has been capped by the state at \$35 million annually since 2009.

Direct Return on Investment outcomes for KBA investments through fiscal year 2012 include:

- **1,664 new jobs** paying an average annual wage of \$73,815, compared to the average Kansas annual wage of \$40,030
- \$133 million in new research funding attracted to the state
- \$119 million in equity investments that help Kansas companies thrive
- **\$294 million in capital expenditures** to build bioscience infrastructure

www.kansasbioauthority.org

Case Study: JCB Laboratories

Background

JCB Laboratories, in Wichita, is a compound drug solution company. The skilled team of pharmacists and lab technicians at JCB, led by Brian Williamson, president and CEO, produces sterile, injectable drugs for a variety of clients in the medical field. JCB's products meet the needs of individual patients, combining all of their regularly administered medications into a single injection. The company also offers a cost-effective solution for health-care providers, combining medications commonly prescribed together for patient treatment. JCB was founded on the premise of exceptional customer service, speedy delivery and efficient follow-through on all orders. Additionally, JCB's facilities ensure the best in quality control, with all products prepared in a 'clean room' where particulate matter is controlled with a unique air filtration system. All products are tested through a third party before being sent to a client for use with patients.

Challenge

Since the 2004 launch of JCB Labs, the company's revenue has consistently climbed by 30 percent each year, requiring additional production to continue the fight against nationwide drug shortages. To accommodate this aggressive growth and meet the company's production goal of quadrupled output, JCB needed funds to add jobs and expand its facilities.

The Kansas Bioscience Authority awarded \$225,000 to JCB Labs to create 15 new jobs and expand its lab space.

Outcomes

JCB Labs is aggressively fighting drug shortages across the nation and making strides towards its production goals with the help of the KBA's investment. It was most recently recognized as one of the nation's leading providers of the leukemia drug methotrexate, which is in short supply. Methotrexate is just one of many drugs in short supply or on back order for which JCB fills the gap.

MASSACHUSETTS

In 2007, Governor Deval Patrick proposed a 10-year, \$1 billion investment package for the life sciences industries in Massachusetts. The state legislature approved the **Life Sciences Initiative** in 2008 and charged the Massachusetts Life Sciences Center (MLSC) with implementing the initiative. The MLSC created several different programs including loans to early-state companies, grants to industryacademic research collaborations, state-of-the-art infrastructure, workforce training and internships that help provide smaller companies with access to the Massachusetts workforce. The emphasis on supporting the growth of small companies in Massachusetts has also helped larger companies who rely on the smaller ones to help them access and develop technology, the result being an increase in both small and large companies in the state of Massachusetts.

As of June 2012, the MLSC has made approximately \$350 million in investments or commitments. The direct return on this investment includes:

- **2,500 new jobs** from just \$56.6 million in tax incentives with an average annual wage of \$105,000.
- \$15.1 million in accelerator loan financing to 24 early-stage companies has led to six of those companies already paying back the loan (before due) as a result of raising more than \$100 million in combined private funding.
- \$1.66 in anticipated tax revenue for every \$1 invested through the MLSC's tax incentive program.

Case Study: Shire

With support from the MLSC's Tax Incentive Program, Shire committed to locating their Human Genetic Therapies Division in Lexington. Thus far the MLSC has awarded Shire \$19 million to support Shire's expansion in the state, and Shire has created nearly 400 new jobs since receiving their first tax incentive award. Shire now employs over 1,300 people in the state of Massachusetts.

Case Study: Biogen Idec

The MLSC awarded Biogen Idec with \$8.8 million in total since the company first received a tax incentive grant to expand its operations in the state of Massachusetts. Since first receiving a grant, Biogen Idec has created more than 500 new jobs, 400 more than they committed to under the tax incentive agreement.

PENNSYLVANIA

The Pennsylvania Life Sciences Greenhouse Initiative (PALSG) was created in 2001 as part of a larger plan to ensure continued growth in Pennsylvania's life sciences. The one-time investment of \$100 million from the Tobacco Settlement into this initiative represents one of the largest technology-based economic development investments in the State's history. The program actively invests in early-stage life science companies and offers relocation and expansion incentives. The three regional organizations that comprise the initiative offer connections to angel investors, strategic partners and resources, and business consulting services. Between 2010–2012, thirty-two new bioscience firms were created.

As of 2012, direct Return on Investment as a result of PALSG's programs include:

- \$2.6 billion in private funds leveraged
- \$93.2 million in Federal research funds obtained
- 156 new companies formed
- 3,465 jobs created
- 2,227 jobs retained

"Because we chose to shape the future we wanted, rather than just wait to see what happens, Massachusetts is now the world's leading life sciences supercluster, and we have the jobs and economic opportunity that come with that."

