WEST VIRGINIA BLUEPRINT FOR TECHNOLOGY-BASED ECONOMIC DEVELOPMENT

BIOTECHNOLOGY

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TechConnect WEST VIRGINIA

A report from: **TechConnectWV**
West Virginia Coalition for Technology Based Economic Development

With consultation and assistance from:
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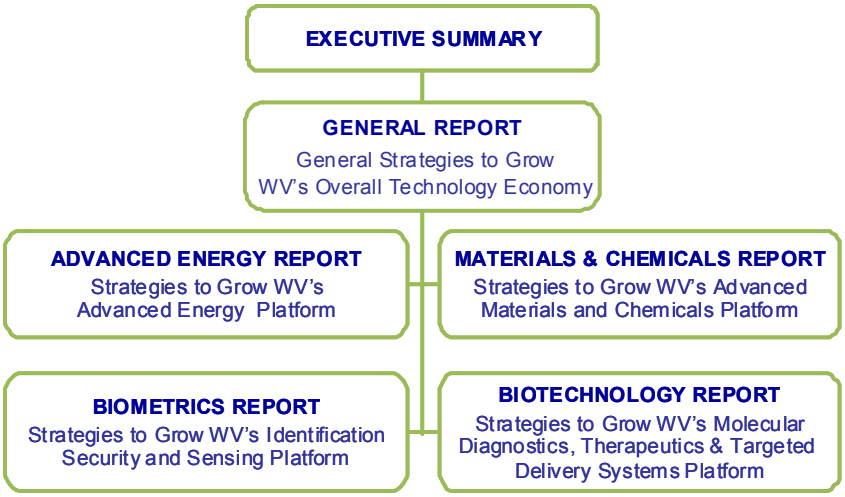
HOW THIS REPORT IS ORGANIZED

This report represents Phase II of West Virginia's Technology-Based Economic Development (WV's TBED) Blueprint. In 2007, Battelle Technology Partnership Practice produced the Phase I report entitled *Gap Analysis and Identification of Strategic Technology Platforms.* This was followed by two technology platform-specific reports, released in March 2009 for the Advanced Energy platform and the Biometrics platform. In 2010 TechConnectWV authorized Battelle to proceed with completing platform-specific reports for the remaining two platforms: Materials and Chemicals, and Biotechnology (molecular therapeutics, diagnostics and targeted delivery systems). This report details findings and conclusions in relation to the Biotechnology (Biomedical Technology) Platform.

Thus the West Virginia TBED Blueprint is organized into six distinct reports:

- **Executive Summary –**
  Provides a synopsis of introductory and background material, general strategies and actions for growing West Virginia's technology economy.

- **General Report -**
  Includes the Executive Summary, but also provides the detailed introductory and background material and detailed information on the general strategies and actions for growing West Virginia's technology economy.



- **Advanced Energy Report –**
  Provides detailed information on the specific strategies and actions for growing West Virginia's Advanced Energy sector.

- **Biometrics Report –** Provides detailed information on the specific strategies and actions for growing West Virginia's Identification, Security and Sensing sector.

- **Advanced Materials and Chemicals Report –** Provides detailed information on the specific strategies and actions for growing West Virginia's Advanced Materials and Chemicals sector.

- **Biotechnology Report –** Provides detailed information on the specific strategies and actions for growing West Virginia's Diagnostics, Therapeutics & Targeted Delivery Systems sector.

The general strategies and actions represent broad recommendations for West Virginia's overall technology economy. They are common activities and tasks that will boost TBED in West Virginia independent of and across all technology areas. Conversely, the specific sector strategies and actions are recommendations explicitly targeted to four, pre-identified technology strength areas in West Virginia. They represent those activities and tasks that will enhance those particular technology platforms. Thus, the general strategies and actions are common to all four technology sectors and to other technology areas as well. While many of the specific sector strategies and actions are unique to particular technology areas, there are common or similar recommendations and thus overlap among the technology platforms. Likewise, there are some common recommendations and overlap between the general and specific sector strategies and actions as well.

*This report is the **BIOTECHNOLOGY REPORT** only.*

This report and all other reports can be found at:
www.TechConnectWV.com

Measures of Success

The ultimate measures of success — or outcomes — of the recommended strategies and actions will reflect the work of many groups, organizations, companies and individuals. No one person or organization will be solely responsible for the overall results — increased investment in technology-based research, development, and commercialization and increased numbers of jobs and new companies in the technology sector in West Virginia. However, **to promote accountability, lead organizations have been recommended** for all actions identified in the strategy.

Likewise, these **outcomes will not come from one particular strategy or action.** Instead, the various strategies and actions will work together to produce the overall results — an overall boost in TBED in the state.

Still, **some actions will impact some outcomes more directly than others.** Thus, those measures of success that will likely be most influenced by a particular action item are also listed as outcomes of that particular action. Consequently, each outcome is listed multiple times under both the general strategy items (summarized in bullet form below) and the specific platform strategies that follow.

Specific measures of success are listed below for the overall Blueprint (and again, are also listed under specific actions where appropriate).

- Continue to **grow the West Virginia academic R&D base** at a pace that significantly exceeds that of the nation with a target of $360 million by 2015
    - *Between 2008 and 2009, R&D at West Virginia's universities and colleges increased by 2.1% while total U.S. academic R&D increased by 5.8%.*
    - *Between 2002 and 2009, R&D at West Virginia's universities and colleges increased an average of 11.4% per year while total U.S. academic R&D increased an average of 7.3% per year.*
    - *Between 2008 and 2009, biomedical R&D at West Virginia's universities and colleges increased by 0.2% while total U.S. biomedical R&D increased by 5.4%.*
    - *Between 2002 and 2009, academic biomedical R&D at West Virginia's universities increased an average of 12.6% per year while U.S. biomedical academic R&D increased an average of 8.6% per year.*
    - *The $360 million target represents an increase of just over 10% per year, roughly equivalent to the average achieved from 2002 to 2009.*

- *Recent West Virginia academic R&D[1]:*

	Total	*Biomedical*
▪	*2002: $ 96,870,000*	*$ 43,985,000*
▪	*2003: $120,514,000*	*$ 57,146,000*
▪	*2004: $130,057,000*	*$ 57,256,000*
▪	*2005: $145,150,000*	*$ 69,280,000*
▪	*2006: $148,615,000*	*$ 74,969,000*
▪	*2007: $167,208,000*	*$ 78,106,000*
▪	*2008: $170,869,000*	*$ 82,495,000*
▪	*2009: $174,486,000*	*$ 82,638,000*

  - *The past growth in West Virginia R&D occurred at a time of increasing federal R&D budgets, including the doubling of NIH funding; future funding will be highly dependent on the growth of future federal R&D funding.*

- **Increase R&D funding in platform areas** in all sectors (academia, nonprofits, and industry)
  - *Because no current baseline data exist for all sectors, there is a need to track over time and form more specific goals as data are gathered.*

- **Increase industry-supported R&D** at West Virginia's universities and colleges to match the national average by 2020
  - *In 2009, 2.9% of total R&D expenditures at West Virginia colleges and universities came from industry, compared with 5.8% in the United States.*
  - *From 2002 to 2009, an average of 3.3% of total R&D expenditures at West Virginia colleges and universities came from industry, compared with 5.4% in the United States.*

- **Increase the number of technology-based companies** in West Virginia at a rate higher than the national average
  - *Because no current baseline data exist, there is a need to track over time and form more specific goals as data are gathered.*

- **Increase employment** in private-sector, technology-based companies in West Virginia to reach national average by 2020
  - *From 2001 to 2008, total employment in West Virginia's biomedical sector[2] of:*

[1] NSF Survey of R& D Expenditures. Biomedical expenditures include the following categories: Biological Sciences, Medical Sciences, Other Life Sciences, and Bioengineering/Biomedical Engineering.
[2] Battelle/BIO State Bioscience Initiatives 2010

  - *Drugs and pharmaceutical grew 37.5%, compared with the national growth of 2.3%*
  - *Medical devices and equipment grew 34.8%, compared with the national growth of 2.0%, and*
  - *Research, testing & medical laboratories grew 68%, compared with the national average of 46.1%.*

- **Increase the number of spin-off companies** developed from technology created at West Virginia's universities to achieve the national average by 2020
  - *Current (2008) national average is one spin-off for every $88 million of academic R&D*
  - *The measure would correspond to about two new start-ups created per year at current academic R&D funding levels or 1 biomedical start-up created per year at current academic R&D funding levels*
  - *The measure would correspond to about four new start-ups created per year if academic funding reaches $360 million in 2015*

Technology Platform Strategies and Actions for Boosting Technology-Based Economic Development in West Virginia

Molecular Diagnostics, Therapeutics and Targeted Delivery Platform

***This platform is often referred** to as "Biotechnology" throughout this report. While the term refers to the broad field of using living organisms and bioprocessing in engineering, technology, medicine and other fields requiring other products, this platform is focused on **biomedical applications** of biotechnology.*

Molecular Diagnostics, Therapeutics, and Targeted Delivery Systems

One of the key R&D growth areas within West Virginia has centered on health and life sciences. In 1997, academic life sciences R&D in West Virginia totaled $28.8 million (45% of total academic R&D); by 2009, this had grown substantially to $83 million (47 percent of total academic R&D).

