



**Knowledge  
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Strategy**

## **Building Life Science Resources in the Lehigh Valley: Strategy for Business Attraction and Growth**



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KLIOS, Inc.  
1000 Atlantic Avenue, Suite 506  
Camden, NJ 08104  
phone: 856-283-4083  
fax: 208-279-1873  
Email: [info@KLIOS.net](mailto:info@KLIOS.net)  
[www.KLIOS.net](http://www.KLIOS.net)

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<u>Contents</u>	<u>Page:</u>
Executive Summary	3
1. Objective of this Study	10
2. Snapshot of Lehigh Valley Life Sciences Today	12
3. Strengths, Weaknesses, Opportunities, Threats (SWOT Analysis)	15
3.1 An Overview of SWOT Analysis	15
3.2 Lehigh Valley Strengths	17
3.3 Community and Regional Challenges	48
3.4 Opportunities on the Horizon	52
3.5 Threats: Watch Out!	54
4 The Potential for Life Sciences Growth in the Lehigh Valley	57
5 Recommendations for Strategy	61
Appendix: Companies	66
Notes	84

## **Building Life Science Resources in the Lehigh Valley: Strategy for Business Attraction and Growth**

### **Executive Summary**

This project consists of an examination of the assets related to life sciences in the Lehigh Valley and an assessment of the potential for new life sciences business attraction in light of those resources. The purpose of the study is to:

1. Review the existing life sciences business environment in the Lehigh Valley;
2. Assess the feasibility of life sciences cluster growth;
3. Identify the means to nurture such growth.

In addition, the study pays attention to the role of the Southside Bethlehem Keystone Innovation Zone (KIZ) in enhancing or augmenting recommendations arising from the analysis—that is, how can the KIZ be used as a lever to accelerate life sciences growth?

While the Lehigh Valley contains many of the resources needed to strengthen and grow the life sciences cluster, the concentration of resources and interconnectedness is not as strong as some would imagine. In particular, while there is a strong focus on assisting early stage companies—that is, start ups—and there have been notable companies attracted to the region, there are many more already in the area for whom integration into a local life sciences community or network could provide significant benefits. Improving the relationships between institutions—such as strategic partnering between companies, industry-academic links and links to the regions hospital and health care network—could be expected to increase benefits and growth for everyone.

### **Lehigh Valley Strengths**

- The Lehigh Valley economy is diverse, performs well and shows tremendous resiliency and adaptability.

- The Lehigh Valley already has a strong life sciences presence upon which to build.
- The Lehigh Valley supports a strong selection of academic institutions engaged in teaching, training, research and community outreach.
- The hub of life sciences activity—education, training and research—is Lehigh University.
- Northampton Community College plays a prominent role in life sciences in the Lehigh Valley through workforce training and technical assistance.
- The Lehigh Valley is home to a number of organizations that provide business development assistance to life sciences companies and others at various stages of maturity. These organizations often collaborate to leverage their resources and impact.
- The Lehigh Valley is home to a sophisticated and extensive hospital and health care network already involved with clinical medicine, education and life sciences research. Three hospital networks are participants in the Southside Bethlehem Keystone Innovation Zone.
- The Lehigh Valley contains a number of life science “success stories”. Many benefited from the strong network of assistance and service providers at work in the community.
- The Lehigh Valley’s location provides distinct advantages to life sciences companies, with respect to access to capital, regulatory markets and strategic partnering.

## **Community and Regional Challenges**

- The life sciences cluster in the Lehigh Valley is developing in the shadow of larger, recognized industry clusters in Pennsylvania.
- The social fabric or network around life sciences activity is not fully developed in the Lehigh Valley.

- Technology commercialization and spin out activity is still immature in the Lehigh Valley.
- There are “missing players in the Lehigh Valley, as compared with other areas focused on growing life sciences.
- Just as weaknesses can become strengths, the opposite is also true. Cost of living, quality of life and business cost indicators have already been impacted as a result of early cluster development success.
- Postsecondary educational attainment in the Lehigh Valley lags the nation, albeit slightly. This is an important workforce issue.

### **Opportunities on the Horizon**

- The world of human medicine is changing at an accelerating rate.
- Traditional big pharma is consolidating while new opportunities arise for niche players as a result of firm specialization and the move away from vertical toward horizontal integration.
- Life sciences cluster drivers—through which indigenous, local growth is achieved—are: available technology; availability of capital; quality of labor force; quality and capacity of physical infrastructure (that is, plant and equipment); the extent and competency of entrepreneurial assistance; the mix of entrepreneurial firms (by life cycle stage); and the social network infrastructure and associated “buzz.”
- The Lehigh Valley has all of the industry components that are suitable building blocks for life sciences cluster growth, but the concentration, impact and interconnectedness must be strengthened.

### **Threats: Watch Out!**

- The Lehigh Valley shows great promise as a Life Sciences center, but there is a lot of work still to be done. The job requires patience, focus, perseverance and tenacity.

- Globalization brings opportunities but also risks. The competition is fierce and the competitive landscape can change rapidly.
- The economic development community is awaiting the Supreme Court’s decision in DaimlerChrysler v. Cuno. A legal decision in this case could impact or even eliminate most economic incentives.
- Much life sciences activity occurs in the face of strict regulatory requirements. The sector is prone to volatility, and takes extensive resources and time to develop.
- Other factors may jeopardize otherwise stable or sustainable life sciences growth in the Lehigh Valley.

## **The Potential for Life Sciences Growth in the Lehigh Valley**

The Lehigh Valley shows some development of all of the industry drivers for life sciences cluster growth. These include: available technology; availability of capital; quality of labor force; quality and capacity of physical infrastructure (that is, plant and equipment); the extent and competency of entrepreneurial assistance; the mix of entrepreneurial firms; and social networking infrastructure, including the associated “buzz.” Life sciences shows significant potential for creating ongoing, growing economic benefits in the Lehigh Valley. The opportunities accrue through the formation of new businesses, the expansion of existing firms, attraction of new businesses, and the corresponding increase in high-paying employment generated directly and by supporting industries.

Life sciences cluster growth is driven by continuous technological advancement. In turn, the pace of technology is driven by innovation—which flourishes in the presence of:

1. Expertise—which can be regarded as a combination of talent and R&D capacity;
2. A strong physical and social network, to enable easy interaction and spontaneous dialogue. The physical network requires proximity (of people and resources) and compatible research facilities;

3. Diversity of thought, discipline and people, which promotes “outside-the-box” thinking (and Aha! and Eureka! Moments).

The recommendations in this report provide a framework for linking smart people and new ideas to foster innovation and generate sustained economic growth.

## **Recommendations for Strategy**

### **1. Strategy: Create and communicate a vision for Lehigh Valley Life Sciences.**

- a. Activity: Create a Vision Statement.
- b. Activity: Develop performance metrics and milestones for achievement. Monitor regularly.
- c. Activity: Create a gateway or “regional portal” for entry to the life sciences community.
- d. Activity: Identify a champion within the community to advance and support the effort.
- e. Activity: Develop a marketing strategy for the Lehigh Valley life sciences cluster.

### **2. Strategy: Create a regional life sciences association.**

- a. Activity: The association’s roles include providing information, becoming a networking forum, communication, acting as a conduit to technical and financial support providers and mentoring.
- b. Activity: Association membership should be open to individuals, firms, service providers, academic institutions, hospitals and others—that is, stakeholders and potential stakeholders—in and outside the region.
- c. Activity: The association’s early agenda should be established based on the stated needs of members.
- d. Activity: There should be regular, frequent meetings.

**3. Strategy: Monitor and support regional infrastructure requirements necessary for growth.**

- a. Activity: Identify and support the requirements for physical space, including wet labs and office space, at both the incubator and post incubator stage of development.
- b. Activity: Identify and support the requirements for common or shared equipment. What is needed? Where should it be housed? What are some of the means to fund acquisition of resources?
- c. Activity: Establish pathways to conduct early clinical trials in the community.
- d. Activity: Identify new funds for early stage development. Leverage investments to maximize return.

**4. Strategy: Strengthen the regional social network.**

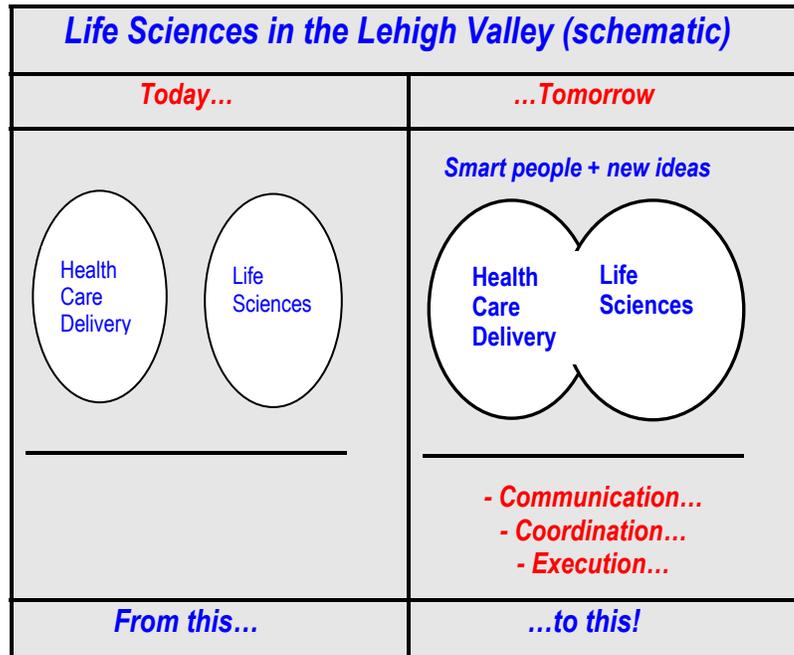
- a. Activity: Expand outreach to companies. Explore strategic partnering opportunities.
- b. Activity: Strengthen industry-academic links. Proactively market academic resources available.
- c. Activity: Create and train “ambassadors”—from industry and academia—to market the region’s resources.
- d. Activity: Explore the role of the hospitals further and expand collaborative activities within the life sciences cluster. How can they achieve their objectives and become more closely integrated into the local life sciences community?

**5. Strategy: Build on early success (past and present). Explore future opportunities.**

- a. Activity: Celebrate every victory, no matter how small. It is too early and there are many gaps—that is, unexplored, missing or undeveloped resources—to declare a particular cluster focus (for example, diagnostics, tissue engineering). Watch how resources develop and opportunistically

capitalize on success.

- b. Activity: Focus on retaining the resources that are here. The Lehigh Valley has proved the ability to “grow its own,” but not necessarily to retain those assets.
- c. Activity: Attraction activities should focus on “base hits,” not “home runs.” The Lehigh Valley nurtures and nourishes growth.
- d. Activity: Develop a strong feedback loop to understand successes and learn from failures. Adjust plans accordingly.



## **1. Objective of this Study**

This study was conducted to: (1) investigate and assess the feasibility for life sciences growth in the Lehigh Valley, and (2) to craft a series of recommendations for top level strategies and actions to support such growth. To do so, an exploration of opportunities for the attraction of new life science related businesses, employment and research activity was conducted, in addition to exploring opportunities and means to retain and grow existing life sciences activity already underway in the area. Throughout the course of the study, particular attention was paid to the role of the Southside Bethlehem Keystone Innovation Zone, which has existed for only a relatively brief period of time and whose role is still evolving.

***Objective: Life Sciences Industrial Cluster Development and Sustainability***

- Identify the means to attract, retain and grow life sciences related activity (that is, establishments, employment and research) in the Lehigh Valley, while paying particular attention to the role of the Southside Bethlehem Keystone Innovation Zone.

One of the challenges of strategic planning is to create a “living document”—that is, one that will continue to grow and remain useful as originally intended. Too often, the end product of fact finding and planning exercises is a well-meaning report that finds itself deposited on a shelf next to earlier, similar studies—if good intentions pave many misguided roads, these studies provide ample foundation material.

This product hopes to evade such a fate by avoiding many pitfalls to which others succumb. While the analysis was conducted and recommendations constructed with a central supporting role for the Southside Bethlehem Keystone Innovation Zone<sup>1</sup> in mind,<sup>2</sup> the analysis and recommendations can both stand independently. The recommendations should be regarded as the building blocks or foundation of a plan for encouraging life sciences cluster growth throughout the Lehigh Valley. As such, they

should become a reference point upon which to base future growth-supporting activities—and in so doing, should gain their own “traction,” thereby becoming indispensable for future planning.

One question that may arise at this point is, “Why focus on life sciences cluster development?” As will be illustrated throughout this report, the Lehigh Valley already has an emerging life sciences cluster, and has shown the ability to grow commercial life sciences activity. The cluster is regarded as a valid target for economic development focus because of that prior success and because of the disproportionate impact that growth of the cluster tends to have.<sup>3</sup> In general, jobs are higher wage<sup>4</sup> and higher quality than elsewhere in the economy, with significant spillover and multiplier impacts.

#### **Why focus on life sciences cluster development?**

- The sector has greater impact—through high wage, high quality jobs and larger spillover benefits and economic multipliers—than many other parts of the economy. The Lehigh Valley already has an emerging life sciences cluster, and has show the ability to generate commercial success.
- A 2004 report prepared for Pennsylvania Bio, found that life sciences jobs in the Commonwealth had an average salary of \$65,000—over 184 percent of the average salary for all Pennsylvania jobs.<sup>5</sup> By comparison, the average salary for all jobs in the Lehigh Valley is just under \$40,000. Average wages have also grown more rapidly for the life sciences sector than for the rest of the economy.
- Life Sciences represents a target cluster for the Southside Bethlehem Keystone Innovation Zone, in the Lehigh Valley.<sup>6</sup>

## 2. Snapshot of Lehigh Valley Life Sciences Today<sup>7</sup>

**Definition: Life Sciences<sup>8</sup>**

- The life sciences sector includes those industries producing or supporting technology-based human bioscience products and processes, as well as related activities.

The Lehigh Valley includes a broad array of institutions engaged in life sciences research and firms of varying size, at various stages of development<sup>9</sup>. These include startups through mature establishments, as well as representative organizations of all intermediate life cycle stages. The mix of firms includes publicly traded corporations, privately held companies, many of domestic ownership, some that are foreign-owned, subsidiaries, spinouts and holding companies. The range of activities spans the production cycle, from research and development, through manufacturing, packaging and distribution. The range of products includes medical devices, instruments, diagnostics and some biological and pharmaceuticals<sup>10</sup>. The Lehigh Valley has experienced life sciences business births, deaths, relocations (into and out of), mergers, acquisitions and consolidations, and expansions.

Private sector life sciences industries (NAICS-based)<sup>11</sup> included for purposes of data collection and analysis in this report (as well as summary definitions), are:

NAICS	Industry
	• <b>Bioscience sectors—including biotechnology, pharmaceutical and diagnostics manufacturers</b>
325411	<b>Medicinal and botanical manufacturing</b> —primarily raw material manufacturers and processors
325412	<b>Pharmaceutical preparation manufacturing</b> —primarily pharmaceutical and biotechnology manufacturers
325413	<b>In-vitro diagnostic substance manufacturing</b> —primarily manufacturers of substances for in-vitro diagnostic testing (such as blood tests and pregnancy kits)
325414	<b>Other biological product (except diagnostic) manufacturing</b> —primarily manufacturers of vaccines and culture (e.g., agar) media

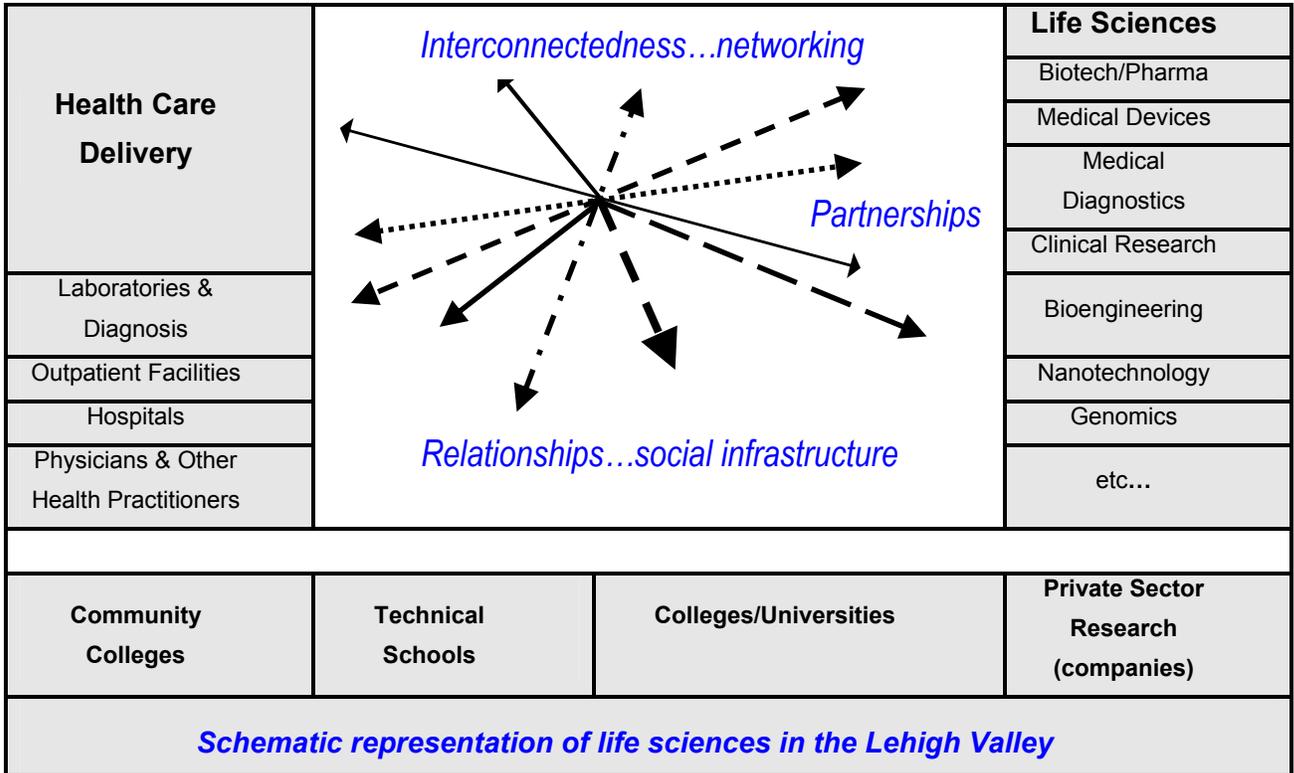
<ul style="list-style-type: none"> <li>• <b>Other life sciences sectors—including manufacturers of input materials; medical devices; tools, equipment and hardware; and companies engaged in contract research</b></li> </ul>	
325188	<b>All other basic inorganic chemical manufacturing</b> —includes inorganic industrial dye and gas manufacturers
325199	<b>All other basic organic chemical manufacturing</b> —includes organic industrial dye and gas manufacturers
334510	<b>Electromedical and electrotherapeutic apparatus</b> —includes magnetic resonance imaging (MRI), ultrasound, pacemakers, hearing aids, electrocardiographs, and endoscopic equipment
334513	<b>Instruments and related products manufacturing for measuring, displaying and controlling industrial process variables</b> —includes a range of nonspecific laboratory and production devices for measuring pressure, temperature, flow, acidity, concentration, etc.
334516	<b>Analytical laboratory instrument manufacturing</b> —includes equipment for measuring the composition or concentration of samples, such as amino acid analyzers, chromatography equipment, electron microscopes, gas analyzers, microprobes, polarizers, protein analyzers, spectrometers, etc.
334517	<b>Irradiation apparatus manufacturing</b> —includes manufacturers of x-ray, irradiation and radiation therapy equipment
339111	<b>Laboratory apparatus and furniture manufacturing</b> —includes manufacturers of laboratory balances, scales, furnaces, ovens, centrifuges, cabinets, cases, benches, tables, etc.
339112	<b>Surgical and medical instrument manufacturing</b> —includes manufacturers of syringes, hypodermic needles, anesthesia equipment, blood transfusion equipment, catheters, surgical clamps, medical thermometers, etc.
339113	<b>Surgical appliance and supplies manufacturing</b> —includes manufacturers of orthopedic devices, prosthetic appliances, surgical dressings, crutches, surgical sutures, personal industrial safety devices, etc.
339114	<b>Dental equipment and supplies manufacturing</b> —includes manufacturers of equipment used by dentists and dental laboratories, such as dental chairs, dental instrument delivery systems, dental hand instruments, dental impression material, dental cements, etc.
339115	<b>Ophthalmic goods manufacturing</b> —includes manufacturers of prescription eyeglasses, contact lenses, protective eyewear and components
339116	<b>Dental laboratories</b> —includes manufacturers of dentures, crowns, bridges, and customized orthodontic appliances
541380	<b>Testing laboratories</b> —includes biological testing laboratories and services
541710	<b>Research and development in the physical, engineering and life sciences</b> —includes for hire laboratories engaged in biology, biotechnology, cancer, genetics, life science and other health-related research and development under contractual arrangements

In addition to commercial establishments, the Lehigh Valley contains an array of academic institutions<sup>12</sup>, including Lehigh University, the region’s only research university. Workforce training, continuing education, undergraduate and graduate education, as well as basic and applied research sponsored by industry and

government, round out the offerings of higher education facilities in the region.