Massachusetts Governor Deval Patrick Press Release 3/26/13

Case Study: MacuLogix, Inc.

MacuLogix, Inc., is the developer of AdaptRx[™], an FDA-cleared device for use by researchers and pharmaceutical companies seeking a treatment for age-related macular degeneration (AMD). AMD is a progressive eye disease and a leading cause of blindness, affecting 13 million people in the U.S. alone. The company's second product, AdaptDx[™], has recently completed a clinical trial and results have been submitted to the FDA. The AdaptDx[™] has the potential to become the first practical diagnostic for early detection and tracking of AMD.

The Life Sciences Greenhouse of Central Pennsylvania (LSGPA) injected the first outside capital in the company, committing \$500,000 in Q4 2008. Maculogix has since raised \$2.7 million in Series A funding. Investors include Berwind Private Equity, and Roche Venture Fund, as well as the Ben Franklin Technology Partners of Central and Northern Pennsylvania. LSGPA invested another \$500,000 as part of the round. "In Texas, we understand that high-tech companies don't just happen overnight but are a product of forethought, sound vision and planning, and strategic investments by both the public and private sectors. Through our Emerging Technology Fund, we are bringing the best scientists and researchers to Texas, attracting high-tech jobs and helping start-up companies get off the ground faster."

Texas Governor Rick Perry http://governor.state.tx.us/ecodev/etf/

TEXAS

The Texas Emerging Technology Fund (TETF) is a \$200 million initiative created by the Texas Legislature in 2005 at Governor Rick Perry's request, and reauthorized in 2007, 2009 and 2011. The TETF is comprised of thirteen committee members, the Lieutenant Governor, Speaker of the House, and two committee members appointed by the Texas House of Representatives. The full committee then makes funding recommendations directly to the Governor of Texas. There are three types of TEFT awards: Incentives for Commercialization Activities, Research Award Matching, and Acquisition of Research Superiority. TEFT also provides grants to regional centers of innovation and commercialization (RCICs) in order to assist potential TEFT applicants. At the close of fiscal year 2012 the TEFT had awarded almost \$195 million dollars to 137 entities just in the Incentives for Commercialization Activities program. Follow-on funding for TETF Incentives for Commercialization Activities exceeded \$761 million. almost quadrupling the original investment from TETF. For the

Biotechnology and Life Sciences sub-cluster a total of 67 grants were awarded totaling almost \$104 million and the grantees raised an additional \$319 million in follow-on funding.

Return on Investment as a result of the Texas Emerging Technology Fund: Incentives for Commercialization Activities, as of 2012

- Number of Awards: 67
- Total Award Amount: \$103,885,520
- Follow-on Funding (Private Sector Investment, Federal Funding, other Contributions): \$318,830,572
- Jobs Retained: 998
- Jobs Created: 238

Case study: Oncolix, Inc.

- TETF Award Amount: \$2,400,000
- Award Date: October 1, 2010
- Region: Gulf Coast
- Higher Education Collaboration: The University of Texas MD
 Anderson Cancer Center

Intended Outcome:

Oncolix is developing Prolanta, a drug to treat ovarian and other gynecological cancers. Prolanta targets prolactin receptors in gynecological cancer cells and triggers a response that results in the destruction of cancerous cells with fewer side effects than chemotherapy. The State's investment went primarily toward completing preclinical development and commencing a human test trial in ovarian cancer.

Actual Outcome:

The company has performed preclinical development studies, toxicology/safety studies, optimized the manufacturing process and developed its Phase I clinical trial design. Oncolix continues to work with The University of Texas MD Anderson Cancer Center under a sponsored research agreement, and has completed Phase I clinical study protocol and received clearance from the U.S. Food and Drug Administration to commence a Phase I clinical study.

Partners Matter in Commercialization and Job Creation

diverse community of public and private stakeholder groups is essential to provide the significant financing and workforce requirements to successfully compete in today's marketplace.

Bioscience industry growth continues to be supported by three essential pillars, each providing support in unique ways. This "triple helix" of technology commercialization include the following:

Industry Participants

Industry collaboration with universities and policymakers is a hallmark of the vibrant U.S. technology industry growth over the past three decades. During that time period, the industry moved to become an active participant in public policy creation by providing insights into its needs for sustained growth. Future state efforts to expand the biotech industry will require continued industry input on the policy tools necessary for success. The symbiotic relationship between academia and industry is important not only for technology transfer purposes but for workforce development as well.

