INTRODUCTION

Grand Forks is the third largest city in North Dakota and serves as a regional center for trade, health care, education and entertainment. It is the home of the University of North Dakota (UND) and the Grand Forks Air Force Base (GFAFB). Grand Forks is located in the fertile Red River Valley of the North where agriculture has been the primary economic engine since early settlement times. The rich farmlands produce sugar beets, potatoes, small grains (wheat & barley) and edible beans. Over the years value-added processing of these local crops has resulted in a substantial food manufacturing industry sector. Because of its dependence on agriculture, Grand Forks’ economic vitality has often been tied to the rise and fall of agricultural markets.

The Grand Forks Region Economic Development Corporation (EDC) recognizes that reliance on one economic engine does not bode well for the region so they have researched and identified three core areas for economic diversification as part of its long-range planning. These strategic sectors include:

- Life Sciences,
- Energy & Environment,
- Aerospace

These four core areas build on industries that already have a foothold in the Red River Valley and build on existing assets at the University of North Dakota, the Grand Forks Air Force Base and the private sector. The EDC feels, in particular, that it is critical to create stronger links between the research pipeline at the University of North Dakota and the strategies outlined in their strategic plan. In today’s knowledge economy higher education institutions are more important than ever to a region’s global competitive advantage.

Historically, agriculture and ag-processing have been the dominant economic forces in the Grand Forks region. During the past five years, however, the regional economy has become more diversified with growth in the manufacturing, energy and environmental technologies, information services, life sciences and aerospace industry sectors. Today’s major employers include the University of North Dakota, Altru Health System, LM Glasfiber, Cirrus Design, Hugo’s Grocery Stores, and JR Simplot Company.

The Base Realignment and Closure (BRAC) proceedings of 2005 recommended that the GFAFB mission be realigned from a fuel tanker mission to an unmanned aircraft systems mission. In response to the BRAC 2005 recommendations, the Base Realignment Impact Committee (BRIC) was established as a partnership between the City of Grand Forks, Grand Forks County, the City of East Grand Forks, the Grand Forks Region Economic Development Corporation and Job Services North Dakota. The focus of BRIC’s work has been to identify and quantify the economic impact, conduct planning to serve the dislocated workers and impacted businesses, and developing economic diversification plans that will create jobs while reducing the dependency on GFAFB.

The life sciences hold considerable potential for Grand Forks because of the research and development capacity of the University of North Dakota and the region’s significant private clinical services. The opportunity to capitalize on this knowledge base and expertise to diversify the regional economy and expand the employment base is a key element of the Grand Forks Region Economic Development Corporation’s targeted strategic initiatives.
The objective of this Life Science Business Development Roadmap is to identify potential market opportunities for the Grand Forks region and to offer recommendations for strategies and action steps that will best capitalize on those opportunities.
THE LIFE SCIENCE INDUSTRY

The life sciences (bioscience) sector encompasses a wide range of scientific disciplines and industries that all focus on the way living organisms function. These include: agricultural feedstocks and chemicals; drugs and pharmaceuticals; medical devices and equipment; research and testing; academic health centers, research hospitals and research institutes.

A report issued by the Biotechnology Industry Organization (BIO) indicates that life sciences research and development in North Dakota (2003) totaled $65.1 million dollars, representing 49% of all university R&D. The state also has a significant foundation in place beyond the university campus including growth companies in agriculture, health research and testing, as well as services, support and manufacturing for biosciences companies.

Due to the extensive and diverse nature of the industry, narrowly defining the life science industry sector is difficult. The federal statistical classification system does not identify one single industry code that encompasses all life/bioscience activities; therefore, defining the industry requires a thorough examination of all industries engaged in bioscience-related work. Battelle Technology Partnership Practice has identified four major sub-sectors that involve key life and bioscience economic activity. The four major sub-sectors are outlined in Table 1.

Table 1. Life Science Sector Industries

1. **Agricultural Feedstock and Chemicals**—firms engaged in agricultural production and processing, organic chemical manufacturing, and fertilizer manufacturing. Includes the emerging use of biocatalysts in organic chemical manufacturing.

2. **Drugs and Pharmaceuticals**—firms that develop and produce biological and medicinal products and manufacture pharmaceuticals and diagnostic substances.

3. **Medical Devices and Equipment**—firms that develop and manufacture surgical and medical instruments and supplies, laboratory equipment, electromedical apparatus including magnetic resonance imaging and ultrasound equipment, dental equipment and supplies, and ophthalmic products.

4. **Research, Testing, and Medical Laboratories**—companies engaged in R&D in the life sciences, testing laboratories, and medical laboratories and other diagnostic centers.

Table 2 presents the industries included within each major bioscience sub-sector identified by Battelle. A fifth center of bioscience activity includes academic health centers, research hospitals, and other research institutions. In this region, they include the UND School of Medicine, the Research Enterprise and Commercialization (REAC) park, the Center of Excellence in Life Sciences and Advanced Technology (COELSAT), the UND Research Foundation, and the Energy and Environmental Research Center (EERC). Likewise, Altru Hospital is partnering with universities and other research institutes to further advances in the biosciences with a particular focus on healthcare applications.
The major life science sub-sectors each have a distinct specialization and their own set of supply chain relationships. To varying degrees, the sub-sectors do intersect, or converge, in beneficial ways. For example, new biological research discoveries – often driven by university research – directly impact the development of new drugs or vaccines or lead to new uses for agricultural feedstocks; testing laboratories provide key breakthroughs for medical devices; and plant and animal scientific findings contribute to further innovation in drugs and pharmaceuticals as well as research and testing.

Table 2. Life/Bioscience Sub-sector Industries

<table>
<thead>
<tr>
<th>NAICS</th>
<th>NAICS Description</th>
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<tbody>
<tr>
<td>311221</td>
<td>Wet corn milling</td>
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<tr>
<td>311222</td>
<td>Soybean processing</td>
</tr>
<tr>
<td>311223</td>
<td>Other oilseed processing</td>
</tr>
<tr>
<td>325193</td>
<td>Ethyl alcohol manufacturing</td>
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<tr>
<td>325199</td>
<td>All other basic organic chemical manufacturing</td>
</tr>
<tr>
<td>325221</td>
<td>Cellulosic organic fiber manufacturing</td>
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<tr>
<td>325311</td>
<td>Nitrogenous fertilizer manufacturing</td>
</tr>
<tr>
<td>325312</td>
<td>Phosphatic fertilizer manufacturing</td>
</tr>
<tr>
<td>325314</td>
<td>Fertilizer (mixing only) manufacturing</td>
</tr>
<tr>
<td>325320</td>
<td>Pesticide and other agricultural chemical mfg.</td>
</tr>
<tr>
<td>325411</td>
<td>Medicinal and botanical manufacturing</td>
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<tr>
<td>325412</td>
<td>Pharmaceutical preparation manufacturing</td>
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<tr>
<td>325413</td>
<td>In-vitro diagnostic substance manufacturing</td>
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<tr>
<td>325414</td>
<td>Other biological product manufacturing</td>
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<tr>
<td>334510</td>
<td>Electromedical apparatus manufacturing</td>
</tr>
<tr>
<td>334516</td>
<td>Analytical laboratory instrument manufacturing</td>
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<tr>
<td>334517</td>
<td>Irradiation apparatus manufacturing</td>
</tr>
<tr>
<td>339111</td>
<td>Laboratory apparatus and furniture manufacturing</td>
</tr>
<tr>
<td>339112</td>
<td>Surgical and medical instrument manufacturing</td>
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<tr>
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<td>Surgical appliance and supplies manufacturing</td>
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<td>339114</td>
<td>Dental equipment and supplies manufacturing</td>
</tr>
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<td>Ophthalmic goods manufacturing</td>
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<td>339116</td>
<td>Dental laboratories</td>
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<tr>
<td>541380*</td>
<td>Testing laboratories</td>
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<tr>
<td>541710*</td>
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<tr>
<td>621511</td>
<td>Medical laboratories</td>
</tr>
<tr>
<td>621512</td>
<td>Diagnostic imaging centers</td>
</tr>
</tbody>
</table>

* Includes only the portion of these industries engaged in relevant biological or other life sciences activities.
Each major bioscience sub-sector varies in its degree of sophistication and maturation related to technology utilization. Similarly, each firm within these sectors varies considerably. Therefore, while some sub-sector companies are leaders in their field and utilize cutting-edge bioscience technologies, others are not currently utilizing higher-order technologies. In reality, this means that the depth, scale, and scope of a bioscience-related sector can vary considerably in any given state or region. The overall presence of this activity within a state or local area, however, provides further potential for economic growth and clustering among various bioscience establishments.

As noted in Figure 2, the national distribution of life science-related employment identifies Medical Devices & Equipment and Research (34%), Testing and Medical Laboratories (33%) having roughly the same share of employment followed by Drugs & Pharmaceuticals (25%) and Agricultural Feedstock and Chemicals (8%).

**Figure 2. U.S. Employment Distribution Among the Life/Bioscience Subsectors, 2006.**

[Graph showing employment distribution]

Source: Battelle Technology Partnership Practice and SSTI.

North Dakota’s life science industry and related employment is concentrated in three major occupational groups, including 1) agricultural, food, nutritional scientists; 2) biological scientists and technicians; and 3) medical and clinical laboratory technicians (Figure 3). These occupational groups reflect the three primary industry sub-sectors, or platforms, prevalent in North Dakota today including 1) agricultural feedstock and chemicals; 2) medical devices, and 3) research, testing & medical – driven by the two flagship institutions in the state, University of North Dakota and North Dakota State University. Increasingly, these facilities also serve as the foundation for new entrepreneurial starts in Grand Forks and Fargo – through access to students, faculty, infrastructure, facilities and partnerships with leading edge research and development.
A review of highly concentrated bioscience occupations within the state (Figure 4) and their subsequent location quotients suggests that there is a firm foundation of agricultural and food science technicians, biological scientists, food scientists and technologists, soil and plant scientists, biological technicians belying the strength of food and agricultural sciences within the state. A location quotient (LQ) is the concentration in the local area divided by the concentration in the nation. LQ compares the composition of occupations to that of the nation. If Grand Forks were segregated exactly like a “typical” economy, it would show a 1.0 for each measure. For instance, North Dakota has over five times more agricultural and food science technicians than an “average” place. A growing segment of medical and clinical laboratory technicians, dental lab technicians and medical and clinical lab technologists support a growing private sector bioscience initiative in vaccinology, immunology and clinical lab testing.
The growth in research is well documented within the state (Figure 5), as overall employment in testing laboratories and physical, engineering and biological research has experienced steady increases from 2001 to 2006 - increasing roughly 50 percent in total employment over the past five years. This growth is being driven both by concerted efforts in clinical research by the universities and colleges and by a growing private business sector that has helped fuel this growth.
As the COELSAT facility opens and further business developments come to fruition, the state and region can expect to see continued growth in this employment sector. As more critical mass develops in the private and public sectors, further opportunities will emerge and stimulate more jobs and development opportunities.