Both West Virginia University (WVU) and Marshall University (MU) have contributed to this growth, particularly within medical sciences. In terms of National Institutes of Health (NIH) awards between 2003 and 2009 these two universities received a combined $170.1 million from the NIH, with MU awarded $41.1 million (24%) and WVU $129 million (76%). **Much of the R&D funded by these NIH awards has been focused in areas directly related to the identification of disease biomarkers and the potential development of diagnostics and therapeutics directed at these markers.** Through the identification of specific molecular targets, in areas such as cancer and neurodegenerative diseases, discovery and development of novel therapeutics and diagnostic tools may then be pursued.

The development of a platform around molecular diagnostics, therapeutics, and targeted delivery systems in West Virginia could be supported not only by the academic R&D programs contained within WVU and MU, but also through building connections to the private pharmaceuticals industry in the state where there is expertise in GMP production (especially, of course, at Mylan). Generally speaking, the development of this platform will require **a long-term commitment** because of the complex chain that must be built from basic science discovery, through advanced translational research, pilot production, clinical research and trials, and then into full production. Many elements of this vertically integrated chain are in place within West Virginia; but, key investments and coordinating activities will be required to produce a fully integrated system. The economic potential of successful development of marketable diagnostics, therapeutics, and drug delivery systems is, however, large and warrants paying strong attention to development of this platform.

In the 2007 Phase I report Battelle identified several research core competencies in West Virginia that underpin a medical biotechnology platform. Notable strengths were observed in:

- Neurology and neurosciences
- Cancer research
- Pharmacology and toxicology
- Biomedical imaging.

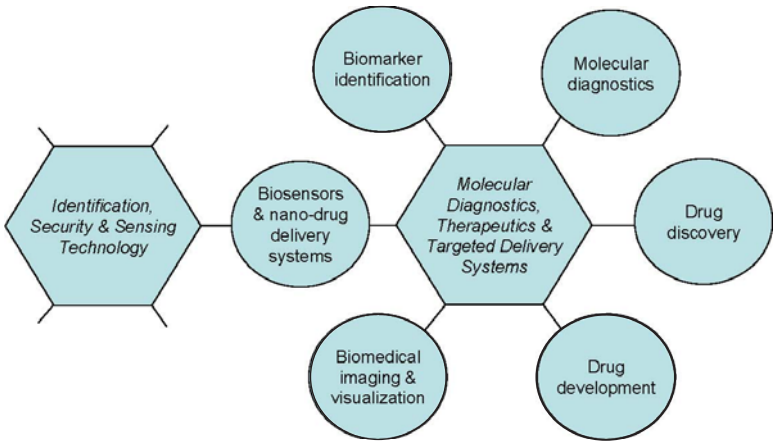
Neurology and neuroscience are long-standing strengths of WVU, reinforced with significant investment in facilities, infrastructure and talent. **Cancer research** is a focus at both WVU and Marshall. Within both these general disciplines, there is a continuum of basic through translational work taking place with application to the development and commercialization of diagnostics and therapeutics. Underpinning strengths in these disciplines are significant university resources in cellular and molecular biology, genetics, pharmacology and toxicology, and biomedical imaging technology, together with an emerging strength in nano-technology with relevance to targeted delivery systems and other biotech applications.

The Phase I report noted that both WVU and Marshall had grown their NIH funding base and that

> *"Much of the R&D funded by these NIH awards has been focused in areas directly related to the identification of disease biomarkers and the potential development of diagnostics and therapeutics directed at these markers. Through the identification of specific molecular targets, in areas such as cancer and neurodegenerative disease, discovery and development of novel therapeutics and diagnostic tools may then be pursued."*

Battelle examined these core competencies and other attributes of the West Virginia TBED space against line-of-sight in the development of commercial biomedical products and services. The preliminary assessment was that a longer-term opportunity may exist for the state in **developing a platform around "Molecular Diagnostics, Therapeutics and Targeted Delivery Systems," especially in relation to neurological, neurodegenerative and cancer related medical conditions and needs.** Preliminarily identified opportunities within this platform are shown on Figure 1:

Figure 1: Medical Biotechnology Platform Conclusions from the 2007 Phase I Report.



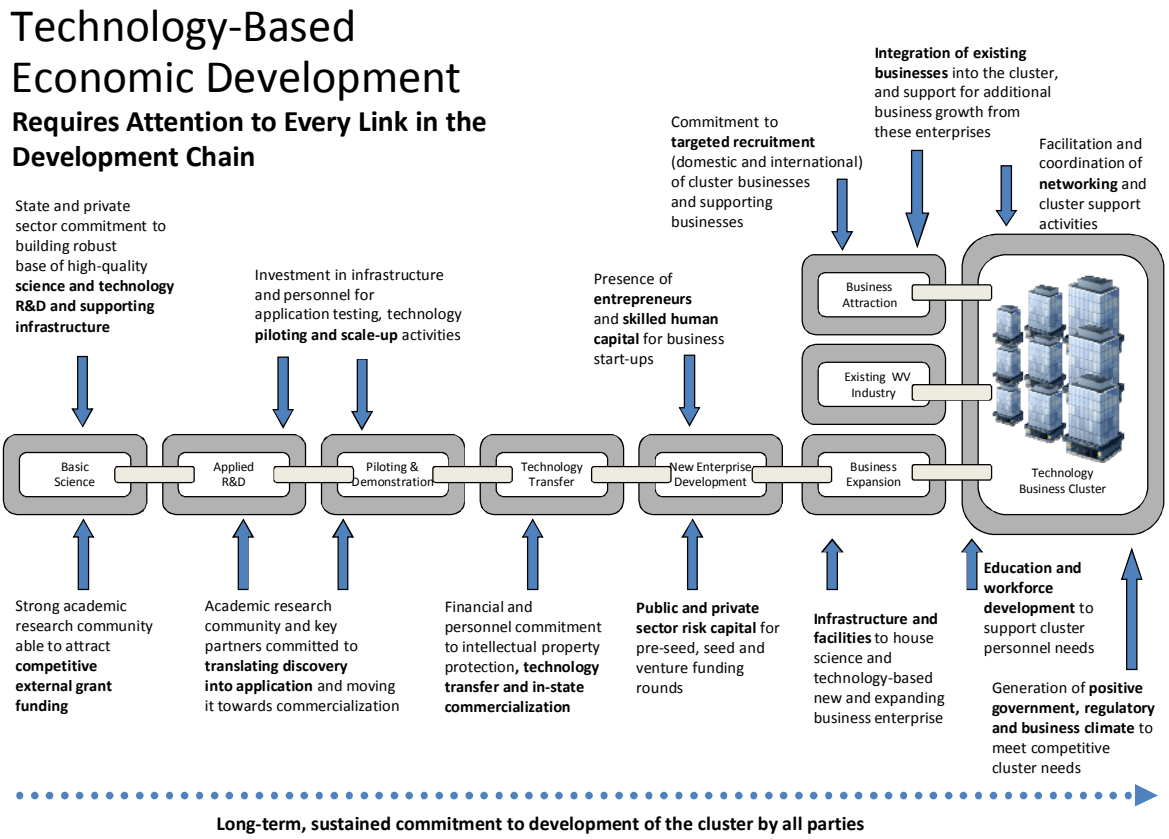
In performing follow-up interviews and focus groups with key biomedical leaders, stakeholders, researchers and industry representatives for the 2010 Phase II analysis, it was found that these general conclusions remain true. WV's strengths in cancer and neuroscience have continued to build, and **there is considerable interest in now building a platform to accelerate discovery and innovations from bench to bedside through a translational development model**. In particular it is felt that ***molecular diagnostics*** are a relatively near-term opportunity for development with lower barriers to entry and development costs than small or large-molecule therapeutics. Likewise, **novel tests or therapeutic delivery systems based on the intersection of biology and nano-technology were felt to be an additional area of opportunity** for the state based on biomedical and research core competencies. Molecular diagnostics and nano-technology also have a natural linkage to the Biometrics Platform (Identification, Security and Sensing Technology) that has continued to develop in the state.

Interviewees noted that while cancer and neuroscience are acknowledged as the key WV academic R&D strength areas, there are also notable clusters of work occurring in diabetes, obesity, cardiovascular diseases and rural health.

Situational Analysis

West Virginia's ability to leverage the medical biotechnology platform for economic development depends on it having, in some manner, each of the links in the technology-based economic development chain in place. As shown in Figure 2, the path from innovation to commercialization and associated economic development is complex and any weak or missing link in the chain will prevent or slow commercialization and its associated benefits from occurring.