There is an extensive network of hospital and health care providers across the Lehigh Valley.<sup>13</sup> Many of the health networks also provide at least some medical-related training, but limited opportunities for research.

The Lehigh Valley contains many of the resources needed to strengthen and grow the life sciences cluster:



The concentration of resources and interconnectedness is not as strong as some would imagine. In particular, while there is a strong focus on assisting early stage companies—that is, start ups—and there have been some notable companies attracted to the region, there are many more already in the area for whom integration into a local life sciences community or network could provide significant benefits. The relationships between institutions—such as strategic partnering between companies, industry-academic links, and links to the regions hospital and health care network—could be improved with the expectation of increased benefits, innovation and growth for all.

### **3. Strengths, Weaknesses, Opportunities, Threats: SWOT Analysis**

In a rapidly changing world, economic development may be regarded as the regional effort to effectively attract and organize resources to improve local economic welfare—that is, to create jobs and raise living standards, thereby improving the quality of life. But regions do not exist in a vacuum. As technology changes, populations age and politics and regulatory frameworks shift, the ability to succeed is measured against that evolving external landscape of new opportunities, new competition and new threats. As a result, local success requires situational awareness, including an assessment of uncertainty and risk, and is tied to the ability to process that information and develop competitive strategy by responding to dynamic shifts in the world.

To assess risk and overcome uncertainty while formulating competitive strategy, large volumes of information must first be gathered from a variety of sources, then systematically organized and finally analyzed. The challenge grows as the number and variety of sources increases. During the course of this study, quantitative and qualitative information relating to the competitive position of the Lehigh Valley and its capacity for life sciences growth was collected from multiple interviews (primarily the qualitative material) and many databases (mostly quantitative). That information examines and characterizes not only strengths and weaknesses endemic to the local community but also the dynamics of the external environment in which local resources must be considered.

A strategic planning tool that is useful for filtering and organizing large volumes of multiparametric material such as what was gathered for this report, is SWOT—for Strengths, Weaknesses, Opportunities and Threats—analysis.

#### **3.1 An Overview of SWOT Analysis**

SWOT analysis originated at Harvard Business School, growing out of efforts to analyze case studies and craft business strategy during the 1950s. Over subsequent decades, the analytic technique has been subjected to rigorous scrutiny and criticism, has been modified and has evolved. Ultimately, SWOT analysis survives as a well-

tested and effective tool for strategic planning.

In its most elemental graphic presentation, SWOT analysis consists of a matrix with four quadrants, listing, respectively, strengths, weaknesses, opportunities and threats. Strengths and weaknesses are internal or community based attributes—both assets and deficits. Often, stakeholders in the community being considered (including policymakers, legislators, educators, businesses and others) can influence strengths and weaknesses, even if they do not absolutely control them—for example, strengths should be pursued or marketed (i.e., advertised), while weaknesses are reversed, eliminated or minimized. By comparison, opportunities and threats characterize the external environment. For the most part, opportunities and threats are outside the sphere of influence of stakeholders. Nevertheless, opportunities represent targets upon which strengths should be focused, while threats are avoided or otherwise diminished in impact. Considered in combination—as the SWOT matrix allows—these attributes and environmental factors round out the situational assessment, thereby allowing an understanding of and response to risks and uncertainty.

<b>SWOT Analysis</b>	
<ul style="list-style-type: none"> <li>SWOT analysis and the associated matrix, is a strategic planning tool for assembling and analyzing information collected from multiple sources, to understand uncertainty, assess risk and craft a response.</li> </ul>	
<p><b><u>Strengths</u></b></p> <p>—internal / community —<i>pursue / market</i></p>	<p><b><u>Opportunities</u></b></p> <p>—external / environmental —<i>target</i></p>
<p><b><u>Weaknesses</u></b></p> <p>—internal / community —<i>eliminate / minimize / reverse</i></p>	<p><b><u>Threats</u></b></p> <p>—external / environmental —<i>avoid / diminish impact</i></p>

The SWOT template provides an effective means of cataloging the findings from this study of the Lehigh Valley’s capacity for life sciences growth, and a suitable framework for making top level recommendations for strategy and actions. One last comment on the general SWOT framework is helpful, however, before applying the template to the Lehigh Valley. It can be argued that very few characteristics or attributes may be seen as only “good” or “bad”—that is, fitting into a single quadrant of the SWOT template without repercussions or impact elsewhere. That is certainly the case with much of reality, so there should be no expectations otherwise with respect to classifying findings about the Lehigh Valley using SWOT analysis.

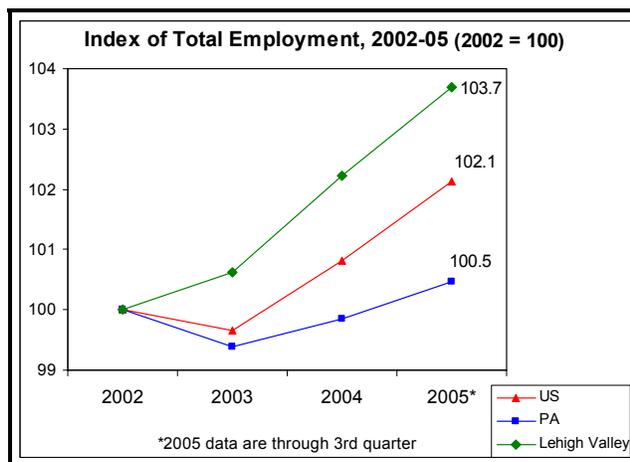
### **3.2 Lehigh Valley Strengths**

The Lehigh Valley’s strength derives from the composition and quality of its local asset base, in general and with specific reference to life sciences related attributes. Domestically and internationally, a substantial number of communities are looking to carve out space and stake a claim in the life sciences arena because of its attractiveness—that is, high wage, high quality jobs and the many predictions of unending growth and continued wealth for communities who succeed in getting the sector to take root. Unless they are the beneficiaries of significant windfalls or largesse, however, for many the reality will prove quite disappointing, since they are beginning their quest with a deficit of quality resources—all of which can be bought, provided the buyer has Midas-like wealth.

That is not the case for the Lehigh Valley, where the resource base is tangible, documented and, above all, already strong and growing. A brief listing of the community’s strengths will make the case:

***The Lehigh Valley economy is diverse, performing well and shows tremendous resiliency and adaptability.***<sup>14</sup> Overall employment growth since the end of the last recession, in late 2001, has been stronger locally than for either the Commonwealth or the nation. In fact, unlike the early “jobless recovery” that struck the nation and the most of the rest of Pennsylvania, the Lehigh Valley employment market

recovered earlier and has grown stronger than either of the other areas. Total employment growth was 3.7 percent in the Lehigh Valley from 2002 through the third quarter of 2005. Over the same period, for the US and Pennsylvania, it was 2.1 percent and 0.5 percent, respectively.



With respect to the composition of employment, the mix of jobs in the Lehigh Valley is suitably diverse. Such a “balanced portfolio” removes the risks associated with so-called “monoculture,” where heavy dependence on a single sector can result in rapid growth but also wild volatility and dramatic declines.

The Lehigh Valley’s past, with historic links to manufacturing—especially the steel industry—is illustrative of single sector dominance. In 1977, 45 percent of employment was in manufacturing. Today, manufacturing accounts for less than 14 percent of total employment. The Lehigh Valley shows tremendous resiliency in light of the declines it has faced in historically prominent industries, as well as a noteworthy ability to adapt to changes in the global competitive landscape. In that way, it mirrors on a local level the durability and resilience of the national economy.

In general, the more closely a region’s economy matches the nation’s, the more diverse it is regarded as being—and the more likely it is to match the nation’s capacity for innovation, job creation and growth. One widely accepted measure of a region’s economic diversity is based on a comparison of the local employment mix with the job mix at the national level through standard mathematical economic formulas known as Location Quotients (LQs).

Location Quotients provide an overall snapshot of regional diversity and can be calculated on a sector by sector basis. For a given sector, an LQ of 1 means that the sector accounts for the same share of the local economy as for the national economy. An LQ greater than 1 indicates greater sector concentration locally than nationally, while an LQ less than 1 indicates lower local concentration.<sup>15</sup> A table of Location Quotients for the Lehigh Valley’s major employment sectors shows the degree of diversity in the economy, as well as local concentrations and sectoral underrepresentation:

Location Quotients: Lehigh Valley		
NAICS 22	Utilities	2.52
NAICS 23	Construction	0.84
NAICS 31-33	Manufacturing	1.23
NAICS 42	Wholesale trade	0.81
NAICS 44-45	Retail trade	0.99
NAICS 48-49	Transportation and warehousing	1.05
NAICS 51	Information	0.95
NAICS 52	Finance and insurance	0.94
NAICS 53	Real estate and rental and leasing	0.64
NAICS 54	Professional and technical services	0.61
NAICS 55	Management of companies and enterprises	1.31
NAICS 56	Administrative and waste services	0.93
NAICS 61	Educational services	1.53
NAICS 62	Health care and social assistance	1.29
NAICS 71	Arts, entertainment, and recreation	0.97
NAICS 72	Accommodation and food services	0.84
<b>Notes:</b> (1) 2004 data; (2) Base industry is total private employment. (3) <b>L.Q. &gt; 1:</b> larger concentration locally, than nationally; <b>L.Q. &lt; 1:</b> smaller local concentration, than nationally; <b>L.Q. = 1:</b> identical concentrations. <b>Source:</b> US Department of Labor, Bureau of Labor Statistics		

Note the strength in “Eds” and “Meds” (education and health care, respectively), two sectors of significance to life sciences cluster development.

***The Lehigh Valley already has a strong life sciences presence upon which it can build.*** Beyond the overall diversity of the Lehigh Valley economy, two sectors that include the greatest concentration of life sciences companies and jobs already

show increased concentrations locally, relative to the nation:

<b>Lehigh Valley Life Sciences Employment Concentration</b>			
		<b>Share of Private Employment</b>	<b>L.Q.</b>
NAICS 325	Chemical manufacturing	2.5%	3.12
NAICS 339	Miscellaneous manufacturing	1.7%	2.84
<p><b>Notes:</b> (1) 2004 data; (2) Base industry is total private employment; (3) Major life sciences industries (based on employment) include:</p> <ul style="list-style-type: none"> <li>• NAICS 325411 – Medicinal and botanical manufacturing</li> <li>• NAICS 325412 – Pharmaceutical preparation manufacturing</li> <li>• NAICS 325413 – In-vitro diagnostic substance manufacturing</li> <li>• NAICS 325414 – Other biological products manufacturing</li> <li>• NAICS 325188 – All other basic inorganic chemical manufacturing</li> <li>• NAICS 325199 – All other basic organic chemical manufacturing</li> <li>• NAICS 339111 – Laboratory apparatus and furniture manufacturing</li> <li>• NAICS 339112 – Surgical and medical instrument manufacturing</li> <li>• NAICS 339113 – Surgical appliance and supplies manufacturing</li> <li>• NAICS 339114 – Dental equipment and supplies manufacturing</li> <li>• NAICS 339115 – Ophthalmic goods manufacturing</li> <li>• NAICS 339116 – Dental laboratories</li> </ul> <p><b>Source:</b> US Department of Labor, Bureau of Labor Statistics</p>			

According to the Cluster Mapping Project at the Harvard Business School’s Institute for Strategy and Competitiveness, medical devices was the seventh largest net jobs producer in the area among all traded clusters, between 1990 and 2003.<sup>16</sup>

In addition, two sectors that provide support to and are vital for the growth of life sciences activity also show increased concentrations locally (as measured by Location Quotients). Those sectors are educational services (L.Q. = 1.53; 2.9 percent of private employment) and health care (L.Q. = 1.29; 16.7 percent of private employment). The HBS Institute for Strategy and Competitiveness Cluster Mapping Project identified Education and Knowledge Creation as the third largest traded cluster net job producer and Health Services as the largest local cluster net job producer between 1990 and 2003.<sup>17</sup> As will be discussed in the Recommendations section of this report, the future success of life sciences activity in the Lehigh Valley, just like the past, will be heavily dependent on the involvement and support of “Meds and Eds”.

High concentrations of life sciences and supporting industry employment in the

Lehigh Valley provide ample evidence that economic development initiatives focused on furthering the cluster’s local growth should not be regarded as either futile efforts or a theoretical exercise. Rather, the seeds have already been planted and the roots have taken hold.

***The Lehigh Valley supports a strong selection of academic institutions engaged in teaching, training, research and community outreach.*** Over 35,000 students are enrolled at ten colleges and universities, as well as several technical training schools in the Lehigh Valley. Those institutions offer a range of coursework from continuing education, vocational training, and certificate programs, through two-year associates degrees, to advanced doctoral degrees and post-doctoral research fellowships. Many institutions participate in workforce training initiatives, often supported by or in partnership with the Commonwealth of Pennsylvania. Several Lehigh Valley higher education institutions offer programs and degrees that attract attention—not to mention students—from around the nation and the world. The relationship or involvement with life sciences activity varies by institution; some are heavily involved while others play ancillary or supporting roles—for example, by providing training that could be useful for life sciences organizations but is not geared specifically to such.

Lehigh Valley Academic Higher Education Training and Research Institutions				
Name	Location	Type / CC / Degrees / Certificates	Notes	URL
Cedar Crest College	Allentown	A / A / A / A	A, B	<a href="http://www.cedarcrest.edu">www.cedarcrest.edu</a>
DeSales University	Center Valley	A / B / A / B	A	<a href="http://www.desales.edu">www.desales.edu</a>
Harrison Career Institute	Allentown	C / n.a. / n.a. / C	C	<a href="http://www.hci.edu">www.hci.edu</a>
Lafayette College	Easton	A / C / B / n.a.	A, D	<a href="http://www.lafayette.edu">www.lafayette.edu</a>
Lehigh Carbon Community College	Schnecksville	B / D / C / D	E, F	<a href="http://www.lccc.edu">www.lccc.edu</a>
Lehigh University	Bethlehem	A / E / D / E	J, N	<a href="http://www.lehigh.edu">www.lehigh.edu</a>
Lehigh Valley College	Center Valley	B / D / C / n.a.		<a href="http://www.lehighvalley.edu">www.lehighvalley.edu</a>
Lincoln Technical Institute	Allentown	B / D / C / D	K	<a href="http://www.lincolntech.com">www.lincolntech.com</a>
Moravian College	Bethlehem	A / C / E / F	L	<a href="http://www.moravian.edu">www.moravian.edu</a>
Muhlenberg College	Allentown	A / C / F / G	M	<a href="http://www.muhlenberg.edu">www.muhlenberg.edu</a>
Northampton Community College	Bethlehem	B / D / C / D	N, O	<a href="http://www.northampton.edu">www.northampton.edu</a>
Pennsylvania School of Business	Allentown	B / D / C / D	P	<a href="http://www.pennschoolofbusiness.edu">www.pennschoolofbusiness.edu</a>
Penn State University-Lehigh Valley	Fogelsville	A / E* / G / n.a.	G	<a href="http://www.an.psu.edu">www.an.psu.edu</a>
St. Lukes Hospital School of Nursing	Bethlehem	B / n.a. / n.a. / H	H	<a href="http://www.slnh-lehighvalley.org">www.slnh-lehighvalley.org</a>
Welder Training and Testing Institute	Allentown	C / n.a. / n.a. / D	I	<a href="http://www.welderinstitute.com">www.welderinstitute.com</a>
<b>Type:</b> (A) 4-year or above; (B) 2-year; (C) less than 2-year				
<b>CC (Carnegie Classification):</b> (A) Baccalaureate Colleges—General – Primarily undergraduate colleges with major emphasis on baccalaureate programs; award less than half of baccalaureate degrees in liberal arts fields; (B) Master’s Colleges and Universities I – Offer a wide range of baccalaureate programs; committed to graduate education through the master’s degree—award 40 or more master’s degrees per year across three or more disciplines; (C) Baccalaureate Colleges—Liberal Arts – Primarily undergraduate colleges with major emphasis on baccalaureate programs; award at least half of baccalaureate degrees in liberal arts fields; (D) Associate’s Colleges: - Offer associate’s degree and certificate programs; with few exceptions, award no baccalaureate degrees; (E) Doctoral/Research Universities—Extensive – Offer a wide range of baccalaureate programs, and are committed to graduate education through the doctorate; award 50 or more doctoral degrees per year across at least 15 disciplines; (E*) Satellite branch of Doctoral/Research University				
<b>Degrees (offered):</b> (A) Master’s, Bachelor’s; (B) Bachelor’s; (C) Associate’s; (D) Doctor’s, Master’s, Bachelor’s; (E) First-professional, Master’s, Bachelor’s; (F) Bachelor’s, Associate’s; (G) Master’s, Bachelor’s, Associate’s				
<b>Certificates (offered):</b> (A) Postbaccalaureate, Less-than-2-years; (B) Post-Master’s, Postbaccalaureate; (C) Less-than-2-years; (D) Less-than-2-years, Less-than-1-year; (E) Post-Master’s; (F) Postbaccalaureate; (G) Less-than-4-years, Less-than-2-years; (H) Less-than-4-years				
<b>Notes:</b> This is general information and a sampling—in no way is it meant to be comprehensive—of activities related to life sciences. (A) Private, not-for-profit, primarily undergraduate enrollment; (B) over 70 percent of incoming freshman ( fall 2005) indicate they will study in the College’s science programs, which include biology and genetic engineering; outreach includes high school “Biology Olympics” (24 <sup>th</sup> annual), to encourage interest in biology and the sciences, with College and corporate sponsorship; (C) private, for-profit, post-secondary technical school; (D) nationally recognized leader in self-directed undergraduate research with faculty mentoring, including science and engineering research; (E) public; (F) offers 2-year Associate’s degrees in (1) Arts (30%) & Sciences (4%)—transfer to a 4-year institution, (2) Applied Sciences (42%)—preparation for employment, (3) certificate programs (13%) and diplomas (11%)—concentrated and occupation-specific, (4) on site Bachelors and Masters degrees granted through Albright College, Kutztown and Temple University; many programs offered with life sciences specialization; (G) offers associate and bachelor degrees, as well as the first two years of more than 160 degrees that can be completed at another Penn State location; state leader (above all other Penn State locations) in generating management development business, consisting of on-site training and continuing education tailored to individual client needs; (H) diploma school of nursing (2-year course); affiliates with Moravian College to offer a baccalaureate (B.S.) nursing degree; offers the only 16-week distance learning program in perioperative nursing in the nation, with Northampton Community College; (I) provides basic, advanced and continuing education in welding; also provides industrial services to corporations requiring third-party services such as inspection, testing, welder qualification, consulting and on-site seminars; (J) academic outreach includes Lehigh Valley Science and Engineering Research Fair (part of Intel International Science and Engineering Fair); accelerated medical programs include (1) 7-year baccalaureate-M.D. program with Drexel University College of Medicine, (2) 7-year baccalaureate-D.M.D. dental program with University of Pennsylvania, (3) 7-year baccalaureate-O.D. optometry program with the State University of New York (SUNY) College of Optometry; (K) offers Associate’s degree in Medical Assisting and Administrative Technology, as well as Pharmacy Technician diploma program and others; (L) houses the St. Luke’s School of Nursing, in partnership with St. Luke’s Hospital; (M) offers 4 cooperative programs linking undergraduate and graduate medical education: (1) with Drexel University College of Medicine and Lehigh Valley Hospital, (2) with University of Pennsylvania School of Dental Medicine, (3) with SUNY College of Optometry, (4) with Jefferson College of Health Professions (for students interested in physical therapy and occupational therapy); (N) Educational Partner, Southside Bethlehem Keystone Innovation Zone; (O) offers Associate’s degree in applied science, with biotechnology major; (P) offers diploma in medical information technology.				
<b>Source:</b> National Center for Education Statistics, US Department of Education; specific academic institution websites				

Several Lehigh Valley higher education institutions are linked through the Lehigh Valley Association of Independent Colleges (LVAIC), whose mission “is to make strong institutions stronger.”<sup>18</sup> LVAIC was established as a non-profit consortium in 1969, to expand educational opportunities for students (such as cross-registration, cooperative programs and special majors), offer professional development programs for faculty and staff, engender greater economy and efficiency in institutional operations and serve local communities. Cooperation through the consortium model allows smaller colleges and universities to retain the advantages that flow naturally from humanly-scaled organizations, while providing many services usually associated with larger-scaled, less personal institutions. Within the consortium, cooperation continues to increase, with significant gains in benefits to participant institutions and the students and communities they serve.

Finally, five area colleges<sup>19</sup> and the DaVinci Discovery Center of Science and Technology, in Allentown, form the Lehigh Valley Partnership, affiliated with the Math Science Partnership of Greater Philadelphia. The Lehigh Valley Partnership works with middle and high school teachers and intermediate units in eight school districts in Pennsylvania<sup>20</sup> and adjacent areas of New Jersey<sup>21</sup>, to improve math and science instruction. Elementary, intermediate and high school education forms the foundation on which competency for higher education and a high quality, skilled labor force—essential for growth of the life sciences sector—is grounded.