These jobs will be critical in the realization of local and regional development efforts. Public-private partnerships will hinge on the access to qualified, trained technologists and scientists that make up the base of new life science starts. Trained personnel, coupled with growing specialized infrastructure, such as the COELSAT and UND’s School of Medicine and Health Sciences will provide added impetus to further growth and development in the life science industry sector in the Grand Forks region.

An examination of the fastest growing life science sub-sectors in the region points to immunology and vaccines (infectious diseases) with significant development in Fargo and Winnipeg and an emerging sector developing in Grand Forks.

Other areas of growth and concentrated expertise and specialty infrastructure indicate specialty areas in:

- Nutrition & food
- Medical devices
- Rural health
- Neurosciences
- Biodefense
- Biofuels

These niche areas are potential growth areas for the region based on existing expertise and specialized infrastructure located at the University of North Dakota and supported by vibrant private business applications emerging at the COELSAT and in Fargo.

The Fargo area has several emerging and already growing sub-sectors including protease research, visual neuroscience, and vaccine and gene therapy. PRACS Institute, Ltd., one of the nation’s premier contract clinical research organizations, is headquartered in Fargo.

Right next door, Minnesota is a major international player in the medical device industry sector. The state’s renowned Life Science Alley is home to more than 8,000 healthcare companies and an international leader in education, networking, regulations, research and emerging technologies. Minnesota is home to some of the biggest names in health and life sciences including Medtronic, May, MGI Pharma and Cargill.

South Dakota’s life science industry sector research is focused on agricultural related research and development including plant and animal science and as well as research in therapeutic and diagnostic technologies for infectious diseases in humans and domestic animals.

The province of Manitoba has developed significant expertise and infrastructure in cardiovascular and respiratory disease, infectious disease and clinical research related to agriculture and health and biopharmaceutical manufacturing.

Common threads in all these neighboring regions include research and development in, and established infrastructure focusing on, infectious diseases, vaccinology, immunology and expertise in a broad spectrum of agricultural related life science research and development. Later in this roadmap, these similar and complementary initiatives and assets will be more fully profiled to explore common interests, areas of leverage, and potential partnerships.
TRENDS IN LIFE SCIENCE BUSINESS DEVELOPMENT

Increased competition, shorter market cycles, greater customer expectations, changing business models and financial constraints are creating unprecedented demands on the life sciences industry’s ability to deliver superior value to shareholders and innovative healthcare to patients across the spectrum of products, processes, services and solutions.

At the same time, rising R&D costs and drug patent expirations are driving consolidation in the industry. Companies are pushing for internal R&D productivity and acceleration, and they are focusing on cost cutting, especially in business processes not directly related to R&D or sales and marketing, such as procurement, supply chain and manufacturing. Meanwhile, there is also greater attention to patient-oriented marketing and overall sales and marketing productivity and effectiveness.

Increasingly, strategic alliances are providing a pathway to financial success for both emerging biotechnology companies and larger biotech and pharmaceutical companies. The larger biotech firms’ cash reserves, thinning product pipelines, and desire to access innovative technologies and products are driving an increase in strategic alliances and mergers and acquisitions with emerging biotech and life science companies. This is good news for biotech companies trying to raise capital, minimize financial and regulatory risk, and enhance enterprise value.

Shortly after the turn of the century Harvard installed its new president, Lawrence Summers, who called the 21st century “the century of biology and life science.” Saying that science, technology, and globalization will demand Harvard’s attention in the future, he stated that graduates should be as conversant in genomes as they are in Shakespeare. Summers felt that the significant innovations of the future would be found at the intersections of traditional academic disciplines.

A fiercely competitive institution, Harvard has been collaborating in the life sciences with its nearby rival MIT for over 30 years. Their joint Health Science and Technology program, drawing from their respective world renowned medical and engineering schools, is the largest engineering and physician-scientist program in the U.S. Early in Summer’s tenure the two institutions built the Broad Institute in order to bring the power of genomics to medicine. Since then, major global pharmaceutical companies have located in Cambridge, where both schools reside.

So far in this century, Boston and/or Massachusetts has consistently placed in the top five in National Institutes of Health funding, metro competitiveness, life science human capital, biotechnological location quotient, life science R&D location quotient, venture funding investment, top innovative-entrepreneurial U.S. regions. Moreover, Boston is one of the top ten world regions for neuro-technology.

Other business development efforts have followed Harvard’s focus on the life sciences. In 2004, 40 states had active life sciences strategies as part of their state economic development strategy. Next door to Grand Forks the Minnesota life science activity is increasing despite a significant statewide budgetary turndown. The lead editorial title in the March 5, 2008, Minneapolis Star Tribune “Biosciences buildings are a must this year,” was arguing that despite the current fiscal crisis, where $4 is being requested for every $1 of state authorized money, the
state should build more bioscience buildings.

TRENDS IMPACTING LIFE SCIENCES

Trend: Inclination in a particular direction; tendency; general direction.

Dr. Summers and his Boston brain trust had many trend-based reasons to label this century as he did. Does their reasoning apply to less-resourced regions such as Grand Forks? Before we examine trends, a few caveats. All trends are not equal, and their impact will vary according to the life science entrepreneur’s (LSE’s) business model. There is often a trend lag - target markets can be highly variable in their adoption of (and payment for) strong, evidence-based innovations. Timing the trends’ market impacts is as crucial as cultures are difficult to change. Many trends are closely associated with one another, and their parsing can be subjective. Although a comprehensive trend analysis cannot be conducted here, significant trends at several levels pertinent to life science business development are discussed.

The goal is to align the Grand Forks region with those trends that work in its favor while fully recognizing and taking steps to minimize those trends that do not.

Mega Trend: Globalization & commercialization.

Increasingly efficient flows of ideas, people, money, products, and services across the globe in conjunction with new foreign commercial markets (will) make local life science efforts as global as the need(s) that they address. Several local area LSEs are currently operating on a global scale.

Highly specialized American medical practitioners have been attracting international customers on the basis of quality innovations for decades (e.g. Mayo in Rochester). Nowadays the flow has become bilateral due to foreign-based, high-quality providers mastering their business plans in low cost, high-end resort destinations. In fact a new term has been coined - ‘health tourist.’ Someone from Grand Forks, for example, can obtain a high quality operation and/or cutting edge products and services in a foreign country while recuperating in a world class resort setting and enjoying total savings greater than 50%.

Health service entrepreneurs have understood this ‘focused factory’ concept for decades, employing a business model based on controlling quality and cost through explicit process management. As globalization effects lower access barriers and quality becomes more transparent, cost becomes a factor in the health services economy - especially as costs are shifted to the individual.

At the life science economic development level, globalization’s impact can be seen in such collaborative efforts as that involving cities along the Mid-Continent Trade Corridor that passes through Grand Forks on its way from Canada to Mexico. Winnipeg, Kansas City, and Monterrey (Mexico) have conceptually leveraged this concrete transportation corridor to a much more abstract virtual knowledge corridor. Stakeholders from these three regions are currently in the process of developing a functional food that will positively impact Type 2 Diabetes by pooling their scientific knowledge and leveraging their entrepreneurial talents. Strategic collaboration becomes a core skill in a global economy.

Globalization can have a dark side, especially when it comes to population health. Civilization effects can promote the emergence of new disease (HIV-AIDS, avian flu, etc.) as well as the re-emergence of once contained threats -
such as tuberculosis - but with greatly enhanced drug resistance. Efficient worldwide transportation networks can promote the rapid spread of such diseases to the point of outstripping the disease surveillance capabilities of public health systems. An immigrant and/or recent traveler coughing in the local emergency department can no longer be assumed to have a simple bronchitis. Such trends can be both a threat to society and an opportunity in the life science industry, depending on one's point of view. Rapid point of service diagnostic products will be in increasing demand, which will be well serviced by firms with expertise in lab(s)-on-a-chip technologies (miniaturization, surface technology, nanotechnology, molecular biology, etc.).

In the global marketplace, business cultures clash as strategic concepts and other norms butt heads. While out of sight and therefore out of mind, how a Chinese LSE formulates and implements her business plan can directly affect the Grand Forks LSE’s target market. Economic competition is global.

**Mega Trend: Knowledge explosion.**

We live in a fascinating age where knowledge is power and it is being produced in an exponential rate (as is technological change). This drives the phenomenon of life-long learning for the (life science) knowledge worker, which in turn drives those in the learning fields to make their products and services much more user-centric. Disciplines are rapidly deepening - increasing the value of the specialist expert in technical matters- while long-standing information asymmetries are rapidly flattening - decreasing the power of traditional business models. Knowledge is well on its way to becoming democratized.

As a result of these factors, this trend - especially when combined with others - gives birth to very powerful, more specific trends in many fields, but especially in the life sciences (see personalized medicine).

Businesses get this trend. They can’t wait for slow and siloed academic cultures to change to address their human capital needs, so they turn to entrepreneurial models and methods of learning. Many large capital companies have their own institutes for specialized post-graduate training. A local life science company is internationally noted for training its own employees in its proprietary processes that have revolutionized its field and brought them sustained success.

Perhaps the greatest effect of this trend (from the business model point of view) will be seen at the organizational level. When groups compete on the rate of processing and implementing emerging information and knowledge, their business strategy changes and forces the development of more adaptable organizational structures, processes, and patterns. Those who are slow to adopt and change will lag their competitors.

**Mega Trend: Demographics.**

The number of humans worldwide is greatly increasing, driving the demand for innovative individual and public health solutions. Something as basic as more people being hungry is a medical problem, a public health problem, a security problem, a business problem, an agriculture problem, an ecological problem, and so on. Consequently, the impact of 8 billion people on the planet by 2030 (UN estimate) poses great challenges for many related life science industry segments.