Policy Makers

The need for a stable and supportive public policy structure is pivotal to bioscience companies, large and small. It is almost impossible for any state to ignore the need for selective infrastructure and development incentives to either hold existing companies or attract new enterprises. From the perspective of public policymakers nationwide, the pursuit of commercial development of the bioscience industry fits the objectives sought to diversify the economic base, generate new jobs, and improve the standard of living for citizens.

No less than forty-two states support programs that provide commercialization assistance to technology companies in an effort to more smoothly transition invention into innovation in the marketplace.

Public and Private Research Centers

Fostering collaborative partnerships between academic research centers and the private sector has emerged as a critical imperative in sustaining the U.S. innovation advantage. The increasing volume and accelerated pace of knowledge creation has transformed the research process to the point where no single scientist or institution can sufficiently conduct wholly independent research programs.

This new reality makes the relationship between academic investigators and industry researchers, made possible by the passage of the Bayh-Dole Act of 1980, a central driver in growth of the bioscience industry.

Bayh-Dole and Technology Transfer

The biotechnology industry is the most research and development intensive and capital-focused industry in the world. The United States currently leads the world in the area of biotechnology because U.S. patent laws and legislation such as the Bayh-Dole Act have provided favorable incentives to mitigate the high risks. The biotechnology industry relies on the protections afforded by the patent laws and on the opportunity to exclusively license discoveries from academic partners through the mechanisms established in the Bayh-Dole Act. Without these protections and incentives, many life-saving discoveries would not have been realized. Prior to the Bayh-Dole legislation, federally funded research was owned by the government and offered for licensing on a nonexclusive basis or simply dedicated to the public. There was little incentive for businesses to undertake the financial risk to develop a product. The result was that only 5% of NIHfunded discoveries ever led to new or improved products. The change in policy affected by Bayh-Dole dramatically stimulated the commercialization of federal governmentsupported research, resulting in important new therapeutics and the wide array of diagnostic testing options available to the medical community today.

"America is the world leader in biotechnology. Our nation's biotechnology industry is comprised of scientists, entrepreneurs, and large and small companies in all 50 states engaged in translating the latest scientific discoveries into innovative new medical therapies and environmental products, increased agricultural production and farm incomes, and greener bio-based products and biofuels. Nationwide, our industry directly employs more than 1.6 million people and indirectly generates jobs for an additional 6.6 million people. These are highquality jobs, paying substantially more than the average U.S. wage."

BIO President and CEO James C. Greenwood Press Release 01/25/12 An examination of those regions that have succeeded in building a robust biopharmaceutical cluster suggests that it requires:

- A strong basic research community able to attract competitive external grant funding
- State and private sectors committed to building a robust base of high-quality science and technology R&D and supportive infrastructure
- Academic and industrial researchers committed to translating discoveries into application and moving them forward to commercialization
- Highly skilled workers and a deep talent pool of both researchers and entrepreneurs
- Public and private sources of risk capital
- Affordable lab space and facilities equipped to house biopharmaceutical companies
- Mechanisms that support networking and cluster development
- Favorable financial incentives and tax policies.

What stands out about the biopharmaceutical industry is that it takes many partners to create economic value. It is not simply a matter of companies bringing together an effective team. To go from new ideas for biopharmaceuticals to bringing patients new innovative treatments calls for a wide range of collaborations from university scientists to physicians and nurses carrying out clinical trials to government regulators to healthcare providers.

Source: Pharmaceutical Research and Manufacturers of America, Driving State Economic Growth in the 21st Century : Advancing the Biopharmaceutical Sector

Highlights of Bioscience State Legislative Initiatives

nce research yields a new discovery, there is still a great deal of work in creating a company and funding that research before the technology can be incorporated into the marketplace. The following are examples of ways industry, universities, and policymakers are coming together to create essential building blocks for bioscience industry growth in company creation and capital for success.

Northern Plains/Midwest

Iowa legislators created an agricultural industry finance corporation to support agricultural biotechnology advancements in the state. In **Kansas**, 2011 legislation provided bonds for the development of both biotechnology facilities and affiliated research. **Michigan's** Economic Growth Authority Board was given authorization to provide tax credits for new or retained jobs in technology fields, including biotechnology research and product development. **Minnesota** authorized sales tax abatements for various businesses including biotechnology.