Figure 2: The TBED Chain



During Battelle's in-depth assessment of West Virginia's readiness for medical biotechnology-based TBED, the following positive and negative characteristics of West Virginia's emerging TBED chain were identified:

The overwhelming majority of academic R&D in West Virginia is undertaken by two research universities—West Virginia University (WVU) and Marshall University (MU)—and both continue to invest in growing their respective R&D enterprises. Of note, MU's level of academic expenditure has increased significantly in recent years, from less than $1 million in 1999 to upward of $40 million in 2009. In biomedical sciences both WVU and MU are continuing to make key investments in new infrastructure and personnel. For example, MU just completed construction of the

$39 million Edwards Comprehensive Cancer Center, which includes an entire floor dedicated to translational research. In addition, MU's 144,000 square-foot Robert C. Byrd Biotechnology Science Center, which opened in August 2006, contains a new, fully equipped Molecular and Biological Imaging Center, a state-of-the-art Genomics Facility, and the Marshall Institute for Interdisciplinary Research. New biomedical research and clinical facilities at WVU include the $40 million, 120,000 square-foot Erma Byrd Biomedical Research Building; the $30 million, 84,000 square-foot Blanchette Rockefeller Neurosciences Institute (BRNI); and the Mary Babb Randolph Cancer Center, offering comprehensive cancer treatment, research and education facilities. While still small in comparison to WVU and MU, both Wheeling Jesuit University and West Virginia State University also increased their R&D funding in 2009.

While biomedical academic research is growing in the state, West Virginia's research institutions do not appear to be strongly linked to industry. West Virginia's universities and colleges received only about 3% in R&D funding from industry in FY 2009. This is significantly below the national average of 5.8%. Largely, this lack of industry involvement results from the industrial makeup of the state and the absence of a mature, established technology sector. But it also results from the state's tendency to be home to companies headquartered and undertaking R&D elsewhere and the tendency of its home grown technology firms to be small. Small start-up and emerging firms usually lack the resources to partner with academic institutions unless a subsidy is provided to allow them to do so. It may also reflect the fact that West Virginia's research programs are still developing and have yet to attract significant industry funding from outside the state.

There exists an expanding entrepreneurial support infrastructure but also a lack of a substantial organized angel investment community and limited sources of commercialization and pre-seed funding. This background context to West Virginia's TBED position is particularly important to prospects for developing a medical biotechnology development platform for the state. Biomedical technologies are among the most complex to commercialize — facing significant regulatory hurdles, requiring a long-term time horizon between discovery and product launch and demanding significant capital for clinical trials and other development piloting and scale-up phases. Biomedical ventures certainly fall into a "high risk" category of investment — but, on the positive side, successful biomedical ventures typically have a high return. In the nearer-term, *Battelle concludes that the most logical technology pathway for West Virginia in this platform would pursue the development of molecular diagnostics* rather than therapeutics since diagnostics time to market and development costs are less onerous than those for therapeutic products. Similarly, the development of diagnostic tests and therapeutics delivery systems based on nano-technology advances may also represent a nearer-term development opportunity. The development of companies commercializing and producing therapeutic products themselves (drugs and biologics) is a more "outside" proposition for West Virginia, and the pursuit of such developments would have a long-term time horizon. It should also be noted that most start-up therapeutics product companies are built on a model of "exit by acquisition," and thus the products of those fledgling companies that may develop will often be licensed to, or

acquired by, large biopharmaceutical companies who will undertake production at their main operations (which would be outside of West Virginia).

Specific Biomedical Challenges and Opportunities for West Virginia

In addition to the macro-conclusions above, interviews and focus groups held during the course of the project identified the following issues and opportunities specific to biomedical development in West Virginia

- **Clinical research remains a weakness**. It was noted that clinician faculty at the research universities in West Virginia have relatively limited clinical research experience and that leadership or participation in clinical trials is quite limited in the state. Development of clinical research is hampered by a lack of faculty with experience in this area, and thus a limited number of experienced faculty to train junior faculty early in their WV careers. It was also noted that weaknesses in biostatistics and public health disciplines also hinder clinical research growth.

- **Recruitment of top-notch bioscience faculty is challenging.** It was noted that while the Bucks for Brains program was a move in the right direction, West Virginia's research institutions still do not have access to sufficient funds to recruit high-profile senior and entrepreneurial faculty in biomedical sciences. Because the Bucks for Brains program was set-up under an endowment structure, it is felt that the funds available for recruitment on an annual basis are too limited. In addition to the endowed research professorships, additional start-up funds are needed. Consensus in one of the focus groups was that it requires between $500,000 and $750,000 to recruit a high-profile faculty member, or between $1.5 and $2 million for a small team.

- **WVU Health Sciences has a degree of autonomy** from the rest of the University and has interest in translational research and commercialization of research findings. Neurosciences is held up as an example of this — with the BRNI focusing on diagnostics and therapeutics development, including the establishment of a special technology commercialization agreement with a major multi-billion dollar biopharmaceutics company. New leadership within WVU Health Sciences and across the University is expressing interest in forming a senior development committee focused on biomedical development opportunities.

- **Low levels of state investment in research excellence and industry-university collaboration incentives hamper competitiveness.** The research universities are challenged by having to rely on tuition dollars for operations and having limited state funding support. In addition, West Virginia does not have the competitive funding programs that have been developed in competing states, such as the Ohio Third Frontier initiative, to incent translational and applied R&D partnerships between academe and industry.

- **Engineering discipline strengths in the field of nano-technology present opportunities for multi-disciplinary collaboration together with biomedical sciences**. At WVU there are upwards of 20 faculty engaged in the nanoscience initiative and there is interest in having these faculty engage with biomedical faculty to investigate medical applications for nano-innovations in devices, materials and sensors.

- **West Virginia, as a state, is well-located relative to surrounding states with distinct biomedical science clusters.** These surrounding states may represent opportunities for cross-state-boundary collaborations. WVU's proximity to Pittsburgh and the strengths of the University of Pittsburgh, UPMC and Carnegie Mellon University represents one example of such a spatial opportunity. With the NIH and other funding agencies encouraging multi-institutional collaborations, West Virginia should further investigate partnering opportunities.

- **West Virginia's stable population provides a potential resource that can intersect with WVU's and Marshall's capabilities in biomarker identification, pharmacogenomics and the movement towards the tools and technologies of personalized medicine.** It is anticipated that this opens an opportunity, particularly in neuroscience and cancer strength areas (but other areas also) for the development of **niche diagnostics** and, potentially, therapeutic products. Ideally, WVU and Marshall could develop a joint institute focused on genotyping and associated clinical research infrastructure to undertake genotyping and evaluate existing and new diagnostics and therapeutics against specific disease profiles. Representatives at WVU titled this "**preemptive testing of patient cohorts**."

- The focus groups composed of the senior biomedical sciences leadership in the state expressed interest in continuing to meet to advance biomedical-based development for the state. Ideas emerged for institutional thrusts focused around pharmacology/rational drug design, patient genomic profiling and the testing and development of diagnostics and new/repurposed drugs, and nanotechnology applications in medicine. **Diagnostics development** was a thrust recommended by participants at both the WVU and Marshall focus groups.

In Summary. West Virginia has experienced success in attracting federal R&D dollars for biomedical research and continues to build its academic and nonprofit research base. But, while West Virginia is changing, the state still faces challenges in building a robust pipeline of innovation-to-commercialization and accelerating the growth of its biotechnology-based technology economy.

There are opportunities, most likely in the development of molecular diagnostics and nano-tech based delivery systems that are observable in the state but realizing the promise in these requires continued investment in the TBED chain.

Strategy and Actions

West Virginia lacks many of the resources of the translational chain possessed by larger more established regions of biomedical innovation. As a result, investments to build the Biomedical Technology Platform must be made strategically with a long-term vision of growth. Significant value exists in examining best practices of the leading regions and applying creative measures to West Virginia's advantage. Key investments in time and funds will continue to build the foundation for exponential growth with time.

The following strategic action items have been developed to confront the challenges and gaps of biomedical technology platform development while acknowledging the economic challenges currently confronting West Virginia as it develops additional technology platforms. Specific challenges and gaps were identified by members of the biomedical community during one-on-one interviews and also the focus groups held in Morgantown and Huntington. The strategies are aligned with those identified in the Technology Blueprint but present action steps for the unique challenges of biomedical platform development in West Virginia. Many of the actions will require time commitments from key stakeholders rather than immediate major financial investments. This, in and of itself, is a challenge since the stakeholders are already time constrained and asking for more — even for such an important initiative — will create challenges. The return on investment will likely be substantial however. Table 1 presents the five strategies and action items that are discussed in greater detail below.