Closer to home, take the demographical impact of the U.S. aging population on a drug or device business model. The ‘boomers’ - a highly educated cohort
who have changed every social system they have come in contact with - are moving into retirement age enjoying another demographic trend - increasing life expectancy. A good bet will be that they will fight disease and death in their retirement years as well as they can - a great market for a drug or device firm. Yet the boomers will face another demographic trend - the decreasing worker to retiree ratio - that in turn will have a huge impact on the Medicare fund that they planned on using to fund their new joints and drugs. It is easy to see that public policy changes in the near future could have a significant impact on reimbursement for the drug or device which in turn will greatly impact the firm’s business model. Financial risk management in the life science industry is a critical skill.

As the chronic disease burden of developed countries is largely borne by the elderly and paid for by the government, life science business models need to understand the dynamics of this market in order to bound their risk. Analyzing demographic patterns of disease (epidemiology; biostatistics), consulting actuarial tables, understanding reimbursement schedules, and applying macroeconomic principles all help in developing the business plan, as does belonging to an association with a strong lobby at the federal level. Geographic information systems linked to the above data can add further discriminatory power to the firm’s marketing plan.

Mega Trend: Information Age.

Much has been said about the new age in which we live - a direct ‘descendent’ of the knowledge explosion trend - especially as computer-based systems evolve and converge with wireless communication systems to form a pervasive computing environment that will eventually have the capability to extend into and network across all life spaces and life science segments.

Information technology has disrupted many business models, allowing small market start-ups to outsource various functions to suppliers as well as digitally communicate and collaborate across time and space with partners anywhere on the grid. A real boon to LSEs based in Grand Forks - in the sense of somewhat equalizing the playing field within the industry - this trend is bringing the necessity of explicitly managing the social capital of the firm into a clearer focus. Many small early-stage development companies have a great business need to form alliances; alliance management is a clear-cut example of social capital management across organizational, cultural, and geographical boundaries.

Selected Science & Tech Trends

Western reductionist thinking has served the LSE well. It has given him/her leverage-able trends such as: miniaturization (nanotechnology, molecular markers, pervasive computing), connectivity (software design, pervasive computing, video conferencing, remote/robotic surgery), and high speed analysis.

These trends - along with advances in materials - contribute in turn to other novel products, services, and processes. Perhaps the most well-know result of breaking things into its parts is the sequencing the human genome, leading to new fields of study (genomics, proteomics) and perhaps the most revolutionary medical trend of all - personalized medicine (see below).

These trends not only provide for new products and services to the consumer, but they have a transformational impact on the business itself, overcoming barriers of time, distance, and resources. Claiming the value of new lodes of intellectual property has had a ripple
effect on the legal profession and other intellectual capital enablers. The LSE scientists/technologists find themselves in an interdependent network of professions as they work towards tangible returns on their personal investment. The economic developer growing a life science cluster does well by ensuring access to all of the necessary partners of the LSE.

One somewhat counter-intuitive result of reductionist thinking is the fuel it provides for combinatory thinking, a driver of innovation. A major value of breaking things apart is the novel combinations of the parts. Reductionist minded LSEs do well by surrounding themselves with combinatory counterparts.

Selected Healthcare Trends

Healthcare delivery in general and medicine in particular is in the midst of transformation, so the outcome(s) are largely speculative. Several strong trends (and their impacts) will continue despite ‘outcome’ uncertainty:

A broader definition of health - a move from ‘the absence of disease’ to one that includes many aspects of well-being and non-western medicine. Impact: market expansion effects.

Innovation (drugs, devices, etc.) will continue to be the major driver of expenditures, which in turn creates cost-shifting behavior between payers, providers, and patients in healthcare systems. Impact: reimbursement considerations - who will pay and willingness to pay are critical aspects of the LSE’s business plan.

Payment reform - a move from pay per visit/procedure to pay for performance/outcomes. Impact: various interdependent effects.


Consumer empowerment - by choice (knowledge effects) and by ‘force’ (cost shifting). Impact: multiple, e.g. direct-to-consumer marketing.

Major health system reform. Impact: too numerous to mention. Keep your eye on the money (some form of rationing will occur, as the pie will be fixed) rather than on the lip service given to the (individual) patient.

Movement of emphasis from individual care (medicine) to a balanced emphasis on population care (public health) and individual care. Both will be appreciated in greater senses, due to homeland security and emerging infectious disease reasons. Impact: greater opportunities - in all sectors - for the life science industry, especially involving sensing and sense-making systems and novel therapeutics.

Selected Business Trends

Life science firms that target humans work in a high-risk business environment. The high costs of safety, quality, and efficacy will continue to drive cost-and-risk shifting and capital seeking behavior. At the beginning of its fourth decade, biotechnology as a whole is growing and is projected to continue to grow. Worldwide there are 4,275 biotech companies with 190,500 employees. Public companies (710) produced $73,478M in revenues with a net loss of $5,446M in 2006. Ernst & Young describes the industry as marching towards maturation and aggregate profitability.

Some 2007 highlights include:

- Stronger pipelines.
- Big pharma’s increasing dependence on biotech’s pipelines.
• Weak IPO valuations, making acquisitions the exit of choice.
• Innovation continues to drive value in R&D, in deal structure, and in go-to-market strategies.
• Drug pricing debates now include the ‘fourth’ hurdle - proving cost-effectiveness before gaining coverage. Life science firms need to be looking at costs and benefits more holistically from the point of view of the buyer.
• Increasing understanding of biotech’s potential to disrupt other industries including energy, agriculture and industrial manufacturing.

Life science business success drives business/management challenges, including:

• ensuring R&D productivity;
• protecting intellectual property;
• attracting and retaining scientific and managerial talent;
• ensuring sales force regulatory compliance;
• responding to pricing pressures;
• thinking/managing globally (e.g. expansion) from day one;
• exit strategies, especially merger and acquisition.

It is important to note that global thinking, outsourcing, IP issues, sales/marketing alliances and other collaborative activities require a significant amount of social capital and strategic collaboration skills. LSEs will do well to honestly assess their capabilities in this critical area and devote resources to enhancing them if need be. Similarly, communities that want to successfully develop life science sectors/clusters will need to create robust networking environments where the “triple helix” of business, education and government can readily and frequently engage in information exchange.

Life science economic developers have understood for quite awhile that competition is global; there is less ownership of the mindset that discounts geopolitical boundaries in favor of regions. The Mid Continent Knowledge Corridor mentioned above highlights that ‘regions’ can be virtual in the sense that the real boundaries are self-defined community boundaries - communities of practice that inhabit a discontinuous and at times virtual geography. Once again, this highlights the need for growing social capital in addition to financial capital and human capital. Economic developers need to be strategic collaborators to serve their LSEs well.

LSEs and economic developers need to be aware that all sectors play in the US healthcare system. There are a few emerging examples of a foundation taking the lead role of the venture capitalist/philanthropist to fund research on specific disease solutions.

In a final note applicable to all global-reaching firms, local entrepreneurs need to understand that in post-modern competition their rivals (especially in the East) may not see the world as they do or hold similar values. Their unseen rivals may deliberately formulate multidimensional strategies that include financial, trade, sanction, media war, ideology, diplomatic, psychological, and natural resource pressures that seem to stop just short of war. Business is not a sport.

CONVERGENCE IN THE LIFE SCIENCES

Of course trends interact. One way they interact is to converge. In this sense, convergence (itself) can be thought of as a meta-trend (a trend of trends) in the life sciences. On the other hand, convergence is a stand alone life science trend in the sense that LSEs are all about combinatory thinking - seeking to combine things in novel ways in order
to enhance existing products, services, and processes or to create new ones.

Convergence can have multiple meanings. Wiktionary defines convergence as ‘the merging of distinct technologies, industries, or devices into a unified whole’. The life science industry takes the Food and Drug Administration’s definition of a combination product and expands it to “the integration of two or more core technologies (diagnostics, devices, and/or drugs) to create an improved health care product.” Familiar examples of product convergence would be:

Drug-device: drug-eluting stents for coronary arteries.

Diagnostic-drug: screening test for a specific gene coupled with targeted drug therapy.

Diagnostic-device-drug: blood sugar monitor with an insulin pump.

As defined in 21 CFR § 3.2(e), the term combination product includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

However, a product-based definition limits convergence’s descriptive and creative utility, as convergence works at many levels:

• convergence of trends (boomer aging and information technologies);
• convergence of sectors (public-private ventures);
• convergence of disciplines (biology and physics) and/or bodies of knowledge (engineering and information science);
• convergence of industries (agriculture and healthcare);
• convergence of technologies (genetic engineering and bio-informatics).

All of these elements play a role in the life sciences, making convergence an extremely fertile concept and activity for innovative LSEs.

A premier example of robust convergence in health care delivery is the Forrester Research concept of “Healthcare Unbound:” Technologies in, on, and around the body that free (unbind) care from formal institutions (bricks and mortar). This is a powerfully authentic approach to individual care that builds on the trends of empowered consumers, changing demographics, globalization, changing reimbursement systems, healthcare systems reform, chronic disease management systems, information systems, web-based communications, miniaturization, etc.
As a concept, it has the attention of major international businesses, healthcare providers, payors, venture capitalists, and LSEs. As an activity, it attracts stakeholders to various types of meetings - conventions, communities of practice, research settings - on an ongoing basis. More importantly it has spawned numerous start up companies who are eager to enter the world of network-based, point-of-care combination products.

"Healthcare Unbound" is a great example of the power of abstract-concrete, multi-level, multi-disciplinary, multi-technological, multi-sector, and multi-system convergence. It fits all definitions of convergence while forming a substantial trend in its own right. It instructs the LSE in how their value can be multiplied through strategic partners, suppliers, and allies.

THE UTILITY OF TRENDS & CONVERGENCE

Trend awareness and trend sense-making vis-à-vis one’s business model is a critical organizational function that is usually tasked to senior management and/or outsourced to membership associations. Some forward-looking firms are explicitly assigning these complementary tasks (sensing and sense making) to a formal organizational role such as Director of Future Studies, etc.

Other firms, often compromised of knowledge workers - try to empower all of their members to develop these capacities, believing that a flattened structure with network redundancies is the organizational form that will serve them well in the post-modern world of business competition, where rapid looping of new information and knowledge is a competitive advantage.

Convergence is at the core of the life science industry as a strategic means to an innovative end (products, services, and processes). It is also at the core of the economic development field, as its practitioners are constantly involved in merging and integrating distinctly different efforts into a unified, functional life science ecology. While it may seem like a buzzword ‘du jour’, its substantial salience in the life sciences will continue to grow on numerous fronts, including the following:

- As LSEs deepen their appreciation of the design of natural bio-systems, they will build their products, services, and processes along those inherently convergent design principles.
- As intellectual property emerges out of basic research, becomes ‘translated’, and attracts commercialization interests, serious attention will be directed towards managing convergence-based risk.