East Coast/Mid Atlantic

Maine authorized funding for the International Northeast Biotechnology Corridor and a seed capital tax credit to encourage investments through private investment capital funds with up to 60% cash credit for fixed assets, research, and working capital. Maryland's 2011 Invest Maryland provides \$100 million in insurance premium tax credits to raise venture capital for the State's entrepreneurs. Two-thirds of the funds will be invested on behalf of the State by private venture capital firms, while the Maryland Venture Fund and the Maryland Small Business Development Financing Authority will administer the remaining one-third. Massachusetts' Cooperative Research Grant now supports industrysponsored research at universities and facilitates scientific discoveries that lead to medical applications with grants of \$250,000 per year for up to three years, in a 1:1 match with its industry partner. New Jersey enacted a \$25 million Investor Tax Credit program to spur investment and growth in that State's innovative and emerging technology sectors including the bioscience industry. Pennsylvania enacted legislation to include "biotechnology" within the scope of its Industrial Development Act to support biotech enterprises as a tool of industrial development

Southeast/Southwest

Arkansas legislation was enacted to provide income tax credits for biotechnology facilities, and associated business expendatures. Kentucky's Unbridled Future provides direction to the Kentucky Cabinet for Economic Development and its partners over the next five years in guiding the State's economic development efforts. The plan includes both the identification of 10 strategic business/industry sectors to focus its economic development efforts and six priority areas with actionable strategies related to each. Targeted industries include bioscience and healthcare technologies. Amendments to the Louisiana Jobs Quality Act now provide tax rebates to businesses that create jobs in the biotechnology field, and funding enhancements. Oklahoma Governor Mary Fallin signed legislation in 2012 to eliminate the EDGE Fund (Economic Development Generating Excellence), and transfer the remaining funds to the Oklahoma State Regents Endowment Trust Fund to match privately funded endowed chairs, mostly in the areas of science, technology and math. North Carolina's Qualified Business Venture tax credit, originally enacted in 1987 was extended thru 2013. Investors can recoup a maximum of 25% of qualified investments as credits against personal income tax.

West/Pacific Northwest

Arizona's Innovation Challenge provides \$3 million in competitive grants to move innovative companies, including biotech, forward in two rounds of funding. In 2012, **California** eliminated inspections conducted by the Food and Drug Branch of the California Department of Public Health that were largely duplicative of those already conducted by the FDA. **Colorado** created advanced technology funds to finance research of biotechnology and technology transfer activities. The State's public employee retirement fund has also launched an investment vehicle that can fund Colorado-based capital formation opportunities. In 2011, **Hawaii** created an exemption from excise taxes for biotechnology research, development, and production. **Washington** State enacted legislation to create biotechnology product and medical device manufacturing tax incentives.

Best Practices in Innovation and Commercialization Partnerships

strong partnership between industry, academia, and state government is essential for the development of a successful bioscience cluster. As states evaluate how to continue to encourage bioscience companies to locate within their borders, they need to review their tax and investment structure and consider incentives in the area of capital acquisition, workforce preparedness/ training, and physical infrastructure that will help companies through all phases of product development and manufacturing.

Arizona

The Arizona Innovation Challenge (AIC), funded through the Arizona Commerce Authority (ACA), is the largest state innovation competition in the nation. The AIC provides \$3 million in competitive grants to innovative technology companies in a spring and fall competition with awards of \$1.5 million in each round. Awards range from \$100,000 to \$250,000 per company.

In 2012, Cancer Prevention Pharmaceuticals (CPP) was one of six companies to share the bi-annual \$1.5 million dollar award. CPP currently has several colon cancer prevention therapies in Phase II and Phase III FDA clinical trials.

http://www.azinnovationchallenge.com/

"We are honored to receive this award from the ACA. We will utilize the award proceeds to support our core clinical operations team who are setting up, initiating, and conducting two Phase III clinical trials, as well as our regulatory and manufacturing efforts."

Jeffrey Jacobs, CEO, Cancer Prevention Pharmaceuticals

California

CONNECT of San Diego links entrepreneurs with critical resources for success by providing networking opportunities as well as expertise to the city's technology-based firms. Through the use of partnerships with the region's industry specific organizations and individuals, CONNECT assists entrepreneurs and bioscience companies with commercializing ideas, patents, and other opportunities surrounding university or private research institute R&D efforts.

The program has built successful mentorship and education programming for entrepreneurs as a part of their many efforts to increase innovation and commercialization in the region.

http://www.connect.org/about/index.htm

Kansas

The Kansas Economic Growth Act demonstrates a deep commitment to continued bioscience growth. The act created the Kansas Bioscience Authority and appropriated \$581 million to invest in the expansion of the state's bioscience clusters, research capacity, startups, and business expansion.