Best Practices: Guide to Growth in West Virginia

Silicon Valley, Route 128 (Massachusetts), the Baltimore-Washington Corridor, and Research Triangle Park are generally regarded as the nation's premier technology-driven centers of commerce. An examination of the factors that have enabled these regions to succeed in growing their technology base demonstrates that they share the following characteristics:

- Engaged universities with active leadership and strong ties to industry
- Intensive networking across sectors and with industry
- Available risk capital covering all stages of the business cycle
- Discretionary federal or other R&D funding support
- Workforce and talent pool upon which to sustain efforts
- Stable and supportive business environment
- Patience and a long-term perspective.

Actions marked critical are those that have the greatest priority, although some may take several years to accomplish. Immediate actions are those that should be undertaken in the first year of implementation. Short-term actions should be undertaken in 1 to 3 years, and mid-term actions should be undertaken in 3 to 5 years.

Table 1: Proposed Biotechnology Strategies and Actions

BIOTECHNOLOGY STRATEGY ONE	Create a "Face of West Virginia Biotechnology"			
ACTION	**PRIORITY**	**TIME FRAME**	**LEAD ORGANIZATIONS**	**RESOURCES**
Action B1.1 Fund a full-time director of BioWV to develop, lead and coordinate activities within the state including interactions with TechConnectWV	Critical	Immediate	BioWV, TechConnectWV	$150,000 annually for salary and activities, with 50/50 match from state and private sector.
Action B1.2 Form a platform steering committee, or "initiative," comprising representatives from BioWV, industry, government, universities and associated institutions in the state	Critical	Immediate	TechConnectWV BioWV	Shared cost under TechConnectWV and BioWV. $35,000 – $50,000 annually with 50/50 match.
BIOTECHNOLOGY STRATEGY TWO	**Continue to Grow Academic Based Research Programs**			
ACTION	**PRIORITY**	**TIME FRAME**	**LEAD ORGANIZATIONS**	**RESOURCES**
Action B2.1 Designate institutional steering committees to identify key opportunities in multi-disciplinary research and host forums for networking of investigators	High	Immediate	WVU and MU	Time commitment
Action B2.2 Promote and facilitate inter-disciplinary and inter-institutional research with multi-year awards for pilot projects and designated space for inter-disciplinary research	High	Immediate	WVU , MU, WVHEPC	$150,000 – $250,000 award with potential 3 years of funding, number of projects dependent on availability of funding
Action B2.3 Examine and revise academic policies that create barriers to inter-disciplinary, inter-institutional research activity and entrepreneurship	High	Immediate	WVU and MU Research Institutions including independent research institutions	Time commitment
Action B2.4 Enhance regional clusters focused on biomedical technology projects	High	Immediate	WVU, MU, BioWV, TechConnectWV, WV Department of Commerce	$300,000 total annual fund with $100,000 max funding per year per collaborative project

BIOTECHNOLOGY STRATEGY THREE	Advance Biomedical Technology Clusters (Regional and Statewide)			
ACTION	**PRIORITY**	**TIME FRAME**	**LEAD ORGANIZATION**	**RESOURCES**
Action B3.1 Increase academic/ industry interactions by research funding designated for collaborative projects; examine opportunities for shared facilities	High	Near-Term	BioWV and its members, TechConnectWV, MU and WVU	$500,000 annually with 1:1 industry match requirement
Action B3.2 Review policies affecting university/private sector collaborations	High	Immediate	TechConnectWV, BioWV, WVU, MU, other research institutions	Time commitment
BIOTECHNOLOGY STRATEGY FOUR	**Develop Skilled Biotechnology Workforce**			
ACTION	**PRIORITY**	**TIME FRAME**	**LEAD ORGANIZATION**	**RESOURCES**
Action B4.1 Recruit top level faculty, graduate students and post doctoral fellows	Medium	Near- Term	WVU, MU, State, WVHEPC	Use of WV Eminent Scholars Recruitment and Enhancement program and STEM Fellows Program
Action B4.2 Identify current and future industry needs by coordination between educational institutions and industry members and develop educational and training programs	Medium	Mid-Term	BioWV and its members, TechConnectWV, WV Dept. of Education, Workforce-WV, WV universities and colleges	Time commitment
Action B4.3 Leverage industry expertise and presence to provide internships and mentorship programs	High	Near-term	BioWV, TechConnectWV, university and college career offices	Time commitment of participants and industry funding of internships
Action B4.4 Develop a network of WV alumni in pharmaceutical, biotechnology industries to serve in the capacity of mentors and advisory panels	High	Near-term	WV university and colleges alumni offices	In-kind support of development and maintenance

BIOTECHNOLOGY STRATEGY FIVE	Enhance the infrastructure to encourage entrepreneurship and assist biotechnology entrepreneurs and start-up companies			
ACTION	**PRIORITY**	**TIME FRAME**	**LEAD ORGANIZATION**	**RESOURCES**
Action B5.1 Provide wet-lab innovation space and skilled support staff	**High**	**Near-Term**	**WVU, MU, BioWV, TechConnectWV**	**$100,000 annually per institution for skilled staff**
Action B5.2 Restore investor tax credit	**Critical**	**Immediate**	**WV Dept. Of Commerce, TechConnectWV, BioWV**	**Initial cap of $2 million**
Action B5.3 Provide "proof of concept" funds for translational projects. Channel funds through the platform committee/initiative.	**High**	**Near-Term**	**WV Dept. of Commerce, TechConnectWV, WVU and MU**	**$500,000 fund annually, funding between $25,000 to $100,000 per project.**
Action B5.4 Form an SBIR/STTR matching funds program at the state level to advance competitiveness of WV entities seeking these federal funds and to increase overall business funding.	**High**	**Near-Team**	**WV Department of Commerce**	**$750,000 annually with a maximum match level between $50,000 and $100,000 per grant.**
Action B5.5 Develop a "mentorship, advisory" network of experienced biotechnology industry executives to advise and prepare entrepreneurs.	**High**	**Near-Term**	**BioWV, TechConnectWV, INNOVA**	**Time commitment**

The strategies and actions that are recommended can access existing WV financing resources in some instances, while new funding streams will need to be developed in support of others. For the facilitation of research, the WV Higher Education Policy Commission administers the "Research Challenge Grants" program supporting significant research projects in STEM disciplines. WVHEPC also operates a mini-grants program to assist academic researchers in preparing proposal submissions to external funding agencies. These funding resources are directly relevant to Action B2.2. "Innovation Grants" and "Instrumentation Grants", also administered through the WVHEPC are relevant to the education and training program development under Action B4.2. Action B4.1 is directly relevant to the existing WV Eminent Scholars Recruitment and Enhancement Program which targets faculty recruitment at WVU and Marshall — funding salaries and start-up packages for nationally competitive researchers in targeted specialties. On the graduate student front, Action B4.1 is also addressed by the WV STEM Fellows program which helps recruit outstanding graduate students in STEM fields via block grant awards to WVU and Marshall.

In most instances across the United States, it is state government that is at the forefront of funding initiatives in support of TBED, with further support provided by industry sponsors, academic institutions, non-profit agencies and foundations. Federal EDA grants and other federal funding sources are also sought in supporting statewide and regional TBED initiatives. For the WV Biotechnology Platform, new sources of funding are needed to implement the recommended suite of strategies and actions — existing WV programs are insufficient to cover the type of intensive activity required to build a medical biotechnology or biomedical technologies cluster. As noted in Table B1, funding support will be needed at the following recommended levels:

Table B1: Recommended levels of funding support

Action	Action Summary	Notes	Total Funding (Annual)	Recommended State Contribution	Contributions by Other Stakeholders (industry, universities, non-profits and other)
B1.1	BioWV support		$150,000	$75,000	$75,000
B1.2	Platform committee support		$50,000	$25,000	$25,000
B2.2	Collaborative research support	Leverage existing WV Research Challenge Fund and supplement as necessary	$1,000,000+	$1,000,000	
B2.4	Support cross-state line collaborations	Leverage existing WV Research Challenge Fund and supplement as necessary	$300,000	$300,000	
B3.1	Support for industry-university R&D collaborations	Leverage existing WV Research Challenge Fund and supplement as necessary	$500,000	$250,000	$250,000
B4.1	Research talent recruitment	Leverage existing WV Eminent Scholar and STEM Fellows programs and supplement as necessary	As available via state	100%	
B4.2	Develop training programs to meet indentified industry needs	Leverage existing WV Innovation Grants and Instrumentation Grants to enhance education programs and supplement as necessary since WVU and MU are not eligible.	As available via state	100%	
B5.1	Wet-Lab innovation/ incubator personnel		$500,000		
B5.2	Restore investor tax credit		Cap of $2 million in investor tax credits annually to begin	100%	
B5.3	Early-stage proof of concept funding		$500,000	$500,000	
B5.4	SBIR/STTR matching funds program		$750,000	$750,000	

It should be noted that state support for TBED activities will often have a high net return on investment, both directly to the state treasury and to the state economy via direct and indirect economic impacts. For example, Ohio's Third Frontier TBED initiative was recently independently evaluated by SRI and found to have high returns for the state (see: http://www.development.ohio.gov/ohiothirdfrontier/MakingAnImpactReport.htm), and likewise Battelle's independent evaluation of the TBED programs of the North Carolina Biotechnology Center shows equally impressive returns for the state.(see: http://www.ncbiotech.org/biotech-basics/growing-the-economy).