Local LSEs were asked (in a one on one setting) their take on convergence in the industry and the area. Various reactions ensued. One felt that the question was visionary, in the sense that (most of) his colleagues don’t think in proactive ways but rather react to trends and events.

One of his colleagues proved him wrong with an interest in the convergence of robotics, super computing, and nanotechnology for faster bio-sample processing. One proved him right by failing to understand the question despite several re-workings. Another had several facile convergences at the tip of his tongue - IT mediated connections between brain waves and large muscle groups, convergence of multiple local institutions around IT, and the application of Microsoft’s supply chain management to healthcare delivery. One local expert envisioned a time when genomic-driven personalized medicine will abolish animal model testing.

While there seems to be an adequate supply of convergent thinking in the
Red River Valley it appears that more robust mechanisms are needed to share them. The interview process revealed that people don’t know much of what is happening in the life sciences within a 70-100 mile radius of themselves, raising the social capital theme once again.

**Conclusion**

Local LSEs have to factor in the impact of these and other trends in much the same way as their counterparts in Boston do. It’s a good time to be in life sciences, whether in Boston, San Diego or Grand Forks. Readily identifiable trends and convergences pose significant challenges - with matching opportunities - to the health of the planet, the health of societies, and the health of individuals.

The importance of trends and convergences is succinctly summarized by Gretzky’s famous answer when the hockey great was asked what the secret to his success was: “I skate to where the puck is going.” Businesses and local or regional economies ignore the force of trends at their peril; those who neglect to understand the convergences at play will be surprised. Which won’t be a good thing when it comes to staying ahead of their competition in the highly interdependent world of life sciences.
An assessment of the current assets, capabilities and infrastructure related to the life science sector in Grand Forks points to a sector that is fairly diverse. The non-agricultural business components of the sector are in their early stages and just starting to forge new university-based partnerships. At the same time, the infrastructure and expertise located at the University of North Dakota and the University of North Dakota School of Medicine and Health Sciences has been a major driver of life science activity in the city and region for some time now.

With significant research and development capacity within the University, academic strengths and a growing physical infrastructure, the community and the University are poised for growth and are already starting to capitalize on private-public opportunities related to the life science and biotech industry growth.

The University of North Dakota School of Medicine and Health Sciences houses several centers that are key to the ongoing research, development and potential commercialization of ongoing research being conducted at the University. These centers include:

The Basic Sciences Imaging Center provides advanced instrumentation for researchers interested in investigating biological processes at the cellular, subcellular, and molecular level. The center consists of two facilities including the light microscopy core and the electron microscopy core.

The light microscopy core is equipped with sophisticated, laser-scanning confocal microscopes that can be used, for example, to study molecular interactions within live cells or the distribution of molecules within human tissue. Renovation of the light microscopy core and purchase of a Zeiss LSM 510 META confocal and FCS system, a state-of-the art confocal microscope and fluorescence correlation spectrometer, was made possible with funds awarded through COBRE. Centers of Biomedical Research Excellence and is an NIH program designed to cultivate research and strengthen research infrastructure in states that do not receive as much NIH funding as some other (larger) states.

The electron microscopy core, housing a Hitachi 7500 TEM and a Hitachi 4700 field emission SEM, provides modern and powerful scanning and transmission electron microscopic capabilities, necessary for examining the fine ultrastructure of cells and tissue down to the level of individual molecules.

The Center for Biomedical Research has a state-of-the-art animal research facility (2060 square feet) on campus. The center is equipped with 10 animal rooms, one quarantine room, 2 Bio-Hazardous Facilities with a common water shower (one with class 2 Biological Safety Cabinet and Chemical Hood and the other has Class 2 Biological Safety Cabinet), one radio isotope room equipped with a Chemical Hood and a water shower. There is a necropsy room equipped with a fume hood in the anteroom and two, small tabletop fume hoods in the procedure room. There is a surgical suite composed of a preparation room, a scrub room, a recovery room, and a large surgery room.

Two of the ten animal rooms have Allentown volume-controlled exit air ducts for individual ventilated caging system. This system provides a barrier between cages and minimizes human exposure to animal allergens. All animal rooms are provided with an Edstrom watering system, which sanitizes the drinking water by a series of filtration...
and acidification. Each animal room has its own supply and exhaust ducts equipped with a VAV (Variable Air Volume) box which controls air flow temperature and humidity.

The Mass Spectrometry Facility was opened in the spring of 2003 as part of a COBRE (Center of Biomedical Research Excellence) program in Pathophysiology of Neurodegenerative Diseases. The facility provides instrumentation, expertise and training in mass spectrometry necessary for the advancement of COBRE research projects. Services are not limited to the COBRE investigators, but are also available to all campus investigators as well as off campus investigators.

COBRE was designed by the National Institutes of Health to cultivate research expertise among junior faculty and strengthen the research infrastructure of states that do not receive as much NIH funding as some large states. In 2002, the University of North Dakota School of Medicine and Health Sciences received a $10.4 million award from the National Institutes of Health (NIH) to establish a nationally recognized center of biomedical research excellence. This five-year grant was renewed in 2007 for another five-year period at $10.1 million. The grant continues to support collaborative projects at Med School, promoting research opportunities for biomedical investigators in North Dakota with broad potential for understanding and treating pathophysiological and neurodegenerative diseases.

There are several key (select) platforms being researched at the University including work focused on possible dietary causes of Alzheimer’s disease, potential causes and treatments for epilepsy (adrenergic modulation of seizures and neurodegeneration), medical devices and research on new vaccines and improved antibiotics to combat bioterrorism and prevent the spread of infectious diseases.

Recently, Dr. Othman Ghribi received a five-year RO1 grant, totaling nearly $1.5 million, from the National Institute of Environmental Health Sciences to study the links between high cholesterol levels and Alzheimer’s disease. This is the largest individual grant awarded to a UND researcher for the study of Alzheimer’s disease (AD). RO1 grants are very competitive and are awarded to relatively few researchers. The NIH grant will support the hiring of three or four employees to work in Ghribi’s laboratory.

Ghribi’s investigations were initially funded by North Dakota Biomedical Research Infrastructure Network (BRIN), now called the North Dakota IDeA Network of Biomedical Research Excellence (INBRE). More recently, these studies have been funded by the Center of Biomedical Research Excellence (COBRE).

UND biomedical researchers Van Doze and James Porter are conducting collaborative research involving the close-up study of the noradrenergic system. They are looking at the mechanics of the neurotransmitters involved in epileptic seizures, the drugs that control those seizures, and the collateral mechanisms in those drug interactions that can, with current therapies, cause learning and memory loss. This research is utilizing undergraduate, graduate and postgrads in their ongoing research.

Matthew Nilles is developing a better understanding at the molecular level of Yersinia pestis, the bacteria that causes bubonic plague. His research could lead to new vaccines and improved antibiotics to combat bioterrorism and prevent the spread of infectious diseases. Nilles’ laboratory is one of a handful in the United States studying the Yersinia bacterium. However, since the terrorist attacks of
Sept. 11 and the anthrax attacks that followed, interest in research on bubonic plague and other infectious diseases is growing. By conducting research that furthers the scientific understanding of how bubonic plague is caused, much of what’s learned about in the laboratory can be broadly applied to other diseases. These include Salmonella, dysentery, infections affecting cystic fibrosis patients and patients with burn wounds.

Dr. Holly Brown-Borg, a faculty member and researcher at the University of North Dakota (UND) School of Medicine and Health Sciences, has received an unprecedented award from the Glenn Foundation, based in California, to support her research on aging.

Brown-Borg, associate professor of pharmacology, physiology and therapeutics, received the Glenn Award for Research in Biological Mechanisms in Aging, totaling $60,000, to support her laboratory technician, a colony of Ames dwarf mice, supplies and other materials. She has one of only five such Ames mice colonies in the United States.

Her research is focused on identifying mechanisms of stress resistance that are associated with health and longevity. For her studies, she has also received grant funding from the National Institutes of Health and the American Federation of Aging Research.

In 2007, the State approved a $2.5 million grant for Enova Medical Technologies, the University of North Dakota (UND) and North Dakota State University (NDSU) to develop and manufacture an innovative thrombectomy (medical) device. Enova Medical Technologies, a privately-held company, is engaged in the development and commercialization of proprietary medical devices and is an experienced provider of product development, manufacturing, and commercialization services for the medical device industry. From Class I to Class III devices, Enova understands the technical challenges of product design, engineering, research and development, the regulatory steps required to successfully commercialize products, and the marketing and sales efforts needed to move inventory off the shelf.

The grant will fund the Center of Excellence for Biomedical Device Research, Development and Commercialization, which will focus on Enova’s patented license for a thrombectomy device that removes clots in blood vessels. Enova will team with researchers at the UND School of Engineering, the UND School of Medicine, and North Dakota State University College of Engineering to develop the device. The mission of the Center of Excellence for Biomedical Device Research, Development and Commercialization is to provide the research, development, and commercialization resources for a range of biomedical devices. Over time, the Center will conduct multiple, concurrent projects for various biomedical companies and cities, thereby providing the potential for economic development throughout North Dakota and the region.

The North Dakota Biomedical Research Infrastructure Network’s (BRIN) purpose is to build biomedical research capacity within the state. Networking and human resource development are key elements of this collaborative effort between the two North Dakota research universities, four baccalaureate institutions in the North Dakota University System and five tribal community colleges. Long-term outcomes include an increase in biomedical research competitiveness and an increase in the number of college graduates entering biomedical research careers.
Grand Forks is also home of the Center for Rural Health that serves as a focal point for rural health in North Dakota. As the federally designated State Office of Rural Health for North Dakota, the Center connects the School of Medicine and Health Sciences and UND to rural communities and their health institutions to facilitate developing and maintaining rural health delivery systems. In this capacity, the Center works at national, state and community levels. Four core areas serve as the focus: education and information dissemination, program development and community assistance, research, and policy analysis.

The University of North Dakota has several other areas of expertise in Life Sciences research focusing on evolution and ecology and cellular and molecular biology. Currently, there are 14 faculty who conduct research in molecular, quantitative and population genetics, systematics, biogeography, evolution of plant reproductive systems, physiological and behavioral ecology, spatial population ecology, ecosystem ecology, and conservation and restoration and nine faculty who conduct research in cellular and molecular biology, neurobiology, genetics, evolution of plant reproductive systems, and physiology.