With respect to life sciences—education, training and research—Lehigh University is the locus of the Valley’s activity, as measured by the number of students, research activities and community outreach. Unusually, a community college, Northampton Community College, also plays a prominent role in the life sciences in the region. In addition to degree granting higher education institutions, several hospitals and healthcare networks play a role in training physicians, nurses, technicians and other life sciences and allied health professionals in the Lehigh Valley.

***The hub of life sciences related activity—education, training and research—in the community, is Lehigh University.*** Besides being one of only two education partners involved with the Southside Bethlehem Keystone Innovation Zone

(the other is Northampton Community College), Lehigh University is the clear center of life sciences activity in northeastern Pennsylvania. Lehigh is the only research university<sup>22</sup> in the Commonwealth's northeast quadrant. The university is a dynamic amalgam of activity, training students, conducting research, working with other support organizations and government agencies to incubate new high-tech companies and participating in an extensive number of industrial research partnerships. Historically, a large portion of the institution's research and industrial outreach reflected the dominance of steel manufacturing in the Lehigh Valley. Today, chemicals and life sciences are two particular areas of interest, based on shifts in economic activity. In recent years, Lehigh University has made a commitment to increased participation in the life sciences, and has backed that up with significant investment activity.

Lehigh's fall 2004 enrollment was nearly 6,650 students, of whom 69 percent were undergraduates. The university is composed of four colleges: the College of Arts and Sciences, the College of Business and Economics, the College of Education and the P.C. Rossin College of Engineering and Applied Science. 1,041 Bachelor degrees, 378 Master's degrees and 75 Doctor's degrees were conferred between July 1, 2004 and June 30, 2005. During the 2004-05 academic year, the largest undergraduate programs were Engineering (277 degrees conferred), Business, Management, Marketing and Related Support Services (267 degrees), Social Sciences (95 degrees), Psychology (75 degrees) and Computer and Information Sciences and Support Services (68 degrees). During the same period, there were 39 doctorates conferred in engineering (chemical engineering = 14, civil engineering = 3, electrical, electronics and communications engineering = 6, environmental/environmental health engineering = 1, industrial engineering = 6, materials engineering = 6, mechanical engineering = 3), 1 in molecular biology, 2 in biopsychology, 2 in general chemistry and 4 in general physics.

Lehigh maintains an extensive array of relationships with industry, government agencies and research laboratories and other academic institutions. At present, more than 150 companies collaborate with the university on joint research projects or otherwise engage the school's faculty, research facilities and equipment. Almost 15 percent of Lehigh's research is funded by industry, more than double the national

average of 7 percent. There are several centers and institutes at Lehigh at which it conducts research in different disciplines. All of the research centers maintain strong connections with industry—local and beyond. Some of the relationships are formal collaborations, while others are less formal. Several research centers maintain Industrial Liaison Programs, in which industry partners can extend their own capabilities through access to faculty, equipment and research findings.

The Pennsylvania Infrastructure Technology Alliance (PITA) is a collaboration of the Commonwealth of Pennsylvania Department for Community and Economic Development (DCED), the Center for Advanced Technology for Large Structural Systems (ATLSS) at Lehigh and the Institute for Complex Engineered Systems (ICES) at Carnegie Mellon University, in Pittsburgh. The mission of the PITA program is to assist the Commonwealth and its companies in increasing operating efficiency and enhancing economic development. Among its activities, PITA sponsors university-based projects, often involving companies involved with biomedical engineering, environmental technology, nanotechnology and clean energy technologies.

Another interdisciplinary teaching, research and industrial outreach arrangement pioneered at Lehigh more a decade ago, is the Integrated Product Development Program (IPD). IPD brings together students in engineering, business and the design arts to successfully commercialize products on behalf of industrial clients. The IPD Program has been widely written about and is the model for similar programs at many institutions. This year, Dr. John Ochs, professor of mechanical engineering at Lehigh, and founder and director of the IPD Program, won the Olympus Innovation Award, which recognizes a university faculty member who fosters an environment of innovative thinking among students through inventive teaching methods and hands-on opportunities. The award is given by Olympus, the healthcare and consumer electronics technology company, in conjunction with its partner, the National Collegiate Inventors and Innovators Alliance (NCIIA). Olympus America, the domestic subsidiary of Tokyo-based Olympus Corporation, is completing the relocation of its headquarters from Long Island to the Lehigh Valley this year.

Over the past four years, through the “Lehigh 20/20” initiative, the university

invested \$75 million in focused research areas<sup>23</sup> and hired 25 percent more faculty. The university's commitment to life sciences gained from the addition of 30 new faculty, in addition to extensive infrastructure and facility improvements, including the construction of a new animal facility and surgery suite—all part of Lehigh's Bioscience and Biotechnology Initiative. Partly in response to these efforts—as well as ongoing activity—Lehigh's funding from the National Institutes of Health (NIH) increased 250 percent over a three year period. Even before the new activities, however, the university was achieving notable recognition in many disciplines. For example, according to the Institute for Scientific Information (ISI), Lehigh's Chemical Engineering Department consistently ranked fifth among the top 100 federally funded US universities, as ranked by average citations per paper in studies that looked at the periods 1994 through 1998 and 1996 through 2000 (latest available data).<sup>24</sup> Further proof of the school's scientific rigor and academic success is evident in the quality and success of its graduates, many of whom go on to distinguished careers<sup>25</sup> in academia, the private sector and government.

New faculty hires in bioscience and biotechnology add to the universities research and development capabilities, including translational research—from “bench to bedside”—and biobusiness—the business aspects of product development. Lehigh continues to develop novel educational and industrial partnerships through the efforts of its faculty, administration and extensive network of alumni throughout industry. The effort creates synergies that benefit company and corporate relationships as well as student learning, as reflected by innovative and interdisciplinary programs such as applied life sciences, bioengineering, health and biopharmaceutical economics and entrepreneurship. Launched in the fall of 2004, the applied life sciences curriculum is for undergraduates interested in health professions, medical device or pharmaceutical marketing and manufacturing, public health, law (in particular, intellectual property), policy, journalism, economics, and ethics. The undergraduate bioengineering curriculum offers specialization in biopharmaceutical engineering, bioelectronics/biophotonics or cell and tissue engineering, offered in a research-centered experiential learning environment. Lehigh's M.S. in Health and

Biopharmaceutical Economics is designed for graduates with life sciences degrees who are interested in exploring the business and entrepreneurial side of life sciences. It emphasizes the application of economic theory and econometric tools to industry, and prepares graduates for careers as healthcare analysts and strategic marketing analysts across the spectrum of life sciences industries.

Entrepreneurial activity and innovative entrepreneurship training is evident across Lehigh's campus. In 2004, Lehigh established the Office of Technology Transfer, Entrepreneurial Research and Education and introduced an undergraduate entrepreneurship curriculum and minor. The goals of the Office of Technology Transfer, Entrepreneurial Research and Education are to smooth the transformation of university innovations into products and services of benefit to the public, enhance educational programs for Lehigh students and increase the university's contributions to regional and economic development. The office helps to obtain appropriate patent, trademark, or copyright protection on intellectual property generated at Lehigh and at Northampton Community College, and to license that intellectual property to appropriate corporate and commercial partners. The office will also stimulate Lehigh faculty, students and staff to think in a more entrepreneurial way and provides a central portal for cooperative programs. The undergraduate entrepreneurship minor is offered through the College of Business and Economics, which also offers to professionals and MBA candidates twelve specialized vSeries seminars in new venture creation and entrepreneurship.

Several research institutes and centers contribute to Lehigh University's growing prominence in life sciences activity. The Biopharmaceutical Technology Institute coordinates education and research activity in the biopharmaceutical/bioprocessing area of the Chemistry and Chemical Engineering Departments. The Institute is focused on the improvement of manufacturing and regulatory activity related to biotechnology and pharmaceutical industry processes and products. A portion of the Institute's outreach consists of BioPilot Services, a suite of capabilities and facilities targeted to industry needs. Meanwhile, the Center for Optical Technology (COT), a multi-institutional initiative housed at the university, advances research and applications of optical and optoelectronic technologies.<sup>26</sup> Currently, COT's two primary research focus

areas are Optical Networking Technologies, and Sensor and Display Technologies.

Lehigh has several partners in this endeavor: Pennsylvania State University for research and education; Lehigh Carbon and Northampton Community Colleges for education and outreach programs and Ben Franklin Technology Partners of Northeastern Pennsylvania for business development. COT also maintains research and business development activities with local and national companies through the Center's Industrial Liaison Program. COT has received recognition as a national leader in optics research, much of which is relevant to life sciences.

***Northampton Community College plays a prominent role in life sciences in the Lehigh Valley through workforce training and technical assistance.*** Like Lehigh University, Northampton Community College participates in the Southside Bethlehem Keystone Innovation Zone as an education partner. The main campus is located in Bethlehem Township, and the college also operates 4 off-campus centers.<sup>27</sup> Students at Northampton can work toward Associate Degree, certificates and specialized diplomas. Graduates enter the workforce and also go on to study at four-year colleges and universities.

The college is involved in life sciences workforce training through its Biotechnology Associate Degree and other training programs. Northampton awarded 792 Associate Degrees between July 1, 2004 and June 30, 2005. Of those, 141 degrees were conferred for Health Professions and Related Clinical Sciences, 10 for Biological Sciences and Biotechnology and 3 for Chemical Technology/Technicians. Over the same period, Northampton also awarded certificates (for less than 1 year and less than 2 year training) in similar disciplines.

Northampton Community College also cooperates with East Stroudsburg University (ESU) on the "2+2+2 Educational Pathway." Under that agreement, students who earn an associate in applied science degree at Northampton with an overall GPA of 2.75 or better may enter the chemical biotechnology program at East Stroudsburg as juniors and are able to complete a bachelors degree with two more years of study. Northampton and ESU both work with key regional secondary schools across northeastern Pennsylvania, to provide biotechnology coursework at the appropriate

education level. This 2+2+2 “pathway” is meant to ensure students a smooth transition from high school through employment, whether they choose to pursue a bachelor’s degree or enter the workforce after high school or upon completing an associate’s degree.<sup>28</sup>

Northampton Community College houses the Electrotechnology Applications Center (ETAC), which provides confidential technical assistance to a range of businesses, to help them increase productivity, improve energy efficiency, and achieve and maintain environmental compliance.

In a 186,000-square-foot building that was formerly home to Bethlehem Steel offices, Northampton is developing its Southside Bethlehem Campus. The site already provides literacy training, and plans are to offer the Southside community a full array of credit and non-credit classes.

Partnerships and community outreach that Northampton Community College is involved with, includes: The Workforce and Economic Development Network of PA (WEDNet of PA), a partnership with 34 other community colleges and state universities to provide workforce training funds and services to area manufacturers and technology companies; the Industry/Faculty Loan Program, which allows faculty members to spend a semester in a local industry or institution; and Pennsylvania CareerLink, a cooperative effort to provide one-stop delivery of career services to job seekers, employers and other interested Individuals.

***The Lehigh Valley is home to a number of organizations that provide business development assistance to life sciences companies and others at various stages of maturity. These organizations often collaborate to leverage their resources and impact.*** From access to technical services and expertise to infrastructure and risk capital, these organizations have proven track records of success with product and process research and development, as well as company growth and development. The Pennsylvania Department of Community and Economic Development (DCED) provides at least some funding for each organization.

**—Ben Franklin Technology Partners of Northeastern Pennsylvania (BFTP/NEP)** is a nonprofit corporation and a wholly owned subsidiary of Lehigh

University. Ben Franklin Technology Partners is state-funded economic development initiative that was created by the Commonwealth in 1983 to play a leadership role in strengthening regional economies, building the state's technology economy and creating and retaining high-wage, high-skill jobs.<sup>29</sup> BFTP/NEP is headquartered on the Lehigh University Campus, and operates 3 regional offices around northeastern Pennsylvania and a technology incubator at Lehigh's Mountaintop Campus. The organization's strategy encompasses 3 key areas:

1. Developing early-stage, technology-oriented companies;
2. Helping established companies creatively apply new technology and business practices to achieve industry leadership;
3. Promoting innovative communitywide initiatives that foster a favorable business environment for high-growth companies.

BFTP/NEP provides access to capital for promising young technology companies through investments that typically range from \$30,000 to \$150,000 per year for up to 3 years. For established companies, the organization provides attractive loan packages, typically for technology development or application.

Companies that work with BFTP/NEP benefit from a comprehensive array of support services that extends from the collective knowledge and business expertise of the organization's staff, to the extensive Solutions Network of advisors, service providers and investors. BFTP/NEP also acts as an intermediary, linking regional companies with the facilities and expertise resident at the state's higher education institutions.

BFTP/NEP established its first business incubator soon after the Ben Franklin initiative commenced, in 1983.<sup>30</sup> Since that time, the BFTP/NEP Business Incubator has graduated 34 companies, grossing more than \$350 million in annual revenue and creating more than 2,460 jobs. The BFTP/NEP Business Incubator on Lehigh's Mountaintop Campus was named 2001 National Business Incubator of the Year, by the National Business Incubation Association (NBIA). Just over half of the facilities 10,400 square feet of lease-space is capable of being outfitted for life sciences applications. Near the end of 2005, the incubator housed 16 companies with a total of 67 employees

and an annual payroll exceeding \$2.6 million.

BFTP/NEP has invested nearly \$8 million in more than 40 life sciences companies since 1987. Overall, from 1983 through 2004, based on surveys that it administers, BFTP/NEP started 337 new companies, created 9,373 new jobs and retained some 17,266 existing jobs. That survey data also reports that BFTP/NEP, through the companies it assists, was involved with the creation of 580 new products and processes.

—**Life Sciences Greenhouse of Central Pennsylvania (LSGPA)** is a non-profit corporation that was created by the Commonwealth of Pennsylvania under The Tobacco Settlement Act of 2001, to accelerate economic growth through commercialization of discoveries in the life sciences.<sup>31</sup> LSGPA became operational in October 2004. The organization provides seed funding and business support services to the most promising early-stage life sciences companies in central and northeastern Pennsylvania, including the Lehigh Valley. LSGPA has three key development targets: rational drug design and delivery, biomedical devices and bio-nanofabrication (the creation of devices at very small scale). LSGPA serves a wide geographic area—49 of Pennsylvania’s 67 counties—with its headquarters at Harrisburg. LSPGA services the Lehigh Valley through an industrial liaison who is Director of the Corporate Life Sciences Program, at Lehigh University.

LSPGA provides access to capital to viable seed-stage or established life sciences companies that have significant potential for commercial growth, by providing up to \$750,000 in milestone-driven convertible debt or equity financing. Funding goals are the accelerated development of technologies or advancement of sponsored research to create significant value in the life sciences field, and the development of promising life sciences companies into stronger businesses capable of attracting follow-on funding.

To date, LSPGA has invested nearly \$8 million across its region, in the form of pre-seed stage capital and technology development funding. That investment has been matched by more than \$30 million from other sources.

—**The Lehigh Valley Economic Development Corporation (LVEDC)** is a non-profit corporation founded in 1995 that works to attract, retain and expand business throughout the Lehigh Valley. LVEDC represents Lehigh and Northampton Counties and the Cities of Allentown, Bethlehem and Easton.

LVEDC operates as a one-stop, full-service business and economic development agency performing several functions: marketing, business retention and attraction, land and site redevelopment, research, regional development and financing. It is the only regional economic development organization that markets the Lehigh Valley’s identity regionally, nationally and internationally. LVEDC provides visitors, newcomers and prospective employers with comprehensive information on the Lehigh Valley, including demographics, housing, healthcare and education information, cultural and recreational opportunities and a listing of the area’s top employers.

LVEDC is the Keystone Innovation Zone (KIZ) Coordinator for the roughly 4 acre parcel that makes up the Southside Bethlehem KIZ—designated for special funding and tax credits due to the presence of existing higher education institutions and potential for sustainable economic development related to research and technology when combined with non-tax incentives. Target industries for development in the Southside Bethlehem KIZ include life sciences; opto/microelectronics and information technology; and advanced materials and nanotechnology. As KIZ Coordinator, LVEDC is responsible for the establishment and effective administration of policies and procedures for the program, in conjunction with its partners. LVEDC is also responsible for the day-to-day operation of the KIZ, as directed by the KIZ Advisory Board.

—**The Electrotechnology Applications Center (ETAC)** at Northampton Community College helps businesses increase their productivity, improve energy efficiency and achieve environmental compliance. ETAC provides confidential testing and development services for companies seeking alternative processes, including heating, drying, coating and curing. The Center helps companies develop and investigate the possible application of these technologies before making large investments or product changes. ETAC develops solutions for businesses by offering a wide variety of plant process audits; pollution prevention and energy efficiency

assessments; technical consulting; equipment demonstrations; research and development; materials and environmental testing; “hands on” training and—via distance learning and on site—technology coursework and energy management training.

ETAC works under confidentiality agreements with companies from throughout the Lehigh Valley and around the nation. Partly as a result of that work, Northampton Community College is among the few community colleges with a fully developed intellectual property policy. The Office of Technology Transfer, Research and Education, at Lehigh University, provides assistance with intellectual property protection at Northampton Community College.

—**John M. Cook Technology Campus in South Bethlehem**, adjacent to Lehigh University, provides post incubator space for the development of high-tech business startups and incubator graduates who often wish to remain close to the university and BFTP/NEP. The campus is built on part of the former Bethlehem Steel site, along the Lehigh River.

The first building on the site, Beth Tech I was developed through a partnership that included 4 economic development organizations. That \$3.7 million, 44,000 square foot facility was completed in 1993, and reached full occupancy in 1995. Financing included a pool of 5 loans totaling \$1.7 million, in addition to grant money. The building was constructed to include research, development and light manufacturing space. Originally, it housed 4 tenants, including 3 who were graduates of the Ben Franklin Incubator. Later, the facility was leased to a single incubator graduate with more than 150 employees.

After the success of Beth Tech I and faced with additional demand for post incubator space, the same team set out in 1999 to build Beth Tech II. This time, a pool of 4 loans and grants totaling \$3.2 million was used for the development of the 32,000 square foot building, which was 80 percent pre-leased and completed in April 2000. After the first year, Beth Tech II was occupied by STC Technologies (which later merged to become OraSure Technologies—see below), a Ben Franklin Incubator graduate and two other companies.

After STC Technologies merged in September 2000 with Epitepe, Inc., of Oregon, to become OraSure Technologies, Inc., the new organization built—on its own—Beth Tech III, a 40,000 square foot structure, at the site. OraSure employs over 250 people at the campus, today.

—**Manufacturers Resource Center** (MRC) is a non-profit corporation founded in 1988 to assist small- and mid-size manufacturers improve productivity and quality, lower business costs and advance competitiveness through state-of-the-art technologies and proven business techniques.<sup>32</sup> MRC offers a variety of assistance, including: assessment/benchmarking, problem solving/management consulting, specific one-on-one assistance, specialized training, resource location and coordination, group activities/users groups and grant application facilitation.

—**The Small Business Development Center** (SBDC) at Lehigh University provides consulting at no cost to businesses in all stages of development, from pre-venture to mature. Assistance includes consulting services, negotiation assistance, educational programs and domestic and international research to entrepreneurs looking to start or grow a small business in the Lehigh Valley<sup>33</sup>. The Center is one of 16 Small Business Development Centers in Pennsylvania, and provides support to over 1,000 small businesses each year across its territory. The Lehigh SBDC is a member of the National Association of Small Business Development Centers network.

Overall, from 2000 through 2004, based on surveys that it administers, Lehigh SBDC clients obtained \$175,558,558 in start-up and expansion funding, were awarded \$7,904,224 in government contracts and achieved \$1,244,000 in export sales.

***The Lehigh Valley is home to a sophisticated and extensive hospital and health care network already involved with clinical medicine, education and life sciences research. Three hospital networks are participants in the Southside Bethlehem Keystone Innovation Zone.*** The two largest employers in the Lehigh Valley are Lehigh Valley Hospital and Health Network and St. Luke's Hospital. Together with Good Shepherd Rehabilitation Hospital (also among the top 35 largest companies, based on employment), they account for more than 14,000 jobs in the area, nearly half of the healthcare jobs in the Lehigh Valley. These hospital networks are

participants in the Southside Bethlehem Keystone Innovation Zone.

—**Lehigh Valley Hospital and Health Network** (LVHHN) is one of the largest teaching facilities in Pennsylvania, offering an extensive array of services to meet patients' health care needs. It has served the Lehigh Valley for more than 100 years. LVHHN operates as an advanced acute care hospital with more than 800 beds at three clinical campuses—two in Allentown and one in Bethlehem. Over 1,100 LVHHN physicians work in more than 50 specialties, along with a staff of hundreds of nurses and other professionals. LVHHN is a leading regional source in its key clinical areas: cancer treatment, cardiovascular medicine, mental health, neurosciences, pediatrics, surgery services, trauma, women's health, perinatal care, kidney transplantation and burn treatment.