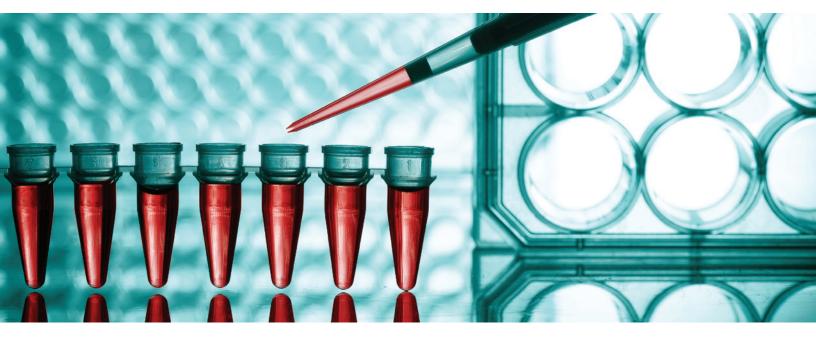
http://kansasbioauthority.org

Massachusetts

In 2010 Massachusetts launched a \$1 billion, 10-year life science initiative including a life sciences tax incentive program through the Massachusetts Life Sciences Center. Created in 2006, the center promotes the life sciences through research, development and commercialization funding, and to build alliances in the industry and promote workforce development.

Top-tier research institutions, including the University of Massachusetts and the Massachusetts Institute of Technology (MIT), are major factors in the state's life sciences success. MIT supports commercialization through proof-of-concept grants up to \$50,000 as well as innovation grants up to \$250,000.

www.masslifesciences.com



Michigan

Michigan's 21st Century Jobs Fund is a \$2 billion, ten-year initiative to accelerate the diversification of the state's economy. It devotes approximately \$800 million for technologies in the targeted sectors of life sciences, alternative energy, and other industries. The annual awards are administered by the Michigan Economic Development Corporation (MEDC) with contracts that establish conditions and mileposts for receipt of funds.

The initiative's Competitive-Edge Technologies Program invests qualified private equity funds, qualified mezzanine funds, and includes qualified venture capital funds as a commercial enhancement program to assist small companies.

http://www.medc.org/about/index.htm.

Ohio

Ohio's Third Frontier program has become an important part of the state's successful efforts to build a strong, technology-based economy. Started in 2002, the \$2.3 billion initiative supports research, commercialization, entrepreneur programs, capital formation, and workforce development. The program has provided new investment leverage outside state government, along with supporting industry growth. "I am proud of the work that has been done by the Maryland Life Sciences Advisory Board and our partner organizations, like the Tech Council of Maryland and MdBio, to help us realize the true potential of this vital industry in Maryland. The investments we make today in biotechnology positions the State for sustained future growth and ensures our global leadership in this industry."

Maryland Governor Martin O'Malley Press Release 05/03/12

www.thirdfrontier.com

Job Creation and Workforce Strategies

n this global economy, nearly every region has access to big breakthroughs in technology and to the equipment and capital to produce standardized products, but those regions that possess the human capital, with its insights, competencies, and experience will have the competitive advantage.

In general, states continue to provide tax credits in exchange for the creation of jobs. Here are examples of efforts by states to utilize public funds to help meet industry needs for a skilled workforce:

Illinois

The Illinois Department of Community Economic Opportunity created the Biotechnology/Bioscience Training Investment Program (BioTIP) to provide state funded grants to companies to cover training costs for graduate students who find part-time employment as lab technicians/engineers in the biotechnology sector, as well as additional training to students to enhance their practical skills. Under this program, employers are reimbursed for up to 50% of the costs of training graduate student employees.

http://www.commerce.state.il.us/dceo/Bureaus/Business_ Development/Grants/ETIP.htm

Missouri

Missouri state government announced nearly \$9 million in grants to establish numerous Innovation Campuses. The initiative will provide high school students with intensive training in science and technology fields through apprenticeships with local employers while they also earn college credit. To participate in the program, corporate partners commit to creating positions or re-training employees for a specified number of jobs. Companies are then supplied with highly trained candidates once the students have completed their degrees and apprenticeships.

www.ded.mo.gov/BCS%20Programs/BCSProgramDetails. aspx?BCSProgramId=110

North Carolina

The North Carolina Legislature approved a law in 1999 that placed tobacco settlement payments into three separate trust funds. One of the trust funds created is the Golden LEAF (Long-term Economic Advancement Foundation). In 2003, The Golden LEAF Foundation's board committed \$60 million to create a statewide training program for bio-manufacturing workers. A portion of this grant, combined with \$4.5 million from the North Carolina Biosciences Organization, provided the

North Carolina State University in Raleigh with \$36 million to construct a bio-manufacturing facility to train workers.