The UND Division of Medical Genetics offers information, diagnostic services, education and support about current and future genetic health concerns. Their comprehensive clinical genetic/birth defects program provides and utilizes an extensive network of services both locally and nationally. The program educates undergraduates, graduate students, and practicing professionals in the areas of medical science and health & human services, and also presents educational programs throughout the surrounding communities.
The breadth and depth of expertise and core competencies in various life science related fields is exhibited by the numerous grants and ongoing support provided to the University by various state and federal programs. An overview of support from the National Institute of Health (2005-2007) points to the importance of research and development for the University and the City of Grand Forks – in advancing life disciplines and as an economic driver.

Table 3. All NIH Grants for FY 2007 – University of North Dakota.

<table>
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<tr>
<th>PI Name</th>
<th>Project Title</th>
<th>Dept Name</th>
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<td>Abeta is a Proinflammatory Ligand for Microglial APP</td>
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<td>Young, Kevin D</td>
<td>Bacterial cell wall synthesis, shape and septation</td>
<td>MICROBIOLOGY/IMM UN/VIROLOGY</td>
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<td>TRPC1 and saliva secretion</td>
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Table 4. All NIH Grants for FY 2006 – University of North Dakota.

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<td>Liu, Rugao</td>
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<td>Darland, Tristan</td>
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Table 5. All NIH Grants for FY 2005 – University of North Dakota.

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<td>Metallothionein Isoform 3 and Renal Cadmium Toxicity</td>
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<td>Liu, Rugao</td>
<td>Motor Neuron Regeneration Model on ALS-Like Mouse Lifes*</td>
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The University of North Dakota Research Foundation (UNDRF) leads the technology transfer and commercialization efforts at the University. UNDRF was formed to advance the University of North Dakota’s research agenda, to commercialize university innovations and discoveries, and to create economic opportunities for Grand Forks and the State of North Dakota. The UNDRF works with UND faculty and staff to build successful and strategic partnerships between the university and private companies for mutual gains.

As part of this work, the University of North Dakota has been designated as North Dakota’s Center of Excellence in Life Sciences and Advanced Technologies (COELSAT). The development of this center will ultimately spur the growth of Grand Forks’ Life Sciences sector by creating jobs from the commercialization of University research innovations developed through corporate partnerships – these efforts will be led by the UNDRF. The primary objective of COELSAT is to provide infrastructure that includes laboratories, pilot manufacturing capabilities, and office space for the corporate partners and business alliances to launch spin-off companies and to form joint ventures with UND.

As part of this effort, the UNDRF has partnered with the City of Grand Forks and the North Dakota Department of Commerce to develop the Research Enterprise and Commercialization (REAC) campus. REAC’s first initiative is to provide key infrastructure, including wet laboratories, equipment and intellectual capital for joint research collaborations and new businesses in the areas of Life Sciences and Advanced Technologies. UNDRF will manage the intellectual property stemming from UND research.

The 50,000-square-foot research building will be managed by the UND Research Foundation and it will have the only Bio Safety Level (BSL) 3 pathogen research lab in the State. It is designated by the state as a center for commercialization, and is looking to implement Current Good Manufacturing Practices (cGMP) labs. These are labs where researchers can develop ways to manufacture biotech products, and the cGMP ensures that these products are not adulterated by outside contaminants. The center will be identifying and recruiting trained cGMP staff to work within the facility.

The center’s mission is to develop commercial products based on life science research. Six corporations will be brought into the facility. Four of them will be from the life sciences area and two from advanced technologies. Three life science focused private-sector companies - Avianax, NovaDigm and Prologic, and three University based entities – Borders, the Center of Infectious Disease and Sunrise, have already designed research and office space in the facility. They will work with UND faculty on joint research projects and to develop student intern projects.

Avianax is based in Grand Forks, and will be researching antibody therapy and vaccines for West Nile virus and the bird flu virus. Vaccines help prepare your body to fight specific diseases. Antibody therapy can be given to an individual following exposure to a disease. This therapy will not cure the disease but will often decrease the severity of the disease.

Antibodies are large proteins made by the immune system that specifically recognize substances that are foreign to the body. Antibodies work with other proteins and cells in the immune system to either prevent disease or recover from infections. Since the body can take three to four months to develop antibodies
Antibody therapy places the antibodies in your body immediately.

This technology is not new, but only in recent years have scientists developed the ability to create new antibodies quickly enough to keep up with the rapid mutation of viruses and bacteria. The mutations make the viruses and bacteria more resilient to antibodies they've been exposed to, requiring new kinds of antibodies. UND holds patents related to this technology, as does Avianax, resulting in a natural partnership. The economic impact, should Avianax succeed, is not limited to Grand Forks alone. The company recently purchased a farm in Tolna, N.D., to supply it with goose eggs and blood for use in testing.

NovaDigm Therapeutics is a Los Angeles-based company that is developing a vaccine for staph bacteria that have grown resistant to antibiotics. One variety has become a major source of infections in hospitals. The company also is researching vaccines for candida, a kind of yeast that infects hospital patients with compromised immune systems. NovaDigm developed the proteins for the vaccines but is seeking to work with UND.

BORDERS (Biological Organic Radiologic Educational Response System) program was developed at UND, following the terrorist attacks of September 11 (9-11) with a $2.4 million grant from the Department of Health and Human Services. The attacks created a need for a program to train medical professionals to be alert for signs of bioterrorism.

Instead of just training medical professionals as did other universities that got similar grants, UND created an electronic training program that could go over the Web or be installed on portable computers. This way, the grant has a lasting impact, especially now that the University has patent protection for the training program. The BORDERS training program has two components – a training course and a new electronic patient chart for the Army.

The electronic patient chart takes the form of a handheld tablet with medical records that goes wherever the patient is. A system keeps track of who has what condition and, if there are new developments, the military can quickly contact the patient's doctors. The chart came about after a $1.3 million grant from the Department of Defense. ProLogic, a Fairmont, W.V, company, is involved as the middleman, finding university research that has potential military applications and arranging the deal between the researchers and the soldiers.

The Center of Infectious Disease was formed by faculty in the medical school to conduct research on diseases such as the plague. An office at the COELSAT will allow access to the BSL3 laboratory expanding the Center’s research capabilities. As noted previously, Matthew Nilles is developing a better understanding at the molecular level of Yersinia pestis, the bacteria that causes bubonic plague. His research could lead to new vaccines and improved antibiotics to combat bioterrorism and prevent the spread of infectious diseases.

SUNRISE is a consortium of UND researchers working to convert canola and soybean oil into jet fuel and plastics. The largest problem related to the use of biofuels is their cold flow properties, i.e. the temperature at which the biofuel gels or solidifies. This is a significant problem for the development of aviation biofuels because of the cold temperatures airplanes are subject to at higher elevations. SUNRISE is resolving this problem, and also utilizing related technologies and their expertise for research on green plastics, which are otherwise made with...
petroleum. The ongoing research and development focusing on biofuels and plastics – based on conversion of canola and soybeans – provides an opportunity to add value to these North Dakota crops.

Grand Forks is also home to several other public and private life science based entities. These organizations capitalize on the ready workforce and access to needed infrastructure either from the University or privately developed.

The US Department of Agriculture’s Grand Forks Human Nutrition Research Center (GFHNRC) conducts research on nutrition and its impact on human health and wellbeing. Working with a number of private sector units, UND and the GFHNRC are working to enhance an understanding of the health benefits associated with locally produced foods. This research may prove effective in combating chronic diseases such as cancer and diabetes.

The GFHNRC is staffed by 15 senior scientists and 82 support personnel. It is one of six Human Nutrition Centers operated by the Agricultural Research Service (ARS) of the United States Department of Agriculture. The Grand Forks Human Nutrition Research Center has been a world leader in nutrition research for more than 30 years. The current foundation of their research is Obesity Prevention, Health Roles of Food and Bone Health.

The Nutrition Center has numerous partnerships with universities, other government agencies as well as commodity groups. A current collaboration with the U. S. Army Institute for Research in Environmental Medicine is pioneering research on high-temperature/exertion sweat losses of nutrients. The Center also has partnerships with Native American communities and tribal colleges to address obesity, diabetes, heart disease and depression in high-need, underserved communities.

The 80,000-square-foot building contains state-of-the-art facilities for research with humans and animals, as well as multiple chemical and biochemical laboratories. It has an annual budget of $9.8 million. The mission of the ARS National Program in Human Nutrition is to conduct basic and applied research to identify and understand how nutrients and other bio-active food components affect health. The ultimate goal of this food-based agricultural research is to identify foods and diets, coupled with genetics and physical activity, that hold the potential to sustain and promote health throughout the life cycle.

PRACS Institute in East Grand Forks, is a full-service contract research operation that offers clinical, bio-analytical, and statistical research services for the pharmaceutical industry. PRACS has addressed industry growth demands by accommodating both in-house and ambulatory clinical studies, expansion of bio-analytical services, establishing in-house clinical laboratory services, broadening their statistical and medical writing services, and expanding information technology support services. The facilities and staff accommodate about 100-115 projects annually in study sizes ranging from 6 to 120 participants per study.

PRACS Institute provides both in-house and ambulatory clinical studies, bioanalytical services, in-house clinical laboratory services, statistical and medical writing services and information technology support services. PRACS (at its Fargo and East Grand Forks locations) offers:

- Experience with Phase I - IV, OTC and cosmetic/personal care research
- On-site CLIA-certified clinical laboratory
- On-site bioanalytical laboratory
• Bioanalytical assay method development, validation, and cross validation
• Protocol and consent document development

PRACS research experience includes:
• Age/Gender-specific studies
• Bioavailability
• Bioequivalence
• Definitive QTc trials
• Dermatology, including topicals and transdermal delivery
• Dose-ranging
• Drug interactions
• Efficacy and claims substantiation
• Pharmacokinetics
• Pharmacodynamic modeling
• Proof-of-concept studies
• Safety and Tolerability

Asgco, Inc. (recently purchased by UAP Distribution, Inc.), with retail locations in Minnesota, Montana, North Dakota, and South Dakota, is a formulator, manufacturer, retailer and distributor of agricultural crop protection products. The capacity of this company directly relates to the Agricultural Feedstock & Chemicals sub-sector outlined previously. These skill sets are especially applicable locally due to the prevalence of agricultural-related business concerns within the region.