Discussion: Individual Strategies and Actions

BIOTECHNOLOGY STRATEGY ONE	**Create a "Face of West Virginia Biotechnology"**

Rationale: West Virginia does not have a long history or a national profile in the biotechnology industry. Without a national or statewide profile that identifies the state as a site of innovative discoveries, potential economic benefits are less likely to be realized. There are notable elements of basic and applied medical research, small start ups and some larger industry entities within West Virginia but no cohesive approach for supporting and leveraging these resources. Organizations in other states such as North Carolina and Massachusetts provide portals for ease of access by internal and external stakeholders via "one stop shopping." The time has come in West Virginia for a dedicated entity and staff that can assist and facilitate interactions, collaborations and education to profile a "Face of West Virginia Biotechnology." The most immediate strategic need is the provision of a coordinating statewide "face of biotechnology" to coordinate internal and outreach efforts essential to support platform growth. Multiple activities can be carried out by this entity that will help leverage and coordinate the resources of the state — developing synergies and creating a whole greater than the parts.

Action B1.1 Fund a Full Time Director for BioWV

Establishment of the Bioscience Association of West Virginia (BioWV) is a very important step to creating a "face of West Virginia Biotechnology" in the state, regionally and nationally. West Virginia has little history as a site of biotechnology innovation and few in the state understand the business and value of biotechnology. A dedicated staff member is essential to the outreach programs that will promote this technology platform and its value to the citizens of the state. As WV builds its technology economy, TechConnectWV promises to become the umbrella organization coordinating activities of multiple technology platforms. BioWV would be one of those organizations dedicated to the biotechnology platform. Key activities of the organization would be to:

1) Establish a Biomedical Innovation Working Group: As an embryonic industry in the state of West Virginia, the biotechnology platform would benefit from a statewide working group that would work with BioWV to provide a global, comprehensive view of the industry and guidance in the implementation of statewide strategic planning efforts. Representatives from each key stakeholder organization would form the core working group.

North Carolina's Intellectual Exchange Networks

The North Carolina Biotechnology Center (NCBC) supports intellectual exchange networks that are designed to foster a research and information-sharing environment for industry and academic partnerships, and professional networking opportunities in the state of North Carolina. Intellectual Exchange Groups (IEGs) are initiated by interested individuals or groups within the life science communities; and participants might be drawn from universities, the business community, or other constituencies. NCBC provides funding to the IECs to cover the cost of meeting expenses.

2) Sponsor Statewide and Regional Innovation Events: While many groups within the state sponsor networking events, there is a need for more comprehensive inclusive forums that could be sponsored by BioWV. There are several approaches with proven value — two of which are a) comprehensive networking meetings that attract all interested parties and b) special interest groups that focus on specific topics. Networks would be initiated by interested parties and participants drawn from universities, communities, industry associations, research organizations, medical organizations and government. A technical network could be formed, for example, of people who are interested in bioinformatics, personalized medicine, and advanced biotechnology-based manufacturing.

MIT Enterprise Forum

This MIT based organization presents a range of technology oriented networking programs for entrepreneurs including:

The Innovation Series – a monthly lecture series featuring luminaries for a diverse audience.

The Startup Clinic – a monthly meeting at which entrepreneurs pitch their company to a panel of experts and general audience and receive advice on taking their companies to the next stage.

Special interest groups – monthly meetings of smaller groups that focus on industry topics.

3) Develop and maintain a single database of statewide resources (including intellectual property) to contribute to a "one stop" portal for

West Virginia biotechnology. It is difficult under any circumstance to determine quickly the resources available within a region. Many interview subjects expressed frustration with their inability to determine quickly the assets and capabilities available within the state and where to find them. The issue is likely to be even more challenging for external parties wishing to learn more about biotechnology and associated opportunities in West Virginia.

Recommend that BioWV be given the funding for a full time director and resources to serve as the face of WV Biomedical Technology

Resources Required: $150,000 for staff and expenses. Financial support and/or in kind support would be provided by state academic and industry members as well as national organizations such as BIO and the Pharmaceutical Research and Manufacturers Association.
Priority: Critical
Timeline: Immediate
Recommended Lead Organizations: BioWV and TechConnectWV
Intended Outcomes:

- **Continue to grow the West Virginia academic R&D base** at a pace that significantly exceeds that of the nation with a target of $360 million by 2015
- **Increase Industry-sponsored R&D** at West Virginia's universities and colleges to match the national average by 2020.
- **Increase the number of biotechnology companies** in the state.
- **Increase employment in the private, technology-based sector** in West Virginia to match the national average by 2020.
- **Increase the number of spin-off companies** developed from technology created at West Virginia's universities and colleges to match the national average by 2020.

Action B1.2 Form a Platform Steering Committee (or "Initiative"), Comprising Representatives from BioWV, Industry, Government, Universities and Other Institutions in the State.

This action is also described in the general report (See Action Eight).

Battelle's experience with many TBED projects across the U.S. shows that a formal organization needs to be formed that comprises leaders from key stakeholder groups within the platform area. Working together, these leaders evaluate and prioritize platform development initiatives and present a unified front in promoting priority projects and securing funds from key external sources.

The steering committee can be quite large, including 15 to 20 individuals. The group should plan on meeting monthly or bimonthly in the initial year to develop an aggressive implementation plan.

Resources Required: Funding to provide staff support could be included in the Overall TechConnectWV budget or the BioWV budget. $50,000 is recommended for this support activity to buy staff time and to provide resources for organizational events and meetings.

Priority: Critical

Timeline: Immediate

Recommended Lead Organizations: BioWV and TechConnectWV

BIOTECHNOLOGY STRATEGY TWO	**Continue to Grow Academic-Based Biomedical Research Programs**

Rationale: It is well documented that academic research institutions are drivers of new industries and economic development. To move from university innovation to commercial development however, the biomedical/biotechnology industry requires inter- and multi-disciplinary research. Leading biomedical regions have strong interplay among engineering, physics, chemistry and the biological sciences.

Successful development of this platform in West Virginia will very much depend on assembling multidisciplinary teams that cross departmental and institutional boundaries and in some cases state borders. Both academic and private sector involvement will be critical to the development of commercializable technology from platform R&D. This need, in terms of the nanoscience elements alone, is highlighted in an article in the *Journal of Molecular Biochemistry,* which notes as follows:

> *Nanoscale science will play a fundamental role in imaging, biosensors, biomarkers, self-assembling tissue implants, and drug delivery over the next decade. Ironically, as devices and agents become smaller, they will require bigger and more multidisciplinary teams to realize the anticipated revolution. In contrast to the time-honored models of academic collaboration among highly focused laboratories, nanoscience efforts will require that investigators learn each other's languages and form partnerships that integrate individual intellectual components into a cohesive team approach. The complexity of the new nanotechnologies and the scope of their clinical and applications require direct and immediate access to diverse "in house" expertise, which could dramatically impact the traditional academic paradigm for doing science.*[3]

Within West Virginia, multiple core competencies were identified that will need to be coordinated in terms of forming an interdisciplinary platform team. Support should not be limited to efforts solely within the state however. As a small state, West Virginia will never have the range of resources available in larger, established areas such as California, Massachusetts, and New York. It does have proximity to dynamic programs in Pennsylvania, Ohio, Kentucky, and Virginia. Establishing, supporting and extending

[3] Wickline, S. A., and G. M. Lanza. "Molecular imaging, targeted therapeutics and nanoscience." *Journal of Cellular Biochemistry,* Supplement 39:90–97, 2002.

support to include regional collaborations as well as in-state collaborations is essential to the growth of the biotechnology industry in West Virginia.

Action B2.1 – Designate a steering committee at key research institutions.

West Virginia investigators have begun outreach efforts in multi-disciplinary research and require support. Accelerating such efforts would benefit from an institutional steering committee that identifies opportunities and necessary resources. These steering committees will provide strategic direction and funding decisions for the growth of biomedical programs within the institution. The steering committees would also work with BioWV (and the biomedical working group) and TechConnectWV to provide input and direction for statewide initiatives.

Recommend designation of steering committees at WVU and MU.

Resources Required: Time commitment by members
Priority: High
Timeline: Immediate
Recommended Lead Organization(s): WVU, MU
Intended Outcomes:

- **Continue to grow the West Virginia academic R&D base** at a pace that significantly exceeds that of the nation with a target of $360 million by 2015
- **Increase R&D funding in platform areas** of all sectors (academia, nonprofits, and industry)
- **Increase the number of spin off companies** developed from technology created at West Virginia's universities and colleges to match the national average by 2020

Action B2.2 – Provide funding for inter-disciplinary and inter-institutional research projects.