For more information: http://goldenleaf.org

Pennsylvania

The Pennsylvania Life Sciences Leadership Advisory Council (LSLAC) includes representation from the Legislature, State Executive Office, Academia, Industry and the Investment Community and is tasked with developing ideas to nurture a Life Science ecosystem to spur job creation and economic development in Pennsylvania. Through a series of meetings, conversations, and analysis from October 2011 through April 2012, the Council identified Pennsylvania's competitive advantages and opportunities to enhance the industry's strength and facilitate future job creation. Input and feedback were collected from the Council and the LSLAC report was issued in May of 2012 with the intention to provide a strategy for sustainable, continued action by both public and private industry partners.

Demonstrating commitment to the Council effort, the Corbett administration increased the R&D tax credit to \$55 million while preserving tradability of the credit for immediate capital for companies not yet profitable. The administration also named a Life Science Ombudsman to help companies navigate the complexity of Government on their behalf so they may remain focused on their business. Most recently, in his first budget address since the report was unveiled, Governor Corbett included several LSLAC report recommendations in his remarks, including a phased increase of the Net Operating Loss deduction cap.

http://www.pabio.org/pdf/2012_LegDay_LSLAC_Release.pdf

Puerto Rico

The Bioprocess Development and Training Complex (BDTC) was conceived as a collaboration between industry, government and academia to strategically enhance Puerto Rico's capabilities in biotechnology manufacturing, research, bioprocess improvement, and training. The BDTC is housed in a 29,000 square foot building located at the Guanajibo Research and Innovation Park (GRIP) in Mayaguez, Puerto Rico. This innovative non-profit institution fosters research interactions between industry and academia in order to strengthen Puerto Rico's capabilities in bioprocess development and improvement, while providing a venue to conduct training in cutting-edge technologies in biotechnology manufacturing and bioprocess engineering.

http://www.bdtc-pr.com/

Seed and Angel Fund Strategies for Companies and Investors

eed and Angel Funding initiatives continue to supply the money needed to bring drug, agricultural, or industrial biotechnology products from the lab bench to the market. The following states were selected as examples of the most diverse and successful initiatives. They include:

Colorado

Colorado's State Retirement Fund in 2012 launched a new investment vehicle—The Colorado Mile High Fund. This program will make millions of dollars available to Colorado's business community. The capital will be earmarked for businesses that have a nexus to Colorado and currently have the support of a financial sponsor. The new fund may also consider uniquely structured capital formation opportunities to private equity and venture capital firms targeting Colorado-based opportunities. The primary focus of this new commitment will be private equity and venture capital opportunities structured as co-investments with financial sponsors.

http://www.advancecolorado.com/news/colorado-peracreates-fund-colorado%E2%80%99s-entrepreneurs.

Kentucky SBIR Matching Fund

The Kentucky Science and Technology Corporation, through the Kentucky Cabinet for Economic Development and Office of Commercialization and Innovation matches funds of up to \$150,000 for Phase 1 and up to \$500,000 for Phase II to Kentuckian companies participating in the Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Since the program's inception in 2007 and as of January, 2013 there have been over 155 grants awarded totaling over \$37 million dollars in state funding.

http://www.kysbirmatchfunds.com/REVISED_Final%20 Guidelines_Round_16.pdf

New Jersey

New Jersey's \$25 million Angel Investor Tax Credit Program will encourage early investment in New Jersey's high-skill, high-wage emerging technology industries - including bioscience companies.

The New Jersey Angel Investor Tax Credit Act provides tax credits for up to 10 percent of a qualified investment in an emerging technology business with a physical presence in New Jersey and that conducts research, manufacturing, or technology commercialization in the state. New Jersey does not presently offer credits against either the corporate business tax or gross income tax for investments in emerging industries.

http://www.njleg.state.nj.us/2012/Bills/AL13/14.PDF

New Mexico

The New Mexico Angel Investment Credit allows a taxpayer who files a state income tax return and who is a "qualified investor" to take a tax credit of up to \$25,000 (25 percent of a qualified investment of not more than \$100,000) for an investment made in a New Mexico company that is engaging in high-technology research or manufacturing. The taxpayer may claim the angel investment credit for up to two qualified investments in a taxable year, provided that each investment is in a different qualified business.

http://www.nmonesource.com/nmpublic/gateway. dll/?f=templates&fn=default.htm

North Carolina

North Carolina's Qualified Business Venture Tax Credit allows investors to recoup a maximum of 25 percent of qualified investments as credits against personal income tax and is particularly important to small companies. It was originally enacted in 1987 and extended by their state legislature through December 31, 2013.