BioLife Plasma Services in Grand Forks, is an industry leader in the collection of high quality plasma that is processed into life-saving plasma-based therapies. The company is licensed by and/or complies with requirements from the Plasma Protein Therapeutics Association (PPTA), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Transportation (DOT), Centers for Medicare and Medicaid Services (CMS) and other state and local regulations.

Altru Health System Research Center is a department within Altru Health System dedicated to providing research support services to physicians and researchers within Altru Health System. Altru Health System is a not-for-profit organization consisting of an acute care hospital, rehabilitation center, a large multi-specialty clinic, a family medicine clinic and several branch clinics.

Altru’s Research Center coordinates research studies and clinical trials ranging from general medicine to multiple specialties including diabetes, cardiology, urology, women’s health, respiratory disease, pain management, vascular disease, renal or kidney disease, orthopedic conditions and nutrition. Sponsors and Clinical Research Organizations that Altru has worked with in the past, or are currently working now, include (select) Abbot Laboratories, Alexion, Amgen, AstraZeneca, Bristol-Myers Squib, Eli Lilly, GlaxoSmithKline, Merck & Co., Pfizer and Aventis.

Conclusion

The Grand Forks region has considerable capacity in the life science industry sector, based primarily on the expertise and infrastructure situated at the University of North Dakota. New private startups are based mostly on partnerships with research and intellectual property emanating from the University. This relationship is positive in that it brings in entrepreneurs and management that are familiar with commercializing technologies and growing business, while providing revenue and research opportunities to the campus.
Life Science Workforce & Training

Education and training related to the life and biosciences industry sector is a critical ingredient from the emerging life science industry, and is centered at the University of North Dakota. This specialized training and education is spread over several departments and programs including the School of Medicine & Health Sciences, Biology and Chemistry. These departments offer both undergraduate and graduate level coursework that would provide the labor force and leadership required to build the Life Science industry sector regionally. Relevant coursework is presented in Table 8.

<table>
<thead>
<tr>
<th>Table 6. University of North Dakota School of Medicine &amp; Health Sciences Curriculum and Programs (select).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Departments</strong></td>
</tr>
<tr>
<td><strong>Biomedical Sciences</strong></td>
</tr>
<tr>
<td>• Anatomy &amp; Cell Biology</td>
</tr>
<tr>
<td>• Biochemistry &amp; Molecular Biology</td>
</tr>
<tr>
<td>• Microbiology &amp; Immunology</td>
</tr>
<tr>
<td>• Pharmacology, Physiology &amp; Therapeutics</td>
</tr>
<tr>
<td><strong>Neuroscience</strong></td>
</tr>
<tr>
<td><strong>Pathology</strong></td>
</tr>
<tr>
<td>• Clinical Laboratory Science</td>
</tr>
<tr>
<td>• Cytotechnology</td>
</tr>
<tr>
<td>• Histotechnology</td>
</tr>
<tr>
<td><strong>Centers</strong></td>
</tr>
<tr>
<td>• BORDERS Alert and Ready</td>
</tr>
<tr>
<td>• Basic Science Imaging Center</td>
</tr>
<tr>
<td>• Center for Biomedical Research</td>
</tr>
<tr>
<td>• Center for Rural Health</td>
</tr>
<tr>
<td>• COBRE</td>
</tr>
<tr>
<td>• INBRE</td>
</tr>
<tr>
<td>• National Center of Excellence in Women’s Health</td>
</tr>
<tr>
<td>• National Resource Center on Native American Aging</td>
</tr>
<tr>
<td>• The Mass Spectrometry Center</td>
</tr>
</tbody>
</table>

These curricula, and associated research programs, provide the foundation for expansion of the life science industry sector here in the region. Retention of graduates will be key to providing the skilled talent that will be needed to further build the industry base. Agricultural Feedstock & Chemicals and Research, Testing, & Medical Laboratories, in particular, will be key sub-sector industries within the region. Additional opportunities will be driven by continued research both in the academic and private sector.

Dr. Jim Petell, University of North Dakota Director of Technology Transfer and Commercialization, identified nine
potential jobs/occupations related to Biotechnology and Life/Health Sciences that he feels are necessary for a functioning bioscience/health science industry here in the region (Table 9).

Table 7. Key Occupations in Life Sciences Industry Sector Regionally – Grand Forks Region.

<table>
<thead>
<tr>
<th>Occupation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiologists</td>
</tr>
<tr>
<td>Medical Scientists, Except Epidemiologists</td>
</tr>
<tr>
<td>Biochemists and Biophysicists</td>
</tr>
<tr>
<td>Chemists</td>
</tr>
<tr>
<td>Medical and Clinical Laboratory Technologists</td>
</tr>
<tr>
<td>Biomedical Engineers</td>
</tr>
<tr>
<td>Chemical Engineers</td>
</tr>
<tr>
<td>Biological Technicians</td>
</tr>
<tr>
<td>Medical and Clinical Laboratory Technicians</td>
</tr>
</tbody>
</table>

Original list from Online Informational Network, US Department of Labor

Location quotients (LQ) were developed for these key occupations specific to Grand Forks and the BRIC impacted region as they relate to life sciences. Quotients less than 1 indicate a lower concentration of employment for a local area. As noted in Table 10, several occupations have a LQ of one or better indicating a higher concentration of these occupations in the BRIC area. These include Biological Technicians; Agricultural and Food Science Technicians; and, Separating, Filtering, Clarifying, Precipitating, and Machine Setters, Operators, and Tenders.

Table 8. Location Quotients for Key Occupations in the Life Science Industry Sector in the Grand Forks Region.

<table>
<thead>
<tr>
<th>Life Sciences</th>
<th>Area LQ 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targeted Occupations</td>
<td>N/A</td>
</tr>
<tr>
<td>Microbiologists</td>
<td>N/A</td>
</tr>
<tr>
<td>Medical Scientists, Except Epidemiologists</td>
<td>N/A</td>
</tr>
<tr>
<td>Biochemists and Biophysicists</td>
<td>N/A</td>
</tr>
<tr>
<td>Chemists</td>
<td>0.99</td>
</tr>
<tr>
<td>Medical and Clinical Laboratory Technologists</td>
<td>0.66</td>
</tr>
<tr>
<td>Biomedical Engineers</td>
<td>N/A</td>
</tr>
<tr>
<td>Chemical Engineers</td>
<td>N/A</td>
</tr>
<tr>
<td>Biological Technicians</td>
<td>1.85</td>
</tr>
<tr>
<td>Medical and Clinical Laboratory Technicians</td>
<td>0.55</td>
</tr>
<tr>
<td>Agricultural and food science technicians</td>
<td>6.89</td>
</tr>
<tr>
<td>Separating, filtering, clarifying, precipitating, and still machine setters, operators, and tenders</td>
<td>6.67</td>
</tr>
<tr>
<td>Mixing and blending machine setters, operators, and tenders</td>
<td>0.75</td>
</tr>
</tbody>
</table>
Occupations with a lower concentration include Microbiologists; Medical Scientists, Except Epidemiologists; Biochemists and Biophysicists; Medical and Clinical Laboratory Technologists; Biomedical Engineers; Biological Technicians; Biomedical Engineers; Chemical Engineers; and, Medical and Clinical Laboratory Technicians. As the region moves forward, significant efforts need to be taken to meet the growing needs of employers in these occupations. Retention of graduates will be key to growing this industry. In the short term, education and recruitment need to focus specifically on these occupations to meet current and future employment needs.

The Bureau of Labor Statistics has identified Life/Biosciences as a High Growth Industry. National High Growth Industries are economically critical, projected to add substantial numbers of new jobs, and are being transformed by technology and innovation (Table 11). Their projections point towards faster than average growth in the occupations identified as critical to growth regionally.


<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Faster than Average</td>
<td>76,000</td>
<td>29-2012.00</td>
<td>Medical and Clinical Laboratory Technicians</td>
</tr>
<tr>
<td>Faster than Average</td>
<td>74,000</td>
<td>29-2011.00</td>
<td>Medical and Clinical Laboratory Technologists</td>
</tr>
<tr>
<td>Faster than Average</td>
<td>37,000</td>
<td>19-1042.00</td>
<td>Medical Scientists, Except Epidemiologists</td>
</tr>
<tr>
<td>Faster than Average</td>
<td>8,000</td>
<td>19-1021.00</td>
<td>Biochemists and Biophysicists</td>
</tr>
<tr>
<td>Faster than Average</td>
<td>5,000</td>
<td>17-2031.00</td>
<td>Biomedical Engineers</td>
</tr>
<tr>
<td>Average</td>
<td>22,000</td>
<td>19-4021.00</td>
<td>Biological Technicians</td>
</tr>
<tr>
<td>Average</td>
<td>12,000</td>
<td>17-2041.00</td>
<td>Chemical Engineers</td>
</tr>
<tr>
<td>Average</td>
<td>7,000</td>
<td>19-1022.00</td>
<td>Microbiologists</td>
</tr>
<tr>
<td>Slower than Average</td>
<td>33,000</td>
<td>19-2031.00</td>
<td>Chemists</td>
</tr>
</tbody>
</table>

Source: Bureau of Labor Statistics

Conclusion

Strong economies, including the life science industry subsector, compete on the basis of high value and high productivity, not solely low cost. In the Grand Forks region, the ability to provide the high-value-added products and services necessary to compete in a global marketplace is bolstered by the region’s strong post-secondary institutions that provide advanced skill sets and a growing knowledge base in emerging technologies, advanced manufacturing processes and industry specific expertise.

A compelling body of research links primary and secondary education to economic development and growth. This research recognizes people as a critical economic asset – “human capital” – and shows that increased investment in skills and knowledge provides future returns to the economy through increased innovation and
productivity. As shown by the preceding analysis, the Grand Forks region has made this key investment to develop the critical mass of both people and skills to meet the growing needs of manufacturers and businesses to compete in the global marketplace.

The Grand Forks region (75 mile radius) is home to a broad array of post-secondary educational institutions (colleges and universities) with a growing and diverse student population that is making a difference in regional economies throughout the state. Led by the state’s two higher education flagships – the University of North Dakota and North Dakota State University – the region is home to over 45,000 students engaged in two-year technical, four-year bachelors, and Master’s and Doctoral programs.