Collaborative interactions among biomedical investigators and those in the nanotechnology initiative, the biometrics initiative, computer science, and chemistry are emerging. These collaborations are critical for creating cutting edge discoveries and for West Virginia to acquire a competitive position in biomedicine. It is recommended that funds be provided of sufficient level and duration for pilot projects that require multi-department, multi-institutional projects to facilitate establishment of team dynamics and production of preliminary data for leverage into external funding.

Recommend funds be provided for inter- and multi-disciplinary research projects.

Resources Required: $150,000 to $250,000 per project, annually; number of projects dependent upon funding available. Leverage existing WV Research Challenge Fund and supplement as necessary.

Priority: High
Timeline: Immediate
Recommended Lead Organization(s): WVU, MU, WVHEPC
Intended Outcomes:

- **Continue to grow the West Virginia academic R&D** base at a pace that significantly exceeds that of the nation with a target of $360 million by 2015
- **Increase R&D funding in platform areas** of all sectors (academia, nonprofits, and industry)
- **Increase the number of spin off companies** developed from technology created at West Virginia's universities and colleges to match the national average by 2020.

Action B2.3 – Examine and revise policies that create barriers to inter – and intra-institutional multi-disciplinary projects and entrepreneurship.

The increased level and value of interdisciplinary research has forced universities to confront policies that no longer support the research needed in today's world. Departments must support and reward collaborative research with other departments and organizations. For example, tenure decisions must acknowledge the value of and reward patents and collaborations so as to not inhibit the growth of research. In addition, institutional policies can create barriers to multi-institutional collaborations. Concerns over intellectual property often lead the list of restrictive policies. A committee of institutional faculty should examine and revise restrictive policies that create barriers to intra- and inter-institutional collaborations.

AzTransNet

AzTransNet is an initiative of the Arizona Biomedical Research Commission that has produced standard, statewide templates for IRB offices and standard MTA's among participants in its recent launch of the AZ Virtual Tissue Repository.

Recommend formation of committees to revisit and revise restrictive institutional policies

Resources Required: Time commitment
Priority: High
Timeline: Immediate
Recommended Lead Organization(s): WVU, MU
Intended Outcomes:

- **Continue to grow the West Virginia academic R&D** base at a pace that significantly exceeds that of the nation with a target of $360 million by 2015
- **Increase R&D funding in platform areas** of all sectors (academia, nonprofits, and industry)
- **Increase the number of spin off companies** developed from technology created at West Virginia's universities and colleges to match the national average by 2020.

Action B2.4 – Enhance regional cluster activities

As a small state, West Virginia needs to build regional as well as internal statewide clusters. Realistically, the large geographic distances within the state currently favor a more natural regional alignment: WVU with Pennsylvania and Northern Virginia, Marshall with Ohio/Kentucky/Southern Virginia. With time, clusters will expand and develop within the state as the necessary infrastructure develops.

Recommend funding be provided for expenses related to hosting regional meetings on special topics and to assist in funding pilot projects with investigators from WVU and UMPC and Marshall and University of Kentucky, for example, which require resources not available within the state.

Resources Required: $300,000 funding for regional research projects with $100,000 max funding per project per year.
Priority: High
Timeline: Immediate
Recommended Lead Organizations: WVU, MU, BioWV, TechConnectWV
Intended Outcomes:

- **Continue to grow the West Virginia R&D base** at a pace that significantly exceeds that of the nation, with a target of $360 million by 2015
- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

BIOTECHNOLOGY STRATEGY THREE	**Advance Biomedical Technology Clusters (Regional and Statewide)**

Rationale: Biomedical clusters require access to universities and academic medical centers; however, the presence of universities, in and of itself, does not necessarily lead to technology-based economic development. Rather, it is the alignment of the research interests of faculty and industry and their collaboration that enables industry to move new discoveries into the marketplace. Biotechnology and biomedical firms flourish in areas where there are many opportunities for R&D collaboration and public/private partnerships that link companies, researchers and clinicians. Key shifts are taking place in how R&D is conducted, demanding new types of strategic alliances to gain competitive advantages from research capabilities. States and regions promoting a broader culture of collaboration across their university and industry sectors will be big winners in this changing environment. It will also become important for

states to ensure that sources of research expertise and capacity exist to support the range of research needs across their specific economic clusters. With the decline of major corporate research laboratories, such as the former Union Carbide/Dow R&D laboratory in Charleston, and a focus by corporations on diversifying their sources of innovation, there is a rising need for strategic alliances across universities and industry to fill the demand for innovation. In the absence of major corporate research laboratories to move technology forward, universities are being pressured to further develop their research discoveries to make them commercially viable.

Action B3.1 – Increase academic-industry interactions

West Virginia must further develop its biomedical industry cluster by building sustained relationships between the state's industry (biotechnology, chemistry, pharmaceutical, and start ups) and its research universities. One proven way to accomplish this is to provide matching funding for collaborative university/industry research projects. Such projects help build relationships between researchers and companies and provide support for activities that help to move technology to the point where private investment capital can be obtained. Twenty-eight states and Puerto Rico reported having programs that provide financial support for university/industry partnerships in 2008.[4]

Recommend that matching funds be provided for joint academic-industry research.

Resources Required: $500,000 annually (with one-to-one match by industry partner). Leverage the existing WV Research Challenge Fund and supplement as necessary.
Priority: High
Timeline: Near- Term
Recommended Lead Organizations: West Virginia Department of Commerce, TechConnectWV, BioWV, WVU, MU, and WVHEPC.

The Maryland Industrial Partnership Program (MIPS)

The MIP has a proven track record of working with industry to accelerate technology commercialization by funding collaborative university/industry product R&D projects. These projects are conducted by university faculty and graduate students in conjunction with company researchers.

Intended Outcomes:

- **Continue to grow the West Virginia R&D base** at a pace that significantly exceeds that of the nation, with a target of $360 million by 2015
- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

[4] *Technology, Talent and Capital: State Bioscience Initiatives 2008*, Prepared by Battelle for BIO, 2008, p. 58,

Action B3.2 – Convene panel to conduct a review of policies and procedures that affect university/private-sector collaborations with a goal of streamlining technology transfer processes and accelerating the number of licenses and start-up companies.

West Virginia can further build its biotechnology industry cluster by enabling and facilitating sustained relationships between the state's emerging companies and its research universities. One way to accomplish this is to minimize barriers to collaborative interactions and technology transfer activities. While not an overwhelming barrier, West Virginia investigators expressed frustration at the difficulty of academia/industry interactions. Projects are required that will help build relationships between researchers and companies and provide support for activities that help to move technology to the point where private investment capital can be obtained. Successful biotechnology clusters have developed policies to facilitate early stage commercialization activity.

Recommend a panel of industry and academic officials be convened to examine and revise as necessary those policies that may inhibit academic/industry collaborations.

Resources Required: Time commitment
Priority: High
Timeline: Immediate
Recommended Lead Organizations: TechConnectWV, BioWV, WVU, MU
Intended Outcomes:

- **Continue to grow the West Virginia R&D base** at a pace that significantly exceeds that of the nation, with a target of $360 million by 2015
- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Carolina Express License Agreement

The University of North Carolina at Chapel Hill has developed the Carolina Express License Agreement, a standard licensing agreement to commercialize academic discoveries that promises to ease the formation of new companies. The agreement was developed by a committee of UNC faculty entrepreneurs, venture capitalists, attorneys, and UNC's Office of Technology Development.

BIOTECHNOLOGY STRATEGY FOUR	Develop Skilled Biotechnology Workforce

Rationale: A supply of qualified, technology-trained workers is critical to the development and sustainability of a technology-based economy. Any knowledge-based industry requires a supply of qualified, trained workers at all levels. Successful regions maintain an adequate supply not only of doctoral-level researchers, but also of technicians with two-year degrees and managerial talent ranging from entrepreneurs to mid- and senior-level executives comfortable with high-technology settings. Regions without a deep, natural pool of talent use a variety of tools, including formal university curricula, marketing programs aimed at worker retention, and peer support for entrepreneurs to increase their talent pools.

Action B4.1 – Recruit top level faculty, graduate students and post-doctoral research fellows

Top level faculty, doctoral students and post-doctoral fellows are the underpinning of a biotechnology knowledge-based economy. Providing funds to top flight investigators may enable both recruitment and retention of a well-trained workforce. Faculty often choose positions where they have access to excellent students and post-doctoral fellows and vice versa — so reinforcing one will typically have positive effects on the other. Post-doctoral fellows often provide a potential source of new academic faculty, industry researchers and/or business leaders. Investments at the “ground floor” have potentially excellent rewards.