LVHHN is a major clinical campus for Penn State University's College of Medicine at the Milton S. Hershey Medical Center. Many staff members hold faculty positions at Penn State. The hospital has played a key role in pioneering new techniques and technologies through its involvement in national and international research projects.

LVHHN combines the roles of progressive teaching hospital and community-based health resource, and is a leader in the patient safety movement. In 2005, LVHHN was recognized by the American Hospital Association (AHA) for its leadership and innovation in quality, safety and commitment to patient care. The network operates the third largest heart surgery program in Pennsylvania and has the fourth largest Cancer Center in the Commonwealth. The Cancer Center is in the top one percent for patient satisfaction nationwide and is a founding member of the Penn State Cancer Institute.

LVHHN is the primary beneficiary of the Dorothy Rider Pool Health Care Trust, established by Leonard Pool, the founder of Air Products and visionary behind Lehigh Valley Hospital. Its stated mission is to, "serve as a resource that enables Lehigh Valley Hospital to be a superior regional hospital and improve the health of the citizens of the region it serves." Priority areas of focus agreed upon by the Pool Trust and Lehigh Valley Hospital, include: recruitment and retention of talented persons at LVH; clinical

innovation; access to care; medical education; community health and health studies. The Trust is administered by the Rider-Pool Foundation and managed by a program staff. Funding decisions are made by the Board of Trustees, in response to formal applications for support.

—**St. Luke’s Hospital and Health Network** is a non-profit, tertiary-care, teaching hospital with campuses in Bethlehem and Allentown. The network includes four hospitals, with more than 41,000 annual admissions, 1,100 physicians, nearly 5,000 employees and 1,000 volunteers. The hospital offers 72 medical specialties. St. Luke’s provides care in 8 Pennsylvania counties.<sup>34</sup>

St. Luke’s actively promotes an academic atmosphere through its affiliations with the University of Pennsylvania School of Medicine, Temple University School of Medicine and the Philadelphia College of Osteopathic Medicine. Medical students from these institutions rotate through all specialties at St. Luke’s. Each year, more than 140 residents train at St. Luke’s. In addition to its clinical facilities, Education Center and library, St. Luke’s offers a Research Institute directed by an experienced, full-time PhD research statistician. The Research Institute helps faculty and house staff in clinical research design and data analysis for papers that are presented at national conferences, regional meetings and/or accepted for publication. The staff of the Research Institute also organizes an annual “research day,” during which residents have the opportunity to showcase research projects from each of the training programs.

St. Luke’s is known for its nationally recognized heart and ICU care, its preeminence as a teaching institution, the excellence of its physician, nursing and other clinical staff and its superior customer service. Recently, the institution purchased a 182 acre site in Bethlehem Township, bordered by Route 33 and Interstate 78. St. Luke’s will break ground shortly for a new state-of-the-art health campus at the site.

—**Good Shepherd** is a nationally recognized rehabilitation network headquartered in Allentown. Good Shepherd provides comprehensive inpatient and outpatient services throughout the Lehigh Valley and adjacent communities,<sup>35</sup> offering a continuum of care for people with physical and mental disabilities. More than 36,000 people come to Good Shepherd each year for specialized programs in stroke,

orthopedics, brain injury, spinal cord injury, pediatrics, amputation, and more. Good Shepherd provides outpatient rehabilitation services at 15 sites across Eastern Pennsylvania. Good Shepherd also operates three inpatient sites, a long-term acute care hospital, two long-term care homes for people with severe disabilities, a supported independent living facility, and a Work Services division that provides employment training and job placement.

Good Shepherd's therapists use two types of technology in the course of treatment: rehabilitative and assistive. Rehabilitative technology is used in the rehabilitation process to improve treatment and recovery. Assistive technology is used to increase, maintain or improve the functional capabilities of individuals with disabilities. With state-of-the-art technology, people with disabilities can attain greater independence and can participate more fully in society.

Good Shepherd's South Allentown Campus is nearing the completion of a multimillion dollar construction project and transformation that began in September 2004. The transformed campus will represent a revolutionary new standard in customer-focused rehabilitation. The centerpiece of the campus will be a new 64,000-square-foot outpatient rehabilitation center, housing the Harry C. Trexler Center for Rehabilitation Technology, an enhanced 90-degree therapy pool, pediatric and orthopedic outpatient services, radiology, a lifestyle products store and education center. The newly transformed campus also will feature technology research and development, healing gardens, personalized evaluation and therapy services, and unique rehabilitation products. The campus will provide one of the most comprehensive assistive technology programs in the world. By catering to the needs of people who seek to maximize wellness, function, and independence, it will serve as a model for rehabilitation providers nationwide.

In June 2003, Good Shepherd and Clarkson University<sup>36</sup> announced a partnership to develop innovative programs and technologies to help individuals with disabilities achieve their full potential. The institutions are working together to identify the challenges and needs, develop engineering solutions, and test prototype solutions for individuals with disabilities. In addition, both institutions aim to commercialize

solutions and share the assistive and adaptive technologies worldwide through their partnership. Good Shepherd and Clarkson have established a faculty and student exchange program, and are developing collaborative workshops, seminars and other educational and research opportunities to share ideas and develop technologies to improve and accelerate rehabilitation therapy. The impetus for the partnership between the two institutions was instigated by Elmer D. Gates, a prominent Lehigh Valley citizen and community leader from Bethlehem, who graduated from Clarkson, and who works closely with Good Shepherd, as a supporter and advisor.<sup>37</sup>

In fall 2003, aided by Good Shepherd personnel, Clarkson undergraduates developed software to assist adults in cognitive rehabilitation. Beginning in 2005, with the assistance of a one-year grant from the National Multiple Sclerosis Society, Clarkson researchers will be paired with ten of Good Shepherd's long-term care residents who have multiple sclerosis, to study and improve a wheelchair mounted robotic arm (WMRA). The study will assess how the WMRA improves the functional abilities of individuals with MS and will also determine design inadequacies in order to improve the technology. At the conclusion of the study, engineers at Clarkson will examine the recommendations and begin work on creating the next generation WMRA.

***The Lehigh Valley already has a number of life science “success stories”. Many benefited from the strong network of assistance and service providers at work in the community.*** Behind every company there is a story—at least one and often, many more. The larger and older a company grows, the more remote its early entrepreneurial history becomes—of success and usually failure or at least a misstep or two—fading into the distance until the founders and early hires with direct corporate knowledge of the early days are gone and the historic record is either assigned to the archives or simply forgotten. One sign of the Lehigh Valley's entrepreneurial dynamism is that so many of the exploits of entrepreneurial startups are still being recounted—in many cases, by the original entrepreneurs themselves, who are still in the area and often involved either with their original creations or with some new business. With respect to life sciences, focus on the industry as an economic development driver didn't even begin to occur until the biotech revolution and the last two decades of the past

century<sup>38</sup>—and the Lehigh Valley has been home to companies that played a role in the birth of biotechnology for longer than that! What follows here is a very limited, very brief selection of Lehigh Valley success stories. (A more comprehensive listing of life sciences related companies in the Lehigh Valley is included in the Appendix to this document).

—**ABEC** (Associated Bio-engineers & Consultants), of Bethlehem, has designed and built more cGMP<sup>39</sup> production bioreactors and fermentors for the pharmaceutical and biotech industries than any other company in the world, since 1975. Bioreactors and fermentors are essential for plant and animal cell culture, which is central ingredient of the biotechnology industry. Jack Wilson, founder of ABEC, started his career in the bioprocess industry as president of Fermentation Design. He founded ABEC in 1974 to produce production scale fermentation and bioprocess reactors. In the early 1970s, he designed and assembled the first commercial computer coupled fermentation unit in the world (still in operation at the Institute for Protein Synthesis in Moscow). He also designed and built the largest mammalian cell bioreactor in existence at that time outside of Europe. In 1983, he designed and ABEC built a production facility for TPA (tissue plasminogen activator), a surgical anticlotting factor that became the world's first commercially successful mammalian cell produced product.

Marvin Charles, PhD, Vice President for Process Technology, has worked at ABEC for over 25 years in the areas of equipment and process design and technology assessment. Dr. Charles is also on the staff of the Biopharmaceutical Technology Institute at Lehigh University.

—**Azevan Pharmaceuticals** is developing novel therapeutics for the treatment of disorders of stress, mood, and behavior. The company was founded in 1999, and is located in the Ben Franklin Business Incubator, at Lehigh University's Mountaintop Campus. Neal G. Simon, Ph.D., Azevan's CEO since 1999, is the former Chair of Biological Sciences at Lehigh University. Dr. Simon is currently Professor of Behavioral Neuroscience in Lehigh's Department of Biological Sciences.

—**GlucoLight Corporation** is a privately held company that is developing a non-invasive glucose monitoring system. Glucose monitoring is essential for the regulation

and control of diabetes. GlucoLight is located in the Ben Franklin Business Incubator, at Lehigh University's Mountaintop Campus. Ray Krauss, CEO of GlucoLight, received his undergraduate degree from Lehigh University. GlucoLight received an early investment of \$150,000 from Ben Franklin Technology Partners of Northeastern Pennsylvania in 2003. Subsequently the company received a \$500,000 investment from the Life Sciences Greenhouse of Central Pennsylvania, that was matched by angel investors. In late 2005, the company closed on a \$4.5 million round of private investment, much of it from a French venture investment group.

Mr. Krauss was already a successful entrepreneur and seasoned life sciences industry executive before founding GlucoLight with Matthew Schurman, Ph.D., in 2003. Mr. Krauss left a career at Johnson & Johnson, where he helped pioneer laser eye surgery, to help grow an early-stage company in Boston that developed the Lasik eye procedure. He retired from that company in 1996 and returned to Bucks County, where he consulted part-time for other startup companies before co-founding GlucoLight.

**—Olympus America** announced that it was moving its headquarters and distribution center operations from Melville, New York, on Long Island, to a 41-acre site at the Stabler Corporate Center in Upper Saucon Township, in April 2004. The move is to be completed by the summer of 2006. Olympus employed about 840 on Long Island. Since some restructuring will occur as a result of the move, the final number of jobs in the Lehigh Valley is still unclear, but company estimates are for more than 500, placing Olympus America among the top 75 employers in the area. While some current employees will move from Long Island, the relocation will create many new job opportunities in the Lehigh Valley. The company's move will have significant economic impact, locally—the result of high quality, high wage jobs that are created, new purchasing activity and all other direct and indirect spending.

Tokyo-based Olympus is a worldwide supplier of healthcare and consumer electronics products. The company's business lines include: gastrointestinal endoscopes, accessories and minimally invasive surgical products; advanced clinical and research microscopes; lab automation systems, chemistry-immuno and blood bank analyzers and reagents; and digital and film cameras and digital voice recorders.

Olympus America serves healthcare, scientific and commercial laboratory markets in the US and Canada.

Olympus America will benefit from access to the talent and expertise of faculty and students at Lehigh University, as well as the university’s research equipment and facilities, in addition to other education institutions in the area. Olympus America is already recruiting new employees on college campuses and elsewhere in the Lehigh Valley.

Recently, Olympus America combined its Scientific Equipment Group, Diagnostic Systems Group and Life Science Business Development unit to create a new Life Science group. The restructuring is meant to prepare the organization for a growing emphasis on translational research—“from bench to bedside”—and personalized medicine in the years ahead. Dr. Stephen S. Tang, who received his M.S. and Ph.D. in chemical engineering from Lehigh University, is the company’s Group Vice President and General Manager, Life Science. Dr. Tang was once Assistant Director and Senior Research Engineer at Lehigh’s Center for Molecular Bioscience and Biotechnology.

The effort to bring Olympus America to the Lehigh Valley was a coordinated and collaborative endeavor. The Lehigh Valley Economic Development Corporation played a key role in bringing this project to fruition. In addition, the Governor’s Action Team of economic-development professionals who report directly to the Governor, worked with Olympus America. The Pennsylvania Department of Transportation agreed to provide \$10 million for roadway improvements to support the project. Olympus America’s new headquarters site was also approved as a Keystone Opportunity Zone (KOZ). The KOZ designation significantly reduces the cost of doing business through exemptions, deductions, abatements and credits of state and local taxes (such as local property tax, state sales and use tax, and Corporate Net Income tax).

—**OraSure Technologies, Inc.** is a publicly traded medical diagnostics company, headquartered in Bethlehem, with a focus on the oral fluid, point-of-care specimen collection and in vitro diagnostic test markets—especially for antibodies to HIV and substance abuse testing—as well as portable cryosurgical systems and other medical devices. OraSure is the leading supplier of oral-fluid collection devices and *in*

*vitro* diagnostic assays for the detection of antibodies to HIV and drugs of abuse to many industrial users, including the employment, criminal justice, drug treatment, life insurance and public health markets. The story of how OraSure began and grew in the Lehigh Valley has achieved acclaim and somewhat mythic status in the community, as “three guys and a dog”.

OraSure’s beginnings date to 1985, when SolarCare Technologies Corporation was formed to develop and market a sunscreen towelette. The genesis of the company was a class project at Carnegie-Mellon University, in Pittsburgh. The original founders were Mike Gausling, a specialist in corporate finance, Bill Hinchey, a sales and marketing executive, and R. Sam Niedbala, a research chemist and graduate of Lehigh University. After receiving technical support from Ben Franklin Technology Partners of Northeastern Pennsylvania, the team developed a business plan, completed their market evaluation and developed a product formulation. SolarCare set up shop in BFTP/NEP’s business incubator, at Lehigh University’s Mountaintop Campus, and received a \$95,000 investment from BFTP/NEP to finalize development of the towelette product. SolarCare was successful at licensing its sunscreen towelette to Schering-Plough—the manufacturer of Coppertone suncare products.

With one success under its belt, the company moved from sunscreen to enzyme immunoassay tests for the insurance risk assessment market. As Chief Scientific Officer of the company at the time, Niedbala steered research efforts toward the development of diagnostics. Solar Care received another investment from BFTP/NEP, for \$140,000 that went toward enhanced product development and commercialization and allowed the company to work with professors from the university.

The company acquired the assets of another BFTP/NEP client, Enzymatics, including its patented saliva alcohol test, in 1994. In 1995, renamed STC Technologies, the company secured exclusive worldwide patent and trade secret licenses for a diagnostic label technology called Up-Converting Phosphor Technology (UPT), and signed multiple party agreements to license the technology worldwide. STC collaborated with California-based SRI International, and Leiden University, in the Netherlands, on the development of the UPT technology.

UPT allows rapid, high sensitivity multiplexed diagnostic testing—in some cases, with orders of magnitude greater sensitivity than previously available tests—for selected biological pathogens, thereby allowing for the earlier detection of diseases in clinical settings. The technology is also the basis for a full panel of rapid test products administered in clinical settings for drugs of abuse testing in oral fluids. STC successfully secured several major research and supply agreements with other companies, based on its broad patent protection for UPT.

STC raised \$4.6 million in a private placement of common stock in 1996. In 1999, STC raised \$9.1 million in venture capital, including an investment from Pennsylvania Early Stage Partners. Then, in 2000, STC merged with Epitope, Inc., of Beaverton, Oregon, to become OraSure Technologies, Inc. Epitope was a publicly traded (NASDAQ) biotechnology company that developed and marketed medical products—including its OraSure fluid collection device—through its Epitope Medical Products Group. Epitope also worked to develop and commercialize novel agricultural products through genetic engineering and other techniques within its Agritope group. The new company was able to combine and leverage the expertise of both companies in oral fluid technology, infectious disease testing and substance abuse testing. OraSure trades on the NASDAQ stock market, and has created more than 200 jobs and millions of dollars in payroll in the Lehigh Valley. Sam Niedbala returned to Lehigh University as Professor of Practice in the Department of Chemistry, after leaving OraSure in 2004.

Early Chronology of a Lehigh Valley Life Sciences Success Story: OraSure Technologies, Inc.		
	Solar Care Technologies, Inc. / STC Technologies, Inc.	Epitope, Inc.
1985	Solar Care begins as a classroom project for “sunscreen on a towelette” at Carnegie-Mellon University. “Three guys and a dog” receive technical support from BFTP/NEP and \$95,000 investment. Move into Mountaintop Incubator.	
1988	The Wall Street Journal features SolarCare in “David vs. Goliath” story. Company receives opening orders from K-Mart and Wal-Mart.	
1991	SolarCare signs license agreement with Coppertone to market SunSense towelette worldwide. SolarCare develops and ships assays to its first insurance customer.	FDA clears the EPI-blot HIV-1 test kit for commercial distribution.
1993	SolarCare completes clinical trials, receives regulatory clearances, and begins to set up distribution to sell its portable cryosurgical system to physicians.	
1994		Receives FDA clearance to sell OraSure to professional markets for the screening of HIV-1 antibodies.
1995	Name changes to STC Technologies, Inc. STC completes purchase of assets from Enzymatics. Begins to sell patented saliva alcohol test. Signs multiple party agreements for worldwide license to Up-Converting Phosphor Technology (UPT) patents.	Enters into agreement with SmithKline Beecham plc for exclusive distribution rights to OraSure.
1996	STC raises \$4.6 million in a private placement of common stock.	FDA approves OraSure Western blot test.
1997		Distribution of second generation OraSure oral fluid collection device begins.
1998	International office established in the Netherlands. Sales grow to \$10.6 million (34%). Important UPT milestones. Acquires exclusive distribution rights for Epitope’s OraSure Oral Specimen Collection Device for use in drugs abuse testing.	5-year supply and distribution agreement with STC Technologies for drug abuse products. Receives approval for testing of life insurance applicants in Japan. Enters into agreement to develop DNA testing kits using OraSure with Analytical Genetic Testing Center, Inc.
1999	Raises \$9.1 million in venture capital. Sales grow to \$14 million (32%). STC prepares to launch Intercept oral fluid drug testing service.	NIH approves SBIR grant to develop syphilis test. Department of Veterans Affairs places OraSure HIV-1 on the Federal Supply Schedule. Receives approval to use European CE Mark for OraSure.
2000	STC becomes anchor tenant in Beth Tech II.	
	STC Technologies, Inc. and Epitope, Inc. merge on September 29, 2000. The merged company is renamed OraSure Technologies, Inc. Headquarters at Bethlehem’s Tech Campus. Builds Beth Tech III.	

***The Lehigh Valley’s location provides distinct advantages to companies in the life sciences industry, with respect to access to capital, regulatory markets and strategic partnering.*** Geographically, the Lehigh Valley is located at one vertex of a highly concentrated triangle of life sciences research, education and commercial activity, running from Wilmington-Greater Philadelphia, northeast across central New Jersey to northern New Jersey-New York City (and suburbs), then west to the Lehigh

Valley, and south again, back to the Philadelphia suburbs. The area contained in that triangle is home to a number of major academic life sciences research institutions; US headquarters and operations of most of the major pharmaceutical companies<sup>40</sup>; some of the largest, most prominent and successful life sciences venture capital firms; and an internationally recognized burgeoning biotechnology cluster (in the Greater Philadelphia area)—not to mention the law firms that specialize in life sciences intellectual property and contracts, the accounting firms, executive search firms and all of the other ancillary support services that help to create and complete a sustainable life sciences “ecosystem.” All of these areas are connected by a comprehensive network of major highways—so that if the resources a company needs are not immediately available in the Lehigh Valley, more than likely they are available within a two-hour car ride.

Looking just outside of this triangle, to the south, one encounters the complex of life sciences research, education and regulatory institutions and establishments running from Baltimore to Washington, DC—much of it less than two hours by train from Philadelphia, which is one hour away from the Lehigh Valley. These resources include the Food and Drug Administration, the National Institutes of Health, Johns Hopkins University and the cluster of biotech companies and research facilities that dot the so-called “DNA Valley,” around Rockville, Maryland. Thus, it is possible to drink your coffee at home in the morning, meet with the nation’s lawmakers; regulators; some of its best scientists; most successful venture capitalists; or largest life sciences companies during the day and be home in time to sleep in your own bed that same evening. Other parts of the world that play a major role in life sciences—the US west coast and the markets or Europe—are almost equidistant in travel time from the Lehigh Valley.

The Lehigh Valley offers distinct advantages over many other locations with respect to cost of living as well as many business costs. While the market for the most educated life sciences workers is national, if not international, lower living and business costs are important for larger companies with big payrolls and vertically integrated elements of research, production, marketing and distribution. In particular, the cost savings—to companies and employees—can be significant in the Lehigh Valley over other locations.

At present, the cost advantages of conducting business and living in the Lehigh Valley favor it over other locations around the US with reputations as life sciences centers. The announcement and move of Olympus America’s headquarters and distribution center operations from Melville, New York, on Long Island, to the Stabler Corporate Center in Upper Saucon Township—to be completed by August 2006—is attributable in part to the savings that will accrue to the company<sup>41</sup> as well as its employees (whose purchasing power, especially for big ticket items like housing, will increase). Olympus America will also benefit from its proximity and access to the talent and expertise of faculty and students at Lehigh University and other education institutions in the area where it may choose to collaborate. Olympus America has already begun recruiting new employees on college campuses in the Lehigh Valley. The company’s Group Vice President and General Manager, Life Science, is Dr. Stephen S. Tang, who received his M.S. and Ph.D. in chemical engineering from Lehigh University, and was once Assistant Director and Senior Research Engineer at Lehigh’s Center for Molecular Bioscience and Biotechnology.