The labor pool that this represents provides Grand Forks, and the broader region, a significant competitive advantage in the development of knowledge-based industries including the life sciences and biotech. While some skill sets are in short supply, there exists a significant educated labor pool to meet the current needs in the community. This asset, coupled with already significant and growing physical infrastructure and research & capabilities located at the University of North Dakota, holds the potential to grow a successful and thriving life science industry sub-sector.
OBSTACLES AND BARRIERS

For the Grand Forks region to fully realize opportunities in a rapidly changing, robust life science industry sector, several key issues need to be addressed. These issues represent current gaps in the innovation pipeline that often begins with the patenting of a technology, licensing that technology or product to an outside firm, or developing a partnership among public/private team members.

Based on extensive interviews and a thorough review of secondary data, the following gaps, voids or perceptions were identified that could serve as obstacles or barriers to realizing increased success in the emerging life science industry initiative within the Grand Forks area.

The life science industry sector in the Grand Forks region is not as well known, developed or connected (nationally or regionally) as it needs to be to capitalize on emerging opportunities in university led - private industry supported - research, development and commercialization.

Opportunities related to the growth in new life science related business in the Grand Forks area may be stymied by lack of recognition of what is available to outside/private firms both in terms of commercial/licensing opportunities and access to a skilled workforce. Within the community/region there is a lack of networking and communication, limiting interaction and awareness of what other departments and/or private firms or businesses are doing and what their collective capacity, expertise and research interests are.

The University and new private industry partners are starting to capitalize on the intellectual property (IP), state and local support, and research & development capabilities inherent at the University, but more needs to be done. Extensive networking, marketing and communication needs to be both developed and executed to bring these extensive capabilities to a wider audience. Ideally, these efforts should be driven by both the Grand Forks Region Economic Development Corporation and the University (led by the University of North Dakota Research Foundation).

While the University of North Dakota (School of Medicine) has a strong reputation and track record as it relates to the life sciences and allied health professions, gaps remain that need to be addressed if the Grand Forks region is to have the talent necessary to address the needs of this emerging industry sector.

The University, through its various schools and departments, provides top notch education and training in a myriad of disciplines and professions but there is a lack of key or critical professions that are needed for a growing and sustainable life science industry. In particular, microbiologists, biomedical engineers, biochemists and biophysicists were identified as lacking in number, or critical mass, to sustain high levels of growth in the region.

There is a lack of experienced life science entrepreneurs and management who can meet the management and business requirements in successfully launching and running a new or emerging business.

Lack of entrepreneurial and management experience, from an industry perspective, makes a start-up or emerging business more risky and ultimately harder to secure financing – be it early seed or venture capital. It is said an “A” management team can execute a “B” business plan more effectively than a “B” management team can execute an “A” business plan. Attracting these type of individuals to an emerging market can be problematic.
in the overall development of a robust and growing life science industry sector.

Capital gaps in the formation and development of new life science industry sector businesses are seen as a potential obstacle or barrier in attracting or recruiting new firms or entrepreneurs to develop or move new firms to the region.

While there are newly established RAIN funds in the state and in Grand Forks, the overall capacity to provide a level of equity investment required to spur growth and support startups in the region in the life science sector is lacking. The lack of pre-seed and seed capital resources is viewed as limiting entrepreneurship at UND and reducing the number of innovation-based companies in the local and regional economy.

Access to physical infrastructure (labs, equipment) is currently limited to the University. Continued growth in this industry will require private sector facilities that are currently lacking.

The UND Medical School and the REAC facility represent the bulk of the available life science infrastructure within the community. The University is the major driver in the local industry, but as new public-private partnerships mature, and new companies look at the community, there will be a need for more commercial-grade space to accommodate spin-offs and new and expanding businesses. Without these facilities, new businesses look outside Grand Forks to start or expand.

The academic community often overlooks commercial applications, contending that there is a lack of incentives to focus on this and it is not their job and as a result potential economic opportunities are lost.

There is considerable intellectual property developed at the University that, through a lack of interest or lack of entrepreneurial drive, is lost. The COELSAT is working to develop a more cohesive approach to finding these opportunities but (may) find push back from faculty. Opportunities to provide incentives to faculty and staff need to be further developed and promoted. This will increase commercial applications (patents, licensing agreements) to grow the life science industry both on campus and in the community.

Conclusion

There are several issues or obstacles facing the community as it relates to fully realizing opportunities related to the life science industry in the Grand Forks region. These include lack of networking in and outside the community, gaps in key personnel including management, capital gaps and future access to hard infrastructure when new businesses and opportunities are realized. These obstacles are not insurmountable, but will require continued vigilance and action to overcome and provide the community with new and growing advantages in the life science arena.
SUGGESTED ENHANCEMENTS TO INFRASTRUCTURE

Grand Forks is well situated to meet the current demand for access to infrastructure with the development of the COELSAT facility and the considerable infrastructure already available at the University of North Dakota. The COELSAT will provide a significant advantage in promoting and developing the life science industry on a local and regional basis. Other facilities on campus are available for research and development activities by university faculty and on a more limited basis for non-university researchers.

The COELSAT will soon offer access to cGMP labs. When completed, the facility will have the only BSL 3 pathogen research lab in the State.

The Basic Sciences Imaging Center, located at the UND Medical school, provides advanced instrumentation for researchers interested in investigating biological processes at the cellular, sub-cellular, and molecular level. The center consists of two facilities including the light microscopy core and the electron microscopy core.

The Center for Biomedical Research is a state-of-the-art animal research facility. There are 10 animal rooms, one quarantine room, 2 Bio-Hazardous Facilities with a common water shower, one radioisotope room equipped with a Chemical Hood. There is a necropsy room as well as a surgical suite composed of a preparation room, a scrub room, a recovery room, and a large surgery room.

The USDA Human Nutrition Lab, adjacent to campus, adds to the existing infrastructure with an 80,000-square-foot building that contains state-of-the-art facilities for research with humans and animals, multiple chemical and biochemical laboratories.

While there is considerable existing public infrastructure, there is a shortage of labs and space for both university researchers and private life science businesses. Additional space will be needed to accommodate businesses as they mature and grow out of the COELSAT facility, and/or new businesses looking to expand operations in the Grand Forks community. In addition, the Medical School could benefit from a $10 to $12 million research building equipped with specialized technologies and lab space that could be customized for specific research.

Some of these gaps include access to clean rooms, wet labs, secure laboratory space, sterile facilities for manufacturing, or a vivarium (research animal holding facility). These needs will be driven by demand, but future needs should be identified and considered as the community moves to fully capitalize on potential growth from public-private partnerships driven by the University and opportunities developed by the EDC.
LABS IN HIGHEST DEMAND

Increasingly, access to appropriate infrastructure and laboratories (Table 12) is critical in the attraction, recruitment and growth of life science based business and research companies. While access and demand for lab space is often driven by research and development platforms specific to an area, recruitment and retention of life science business concerns from a development perspective will play a significant part in driving demand.

As the industry grows locally and regionally, the emerging REAC facility is well poised to meet the current and potential future demands for secure laboratory space.

As noted, the demand for specific labs is often driven by R&D platforms unique or strong within a region or community. Within the Grand Forks region there is a strong initiative and push towards the development of biodefense focus, driven by the University and the new Center for Infectious Disease and emerging business developments focusing on vaccinology and immunology located at the new REAC facility.

These local developments mirror strengths regionally, with considerable growth in the Fargo-Moorhead region in platforms related to the purification of biological materials (protein, DNA), cell-based assays and products and services to the DNA Vaccine and Gene Therapy community.

Regionally, Winnipeg is home to the Canadian Science Centre for Human and Animal Health (a center with level 4 bio-containment capability for the study of both human and animal diseases) and the National Research Council Institute for Biodiagnostics, the most state-of-the-art facility in Canada for studying and developing NMR (nuclear magnetic resonance) and MRI (magnetic resonance imaging) technologies. Access to these labs is significant in the development of their robust life science initiatives.

The Manitoba life science sector is strong too in biodefense, immunology and related platforms. Companies such as Cangene, a biopharmaceutical company that develops, manufactures and markets specialty plasma products (hyperimmunes), and recombinant therapeutic products require/demand access to higher level bio-containment labs in the development and growth of their businesses.

Conclusion

The demand for lab space is driven by both R&D platforms specific to an area, and from recruitment and retention of life science business. Here in the region this demand points to the need and demand for, at a minimum, a BSL 3 lab as proposed by the REAC facility at UND. This demand is driven by a regional focus on biodefense and related immunology and vaccinology initiatives that require a high level of safety due to their work with infectious agents that may cause serious or potentially lethal diseases as a result of exposure by the inhalation route.
# Table 10. Biosafety Laboratories Defined.

## Biosafety Level 1
BSL-1 is appropriate for working with microorganisms that are not known to cause disease in healthy human humans. This is the type of laboratory found in municipal water-testing laboratories, in high schools, and in some community colleges teaching introductory microbiology classes, where the agents are not considered hazardous.

## Biosafety Level 2
The facility, the containment devices, the administrative controls, and the practices and procedures that constitute BSL-2 are designed to maximize safe working conditions for laboratorians working with agents of moderate risk to personnel and the environment. The agents manipulated at BSL-2 are often ones to which the workers have had exposure to in the community, often as children, and to which they have already experienced an immune response. Unlike the guidelines for BSL-1, there are a number of immunizations recommended before working with specific agents. Most notable is Hepatitis B virus immunization that is recommended by the Occupational Safety and Health Administration for persons, including laboratorians, at high risk of exposure to blood and blood products. These agents are generally transmissible following ingestion, exposure of mucous membranes, or intra-dermal exposure.

## Biosafety Level 3
BSL-3 is suitable for work with infectious agents that may cause serious or potentially lethal diseases as a result of exposure by the inhalation route. BSL-3 laboratories should be located away from high-traffic areas. Examples of agents that should be manipulated at BSL-3 are *M. tuberculosis* (research activities), St. Louis encephalitis virus, and *Coxiella burnetii*.

There are some specific secondary barriers, needed at BSL-3, that tend to set these laboratories apart from BSL-2 laboratories; ceilings should be waterproof for ease of cleaning Centrifuge tubes are placed into containment cups or heads in the BSC, transferred to the centrifuge, spun, then returned to the BSC to be unloaded. In some laboratories the centrifuges themselves are enclosed in a vented area to minimize possible aerosol exposures created in the event of a centrifuge failure. Vacuum lines are protected with HEPA filters so that maintenance personnel are not exposed to infectious aerosols.