www.ncleg.net/Sessions/2011/Bills/House/PDF/H1025v4.pdf

Successful Transfer of Technology

he past two years have seen a significant increase in the cooperation between academic research centers and industry. This cooperation has largely focused on identifying new mechanisms for collaboration in moving knowledge in an academic setting into viable research and development for products for the marketplace. The following examples illustrate new and innovative mechanisms for cooperation:

Colorado Bioscience Evaluation Grants

Colorado's Bioscience Discovery Evaluation Grant Program (BDEGP) provides grants to technology transfer offices at Colorado research institutions for advancing bioscience research toward commercialization. Grants are also available to, early-stage Colorado bioscience companies that are commercializing technologies founded at one of Colorado's qualified research institutions.

Since BDEGP's inception in 2007, 184 grants have been given to researchers at Colorado research institutions and universities including 44 grants that have been awarded to early stage biotech companies. The BDEGP grants have totaled over \$22 million dollars and have encouraged additional outside investment of over \$100 million dollars. Thirty four new companies have been formed as a result of the BDEGP grants which has created over 300 new direct jobs and has had an employment impact of over 1,000 new jobs. Awardees cover a diverse field of research areas including research into therapies for Alzheimer's disease, cardiac disease, cancer, and autoimmune diseases as well as projects into biotechnology agriculture and biofuels.

www.colorado.gov/cs/Satellite?c=Page&cid=116792801774 2&pagename=OEDIT%2FOED.

Georgia Centers of Innovation

Georgia's six Centers of Innovation provide unique, technologyoriented support to businesses and start-ups in the areas of Aerospace, Agribusiness, Energy, Life Sciences, Logistics and Advanced Manufacturing. Each center provides direct access to university and technical college applied research, commercialization resources, technology connections, matching grant funds, potential investor networks and key government agencies. Client companies are connected with industry-specific experts who are on the leading edge of technology and new ideas.

Oregon University Venture Development Fund

Oregon's University Venture Development Fund, authorized by the state legislature in 2007, allows the state's taxpayers to receive a 60 percent income tax credit on contributions that will be applied toward commercialization and entrepreneurial programs at Oregon's eight public universities. The fund will enable an aggregate \$14 million to be provided to the universities, with each institution's allocation formulated by its annual income from research grants and contracts. Link to the legislation:

http://www.leg.state.or.us/07reg/measpdf/sb0500.dir/ sb0582.en.pdf

Texas: Emerging Technology Fund

The Texas legislature created the Emerging Technology Fund in 2005 and reauthorized it 2007. This program has achieved its goal of expediting the process of commercialization and thereby generating new jobs and companies. Dedicated to recruiting research talent and matching grants to help to draw down federal dollars, this legislation also created Regional Centers of Innovation and Commercialization (RCICs). These RCICs foster collaboration on emerging technologies between public and private entities and institutions of higher education.

http://www.statutes.legis.state.tx.us/SOTWDocs/GV/pdf/ GV.490.pdf

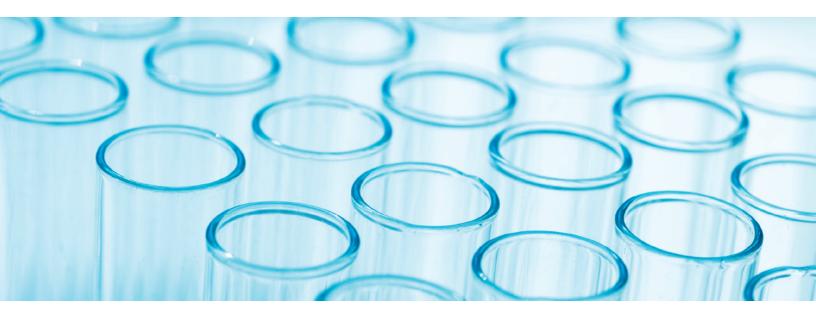
Virginia

Virginia's 2012 Special Session budget provided \$5 million over two years to establish a research consortium comprised of six universities that contract with private entities, foundations and other government sources to capture and perform research in bioscience. The fund provides a matching dollar-for-dollar investment from the state in approved bioscience research.

http://lis.virginia.gov/122/bud/budsum/HB1301re.pdf

http://www.georgiainnovation.org

Conclusion



ven though the recent economic downturn impacted the financial wellbeing of America's bioscience industry, almost every state in the country continues to actively engage in building bioscience industry infrastructure. State sponsored programs to encourage investment and help bioscience companies leverage existing resources has been shown to be instrumental in helping these innovative companies survive this economic cycle.