A general framework for understanding business geography preference based on establishment function is presented in a 2000 Working Paper, “Business Location Decision-making and the Cities: Bringing Companies Back,” prepared for the Brookings Institution.<sup>42</sup> The framework was based on interviews with corporate site selection managers, planning and location consultants, economic development specialists and academics who study corporate location, as well as a review of trade literature, “white papers,” and consulting firms’ industry reports.

<b>Business Geography Preference as a Function of Establishment Type</b>			
<b>Establishment Function / Type</b>	<b>Location Priorities</b>	<b>Sensitivity to Cost</b>	<b>Examples of Preferred Locations</b>
<b>Headquarters</b>	<ul style="list-style-type: none"> <li>• Accessible international air service</li> <li>• High-end hotels, restaurants, entertainment, cultural events; major league sports team / stadium with skyboxes to facilitate heavy inter-company face-to-face interaction</li> <li>• Professional support services, good choice of office space or availability of land to build-to-suit</li> <li>• Diverse professional employee base</li> <li>• Attractive housing for executives, affordable housing for managers and support staff within reasonable commute</li> <li>• Strong educational system for employee's children and continuing adult education</li> </ul>	Cost sensitivity (within a normal range) is less important than availability of key requirements.	Central cities or strong first tier suburbs (e.g., Washington, DC's suburbs: Prince William, Fairfax and Loudon Counties); northern suburban Atlanta, Charlotte, Dallas, Raleigh-Durham
<b>Research &amp; Development</b>	<ul style="list-style-type: none"> <li>• Proximity to concentration of universities</li> <li>• Clusters of highly educated workers, or alternatively, lifestyle amenities that are attractive to this pool of talent</li> <li>• Control over physical environment—to buffer company from nosy neighbors, sharing of secrets by employees</li> </ul>	Cost sensitivity is less important than the availability of talent and other requirements (although R&D may be more sensitive to cost than headquarters)	Near universities, in large metropolitan areas; campus locations favored; Route 1 near Princeton, NJ, home of several pharmaceutical companies
<b>Back Office</b>	<ul style="list-style-type: none"> <li>• State of the art telecommunications capacity</li> <li>• Affordable housing costs</li> <li>• Quality labor force with technical skills</li> <li>• Good schools for employee recruitment and their children</li> <li>• On-going available adult education and training</li> </ul>	Sensitivity to cost: real estate, telecommunications, housing, taxes	Medium and small sized cities: Tampa, FL; Tucson, AZ; former military installations; in large metropolitan areas prefer suburbs
<b>Manufacturing &amp; Distribution</b>	<ul style="list-style-type: none"> <li>• Good transportation system; near major interstates</li> <li>• Strong utility systems: electric, water, wastewater, gas</li> <li>• Well-educated workforce; strong specialized training programs</li> </ul>	Sensitivity to housing costs, taxes, utility rates	On interstate, near large markets; access to suppliers (Chicago-Aurora; Cincinnati south suburbs and northern KY; Jacksonville, FL; Kansas City, MO western suburbs)
<b>Source:</b> "Business Location Decision-making and the Cities: Bringing Companies Back"; Natalie Cohen; Working Paper prepared for the Brookings Institution Center on Urban and Metropolitan Policy; April 200; p. 8.			

### **3.3 Community and Regional Challenges**

In a multidimensional world, there are usually two sides to every story—at least. And so, there can be no strengths without weakness. The optimist and the realist both recognize that circumstances change and often—with some effort—can be changed. Weakness can be eliminated or turned into strength. But first it has to be identified.

***Life sciences activities in the Lehigh Valley are taking place in the shadow of recognized life sciences clusters elsewhere in Pennsylvania.*** As a result, at the present time, outside of the Commonwealth, the Lehigh Valley remains, albeit unintentionally, a well-kept secret. Furthermore, inside Pennsylvania, there is a tendency to associate life sciences activity with other parts of the state, not the Lehigh Valley.

It may not be quite as simple as Anonymous once said, “If you won’t blow your own horn, you can’t be in the parade”; nevertheless, part of the challenge to growing life sciences activity in the Lehigh Valley has to do with capturing and conveying the sector’s impact. While other parts of the state may have larger concentrations of life sciences activity—and more specificity as regards the disciplinary characteristics of activity (for example, at the most rudimentary level, tissue engineering or medical devices or biopharmaceuticals, etc.)—the Lehigh Valley does have in sufficient concentration many of the elements and characteristics that comprise an industrial cluster, but the elements are not as interconnected as they need to be. At the present time, the life sciences cluster in the Lehigh Valley is in its nascent or emergent stage. Much of the work that has to occur is internal and has to do with linking resources—that is, building interconnectedness.—in addition to external activities like marketing to attract new resources. While some activities—internal and external—can be conducted in parallel, it is best to work on strengthening the Lehigh Valley’s interconnectedness before a full scale outward campaign to advertise and bring in new resources. Otherwise, attraction strategies could exceed the capacity to integrate new resources.

And how to determine when the cluster has achieved sufficient mass to be sustainable? Anecdotally, two measures are when employees can “job hop” easily

within the sector and when the well-documented daily commute out of the Lehigh Valley (toward Manhattan) begins to subside.

***The social fabric or network around life sciences activity is not fully developed in the Lehigh Valley.*** This observation is an extension of the previous thought. Specifically, the links that connect industry with academia, industry with industry (as, for example, strategic partnering) and the health care delivery system with other elements of the life sciences cluster are not fully functional. There are companies in the area that are not part of the local life sciences community but should be. There are roles that are not being played but that are the responsibility of local institutions. In some cases, the results of such omissions are negligible, while in others they represent major obstacles to progress on the way to sustainability and growth within the cluster.

In the early stages of cluster development, many informal relationships grow between individuals in various institutions—that is, sometimes the only way to get something done if you cannot do it yourself, is to pick up the telephone, call someone and ask them to do it. That may require individuals to step outside of their perceived roles or to assume responsibility that extends beyond their sphere of influence; neither situation is particularly effective or desirable.

For the cluster to succeed, roles and responsibilities need to be institutionalized. The responsible organizations must have the appropriate organizational capacity. Typically, that means appropriate staff capacity—appropriate skills, the appropriate number of employees, appropriate departments and responsibilities. To build and sustain institutional and organizational relationships the roles of liaison, contacts, and others have to exist in somewhat standalone fashion, and not be added as responsibilities to individuals whose time and job descriptions suggest otherwise. Champions and advocates may come and go, as will those with “informal” responsibility for building bridges. The need for creating liaison positions with appropriate authority, responsibility and accountability inside various institutions is very real. For other, smaller organizations, an external coordinator—inside a public organization—may be appropriate.

***Technology commercialization and spin out activity is still immature in the Lehigh Valley.***<sup>43</sup> Of all the higher education institutions in the area, only Lehigh University has a technology transfer department—which also works to review and protect intellectual property at Northampton Community College. Lehigh is also the only research university in the area. The tech transfer department at the university is still very young—and like most, if not all universities, the incentives for faculty (in particular, junior faculty still working to obtain tenure) have nothing to do with patenting or commercialization.

With respect to spin out activity from commercial establishments, the record is mixed. Some local start ups are working with technology that was licensed from companies in the area (or just outside), but just as many are working with technology licensed in from well beyond the Lehigh Valley. A few local companies in the life sciences sector began as spin outs, not many.

***There are “missing players in the Lehigh Valley, as compared with other areas that are focused on growing life sciences activity.*** For example, there is no local medical school.<sup>44</sup> While there is seed money available, there are no local venture firms engaged in life sciences investing. While the hospital network in the Lehigh Valley is extensive, the provision of clinical care is the primary focus, not research or teaching.

All of these shortcomings can be rectified in one of two ways. The first way requires a lot of money and a lot of time—and is not likely to occur, given fiscal and political realities. The alternative—and more immediate solution—is to connect with the necessary institutions that exist just beyond the Lehigh Valley—for example, in Greater Philadelphia, north and central New Jersey and New York. The Lehigh Valley’s location (see “Lehigh Valley Strengths”) provides ample opportunities for making such connections. Such efforts require dedicated resources and commitment to succeed.

***Just as weaknesses can become strengths, the opposite is also true.*** Already, the cost of living in the Lehigh Valley is rising, traffic congestion and suburban sprawl are growing, and some would argue that the Quality of Life advantages offered by the area are beginning to fade. The December 2003, report of the Brookings Institution, “Back to Prosperity: A Competitive Agenda for Renewing Pennsylvania,”

documented many of these challenges and took a close look at such activity in the Lehigh Valley.<sup>45</sup> The report also made recommendations for reversing many of these trends, although some would argue that they are the byproducts of success rather than failures in and of themselves.

**Postsecondary educational attainment in the Lehigh Valley lags the nation, albeit slightly.** This is an important workforce issue for a region that intends to pursue high tech economic development<sup>46</sup>—especially in the life sciences.<sup>47</sup> The Lehigh Valley does present a better picture, in terms of postsecondary educational attainment, than the entire Commonwealth.

<b>Educational Attainment in the Lehigh Valley, PA and US (2003)</b>			
<b>Population 25 years and over, 2003</b>	<b>US</b>	<b>PA</b>	<b>L.V.</b>
<b>Graduate or professional degree</b>	9.65%	8.82%	9.35%
<b>Bachelor's degree</b>	16.89%	15.39%	16.18%
<b>Associate degree</b>	6.99%	6.66%	9.60%
<b>Some college, no degree</b>	20.29%	15.39%	12.97%
<b>High school graduate (incl. equivalency)</b>	29.80%	39.35%	37.43%
<b>9<sup>th</sup> to 12<sup>th</sup> grade, no diploma</b>	9.94%	10.53%	9.83%
<b>Less than 9<sup>th</sup> grade</b>	6.45%	3.86%	4.65%
<b>Source:</b> US Census Bureau, American Community Survey, 2003 Data Profile			
<b>Note:</b> Data universe is limited to the household population, and excludes those living in institutions, college dormitories and other groups.			

To an extent, educational attainment reflects the composition of industry and types of jobs available in a community—that is, with the exception of college students, residents typically live close to where they work—and where they can find work. Likewise, companies prefer to locate in regions where the workforce meets their needs, in terms of size, availability and skill set (including degrees and other credentials).

Startup companies in the life sciences sector are especially knowledge-intensive. As those companies grow, their labor requirements change. The high concentration of residents in the Lehigh Valley with associates degrees may prove advantageous to larger companies who require technicians and similar occupations.

### **3.4 Opportunities on the Horizon**

***The world of human medicine is changing at an accelerating rate.*** Several factors are driving the market—for example, demographics (the population is aging, while living longer and remaining active); financial factors such as reimbursement, the exorbitant cost of (and time associated with) bringing new drugs from the laboratory to the market and the risk of commercial failure, and a hungry venture capital investment community; the rapid pace of scientific discovery; and regulation. The result is continued transformation and evolution of the life sciences sector, along with continued demand for new products—devices, diagnostics and biologic agents—albeit produced via a different model than in the past.

***Traditional big pharma is consolidating while new opportunities arise for niche players as a result of firm specialization and the move away from vertical toward horizontal integration.*** The genomic and proteomic revolutions; the focus on translational research—accelerating “bench to bedside”; personalized medicine to target and increase efficacy and effectiveness—these are among the waves beginning to build. From 1992 through 2001, \$16.6 billion (1996\$) of venture funding was invested in 526 biopharma firms, with an additional \$8.9 billion and \$10.6 billion going into device companies and medical information services/health care, respectively.<sup>48</sup> The total expenditure on biopharma R&D in 2004 was estimated to be over \$47 billion<sup>49</sup>, and the total domestic market for medical devices and diagnostics was over \$80 billion.<sup>50</sup> Within those numbers are many stories and many opportunities.

For the Lehigh Valley, with an array of suitable components for developing a sustainable life sciences cluster, the opportunities arise because the old models for drug discovery and development are fading; the dominance of big pharmaceutical companies is waning (and they are still terrific repositories of experienced management talent, competent scientists and technicians); outsourced research and development have gained wide acceptance; and firm specialization and niche opportunity targets are growing. In 2001, out of 308 venture-back biotech firms nationwide, nearly 50 percent had 20 or fewer employees and 80 percent had 50 or fewer.<sup>51</sup> Likewise, out of a

universe of more than 5,000 medical device and diagnostics firms nationwide (all ownership types), two-thirds had fewer than 20 employees.<sup>52</sup> Outside investment in such firms and internal spending on R&D were both substantial numbers. Clearly, the opportunities are no longer just with the old and mighty but today also with the young and innovative.

***Life sciences cluster drivers—through which indigenous, local growth is achieved—are available technology; availability of capital; quality of labor force; quality and capacity of physical infrastructure (that is, plant and equipment); the extent and competency of entrepreneurial assistance; the mix of entrepreneurial firms (by life cycle stage); and the social network infrastructure and associated “buzz.”*** By comparison, life sciences industry drivers today, beyond demographics, are research, development, manufacturing, sales and distribution associated with specialization and vertical integration; innovation and new technology. Industry drivers help explain and predict total market size, while cluster drivers explain where such growth will occur.

Major technological breakthroughs driving life sciences and the quest for personalized medicine include genetic sequencing; the development of new molecular techniques, advances in imaging, the integration of advanced information technology into life sciences and nanotechnology. Innovation and new technology is allowing for increased understanding of disease processes, greater prevention, earlier detection, more effective treatments and cures.

***The Lehigh Valley has all of the industry components that are suitable building blocks for life sciences cluster growth—to some extent.*** The concentration, impact and interconnectedness of these assets must be strengthened.

### **3.5 Threats: Watch Out!**

What could spoil the party for life sciences growth in the Lehigh Valley? The bad news is, a lot. The good news is that most of the threats are not unique to the location; so while the playing field may not be level, very few regions are assured of success, and most face the same or similar threats, albeit to different degrees.

***While the Lehigh Valley shows great promise as a Life Sciences center, there is a lot of work that remains to be done.*** The region has seen its share of success turned upside down in the past. Once it was among the top producers of steel in the world, as well as a major producer of cement. More recently, during the nineties there was widespread enthusiasm for telecommunications as a high tech panacea. The meltdown at the end of the decade tempered expectations.

It would be prudent to approach life sciences cluster development with realistic, pragmatic expectations—the rewards of success can be great, but there is a lot of hard work that needs to be done. Job creation tends to be slow at first, but almost all of the jobs that are created are high quality with relatively high wages as compared to other sectors. As a result, there is intense competition—instate, as well as nationally and internationally—to grow life sciences. Some regions will lose. Some will suffer the winner’s curse—that is, overpaying for what they get.

Without excess funds to “buy” rather than build a life sciences cluster, the best efforts will be those that pay attention to existing resources—to grow them and retain them while also looking to attract outside resources. In that way capacity building becomes organic and sustainable—and outsiders will notice and look to join the successful effort—rather than chronically requiring new infusions of capital to attract new companies to replace the ones that keep leaving. Some turnover is inevitable and even necessary to maintain vitality—that is, economic churn or, as Schumpeter put it, “creative destruction”—but a healthy cluster, like a healthy ecosystem, must achieve equilibrium even before growth. This sort of dynamic equilibrium requires focus and discipline to achieve. Growing a sustainable life sciences cluster in the Lehigh Valley will require considerable patience, perseverance and tenacity.

Recently, while not high tech, there is competition from and growing favor among some proportion of the Lehigh Valley’s population and government representatives for casino gambling and related development as an economic development alternative. Unlike the incentive packages and “patient” capital required for much high technology to firmly root and grow, the gaming industry appears to many to be a ready source of tax revenue and jobs. Besides creating some immediate challenges relating to real estate speculation, it remains to be seen whether this will sap enthusiasm for high tech economic development such as life sciences, whether it will be a chimera or will bring the economic rewards so highly touted,<sup>53</sup> and whether it can coexist with other emerging economic drivers.

***Globalization brings opportunities but also risks.*** The future may be more difficult to predict—and prepare for—than ever. The competitive landscape can change dramatically and suddenly. At the present time, many communities and economic development initiatives are focused on the development of life sciences. The competition is local, national and international, with many players willing to commit tens, if not hundreds, of millions of dollars. Some aspects of the drug development process (for example, some clinical trials) have effectively been *outsourced* as well as *offshored*.<sup>54</sup> Countries such as India can no longer be regarded as Third World, when it comes to advanced technology—the Indian healthcare system even benefits from the number of repatriated physicians and researchers who have spent time working in or have been trained in the United States.

***The economic development community is awaiting the Supreme Court’s decision in DaimlerChrysler v. Cuno***, the case that questions the legality of local economic development incentives. The plaintiffs argue that such incentives violate the Commerce Clause of the US Constitution. The Court heard the case during this session<sup>55</sup>, and is scheduled to rule later this year. The decision could have major implications for many economic development strategies that are based on incentives and other concessions, the merits of which have been under scrutiny by economists for many years.<sup>56</sup>

***Much life sciences activity occurs in the face of strict regulatory requirements.*** In combination with other factors, business growth in the sector remains highly volatile, expensive and full of risk. According to the Tufts Center for the Study of Drug Development (CSDD)<sup>57</sup>, annual R&D spending adjusted for inflation has “risen sharply in recent years”<sup>58</sup> (from just under \$5 billion [2004\$] in 1980, to just under \$35 billion [2004\$] in 2004), while the number of new drug approvals (NCEs) has declined.<sup>59</sup> In 2003, CSDD determined that the average R&D cost per new drug was \$802 million (2000\$; including post approval development raised the average capitalized cost to \$897 million).<sup>60</sup>

### New Drug Development Process (representative)

- Discovery & pre-clinical testing (1-3 yrs.; avg. = 18 months)
  - Combinatorial chemistry → synthesis & purification
  - = Compound library (**5,000 NCEs/candidates**)
  - Animal testing (short-, long-term; **250 compounds**)
- **IND** application to FDA (**5 drugs**) → clinical testing
- **Phase I** – safety & dose response (20-100 healthy subjects; **6 mos.-1 yr.**)
- **Phase II** – safety, effectiveness, side effects (100-500 patients; **6 mos.-1 yr.**)
- **Phase III** – comprehensive statistical data (1,000-5,000 pts; **1-4 yrs.**)
- **NDA** submission & FDA review (avg. = **24 mos.**; **1 drug approved**)
- Post-approval surveillance & development

**On average:**

- 5,000 New Chemical Entities are reviewed for every 1 that is approved.
- New medicines required 8.5 years to reach approval (2002-04).
- Capitalized cost per new medicines is \$800 million (2000\$) to reach approval.
  - Nearly \$900 including post-approval development costs.

**Source:** US Food and Drug Administration; Tufts Center for the Study of Drug Development; “The Cost of New Drug Discovery and Development”; Michael Dickson and Jean Paul Gagnon, in “Discovery Medicine,” V. 4, N. 22; June 2004; pp. 172-179.

The length of time to bring regulated devices and diagnostics to market (also with no guarantees of commercial success or recovery of costs) is somewhat shorter and slightly less costly but daunting, nonetheless. Such challenges are behind the push for

new innovations and business models to reduce or otherwise mitigate risks.

***Other factors may put stable or sustainable life sciences growth in the Lehigh Valley, at risk.*** In other words, “we don’t know what we don’t know.”<sup>61</sup>

#### **4. The Potential for Life Sciences Growth in the Lehigh Valley**

In addition to the important contributions that life sciences discoveries bring to all of humanity, the sector shows significant potential for creating economic benefits in the Lehigh Valley. Those opportunities accrue through the formation of new businesses, the expansion of existing firms and attraction of new firms and the corresponding increase in high-paying employment generated directly and by supporting industries.

In order for such activity to occur, it is necessary to provide the appropriate infrastructure and connecting support fabric. The Lehigh Valley shows great promise of success for life sciences cluster development. It has, to varying extent, all of the industry components that are suitable building blocks for life sciences cluster growth. Much work and many activities must occur, however, before life sciences cluster development in the Lehigh Valley achieves a sustainable dynamic equilibrium.

- The Lehigh Valley shows some development of all of the industry drivers necessary for life sciences cluster growth. These include: available technology; availability of capital; quality of labor force; quality and capacity of physical infrastructure (that is, plant and equipment); the extent and competency of entrepreneurial assistance; the mix of entrepreneurial firms (by life cycle stage); and the social network infrastructure and associated “buzz.”

Much of the emphasis today on knowledge-driven or technology-based economic development is rooted in the theoretical work of Stanford economist Paul Romer and his

predecessors, such as MIT economist, Robert Solow. Solow addressed the problem of diminishing returns to labor and capital by including a new variable in his economic growth equation—technology—for which he won the Nobel Prize in Economics in 1987. Romer was one of the primary developers of New Growth Theory, which explains *increasing returns* through technology as a result of continuous innovation.<sup>62</sup> The praxis of economic development posited on New Growth Theory has been widespread, with Michael Porter, of Harvard University advancing the notion of geographically concentrated competitive economic clusters.