Recommend provision of funds to recruit and support top level post-doctoral fellows for a period of one to two years per position.

Resources Required: $120,000 to $150,000 annually ($30,000 per post-doctoral fellow). Faculty recruitment via the existing WV Eminent Scholars Program and student/post-docs supported via existing WV STEM Fellows program.
Priority: Medium
Timeline: Near-Term
Recommended Lead Organizations: WVU, MU, WVHEPC
Intended Outcomes:

- **Continue to grow the West Virginia R&D base** at a pace that significantly exceeds that of the nation, with a target of $360 million by 2015
- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020

- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Action B4.2 – Identify current and future biomedical industry needs at all levels and coordinate education and training programs to proactively develop a trained workforce at all levels, including expertise in regulatory and compliance, professional management, and advanced manufacturing.

Not all biomedical industry positions will require a graduate degree, but the vast majority will require postsecondary education. To grow the biotechnology industry in West Virginia, workers will be needed in advanced manufacturing, compliance, regulatory affairs and a number of other positions. Training for these positions is not an overnight proposition. In fact, in some cases, programs will need to be developed (nanotechnology based manufacturing for example). West Virginia can meet the challenge of developing a technology-based workforce by close communication among educational and industry members to proactively identify current and future needs and develop programs that will produce the necessary workforce to support the platform as it develops. Battelle further recommends that WV consult with the North Carolina Biotechnology Center (NCBC) in regards to workforce and skills development programs proven to be highly effective in this sector. Battelle TPP has evaluated the impact of NCBC programs and finds them to be the benchmark for such initiatives.

Recommend a coordinated program to identify and communicate industry needs to institutions of higher education to facilitate proactive biomedical workforce educational and training programs.

Resources Required: Time commitment and variable program development expenses. Leverage existing WV Innovation Grants and Instrumentation Grants to assist in the enhancement and development of education and training programs – but supplement these because Marshall and WVU are currently ineligible for these funds.
Priority: Medium
Timeline: Long-Term
Recommended Lead Organizations: TechConnectWV, BioWV and its members, West Virginia colleges and universities, WVHEPC
Intended Outcomes:

- **Increase employment** in private-sector, technology-based companies in West Virginia to reach national average by 2020

Action B4.3 – Leverage industry connections to develop internships, and mentoring programs

Another valuable method of developing a trained workforce is through internships and mentoring programs. A 2010 survey of the 884 industry members of the National Association of Colleges and Employers revealed that 82.5% of employers surveyed have an internship or co-op program. Furthermore, over 50% of interns accept full-time employment with the company for whom they interned.

Student internships can serve to establish relationships between bioscience employers and students in West Virginia. The biomedical industry would contribute to and benefit from access to university/college students for work on projects at a number of levels. Many of these positions are likely to result in longer-term employment. The act of mentorship that would occur during these projects would expand the biotechnology network in the state.

Resources Required: Salary expenses donated by industry partner
Timeline: Near - term
Priority: High
Recommended Lead Organizations: TechConnectWV, BioWV, university and college career offices
Intended Outcomes:

- **Increase employment** in private-sector, technology-based companies in West Virginia to reach national average by 2020

Action B4.4 – Develop a network of WV alumni currently employed in biotechnology and pharmaceutical companies to serve as mentors

Interviews and discussions revealed that West Virginia universities have a number of alumni in the pharmaceutical and biotechnology industries. These individuals represent a valuable source of forum speakers, advisory panel members and mentors. Alumni are often enthusiastic about contributing to their alma mater and home state but they need to be asked. BioWV should work with WVU's and MU's alumni offices to identify such individuals and reach out to them to inform them about developments within West Virginia's bioscience industry and to request their support for the development of this industry sector in the state.

Recommend development of a network of WV alumni involved in bioscience development.

Resources Required: In-kind support
Priority: High
Timeline: Near-Term
Recommended Lead Organizations: TechConnectWV, BioWV, WVU and MU alumni offices

Intended Outcomes:

- **Increase employment** in private-sector, technology-based companies in West Virginia to reach national average by 2020

BIOTECHNOLOGY STRATEGY FIVE	**Enhance the infrastructure to encourage entrepreneurship and assist biotechnology entrepreneurs and start-up companies**

Rationale: Leading regions have spent decades building a large infrastructure to support the full chain of innovation and technology development. Such infrastructure extends beyond physical structures and workforce entities. The business environment is such that there is significant competition among states to provide incentives that retain and attract companies.

Action B5.1 – Provide wet lab innovation space and skilled support staff

Wisconsin Institutes for Discovery

The Wisconsin Institutes for Discovery combines a private (Morgridge Institute for Research) and public (Wisconsin Institute for Discovery — a multi disciplinary research facility) under one roof. Funding was provided by private, state and university donations.

A key need for entrepreneurs is the availability of wet-lab space that can support the translation of basic research discoveries into the translational stage. Incubator space is provided at the WVU Business Incubator (currently office space only), the HADCO/Marshall Biotech Incubator, the WV Education, Research & Technology Park and MATRIC (with these latter three having wet-lab space). Space is not the only need — skilled dedicated staff to perform specialized experiments is crucial. In addition to requests for additional, convenient wet lab space, a key gap is the availability of skilled support staff located in these facilities. Two recently submitted federal government bills recognize the importance of skilled workers to facilitate translational research and development.

These bills propose modifications that would allow use of federal funds by those institutions that qualify for provision of skilled staff if needed for an incubator to become self sustaining.

Boston Seaport Square

The Seaport Square is a private development envisioned as an Innovation District. The Innovation Center will be a mixed use single building with space for small entrepreneurial and developing companies as well as a private businesses and civic space.

West Virginia investigators also expressed the desire for private/public space that would allow research groups to work in close proximity — innovation space in other words. Single building private-public space as demonstrated by the University of Wisconsin Institutes of Discovery, the Carnegie Mellon Co-Lab Building and the recently approved development of an innovation center in Boston are being used to enhance collaborative efforts. Such space would help to accelerate development while also providing opportunities for creative financing of facilities.

Recommend development of sufficient innovation space and provision of funds to support skilled translational research staff in innovation space.

Resources Required: $100,000 annually per site for staff salaries, with maximum annual budget support from the state of $500,000
Priority: High
Timeline: Near -Term
Recommended Lead Organizations: TechConnectWV, BioWV, WVU, MU
Intended Outcomes:

- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Action B5.2 – Restore Investor Tax Credit

Technology-based economies thrive in a stable and supportive environment in which tax and incentive policies are used to spur growth. Technology-intensive companies need a tax environment that values their contribution to regional economic vitality and recognizes their specific requirements. Policies that recognize the long development cycle in technology, particularly in the life sciences, can help firms maintain a sound capital structure and ensure a level playing field with respect to old economy industries. Six states — Arizona, Kansas, Maryland, North Carolina, Virginia, and Wisconsin — offer angel investor tax credits specifically targeted to the biosciences. Minnesota has recently offered such angel investor credits in response to competitive pressures from Wisconsin. West Virginia needs to restore the investor tax credit in order to attract financial support if it hopes to support and retain the fledgling biomedical industry.

Recommend restoration of investor tax credit with a cap of $2 million

Resources Required: Cap should be set at $2 million
Priority: Critical
Timeline: Immediate
Recommended Lead Organizations: WV Department of Commerce, TechConnectWV, BioWV
Intended Outcomes:

- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Action B5.3 – Provide early- stage and proof-of-concept funding for translational research projects. Channel funds through the platform committee/initiative.

Access to early-stage risk capital is a critical factor in building a technology-driven economy. One characteristic shared by leading technology regions is that they are home to a venture capital community committed to early-stage local investment. These regions also have networks of successful entrepreneurs who act as angel investors, willing to invest in very early-stage start-up companies. There was a consensus among interview participants that West Virginia lacks a base of sophisticated biotechnology investors. Resident expertise is currently concentrated in the energy and chemistry fields making it difficult for biotechnology entrepreneurs to acquire early-stage funding. West Virginia has the beginnings of a biotechnology-oriented investment community but entrepreneurs find themselves seeking advice and funding outside the state.

Georgia Research Alliance VentureLab Program

Phase I grants of up to $50,000 to answer questions of commercialization feasibility; Phase II grants of up to $100,000 to continue prototype development and company formation; Phase II loans of up to $250,000 to eligible companies that have a fully executed license from the university.

West Virginia investigators also expressed the need for biomedical focused proof-of-principle funding. Such activities are almost never fundable through conventional peer-reviewed federal awards and must be funded under a set of criteria focused mainly on economic development. Thirty-three states reported offering proof-of-concept funding in 2008. About half of the state programs fund university principal investigators only in an active university/industry partnership, and eight fund for-profit companies only in an active university/industry partnership. Seven of the programs provide funds to university technology transfer programs.

Recommend establishment of proof-of-concept funds for biomedical discoveries and technologies.