This best practices guide provides examples of state efforts to invest in the fundamental components of early stage research and efforts to encourage outside capital investment. Moreover, it demonstrates the importance of developing a skilled workforce to help create, grow, and retain bioscience companies. This document is intended to support state government leadership as they explore measures that include the bioscience industry as a key component of their economic development initiatives. "I believe that the key to our economic recovery lies in investment in innovative industries, such as the biotech sector, that spur the type of economic growth and job creation that makes Illinois a great place to do business."

Illinois Governor Pat Quinn Press Release 06/09/11

Glossary of Economic Development Tax Support Terms for the Biosciences Sector

Angel Investors: Angel investors typically invest their own funds, unlike venture capitalists that manage the pooled money of others in a professionally managed fund. Angel capital fills the gap in start-up financing between "friends and family who provide seed funding and formal venture capital.

Bioscience Research: The basic, applied, or translational research that leads to the development of therapeutics, diagnostics, or devices to improve human health or agriculture.

Business incubation: A business support process that accelerates the successful development of start-up and fledgling companies by providing entrepreneurs with an array of targeted resources and services

Business retention: An effort by an enterprise to keep customers or a community to protect its economic well being by doing things to hold on to existing enterprises.

Clusters: An industry cluster is a grouping of related industries and institutions in an area or region. The industries are inter-linked and connected in many different ways. Some industries in the cluster will be suppliers to others; some will be buyers from others; some will share labor or resources.

Drug development costs: The fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages \$1.2 billion, according to a 2012 analysis by the Tufts Center for the Study of Drug Development. The figure includes total average preclinical and clinical costs up to the time of receiving FDA marketing approval.

Economic development: a process that begins when a community makes itself ready to accommodate the retention, startup, location, or expansion of an enterprise. Economic development occurs when a local economy is vitalized by the creation of one or more jobs, an increase in community wealth, or the useful distribution of capital that arrives from outside sources.

Emerging growth industry: a business classification in which the individual enterprise units measured as a whole show a statistical mode of expansion/development that allows for a prediction that the trend will continue. The word emerging suggests that the growth within the industry group is a relatively recent occurrence.

FDA Testing: The regulatory process that the US Food and Drug Administration utilize to test the safety and efficacy of human health products in three phases of testing.

Human capital: Human capital is the pool of workers, their talent, skills, productivity and ideas. Locations where there are chances to make contacts and exchange information are favorable places for firms. This tends to draw companies close to each other and to universities or other places where research is conducted.

Incentives: Benefits offered to firms as part of an industrial attraction strategy. A few incentives are tax abatements and credits, low interest loans, infrastructure improvements, job training, and land grants.

IPO Initial Public Offering: When a company first sells its shares to the public.

Public-private partnership: A venture entered into jointly by a government and non-government entity, generally as a means for organizing the financing and/or management structure for available for public use or the public good.

Seed Capital: Equity money supplied to help a company get off the ground. The capital is almost always supplied by an entrepreneur and his/her family, friends, and relatives. Used to help attract (leverage) other investments.

Tax Credit: Money directly subtracted from a tax bill after a tax liability has been incurred. Provides income tax credits and wage assessments to new and existing buineess to companies that locate or expand operations in a state. **Tax Exemption:** Policy that reduces the base activity which property is assessed; accomplished by subtracting a given amount of money from the assessed market rate. Tax exemptions are often granted to individuals, institutions, or types of property.

Tax Incentives: The use of various tax relief measures such as tax exemptions, tax credits or tax abatements to recruit and attract businesses to a community or help local businesses expand.

Technology incubators: A research park or technology incubator is as an existing or planned land and buildings designed primarily for private and public research and development facilities, high technology and science based companies, and support services; A contractual and/ or formal ownership or operational relationship with one or more universities or other institutions of higher education, and science research

Technology transfer: The sharing of knowledge and facilities among Federal laboratories, Industry, Universities, Federal, state, and local governments, and third party intermediaries.

Venture capital: Money provided by professionals who invest alongside management in young, rapidly growing companies that have the potential to develop into significant economic contributors. Venture capital is an important source of equity for start- up companies.

Workforce development: An essential consideration when doing location work; an element of enterprise development related to demographics. Development of a work force-acceptable to prospects and the ability to present them with facts about it is important for any community that wants economic development.



Every job in the larger bioscience industry creates another 3.2 jobs in the overall economy at the national level.

Battelle/BIO State Bioscience Industry Development 2012 May, 2012 www.bio.org



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