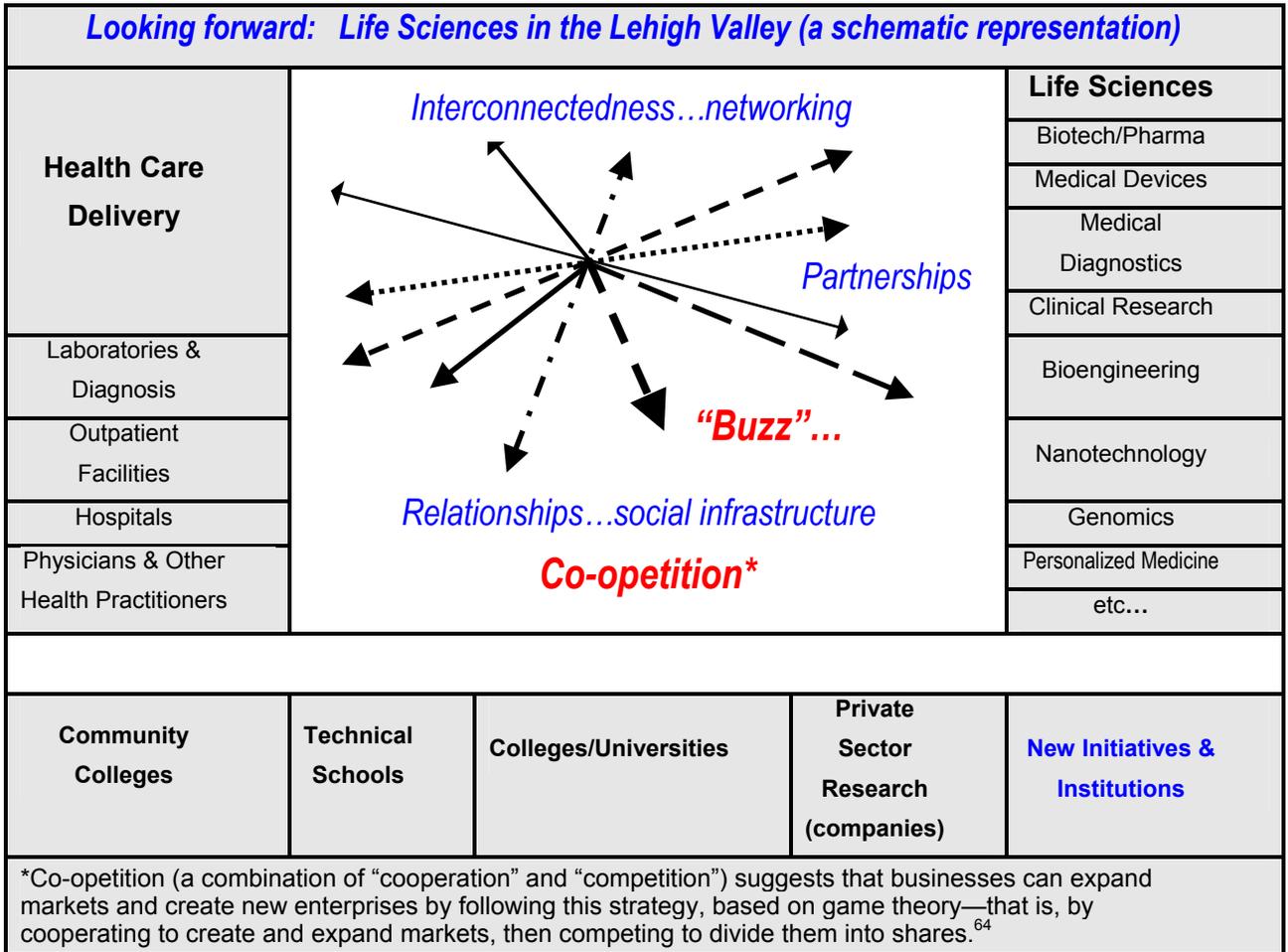
- **Life sciences cluster growth as an economic development tool is rooted in the premise of increasing returns that are driven by technological advancement and innovation.**
- **Innovation flourishes in the presence of:**
  1. Expertise—which can be regarded as a combination of talent and R&D capacity;
  2. A strong physical (for example, proximity and compatible research facilities) and social network to enable easy interaction and spontaneous dialogue;
  3. Diversity of thought, discipline and people—to promote “outside-the-box” (Aha!...Eureka!!) thinking.

The Council on Competitiveness engaged Michael Porter to lead the analysis for its Clusters of Innovation initiative, which ran from 1998 to 2001.<sup>63</sup> The initiative developed a framework to assess cluster development and innovative performance at the regional level. Research focused on how clusters form, why they are critical to a region’s economic future, and how stakeholders can help regional clusters thrive. Among the findings regarding cluster development:

1. Raising awareness of the cluster among local businesses and institutions increases cluster success.
2. The intersection of existing clusters creates new opportunities for firm and cluster development.
3. Anchor companies play a disproportionate role in cluster development.
4. The success rate for start ups can be raised—and failures reduced—through a hospitable environment and appropriate mechanisms for collaboration.

With respect to formulating regional strategy for cluster development, the research found that:

1. Regions often encounter a common set of challenges requiring regionally crafted solutions.
2. Regional transition is challenged by the need to move off performance plateaus.
3. Broad-based collaboration is a necessity for successful development strategies.
4. To engage broad support and coordinate activities requires shared economic vision.
5. Strong leadership is a necessity.
6. The process is simplified where a coordinating organization exists.



The recommendations in the next section, for growing the life sciences cluster in the Lehigh Valley, are based on a synthesis of the analysis and interviews carried out for this project and detailed throughout this report, as well as the extensive body of literature dealing with cluster development praxis (and briefly cited in this section.)

## 5. Recommendations for Strategy

Much of the work related to growing Lehigh Valley life sciences can be summarized thusly: *Communicate, Coordinate, Execute*. The strategy contained herein can be implemented without significant additional investment, thus there are few recommendations for large capital improvements. It mostly involves hard work—sweat equity—and in many cases it may require the reorganization or realignment of existing resources and efforts. In greater detail:

### 1. Strategy: Create and communicate a vision for Lehigh Valley Life Sciences.

- a. Activity: Create a Vision Statement.
- b. Activity: Develop performance metrics and milestones for achievement. Monitor regularly.

- Performance metrics must be scientific and commercial. Metrics can change over time—as the cluster matures.
- The goal for life sciences in the Lehigh Valley is to build a cluster of sustainable, profitable companies.
- Example metrics include (but are not limited to):
  - Number of companies,
  - Number of profitable companies,
  - Number and value of products (drugs, diagnostics, devices/instruments, etc.)—launched and in the pipeline,
  - Output growth,
  - Revenue growth,
  - Profitability,
  - Employment growth,
  - R&D spending,
  - External capital attracted—for example, venture capital, federal and industrial research investment,
  - Number and type of strategic partnerships,
- When performance metric achievement becomes the goal, be S.M.A.R.T.:
  - Specific / Significant,
  - Measurable,
  - Attainable / Actionable / Agreed upon,
  - Realistic / Results-oriented / Responsible,
  - Time-based / Trackable / Transparent.

- c. Activity: Create a gateway or “regional portal” for entry to the life sciences community.

There should be “lighthouse” for life sciences in the Lehigh Valley, to promote cluster awareness within the community and beyond. Other activities should utilize this hub. While a life sciences association may be a dues-paying membership organization, the hub should be a resource (to some extent) for all. The success of life sciences cluster development depends not just on the companies and institutions directly involved, but also on community support.

- d. Activity: Identify a champion within the community to advance and support the effort.
- e. Activity: Develop a marketing strategy for the Lehigh Valley life sciences cluster.

## **2. Strategy: Create a regional life sciences association.**

The Regional Biotech Council of Central Bucks County (<http://www.rbccb.com>) is a nearby community-based life sciences association that can serve as an example—and resource—on which to model a Lehigh Valley life sciences association. There are many other examples available for study. The Lehigh Valley should utilize these resources to design the organization that fits its needs.

- a. Activity: The association’s roles include providing information, becoming a networking forum, communication, acting as a conduit to technical and financial support providers, mentoring and community outreach.
- b. Activity: Association membership should be open to individuals, firms, service providers, academic institutions, hospitals and others—that is stakeholders and potential stakeholders—in and outside the region.

- c. Activity: The association’s early agenda should be established based on the needs of members.
- d. Activity: There should be regular, frequent meetings.

**3. Strategy: Monitor and support regional infrastructure requirements necessary for growth.**

- a. Activity: Identify and support the requirements for physical space, including wet labs and office space, at both the incubator and post incubator stage of development.
- b. Activity: Identify and support the requirements for common or shared equipment. What is needed? Where should it be housed? What are some of the means to fund its acquisition?
- c. Activity: Establish pathways to conduct early clinical trials in the community.
- d. Activity: Identify new funds for early stage development. Leverage investments to maximize return.

**4. Strategy: Strengthen the regional social network.**

- a. Activity: Expand outreach to companies. Explore strategic partnering opportunities.<sup>65</sup>
- b. Activity: Strengthen industry-academic links. Proactively market academic resources available.
- c. Activity: Create and train “ambassadors”—from industry and academia—to market the region’s resources.

- d. Activity: Explore the role of the hospitals further. How can they achieve their objectives and become more closely integrated into the local life sciences community?

The Pittsburgh Regional Healthcare Initiative (<http://www.prhi.org>) is an example of a regional consortium of medical, business, academic and civic organizations engaged in activities to improve safety and quality in health care, forge partnerships and become industry leaders in innovation. The Lehigh Valley has the resources to develop its own model that would provide benefits to all of the community stakeholders in addition to becoming a national model.

**5. Strategy: Build on early success (past and present). Explore future opportunities.**

The Critical Path Institute (C-Path; <http://www.c-path.org>) is an independent, publicly funded, non-profit organization in Tucson, Arizona, dedicated to the Critical Path Initiative, announced by the US Food and Drug Administration (FDA) in 2004. In a white paper published in March 2004, FDA called attention to the declining number of new medical product submissions and cited the need for innovations in drug development. During the past decade, R&D expenditures for the US biopharma industry rose 250 percent, and the National Institutes of Health (NIH) budget for biomedical research doubled, yet the number of innovative new therapies submitted for FDA approval declined by approximately 50 percent.<sup>66</sup> That report and subsequent studies concluded that the time-consuming and inefficient process for preclinical and clinical testing of drugs is a major factor contributing to the bottleneck in drug development.

The Critical Path Institute is dedicated to the accelerated, safe development of new medicines. C-Path has three founding partners: US FDA, the University of Arizona<sup>67</sup> and SRI International (Menlo Park, CA).

The FDA's focus on the Critical Path Initiative and the NIH Roadmap for Medical Research, with a focus on translational research, create opportunities that should be explored as the Lehigh Valley life sciences cluster develops.

- a. Activity: Celebrate every victory, no matter how small. It is too early and there are too many gaps—that is, unexplored, missing or undeveloped resources—to declare a particular cluster focus (for example, diagnostics, tissue engineering). Watch how resources develop.
- b. Activity: Focus on retaining the resources that are here. The Lehigh Valley has proved the ability to “grow its own,” but not to retain those assets.
- c. Activity: Attraction activities should focus on “base hits,” not “home runs.” The Lehigh Valley nurtures and nourishes growth.
- d. Activity: Develop a strong feedback loop to understand successes and learn from failures. Adjust accordingly.

## **Appendix: Companies**

[This appendix contains a listing of publicly traded and privately companies active in various aspects of the life sciences in the Lehigh Valley, including research, development, manufacturing and distribution. Material in this index was compiled from company websites, industry trade directories and other sources. This appendix does not include information on hospitals and higher education institutions, much of which is detailed elsewhere in this report.]

## **Appendix: Companies**

- **ABEC, Inc.** (Symbol: Private)  
3998 Schelden Circle  
Bethlehem, PA 18017  
Phone: 610-861-4666  
[www.abec.com](http://www.abec.com)

**Industry Classification:**  
Scientific & Technical Instruments

ABEC, Inc. designs and manufactures cGMP production bioreactors and fermentors for the pharmaceutical and biotech industries. It was founded in 1975 to design and manufacture aseptic pilot and production scale bioprocess equipment. The company has implemented numerous bioreactor and fermentor design innovations and refinements, many of which have become industry standards.

ABEC's early innovations include electropolished vessel surfaces to improve cleanability and a non-pressurized agitator seal housing to eliminate the possibility of contamination from the outside environment. The company designs and manufactures: Bioreactors, Fermentors, Dual Purpose (Cell Culture/Microbial), Custom Control Systems, CIP Carts, CIP/SIP Stations, and Ancillary Equipment. The company provides its clients with rapid equipment validation, high system uptime, and superior process performance.

- **Advanced Research System, Inc.** (Symbol: Private)  
7476 Industrial Park Way  
Macungie, PA 18062  
Phone: 610-967-2120  
[www.arscryo.com](http://www.arscryo.com)

**Industry Classification:**  
Scientific & Technical Instruments

Advanced Research Systems, Inc. designs and manufactures cryogenic equipment and supplies. These include closed and open cycle cryogenic coolers and their standard or custom application interfaces that operate in the 1.7 to 800K temperature range.

- **Aesculap, Inc.** (Symbol: Private)

3773 Corporate Parkway

Center Valley, PA 18034

Phone: 800-258-1946

[www.aesculapusa.com](http://www.aesculapusa.com)

**Industry Classification:**

Scientific & Technical Instruments

Aesculap is the world's largest surgical instrument manufacturer. Aesculap designs and produces surgical instruments, implants and motors for several surgical specialties including ENT, plastic and reconstructive, thoracic, cardiovascular, orthopedic, gynecologic and general surgery as well as neurosurgery and minimally-invasive. The company was established in 1867.

Aesculap's product line include: Surgical Instruments for Laproscopy, Endoscopy, Neurosurgery, Orthopaedics, and Spine. The company's services include: STERILCONTAINER™ Systems, Sutures, Surgical Quality Management, Operations & Supply Chain Management, Education & Implementation, Per-Procedure Programs, Repair Services, and Consulting Service.

- **Air Products and Chemicals, Inc.** (Symbol: APD)

7201 Hamilton Boulevard

Allentown, PA, 18195

Phone: 610-481-4911

[www.airproducts.com](http://www.airproducts.com)

**Industry Classification:**

Product/Supplies

Air Products was founded by Leonard P. Pool, in Detroit, Michigan, in 1940. The company was built on the concept of producing and supplying industrial gases (primarily oxygen) on-site. Today, Air Products is an international company headquartered on a 600-acre campus in the Lehigh Valley. Air Products provides atmospheric gases, process and specialty gases, performance materials and chemical intermediates, serving customers worldwide in technology, energy, healthcare and industrial markets. Air Products has built leading positions in key growth markets such as semiconductor materials, refinery hydrogen, home healthcare services, natural gas liquefaction, and advanced coatings and adhesives.

Air Products has been providing products and services to the medical industry for over 50 years. In 2002, Air Products entered the U.S. homecare business, with the acquisition of American Homecare Supply (AHS), a privately-held corporation then ranked among the ten largest US homecare providers of respiratory therapy and home

medical equipment. With the AHS acquisition, the Air Products and its affiliates provides home medical services to more than 275,000 patients in 14 countries from more than 200 locations.

- **Applied Separations, Inc** (Symbol: Private)  
930 Hamilton Street  
Allentown, PA 18101  
Phone: 610-770-0900  
<http://www.appliedseparations.com>

**Industry Classification:**

Process R&D  
R&D Services (CRO)  
Instrument services  
Packaging (CRO)  
Services (CRO)

Applied Separations is a manufacturer and supplier of sample preparation and purification products for analytical laboratory and pilot plant. The company was started in 1987 to provide sample preparation products to analytical laboratories. To support and advance that mission, the decision was made to supply consumable products and instrumentation to the market.

Applied Separations secured research grants to develop manufacturing methods to produce consistently high quality Solid Phase Extraction (SPE) chromatography sorbents. The line of consumable SPE cartridges was marketed under the trade name Spe-ed – solid phase extraction and elution device. The company also started the Spe-ed SFE (supercritical fluid extraction) project. The SFE endeavor has been expanded with new models to meet specific needs of various markets, such as food and natural products. Due to customer demand, the company started engineering larger-scale SFE systems for process manufacturing, beginning in 1996.

Applied Separations has added two product lines: The fast PSE and one PSE. They were developed to fill a need in the pressurized solvent extraction field. The PSE replaces slow traditional extraction methods and saves time, money and solvents. In addition, the company has expanded its SPE line to include Flash Chromatography products. It has designed and manufactured Spe-ed Flash columns to meet the needs of researchers using automated organic purification instruments.

Applied Separations was one of the early participants in the Ben Franklin Technology Partnership, an incubator program for high technology start-up companies. In 1992, the company entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Department of Agriculture. In May 2001, it received an Allentown Downtown Economic Development Achievement Award.

- **NPR Healthcare** (Symbol: Private)

3894 Courtney St., Suite 180

Bethlehem, PA 18017

Phone: 1-888-786-7627

[www.atforyou.com](http://www.atforyou.com)

**Industry Classification:**

Retail Drug/OTC/Consumer Products

NPR Healthcare delivers innovative technology for advanced skin care. Applied Therapeutics<sup>®</sup> skin care and treatment products offer patients clinically proven solar ultraviolet protection and skin care treatment results. Applied Therapeutics<sup>®</sup> skin care and treatment products are designed for the prevention, as well as repair, of skin damage resulting from solar radiation exposure.

- **Arista Biologicals Inc** (Symbol: Private)

1101 Hamilton Street

Allentown, PA 18101

Phone: 484-223-0309

[www.aristabiologicals.com](http://www.aristabiologicals.com)

**Industry Classification:**

Product/Supplies

Arista Biologicals Inc is a manufacturer and supplier of rapid diagnostic reagents and equipment. It was founded in 1993 by Dr. John Colanduoni. Arista Biologicals designs, develops, manufactures, and markets reagents for the rapid diagnostic test industry. These biological reagents are primarily sold to diagnostic kit manufacturers. It offers technical assistance and components for rapid membrane based assays for fertility, DOA, infectious diseases, etc. Its reagents include colloidal gold conjugates, antigens, and antibodies including custom reagent operations, and assay development.

The company's other services include custom molding, devices, pipettes, desiccants, or arranging inexpensive OEM manufacturing overseas of components or kits. The company's custom applications have included veterinary, agriculture, environmental testing, tumor markers, and other disease state applications.

- **Azevan Pharmaceuticals, Inc.** (Symbol: Private)

115 Research Drive  
Bethlehem, PA 18015  
Phone: 610-758-5954  
[www.azevan.com](http://www.azevan.com)

**Industry Classification:**

Pharmaceuticals

Azevan Pharmaceuticals is developing next generation pharmaceuticals for the treatment of central nervous system disorders and cardiovascular disease. Their initial approach is to build on previous discoveries that the naturally occurring chemical arginine vasopressin (AVP) plays a significant role in psychiatric disorders related to anxiety/depression and the pathophysiology of congestive heart failure (CHF).

Azevan has three distinct AVP receptors – V1A, V1B, and V2. The V1A and V1B receptors are found in the brain. The V1A receptor also is found in the heart and blood vessels while the V2 is located in the kidneys. As a drug target, antagonism of these AVP receptors has been validated by the scientific community in animal models and clinical trials that show efficacy in diseases that include anxiety/depression, primary dysmenorrhea, CHF, edema, preterm labor, impulsivity/violence, and glaucoma. The company is developing products SRX251 for Primary Dysmenorrhea, SRX246 for Stress-related Affective Illness and SRX246 for Congestive Heart Failure.

- **Bio Med Sciences, Inc** (Symbol: Private)

7584 Morris Court, Suite 218  
Allentown, PA 18106  
Phone: 610-432-8220  
<http://www.silon.com/>

**Industry Classification:**

Wound Care

Bio Med Sciences Inc. (BMS) is a leading provider of scar management and advanced wound care products. The company was founded in 1987 to develop and market advanced materials for biomedical applications.

Bio Med has developed a technology that relates to the unusual physical and chemical properties of a blend of polydimethylsiloxane (silicone) and polytetrafluoroethylene (PTFE). Bio Med has successfully developed a product line using proprietary technology. Its product line consists of the Silon family of wound care and scar management products, sold into the burn treatment, plastic surgery, dermatology, and long-term care and rehabilitation markets. The company manufactures and markets the Silon®, Oleeva®, and Neosporin® Scar Solution™

brands of scar management products for the professional market, including burn centers and plastic surgeons.

BMS was able to gain the funds and recognition needed to succeed in a challenging market through a combination of state and local programs. BMS has received the Product Innovation award presented by the Ben Franklin Technology Partners of Northeastern Pennsylvania. Bio Med also received \$100,000 dollars in research funds from the Life Sciences Greenhouse of Central PA (LSGPA) to pursue Improved Topical Treatments for Hypertrophic Scars and Keloids. The company has a licensing agreement with Pfizer Inc for Neosporin® Scar Solution™.