Resources Required: $500,000 annual fund. Funding projects at between $25,000 and $100,000 per project.
Priority: High
Timeline: Near -Term
Recommended Lead Organizations: WV Department of Commerce
Intended Outcomes:

- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Action B5.4 – Form an SBIR/STTR matching funds program at the state level to advance competitiveness of WV entities seeking these federal funds and to increase overall business funding.

The Office of Technology at the Federal Government's Small Business Administration (SBA) administers the Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program. Through these two competitive programs, SBA helps to fund small, high-tech, innovative businesses' applied research and development efforts. Eleven federal departments participate in the SBIR program; five departments participate in the STTR program awarding $2 billion annually to small high-tech businesses.

Kentucky's SBIR Program

Kentucky's SBIR program has been successful in both attracting companies to the state and in helping Kentucky companies to compete successfully for SBIR awards. The program, which was initiated in 2006, matches Phase I awards up to $150,000 and Phase II awards up to $500,000. Between 2006 and 2009, 51 Kentucky companies received Phase I SBIR awards and 19 received

Receiving SBIR or STTR funds is a vote of confidence in the scientific or technical merit of the R&D being pursued, and these SBA funded projects merit being further accelerated via matching state grant funding.

Resources Required: $750,000 annual matching fund, supporting a 1:1 match on SBIR/STTR awards to WV biotechnology or biomedical companies considered to be a fit to this platform by the platform committee. Recommend capping WV match to maximum o $100,000 per grant to spread risk across opportunities.
Priority: High
Timeline: Near -Term
Recommended Lead Organizations: WV Department of Commerce, TechConnectWV
Intended Outcomes:

- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

Action B5.5 – Develop a "mentorship, advisory" network of experienced biotechnology executives and successful entrepreneurs

In the biotechnology industry, "been there, done that" experience is invaluable. Entrepreneurs often need assistance in developing business plans, preparing for VC presentations, and accessing specialized equipment and expertise to solve development issues as projects progress. Experienced individuals can provide in-depth business development skills and assist in the proactive identification of potential new

opportunities**.** West Virginia has geographic proximity to regions with experienced personnel and should access this expertise to provide mentoring from experienced, successful entrepreneurs, entrepreneur networks and business executives.

Recommend the establishment of a network of experienced mentors to assist entrepreneurs.

Resources Required: In-kind contributions by executives and entrepreneurs
Priority: Important
Timeline: Near -Term
Recommended Lead Organizations: BioWV, TechConnectWV, INNOVA, MATRIC
Intended Outcomes:

- **Increase R&D funding in platform areas** in all sectors (academic, nonprofits and industry)
- **Increase industry-sponsored R&D** at all West Virginia universities and colleges to match the national average by 2020
- **Increase the number of spin off companies** developed from technologies created at West Virginia universities and colleges to achieve the national average by 2020

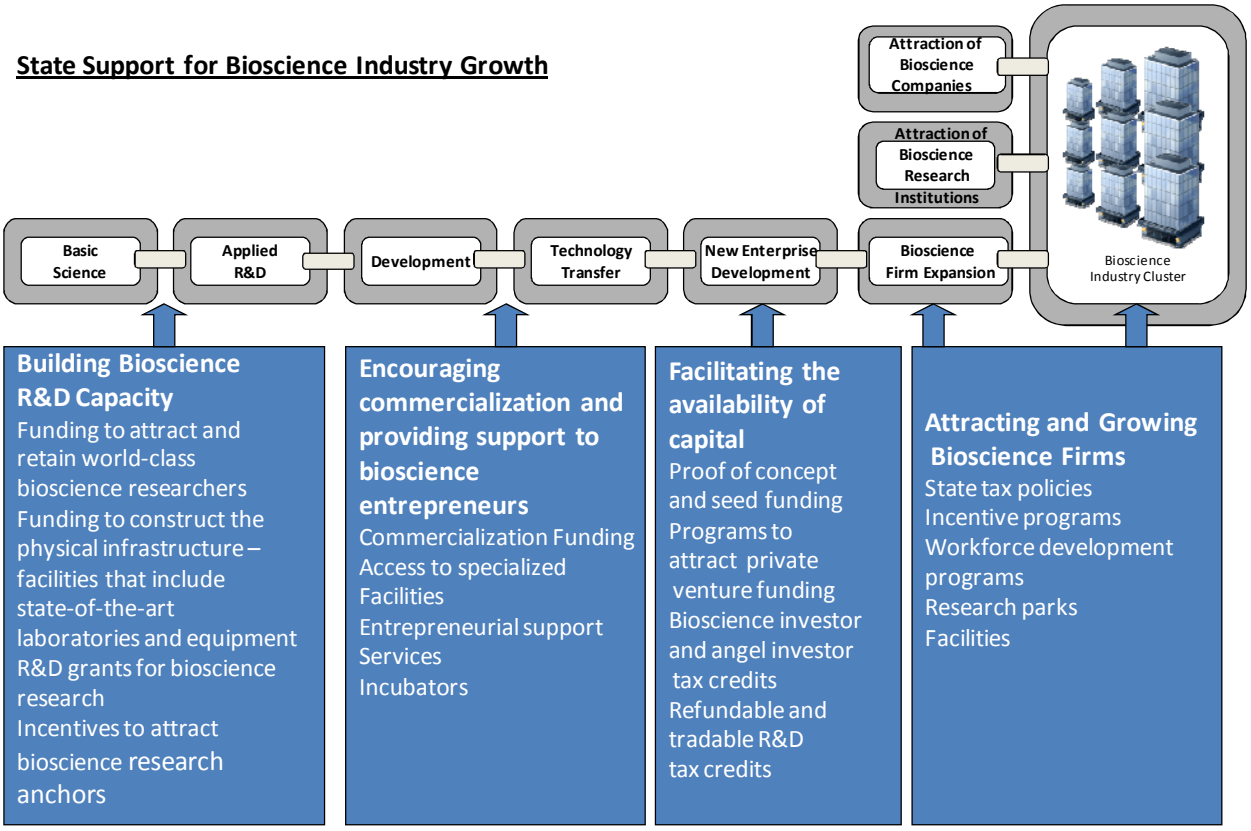
SUMMARY

West Virginia is at a critical juncture in the development of its economy. The vision of a number of the state's public and private leaders has created multiple technology assets, in the form of federal and nonprofit R&D organizations, on which to build a knowledge-driven economy. Both Marshall University and West Virginia University are developing R&D programs that can grow to become key drivers of the state's economy both in their respective regions and statewide. The state has growing technology industry sectors and a small cadre of technology-based start-up companies.

The biomedical technology industry in West Virginia, however, is still in an embryonic stage and it is essential to generate a cohesive approach for strategic investments needed to position West Virginia competitively statewide, regionally and nationally.

Generally speaking, the development of this platform will require a long-term commitment because of the complex chain that must be built from basic science discovery, through advanced translational research, pilot production, clinical research and trials, and then into full production. (See Figure 3 below).

Figure 3: The Integrated Chain of Biotechnology Development



Only a few regions encompass expertise in all elements yet all components need to be in place in some form for full technology-based economic development to occur. As a small state with a very limited engagement in biotechnology, West Virginia will need to be creative, focus on key strengths, access expertise via partnerships and collaborations and invest state resources where appropriate.

Creative approaches will facilitate obtaining resources via strategic partnerships and collaborations and outsourcing until relevant resources are developed within the state. This will require continued investment in West Virginia University and Marshall University to enable them to build critical mass in key areas of research. It also will require greater industry-university collaboration, a focus on commercialization, and technical and financial support for entrepreneurs and start-up and emerging technology companies. In addition, West Virginia must grow, retain, and attract talent from world-class researchers to senior management to skilled technicians. Also, the state will need to tell both the world and its own citizens that West Virginia is changing; West Virginia is building a 21st century economy.

The economic potential of successful development of marketable diagnostics, therapeutics, and drug delivery systems is large and warrants paying strong attention to development of this platform. Economic development occurs at multiple steps in biotechnology and can be viewed as a portfolio of opportunities: licensing, co-development, spin-off companies that are acquired by larger companies, spin-off companies that remain independent. At each stage, excellent, high-wage jobs can be created.

In Conclusion: Make the case — stay the course.

One final lesson from every successful technology community is that success takes time. Silicon Valley and Route 128 trace their origins in electronics to the 1950s and in the life sciences to the 1970s. Research Triangle Park represents a 50-year strategy that has only recently found its footing in the biosciences and is still working to develop full capability in the entrepreneurial sector. Success requires a long-term perspective and patient commitment. Continuous communication of the value of biotechnology to the citizens of West Virginia will be a major element of the long-term process.

This report and all other related reports — as well as other information about West Virginia's technology economy — can be found at...

www.TechConnectWV.com

*This report is the **BIOTECHNOLOGY REPORT** only.*

The full reports can be found at:

www.TechConnectWV.com

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