- **Biocode Limited** (Symbol: Private)  
115 Research Drive  
Bethlehem, PA 18015  
Phone: 610-861-6965  
[www.biocode.com](http://www.biocode.com)

**Industry Classification:**  
Diagnostic/Imaging

Biocode owns a patented verification technology based on highly specific bio-engineered recognition molecules that detect inert chemical markers in or on products. The company specializes in human diagnostics and uses monoclonal antibody technology to identify minute quantities of various marker chemicals, which can be introduced otherwise undetectably into branded fibres, textiles and textile products. Biocode's clients include clinical biology labs and hospital labs.

- **Bioscience, Inc** (Symbol: Private)  
1550 Valley Center Parkway, Suite 140  
Bethlehem, PA 18017  
Phone: 610-974-9693  
[www.bioscienceinc.com](http://www.bioscienceinc.com)

**Industry Classification:**  
Agricultural/Environmental

Since 1984, Bioscience, Inc. has provided products, services and support for environmentally sound and efficient treatment of wastewater, wastewater sludge, contaminated soils, and biotreatment for aquaculture and agriculture.

Bioscience's Ampulmatic automatically produces a hemispherical flame seal on ampules from 1 to 50 ml in size, using technical grade oxygen and natural gas or propane. The company's AIRMASTER AERATOR "TURBO" is among the most advanced aerator technology. Company services include treatability testing, design,

materials supply, and turn-key projects.

Bioscience, Inc. has a new biological product for maintaining water clarity of lakes, fish farms, lagoons, polishing ponds and other slow-moving bodies of water known as MICROCAT®-AL. The company develops MICROCAT® products for wastewater treatment in petroleum refining are MICROCAT®-PR, MICROCAT®-HX, MICROCAT®-HT, MICROCAT®-ANL.

- **Calcigen Corp.** (Symbol: Private)  
115 Research Drive, Suite 169  
Bethlehem, PA 18015  
Phone: 610-419-2219  
[www.calcigen.com](http://www.calcigen.com)

**Industry Classification:**

Biomaterials & Tissue Regeneration

Calcigen Corporation is a biomaterials R&D company developing a pipeline of high value biomaterials for the biosurgery market. The company was formed in July 2000 to address demand for biochemicals with low or no immunogenicity. The company is developing core biotechnology processes to meet these growing needs. Its platform technologies will generate virtually no hazardous chemical waste, require significantly less processing time, and yield higher purities.

Calcigen Corporation has developed two biomaterials platforms:

(1) Bioscaffold™: The applications of company's biomaterials span multiple growing market segments in the biosurgical industry, including: tissue repair and regeneration, adhesion prevention, ophthalmic devices, orthopedics, aesthetics and drug delivery. The company's initial target application with Bioscaffold™ is the soft tissue repair and regeneration market. The platform can be adapted to create materials with traits suitable to a variety of applications and can be compounded with other biomaterials to provide custom tailored functionality.

(2) Novel processing platform for hyaluronan (HA). Applications for HA include use in the prevention of surgical adhesions, as a viscoelastic in cataract surgery, orthopedic viscosupplementation, urinary incontinence, aesthetics and drug delivery.

- **Coulbourn Instruments, Inc.** (Symbol: Private)

7462 Penn Drive  
Allentown, PA 18106  
Phone: 610-395-3771  
[www.coulbourn.com](http://www.coulbourn.com)

**Industry Classification:**

Veterinary  
Internet/Information Technologies  
Scientific & Technical Instruments

Coulbourn Instruments, Inc. provides instrumentation and software to the pharmaceutical industry, contract research organizations and academia. The company was founded by John Coulbourn in 1971 to supply instrument systems and software for the study of behavior and physiology.

Coulbourn's products are focused in behavioral and neurosciences: activity, behavior, circadian rhythm, physiology, startle/response, and control software. Its product line includes bio-amplifiers, filters and integrators for use in ECG, EEG, EMG, ENG, EOG, skin conductance, respiration and other applications. Coulbourn manufactures electronic instrumentation for laboratory animal research, including operant test environment pellet dispensers utilizing precise dosage pellets, or tablets, manufactured by Research Diets. The company's engineering proficiency was enhanced through acquisition of Cobalt Computers, Inc., a manufacturer of high-end data capture and analysis systems, with expertise in computing technology for the biological and pharmaceutical research laboratory environment.

- **Digestive Care, Inc** (Symbol: Private)

1120 Win Drive  
Bethlehem, PA 18017  
Phone: 610-882-5950  
[www.digestivecare.com](http://www.digestivecare.com)

**Industry Classification:**

Retail Drug/Consumer Products

Digestive Care's PANCRECARB® provides optimized digestive enzyme supplementation therapy and a rapid, significant reduction in abdominal pain, cramps, flatulence and stool frequency associated with poor digestion of foods. PANCRECARB® helps maintain intestinal regularity and general health. PANCRECARB® provides a protected environment for the safe passage of bicarbonate to the upper intestine, where it is needed to neutralize acid containing foods and to provide a microenvironment for maximized lipase activity.

- **Entopath Inc.** (Symbol: Private)

3555 Timberlane Drive

Easton, PA 18045

Phone: 610-438-4124

[www.entopath.com](http://www.entopath.com)

**Industry Classification:**

Services (CRO)

Entopath's overall objective is to commercialize living insect larvae as "bioreactors" for the production of recombinant protein. Insects produce proteins faster, better and for less money than do other recombinant systems.

Entopath's Larval Express® allows researchers to learn the advantages of the in vivo insect system and to produce recombinant protein(s) at research scales. The company also offers small-scale larval infection services for customers not wanting to use kits in their laboratories.

- **EMV Technologies, LLC** (Symbol: Private)

115 Research Drive

Bethlehem, PA 18015

Phone: 610-419-4952

[www.emvtechnologies.com](http://www.emvtechnologies.com)

**Industry Classification:**

R&D Services (CRO)

EMV Technologies: (1) provides technical assistance and guidance to companies focused on material forming and processing technologies; (2) provides proprietary and general research for individual companies or joint government-industry projects; (3) aids in the interdisciplinary education of undergraduate, graduate, and post – graduate programs to develop future leaders in the area of materials processing and manufacturing.

- **Fisher Clinical Services** (Symbol: Private)

7554 Schantz Road

Allentown, PA 18106

Phone: 610-391-0800

[www.fisherclinicalservices.com](http://www.fisherclinicalservices.com)

**Industry Classification:**

Drug Discovery Support Services

Bottle

Blister

Secondary Packaging Materials

Labeling

Distribution, Commercial

Clinical Supply Management

Fisher Clinical Services was founded in 1989. The company is a leader in providing clinical trial supply services such as clinical supply packaging to meet client requirements for strategic outsourcing.

Fisher Clinical Services designed ClinPacker™ technology to deliver fast, cost-effective multi-product blister capability.

Fisher Clinical Services offers comprehensive, reliable and responsive analytical testing services to meet individual client needs. Services include design; manufacturing; packaging; labeling; storage; distribution; site management, including patient randomization and kit assignment, return processing and drug destruction. The company has extended its range of services with the addition of Fisher Automated Clinical Trials Services (FACTS).

- **GlucoLight Corporation** (Symbol: Private)

115 Research Drive

Bethlehem, PA 18015

Phone: 610-419-6250

[www.glucolight.com](http://www.glucolight.com)

**Industry Classification:**

Diagnostic/Imaging

Medical Devices

GlucoLight was founded in April 2003, and is developing a non-invasive glucose monitoring system that can be utilized as a continuous monitor in a hospital environment and ultimately as a low cost, portable monitor for use by diabetic patients.

- **Halide Group, Inc.** (Symbol: Private)  
5050 Tilghman Street, Suite 120  
Allentown, PA 18104  
Halide Group, Inc.  
Phone: 610-398-1400  
[www.halidegroup.com](http://www.halidegroup.com)

**Industry Classification:**  
Services

The company provides services to the fluorine and fluoro-chemical manufacturing and applications industries and to polymer processing and fabrication companies.

- **Lehigh Valley Technologies, Inc.**  
514 N 12<sup>th</sup> St.  
Allentown, PA 18102  
Phone: 610-782-9780

**Industry Classification:**  
Wholesale Pharmaceuticals

- **Membrane Assays, Inc.** (Symbol: Private)  
115 Research Drive  
Bethlehem, PA 18015

**Industry Classification:**  
Scientific & Technical Instruments

Membrane Assays (MAI) is commercializing new tools to rapidly identify drug candidates. MAI's technology utilizes integrated circuits in a disposable microwell plate to test cell response to potential new drugs. The circuits simulate living cells with an electric field.

- **Micro-Clean, Inc.** (Symbol: Private)  
177 N. Commerce Way  
Bethlehem, PA 18017  
Phone: 800-523-9852  
[www.microcln.com](http://www.microcln.com)

**Industry Classification:**  
Services

Micro-Clean Inc. is a full-service provider of performance testing, certification, compliant documentation, consulting and training to assure optimum performance of critical

environments to pharmaceutical, healthcare, and biotechnology industries. The company was founded in 1974.

- **Minrad International Inc** (Symbol: BUF) (Northampton Co.)

3950 Sheldon Cir.  
Bethlehem, PA 18017  
Phone: 610-974-9760  
847 Main Street  
Buffalo, New York 14203  
Phone: 716-855-1068  
[www.minrad.com](http://www.minrad.com)

**Industry Classification:**

Devices  
Diagnostics  
Pharmaceuticals  
Veterinary

Minrad International, Inc. operates as an acute medical device and pharmaceutical company. Key product lines include anesthesia pharmaceuticals, real time image-guidance and a program to develop a conscious sedation drug/drug delivery system. The company is currently located in two locations: Buffalo, New York and Bethlehem, Pennsylvania. The Buffalo location is the company headquarters and manufactures Image Guidance Devices, MR-tested Medical Devices and Acute Care Anesthetic/Analgesic Devices. MINRAD's Bethlehem plant manufactures the Acute Care Inhalation Anesthetic Pharmaceuticals.

- **NanoBlox, Inc.** (Symbol: Private)

Innovation Center at FAU  
3998 FAU Boulevard, Suite 305  
Boca Raton, FL 33431  
[www.nanobloxinc.com](http://www.nanobloxinc.com)

NanoBlox, Inc. develops proprietary products and processes based on a new phase of carbon produced in accordance with NanoBlox patent(s). The building block for the company's technology is a 5 nanometer diameter, sp<sup>3</sup> carbon, nanodiamond particle with a chemically tunable surface. NanoBlox, Inc. has contracted with Lehigh University's Center for Advanced Materials and Nanotechnology (CAMN) to utilize Lehigh's "state-of-the-art" microscopy capabilities for further analysis and characterization of NanoBlox nano particles.

- **OraSure Technologies Inc** (Symbol: OSUR)

220 East First Street  
Bethlehem, Pennsylvania  
United States, 18015  
Phone: 610-882-1820  
[www.orasure.com](http://www.orasure.com)

**Industry Classification:**

Devices  
Diagnostics

OraSure Technologies, Inc. engages in developing, manufacturing, and marketing oral specimen collection devices using proprietary oral fluid technologies; diagnostic products, including immunoassays and other in vitro diagnostic tests that are used on other specimen types; and other medical devices. OraSure and its predecessors have a long history in the Lehigh Valley.

OraSure's principal products include the OraQuick rapid HIV-1 antibody test; the OraSure oral fluid collection device for the detection of antibodies to HIV-1, and Intercept Oral fluid collection device for oral fluid drug testing; and Histofreezer, a cryosurgical (freezing) system for the removal of warts and other benign skin lesions. The company also offers an oral fluid Western Blot HIV-1 confirmatory test to confirm positive results of initial oral fluid HIV-1 enzyme immunoassay screening tests; a Q.E.D. saliva alcohol test, which is a saliva-based method for the detection of ethanol; and MICRO-PLATE and AUTO-LYTE immunoassay tests.

OraSure supplies its oral-fluid collection devices and assays to the life insurance industry and public health markets. It sells its products to its customers through a combination of direct sales, strategic partnerships, and independent distributors. The company has made a research and development agreement with Drager Safety AG & Co. KgaA to develop uplink system for rapid detection of drugs of abuse in oral fluid. It has made an agreement with Abbott for the distribution of the company's technologies OraQuick™ ADVANCE™ rapid antibody test for the detection of antibodies to the human immunodeficiency virus Type 1 (HIV-1) and Type 2 (HIV-2).

- **Pharmachem Corporation** (Symbol: Private)

719 Stefko Blvd.  
Bethlehem, PA, 18018  
Phone: 610-867-4654  
[www.pharmachemcorp.com](http://www.pharmachemcorp.com)

**Industry Classification:**

Pharmaceuticals

Pharmachem Corporation is a biotechnology company focusing on supplying and developing dextran products. Its mission is to produce biologically active organic compounds for the health care, food, and chemical industry.

Pharmachem Corporation's range of products includes: Dextran, Dextran Sulfate, DEAE Dextran, and Iron Dextran. The company's Dextran is a bio-polymer formed from enzyme technology and has a variety of uses in mining operations, photographic industry, and also help arthritic conditions. In addition it's Iron Dextran is used to combat iron-deficiency anemia.

- **Precision Medical Inc** (Symbol: Private)  
300 Held Drive  
Northampton, PA 18067  
Phone: 610-262-6090  
[www.precisionmedical.com](http://www.precisionmedical.com)

**Industry Classification:**

Medical Devices  
Suppliers (CRO)

Precision Medical Inc., manufactures respiratory products. The products of the company are the “world’s smallest” oxygen regulators, oxygen conserving devices, nebulizer compressors, battery operated & AC suction, air compressors, vacuum regulators and flowmeters. The company supplies products to the hospital, homecare, long term care, sub-acute, EMS and related healthcare markets worldwide. Precision Medical is a worldwide company with manufacturing and research facilities located in Northampton, Pennsylvania.

- **Saladax Biomedical, Inc** (Symbol: Private)  
115 Research Drive,  
Bethlehem, PA 18015, USA  
Phone: 610-419-6731  
[www.saladax.com](http://www.saladax.com)

**Industry Classification:**

Devices  
Diagnostics

Saladax Biomedical Inc. was founded in 2004, and is developing innovative patented immunoassays that make accurate measurement of chemotherapy blood levels readily available. Saladax is developing a line of eleven Personalized Chemotherapy Management (PCM) assays for the most common anti-cancer drugs.

- **Sanofi-Aventis / Sanofi Pasteur, Inc.**

Discovery Drive  
Swiftwater, PA 18370 (Monroe County)  
Phone: 550-839-7197  
[www.sanofi-aventis.us](http://www.sanofi-aventis.us)

**Industry Classification:**

Pharmaceuticals  
Vaccines

Sanofi-Aventis is engaged in the research, development, manufacture, and marketing of pharmaceutical products for sale principally in the prescription market worldwide. The company offers prescription pharmaceuticals in six therapeutic areas: cardiovascular, thrombosis, metabolic disorders, oncology, central nervous system, and internal medicine. Sanofi Pasteur's Swiftwater facility core competencies include conjugate and recombinant vaccines. The company is the nation's largest supplier of influenza vaccine, with the Swiftwater plant producing more than one half of the influenza vaccine used in the US.

- **Sartorius BBI Systems (formerly B. Braun Biotech International)** (Symbol: Private)

2800 Baglyos Circle  
Bethlehem, PA 18020  
Phone: 610-866-4800  
[www.sartorius-bbi-systems.com](http://www.sartorius-bbi-systems.com)

**Industry Classification:**

Research Services & Supplies  
Scientific & Technical Instruments

Sartorius BBI Systems (formerly B. Braun Biotech International) is a supplier of biotechnology equipment systems such as fermenters, cell culture equipment and bioreactors. The company has provided a range of innovative bioreactor products and support services to biotechnology and pharmaceutical companies for more than 35 years. The company's US subsidiary was founded in 1978. The company changed its name from B. Braun Biotech International to Sartorius BBI Systems in March 2004.

Sartorius BBI Systems designs and manufactures laboratory fermenters, cell culture and bioprocess automation systems for the life science, bioscience, fermentation and cell culture markets. The company's bioreactor products and support services extend from bench top, laboratory and pilot scale operation through to high volume automated production plants. Sartorius BBI Systems also provides cross flow filtration systems (SARTOFLOW), ancillary bioprocessing equipment, and general laboratory equipment such as shakers (CERTOMAT), shaking incubators and cabinets, and homogenizers.

- **Supercritical Solutions LLC / Supercritical Technology Consultants**

PO Box 3350

Allentown, PA 18106

Phone: 610-967-2997

**Industry Classification:**

Services

## About KLIOS, Inc.

KLIOS, Inc. is an economics and strategy consulting firm focused on regional analysis, economic and industrial development, economic growth and performance. We provide:

- Regional economic analysis;
- Technical business assistance, including strategy and a variety of research functions;
- Entrepreneurship training;
- Technology-based economic development assistance and public policy analysis.

The KLIOS Mission: *Improving the economic well-being of regions, their businesses and residents.*

[www.KLIOS.net](http://www.KLIOS.net)

## Notes

<sup>1</sup> In 2004, Lehigh University and Franklin & Marshall College, in Lancaster, became the first institutions certified by the Pennsylvania Department of Community and Economic Development to participate in the Keystone Innovation Zone Program (KIZ). The KIZ program is part of Governor Rendell's economic stimulus initiative, and designates geographic zones adjacent to or linked to college and universities as springboards for stimulating and accelerating innovation and entrepreneurship. Through a combination of tax and non-tax economic incentives, the initiative is designed to assist with technology transfer and the commercialization of research developed at higher education institutions. Individual KIZs focus on local competencies found within a community, specialized facilities such as hospital and universities, workforce skills and private industry clusters or concentrations. The Southside Bethlehem KIZ has a plan that targets both economic and community development. Target industries for the Southside Bethlehem KIZ include life sciences; opto/microelectronics and information technology; and advanced materials/nanotechnology.

<sup>2</sup> The symbiotic relationship between the KIZ and recommendations for life sciences cluster growth should become apparent as the reader progresses through this report—it is hoped that this report further substantiates the rationale for the KIZ as a catalyst for life sciences growth, and further builds the value proposition for its ongoing and future funding.

<sup>3</sup> Depending on the occupation, life sciences jobs require technical training and, in many cases, college degrees—often advanced degrees, in the case of senior scientists, physicians and other researchers. A 2003 study by the Brookings Institution, “Back to Prosperity: A Competitive Agenda for Renewing Pennsylvania,” found that for Pennsylvania metropolitan areas during the 1990s, income grew about 1 percent for every 2 percent growth in the share of college graduates—making the case for economic development initiatives that create and retain high quality jobs; website citation: [http://www.brookings.edu/es/urban/speeches/200312\\_PAPartOne.ppt](http://www.brookings.edu/es/urban/speeches/200312_PAPartOne.ppt) .

<sup>4</sup> For example, in 2001, the average wage in pharmaceutical and medical manufacturing was 156 percent of the average for all industries in the Lehigh Valley. For medical equipment and supplies manufacturing, the average wage in the Lehigh Valley in 2004 was 130 percent of the average for all industries.

<sup>5</sup> Pennsylvania Bioscience Industry Report; page 8; June 2004; website citation: <http://www.pabio.org/Pennsylvania%20Bio%20Report.pdf> .

<sup>6</sup> The other target industries are: (1) Opto/Microelectronics and Information Technology; (2) Advanced Materials/Nanotechnology.

<sup>7</sup> Additional detail and specifics on the characteristics, components and attributes of the Lehigh Valley life sciences sector is provided in other sections of this report.

<sup>8</sup> This definition excludes veterinary medicine and agricultural and industrial applications of biotechnology as areas of primary interest. Nevertheless, there is considerable overlap among the sectors.

<sup>9</sup> Entrepreneurial firms are typically regarded as passing through four life cycle stages of development, each with its own unique set of challenges and requirements. A vibrant and sustainable life sciences cluster includes firms at each stage. Different authors and different studies may use different nomenclature, but each describes essentially the same set of characteristics:

Stage 1: Business conception or startup (birth): Small enterprises, often with no more than one or two principals engaged in research—typically, proof-of-concept. Companies tend to be self-funded and without a revenue stream. These enterprises need cash to cover operating expenses and expertise to solve technical and business problems. Challenges at this stage often relate to: technical feasibility, intellectual property ownership/technology transfer, financial support, tactical and strategic business planning, legal assistance, time management.

Stage 2: Formation (fledgling) firms: These firms differ from startups in terms of duration, rather than size. Fledglings have overcome the immediate challenges of birth (where good ideas often fail), and are on the way to longer term survival and some growth—perhaps in employment, if not sales. Entrepreneurs engaged in running fledgling life sciences firms remain preoccupied by issues that are internal to the firm, however survival may depend more on the ability to learn from others and to enter into successful partnerships for production, research and financial support. Challenges at this stage often relate to: technical feasibility, intellectual property ownership/technology transfer, ongoing financial support, production scale up, business planning, strategic partnering, legal assistance, location (for growth) and space requirements, next-stage financing.

Stage 3: Adolescent and growth firms: Firms in this stage of development differ significantly from younger, earlier stage firms. They almost always require professional, experienced managers and financing from a variety of sources and instruments. Employment may be much larger, and they may or may not have positive sales growth. Often, they are still involved in lengthy and expensive testing and regulatory approval, which must occur before products can be commercialized. A balanced portfolio approach to product development, with products at various stages from research through commercialization, may be employed to diversify and mitigate risk. These companies may still operate in “virtual” mode, with a significant degree of outsourcing to obtain expertise. Challenges at this stage often relate to: licensing arrangements, regulatory approval, multiple financing arrangements, production scale manufacturing, attraction and retention of specialized labor and management, access to markets for sales, access to capital markets, innovation and new product development.

Stage 4: These are mature firms. They have survived long enough to achieve profitability, and working to maintain and grow market share and remain competitive. Typically, maturity implies that the companies are publicly traded, multidisciplinary organizations. Larger, mature firms often focus on growth through sales volume and economies of scale. They tend to engage in less risk-taking activities, although innovation is often the path to future economic success. Challenges at this stage cover an extensive range of topics and often relate to: sustained profitability and commercial viability, market dominance, economies of scale, research and development, innovation, attraction and retention of specialized labor and management, access to raw materials, ongoing regulatory requirements, new business development.

<sup>10</sup> The core areas of life sciences discipline specialization can be subdivided as follows: organic and agricultural chemicals; drug and pharmaceutical therapeutics; medical diagnostics; medical devices and instruments; hospitals and laboratories; and research and testing activities. Companies may develop expertise in a discipline or even multiple disciplines—or they may further specialize by developing horizontal integration—that is niche specialty—expertise. Alternate categorization schemes exist which break out supplier and service companies. The total breadth of life sciences is similar, however, under both schemes.

<sup>11</sup> Data for this report was collected using a definition based on the 2002 North American Industry Classification System (NAICS). NAICS are the statistical classification system that forms the basis for all establishment-based Federal economic industry statistics, including employment and wage data collected for the Quarterly Census of Employment and Wages (QCEW). QCEW represents the most comprehensive survey of employment in the United States. The NAICS-based definition used for this report includes “core” life sciences sectors, as well as industries that may not be among the core but are largely and directly related to life sciences. Part of the affiliation between core and non-core—that is, “related”—sectors is based on supply-chain relationships and part is based on similar labor requirements or other commonalities.

<sup>12</sup> A December 2005 publication by the Brookings Institution, “Higher Education in Pennsylvania: A Competitive Asset for Communities,” (Jennifer S. Vey, author; website citation: [http://www.brookings.edu/metro/pubs/20051205\\_highedPA.pdf](http://www.brookings.edu/metro/pubs/20051205_highedPA.pdf)) cited 30 higher education institutions in the Lehigh Valley (7 4-year colleges/universities, 7 2-year colleges, 16 other education institutions), the third highest concentration in the Commonwealth, after the Philadelphia and Pittsburgh metropolitan areas, respectively.

<sup>13</sup> The Census Bureau’s 2003 County Business Patterns lists 15 hospital establishments in the Lehigh Valley. Health care employment for all establishments (including hospitals, outpatient centers, service provider offices, medical and diagnostic laboratories and related facilities) was over 33,000 employees—almost 14 percent of the total.

<sup>14</sup> For the past two years, the Allentown-Bethlehem-Easton metropolitan area has shown strong improvements in rank in the Milken Institute’s Best Performing Cities Index (website citation: <http://bestcities.milkeninstitute.org/>), a composite index that ranks the nation’s largest 200 metropolitan areas on job creation and economic performance.

<sup>15</sup> A Location Quotient compares the regional concentration of some indicator with the national (or other base) concentration of the same indicator. LQs can be calculated for almost any indicator for which regional and national data is available. Most frequently, LQs are most frequently calculated for employment, wages or output, as these are among the measures that provide the quickest, most comprehensive overview of a region’s economy. Mathematically:

$$\text{Location Quotient} = \frac{(\text{regional sector/regional total})}{(\text{national sector/national total})}$$

Thus, for example, an LQ of 1.3 indicates that a measure is 30 percent more concentrated in the region, than nationally, and an LQ of 0.3 indicates that a measure is only 30 percent as concentrated locally than nationally.

<sup>16</sup> Traded clusters represent “exports” and “imports” (although not always foreign), reflecting commerce between economic areas. The Cluster Mapping Project defines the area according to the 2003 definition of the Allentown-Bethlehem-Easton PA-NJ Metropolitan Area, which includes Carbon County (PA) and Warren County (NJ), in addition to Lehigh and Northampton County. Website citation: <http://data.isc.hbs.edu/isc/index.jsp>.

<sup>17</sup> The Cluster Mapping Project identifies health services including hospitals as a local rather than traded cluster—that is, no imports or exports. While many components of the health services sector, as defined by the Cluster Mapping Project, are local—for example, drug stores, healthcare provider offices and home and residential care—in the case of the Lehigh Valley, some proportion of hospital activity likely relates to local treatment administered to individuals from outside the area—that is, traded activity. As with medical devices, the Cluster Mapping Project found that health services grew significantly faster locally than the national or benchmark growth rate. That “excess” growth is probably related to traded—or interarea—activity. Ibid.

<sup>18</sup> LVAIC website. <http://www.lvaic.org/about.html>. LVAIC member colleges are: Cedar Crest College, DeSales University, Lafayette College, Lehigh University, Moravian College and Muhlenberg College. LVAIC Associate member institutions participate in the Business Services and Group Purchasing programs, to reduce expenses through greater buying power and improved efficiencies in operations. LVAIC endorsed vendors offer member institutions a variety of products and services at discounted rates. LVAIC Associate members are: Albright College (Reading, PA), Alvernia College (Reading, PA), Delaware Valley College (Doylestown, PA), Lehigh Carbon Community College, Moravian Academy

(private K-12; Bethlehem), Neumann College (Aston, PA) and Northampton Community College.

<sup>19</sup> Cedar Crest College, Lehigh Carbon Community College, Moravian College, Muhlenberg College and Northampton Community College.

<sup>20</sup> Allentown, Bangor Area, Bethlehem Area, Easton Area, Nazareth Area, Northampton Area and Saucon Valley.

<sup>21</sup> Phillipsburg.

<sup>22</sup> In an unpublished study using National Center for Education Statistics data for the year 2000, Lehigh University was the 9<sup>th</sup> smallest research university, based on total enrollment (6,476), ranking just ahead of Princeton (6,547) and Brown (7,723). The smallest research university, according to the data, was the California Institute of Technology (1,968). The largest independent, non-profit research university—as Lehigh—was New York University (37,150). The largest public research university was the University of Texas, Austin (49,996).

<sup>23</sup> Biotechnology, Materials Science, Nanotechnology and Optical Technology.

<sup>24</sup> ISI, a Philadelphia-based organization that has indexed the world's scholarly literature in science and social science for 40 years, surveyed only universities that published at least 100 papers in ISI-indexed journals of chemical engineering during each period. From 1994 through 1998, Lehigh researchers had an average of 4.36 citations per paper. From 1996 through 2000, the university's researchers had an average of 3.74 citations per paper. Two of the other three universities in the top five during each study also experienced a decline in the average number of citations per paper over the two periods. More recently, ISI designated Martin Harmer, the Alcoa Foundation Professor of materials science and engineering and director of the Materials Research Center, as a "Highly Cited Researcher". Highly Cited Researchers make up less than one-half of one percent of all publishing researchers, according to ISI.

<sup>25</sup> This report is too brief to mention or provide detail on all but a few Lehigh graduates—in addition, that is not the principle intent of this document. Nonetheless, some Lehigh graduates are mentioned by name in the body of this report. One further anecdote about a Lehigh alumnus may shed additional light on the quality of the school's output—as well as the interdisciplinary overlap of life sciences research and development. Several articles earlier this year described the accomplishments of Jesse Nawrocki, who earned three degrees (B.S., M.S., Ph.D.) in materials science and engineering from Lehigh. Nawrocki, a senior engineer with Ethicon Inc., received a Johnson Medal, the top award given by Johnson & Johnson, for inventing a needle coating technology that enables surgeons to close wounds with greater control, flexibility and comfort. Ethicon is a Johnson & Johnson subsidiary that makes needles, sutures and other surgical devices. In 2004, Nawrocki received Johnson & Johnson's Philip B. Hofmann Research Award for his work in MultiPass Needle Coating. Nawrocki's invention is credited by Johnson & Johnson with generating \$100 million in total sales in 2004.

<sup>26</sup> COT's stated mission is, "to generate advances in the science and application of optical technologies, and to forge partnerships that drive growth and diversity in the industry."

<sup>27</sup> Planning is underway to offer a full array of credit and noncredit classes at Northampton's new Southside Bethlehem educational center.

<sup>28</sup> This cooperative effort is funded through a Workforce Leadership grant from the Pennsylvania Department of Community and Economic Development.

<sup>29</sup> Ben Franklin Technology Partners operates on a regional level through four centers distributed across the Commonwealth, with main offices in Pittsburgh, State College, Bethlehem, and Philadelphia. Each

center serves specific counties and offers distinct regional activities.

<sup>30</sup> Other business incubators in the Lehigh Valley include the Bridgeworks Enterprise Center, and Hamilton Business Center, both in Allentown. Started by the Allentown Economic Development Corporation in 1989 in an 84,000 square foot building formerly owned by Mack Trucks, Bridgeworks has helped 25 businesses that created 350 jobs. Bridgeworks is also part of the BFTP/NEP incubator network. The Hamilton Business Center is a privately run 120,000 square foot facility. While both facilities have housed technology and life sciences startups, neither is outfitted with wet lab space.

<sup>31</sup> The Life Sciences Greenhouse initiative was part of the Commonwealth's \$2 billion-plus Life Sciences Enterprise commitment to fuel life sciences research & development, attract venture capital, and support early-stage investment. The \$2 billion investment is overseen by the Pennsylvania Department of Community and Economic Development, and is divided into four major components:

1. \$1.6 billion for life sciences and biomedical research, to be distributed to Pennsylvania-based research institutions, beginning in 2002 (approximately \$64 million per annum for 25 years);
2. \$100 million committed in 2002 for the initiation of three life sciences greenhouses across the Commonwealth, based in Harrisburg, Philadelphia and Pittsburgh;
3. \$60 million committed in 2002 as start-up resources for a venture capital fund to support commercialization of demonstrated new life science business opportunities;
4. \$140 million in projected matching funds for the venture capital fund.

<sup>32</sup> MRC is one of seven Industrial Resource Centers funded by the Pennsylvania Department of Community and Economic Development. MRC is also affiliated with the Manufacturing Extension Partnership of 70 centers nationwide, sponsored by the National Institute of Standards and Technology. That affiliation ties MRC ties to an extensive network of topical experts, as well as the national research laboratories and federal funding resources.

<sup>33</sup> The Lehigh SBDC offers assistance throughout Lehigh, Northampton, Upper Bucks and Northern Montgomery counties.

<sup>34</sup> Lehigh, Northampton, Carbon, Schuylkill, Bucks, Montgomery, Berks and Monroe Counties.

<sup>35</sup> Areas served include Allentown, Bethlehem, Easton, Kutztown, and the Poconos.

<sup>36</sup> Clarkson University is located in Potsdam, New York, and is an independent technological university with a reputation for developing innovative leaders in technology-based fields. Clarkson offers Physical Therapy teaching and research programs. In May, 2002, the Wallace H. Coulter Foundation made a \$30-million commitment to the University, in support of ongoing excellence in engineering. Wallace Coulter was a trustee of Clarkson University, and was co-founder of Coulter Corporation, with his brother, Joseph. Coulter Corporation (today, Beckman Coulter) is known for breakthroughs in hematology analysis—the Coulter Counter, which radically changed hematology by allowing more accurate and faster CBC (Complete Blood Count) analysis, was the first. A portion of the bequest to Clarkson, will be used to fund new initiatives in bioengineering and rehabilitation engineering.

<sup>37</sup> Clarkson Magazine; Fall 2003; website citation:  
[http://clarksonalumni.com/stay\\_connected/magazine/fall\\_03/clarkson\\_shepherd.html](http://clarksonalumni.com/stay_connected/magazine/fall_03/clarkson_shepherd.html)

<sup>38</sup> Herbert Boyer, of the University of California at San Francisco, and Robert Swanson incorporated Genentech in 1976, following discussions which began the previous year. Genentech developed the technology to synthesize human insulin in the laboratory in 1978. Subsequently, the company granted a license for the technology to Eli Lilly. In 1985, Genentech became the first biotechnology company to launch its own biopharmaceutical product, human growth hormone. Of anecdotal interest, Boyer was

born and grew up in western Pennsylvania, receiving undergraduate and graduate degrees from St.

Vincent's College in Latrobe and the University of Pittsburgh, respectively.

<sup>39</sup> US Food and Drug Administration (FDA) current good manufacturing practice regulations.

<sup>40</sup> Eleven of the thirteen largest pharmaceutical companies in the nation are within a 40- to 90- minute drive.

<sup>41</sup> The Team Pennsylvania Foundation commissioned KPMG to run a comparative tax analysis for Olympus America, while the company was in the process of considering whether to remain in New York or relocate to Pennsylvania. The analysis indicated that the company would save \$55 million in taxes overall by moving to the Commonwealth.

<sup>42</sup> Natalie Cohen, author; April 2000; website citation: <http://www.brookings.edu/es/urban/cohen.pdf>; p. 8.

<sup>43</sup> A good background paper and overview of technology transfer and commercialization, with reference to life sciences, is the Final Report of the Panel of Advisors on the Life Sciences to the Ewing Marion Kauffman Foundation, "Accelerating Technology Transfer & Commercialization In The Life & Health Sciences"; August 2003; website citation: [http://www.kauffman.org/pdf/TechTranPanel\\_Report.pdf](http://www.kauffman.org/pdf/TechTranPanel_Report.pdf).

<sup>44</sup> Nor will this document take a position on whether there should be one.

<sup>45</sup> Webcite citation: <http://www.brookings.edu/es/urban/pa/Lehigh.pdf> (Lehigh Valley extract); <http://www.brookings.edu/metro/publications/pa.htm> (complete report, supporting material).

<sup>46</sup> Based on US Census Bureau population estimates for 2004, the Lehigh Valley (88.4% White, 4.3% Black, 2.3% Asian, 10.6% Hispanic or Latino of any race) is also not as ethnically diverse as the nation (75.6% White, 12.2% Black, 4.2% Asian, 14.2% Hispanic or Latino of any race) and exhibits a different composition than the entire Commonwealth of Pennsylvania (84.8% White, 10.0% Black, 2.2% Asian, 3.7% Hispanic or Latino of any race). This was mentioned as a disadvantage when it comes to workforce recruiting by some interviewees. The role of immigrants in the development of high technology clusters has been widely explored in other studies.

<sup>47</sup> A report produced by the Public Policy Institute of California, "The Dynamics of California's Biotechnology Industry," (Junfu Zhang and Nikesh Patel; April 2005) found that the life sciences are among the most knowledge-intensive of industries, even more than information technology. The authors' analysis found that forty-seven percent of the founders of venture-funded biotech companies were university professors, scientists at research institutions or newly-minted Ph.D.s, while almost forty-three percent of US biotech C.E.O.s hold doctorates. The percentages among R&D officers (82%) and chief scientists (91%) were even higher. Website citation: [http://www.ppic.org/content/pubs/report/R\\_405JZR.pdf](http://www.ppic.org/content/pubs/report/R_405JZR.pdf); p. 11.

<sup>48</sup> Ibid; p. 34.

<sup>49</sup> "Pharmaceutical Industry Profile, 2006"; Pharmaceutical Research and Manufacturers Association of America (PhRMA); p. 52; web citation: <http://www.phrma.org/files/2006%20Industry%20Profile.pdf>.

<sup>50</sup> US Department of Commerce data, as cited in "U.S. Medical Technology Industry Fact Sheet, 2003"; Advanced Medical Technology Association (AdvaMed); website citation: [http://www.advamed.org/publicdocs/fact\\_sheet\\_2003.pdf](http://www.advamed.org/publicdocs/fact_sheet_2003.pdf).

<sup>51</sup> Zhang, Patel; op cit.; p. 51.

<sup>52</sup> US Department of Commerce data, as cited in “The Medical Technology Industry at a Glance: 2004”; Advanced Medical Technology Association; p. 4; website citation: <http://www.advamed.org/newsroom/chartbook.pdf>.

<sup>53</sup> In the national summary to the Council on Competitiveness’ Clusters of Innovation Initiative, the distinction between growth for growth’s sake and prosperity is spelled out clearly in the introduction:

“Growth is not the same as prosperity. Growth is only desirable if the standard of living of citizens rises. High growth per se often leads to a rising cost of living that erodes prosperity and degrades natural resources and physical infrastructure that support quality of life.”

Website citation: [http://www.compete.org/pdf/national\\_execsummary.pdf](http://www.compete.org/pdf/national_execsummary.pdf); p. xi.

<sup>54</sup> “Outlook 2006,” Tufts Center for the Study of Drug Development; January 2006. Website citation: <http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2006.pdf>.

<sup>55</sup> For a transcript of the session, heard on March 1, 2006, see: [http://www.supremecourtus.gov/oral\\_arguments/argument\\_transcripts/04-1704.pdf](http://www.supremecourtus.gov/oral_arguments/argument_transcripts/04-1704.pdf).

<sup>56</sup> See, for example, the essay in the 1994 Annual Report of the Federal Reserve Bank of Minneapolis, by Melvin Burstein (general counsel) and Arthur Rolnick (Senior Vice President and Director of Research), “Congress Should End the Economic War Among the States”; website citation: <http://minneapolisfed.org/pubs/ar/ar1994.cfm>, or the proceedings of a 1996 conference in Washington, DC, hosted by Minnesota Public Radio; website citation: <http://minneapolisfed.org/research/studies/econwar/conf.cfm> (summarized in the June 1996 issue of *The Region*, a banking and policy issues magazine published by the Minneapolis Fed; website citation: <http://minneapolisfed.org/pubs/region/96-06/index.cfm>).

<sup>57</sup> An independent, academic non-profit research group affiliated with Tufts University, which has been studying the pace and nature of drug development since 1976. Website: <http://csdd.tufts.edu/>.

<sup>58</sup> “Outlook 2006”; p. 2; website citation: <http://csdd.tufts.edu/InfoServices/OutlookPDFs/Outlook2006.pdf>.

<sup>59</sup> *Ibid.*

<sup>60</sup> “Impact Report”; May/June 2003; website citation: [http://csdd.tufts.edu/documents/www/Doc\\_309\\_36\\_893.pdf](http://csdd.tufts.edu/documents/www/Doc_309_36_893.pdf).

<sup>61</sup> A specific example of the theoretical underpinnings of this seemingly vague notion is found in the work of Michael Porter, of Harvard University. His “diamond framework” for assessing the productivity and innovative capacity of local economies—that is, the cluster-supporting competitive advantage—considers the role of government and also *chance*—which can impact each of the four major interacting determinants of productivity:

1. Context for firm strategy and rivalry,
2. Factor (input) conditions,
3. Demand conditions,
4. Related and supporting industries.

<sup>62</sup> A good background paper and nontechnical overview of New Growth Theory for economic development practitioners is, “New Growth Theory, Technology and Learning: A Practitioner’s Guide,” by Joseph Cortright, of Impresa, Inc. (2001); website citation: [http://www.impresaconsulting.com/cortright\\_ngt.pdf](http://www.impresaconsulting.com/cortright_ngt.pdf).

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<sup>63</sup> The ten-point summation that follows, is derived from the national summary to the Council on Competitiveness' Clusters of Innovation Initiative; website citation: [http://www.compete.org/pdf/national\\_execsummary.pdf](http://www.compete.org/pdf/national_execsummary.pdf); p. xvi.

<sup>64</sup> "Co-opetition" is the business strategy described in 1996 by Adam Brandenburger, who was at Harvard at the time and is now at New York University, and Barry Nalebuff, of Yale, in their book of the same name. The term was first used by Ray Noorda, founder of Novell, to describe a strategy widely employed within the computer industry, where strategic alliances are commonly employed to develop new products and markets. Website citation: <http://mayet.som.yale.edu/coopetition>.

<sup>65</sup> A 2005 retrospective study published in the *Journal of Health Economics*, found that alliances between smaller firms and larger research partners improved clinical trials success, especially for more complex later stage trials. Nearly two-thirds of compounds were under co-development by Phase III, based on examination of more than 900 firms from 1988 to 2000. In addition, compounds developed by alliances were more likely to move to the next stage, especially for compounds in Phase II and Phase III of development. P.M. Danzon, S. Nicholson, N.S. Pereira, "Productivity in Pharmaceutical-Biotechnology R&D: The Role of Experience and Alliances," *Journal of Health Economics*, 24 (2005); pp. 317-339.

<sup>66</sup> Despite the doubling in research investment, the number of new drugs that received US FDA approval dropped from an average of 35.5 per year between 1994-1997, to 23.3 per year between 2001-2004. Mary Woolley; Stacie M. Propst, "Public Attitudes and Perceptions About Health-Related Research," *Journal of the American Medical Association*, 294 (2005); pp. 1380-1384.

<sup>67</sup> The outgoing president of the University of Arizona, is Peter Likens. Dr. Likens was previously president of Lehigh University.