Standard microbiological practices are the same as for BSL-1 and BSL-2 laboratories. Class II type A biological safety cabinets are suitable in BSL-3 laboratories. Sometimes Class II type B3 cabinets are installed, requiring thimble connection to the building exhaust systems. Depending on the nature of the work being done in the BSL-3 laboratory, additional personnel protective devices may be worn, such as respirators. When pulmonary protection is required, the laboratorians need to have appropriate medical evaluations and be trained in proper fit testing and care of their respirators.

Source: Centers for Disease Control.
The biosciences are clearly viewed across the nation as a key targeted industry for development. A recent report issued by BIO identified that 40 states are actively focusing on bioscience development. Moreover, nearly every community with a major academic medical center – and even many without – is targeting bioscience development as part of its economic development efforts. ... It is important to recognize that no two regions are exactly alike, and their success will be found in pursuing specific strategies that fit their regional context.

(Life Sciences: A 21st Century Economic Driver for Central Indiana)

Regional Partnerships Key to Life Sciences Success

States and cities throughout the U.S. are competing for the business revenues, research dollars and thousands of life science jobs expected over the next decade. In 2001, 14 states were trying to grow life sciences industries. Today over 40 states have invested significantly in the life sciences and all 50 states are offering economic incentives for bioscience companies as part of their economic development plans.

Once concentrated in large metropolitan areas, the industry is now making moves to smaller, less costly and more manageable metropolitan areas. “It’s less important to be in San Francisco and more important to be virtually integrated” according to venture capitalist Steve Burrill.

Other common hurdles facing the more entrenched life science centers are lack of trained workers with two and four year degrees, highly fluid labor markets where life science workers frequently shift from company to company, and lack of awareness and interest in life science careers among k-12 students. Places where life science initiatives are succeeding share a few key characteristics, including local networking, collaboration, strong academics and mechanisms for translating research into products. The Grand Forks region can successfully compete in this context if its life science companies and institutions can capitalize on a core set of present and future opportunities to sustain research and bring new products to market readily. Local life science business entities, researchers and developers will also need to be able to leverage the capabilities and resources of companies and institutions throughout the broader region – a region that is growing in capacity and has high potential for collaborative relationships. The region is also home to companies and institutions that may also be customers for products and services provided by new and/or existing businesses.

The connections and intersections between Grand Forks and these other regional centers (i.e. Winnipeg, Minneapolis, Rochester) could be as important to innovation and growth as those occurring at the intersecting segments of the life sciences industry itself. The convergence of multiple scientific disciplines (including genetics, microbiology, biophysics, biochemistry, chemical engineering and computer science) have re-defined science and scientific products in the last decade. These overlapping and intersecting areas of research offer almost endless applications in the marketplace.
Fargo-Moorhead

Fargo Moorhead represents the nearest concentration of life sciences companies and institutions and holds significant potential for collaborative and customer connections for the life sciences sector in Grand Forks. The Fargo Moorhead area is home to the following selected centers and companies.

- The NDSU College of Pharmacy trains and supplies high-quality pharmacists and researchers. Accredited by the American Council on Pharmaceutical Education, the college’s students learn and apply the latest advances in pharmacy practices and technology. The college has a highly competitive research program in pharmaceutical sciences, and it regularly attracts funding from the National Institutes of Health and other sources.

- The Center for Protease Research, which is a multidisciplinary research center focusing on matrix metalloproteinases to help combat diseases.

- The Center for Visual Neuroscience, which is home to two state-of-the-art EEG laboratories conducting electrical brain-imaging experiments.

- NDSU has the best-equipped high-throughput laboratory in the world in the area of combinatorial materials science, especially in the areas of polymer synthesis and coating formulation. Located in the Center for Nanoscale Science & Engineering, the Combinatorial Lab is an innovator in developing new materials for coatings and designing methods for development, analysis and large-scale production. With cutting-edge robotics equipment and control software, scientists can generate and test up to 300 samples in one day, cutting experiment times from weeks to days.

- Specialized life sciences educational programming at Moorhead State University, which includes techniques such as QA/QC methods, which provide a realistic research experience that is designed to meet the needs of biotechnology companies.

A growing number of life sciences-focused companies are already conducting profitable business in Greater Fargo Moorhead. They include the following:

- PRACS Institute (with locations in East Grand Forks and Fargo) – a contract research organization that conducts both in-house and ambulatory clinical studies, bioanalytical services, in-house clinical laboratory services, statistical and medical writing services and information technology support services.

- Clinical Supplies Management Inc. provides services in two distinct areas: clinical supplies and subject retention & compliance. CSM’s customers are biotechnology and pharmaceutical companies interested in shortening timelines, improving study quality, and saving money in their clinical trials program.

- DragonTech Biotechnology provides R&D, federal policy consulting, purification of biological materials and validation services for universities and pharmaceutical/biotechnology companies. DragonTech can supply purified protein, DNA, cell based assays and many other needs.

- Aldevron offers products and services to the DNA vaccine and gene therapy community. Its core
technology is a proprietary method to produce and purify plasmid DNA.

- Dakota Technologies specializes in the research, development, and commercial application of innovative technologies that rapidly detect, log, and sample contaminants in soil, water, and air. Dakota Technologies combines a number of technologies including lasers, optics, electronics, and advanced materials to form products/services that solve their customer’s problems.

**Minnesota**

Minnesota is a major international powerhouse in the medical device industry. Within the United States, Minnesota and Massachusetts are roughly equal in employment numbers, second only to California. In 2002, almost 22,000 employees, or 78 percent of Minnesota’s bio-business technology employees, worked in the medical device industry.

The state is known for Medical Alley, a 350-mile-long corridor that is home to more than 8,000 healthcare companies and extends from Rochester through the Twin Cities to northern Minnesota. For the bio-business technology industry as a whole, the state is slightly stronger than average in generating employment, revenue and payroll, and slightly weaker than average in generating enterprises. Thus, Minnesota is less entrepreneurial in bio-business technology than other states, even if its overall economic performance in the industry is competitive.

LifeScience Alley™ is a Minnesota-based trade association that represents more than 500 member organizations. It provides access to top industry leaders, opportunities to build and grow businesses through education and networking, insights into current trends, regulations, research and emerging technologies. The life sciences sector in Minnesota includes some of the biggest names in the field including Medtronic, MGI Pharma, Mayo Clinic, and Cargill, as well as numerous small start-ups and firms that specialize in professional services for life science organizations.

**South Dakota**

In South Dakota, a Biotech Association was formed in March of 2006 and became the 41st State Affiliate of the Biotechnology Industry Organization (BIO). The association is a resource for the emerging biotech industry in South Dakota and represents companies whose regular business activities involve biotechnology or products derived from biotechnology as well as researchers and other interested individuals. Primarily, member companies are directly involved with the medical science, life science, animal science, plant science and environmental/industrial biotechnology. The South Dakota alliance is dedicated to the development of biotechnology industries through expansion of bio-based research, investment, education and promotion.

The closest concentration of life sciences companies and institutions is in Brookings. South Dakota State University is home to the Center for Infectious Disease Research and Vaccinology which partners with several biomedical corporations to research therapeutic and diagnostic technologies and products for infectious diseases in humans and domestic animals. The priority research areas include:

- Large animal models of human disease
- SPF/Germ-free animal delivery
- Diagnostic reagent and test development
- Immunopathogenesis
Vaccine development and assessment

Several companies in the Brookings area have been started by SDSU faculty or are using faculty expertise, including:

- SCSA Diagnostics conducts genetic analysis of sperm DNA as related to fertility potential and reproductive toxicology.
- TJ Technologies conducts research that is designed to maximize the profit from high performance plant genetics through the use of homogenous micronutrients and microbiology.
- Identify Genetics specializes in providing human DNA paternity testing services and forensic analyses.
- Biogenetic Services provides protein and DNA analyses for seed companies, seed growers and others in the agriculture industry.

Manitoba

Winnipeg Manitoba has developed substantial, specialized expertise and infrastructure in cardiovascular and respiratory disease, oncology, infectious disease, medical imaging, clinical research and clinical trials, agriculture and health, and contract pharmaceutical manufacturing.

The sector generates over $500 million in revenue annually; includes 30 research and development centers, 23 service firms, and 41 companies (a third of which are fairly recent start-ups); and employs over 4,200 people, a tenfold increase over the last 15 years. The Government of Canada recently announced a $5.7 million investment over three years in Winnipeg's biomedical technology cluster.

The province’s extensive infrastructure of research facilities includes:

- The Canadian Science Centre for Human and Animal Health - the first and only centre with level-4 biocontainment capability for the study of both human and animal disease.
- The National Research Council Institute for Biodiagnostics (IBD) - the most state-of-the-art facility in Canada for studying and developing NMR and MRI technologies.
- Agriculture and Agri-Food Canada’s Cereal Research Centre - the national headquarters for R&D within the areas of cereal genomics, pathology and biotechnology related to development of improved wheat and oat varieties.
- The National Centre for Agri-Food Research In Medicine - a unique facility in Canada that examines the effects that nutraceuticals, functional foods and food components have on human health and well-being.
- Red River College’s biopharmaceutical manufacturing training facility, the first of its kind in Western Canada.

Manitoba’s biotechnology sector also includes researchers, start-up companies, SMEs and large international corporations, all linked to a network of biotech suppliers. Manitoba is internationally recognized for technical expertise in:

- Proteomics
- Bioinformatics
- Biological mass spectrometry
- Gene expression analysis
- Marker-assisted selection of genes
- Population analysis
- Conventional and hybrid breeding
- Bacterial fermentation
The Life Sciences Association of Manitoba (LSAM) represents members from Manitoba’s biotechnology, pharmaceutical, medical device, and health research industries as well as related service providers/suppliers. Organized in 1990, LSAM programs have addressed shortages of qualified labor within the life science and health products sector. The association is also active in the promotion of Manitoba’s Life Science clusters, community networking, facilitation of partnerships between public and private constituents, promotion of public awareness and acceptance of the sector, enhancement of international visibility of the local sector, and exploration of means to drive capital formation for a sustainable biotechnology community.

**Conclusion**

The evidence suggests that successful life science initiatives at the state or city level show considerable local networking and connections and partnerships with other life science centers. Grand Forks is in the enviable position of being strategically located within a mosaic of very capable life science centers in the Great Plains of the USA and Canada. This affords the Grand Forks region with the opportunity to leverage these capabilities and resources and to approach these as demand centers for both services and products.
As noted previously, over 40 states have invested significantly in the life sciences and all 50 states are offering economic incentives for bioscience companies as part of their economic development plans. With this type of activity there is a lot of competition at the local, regional and national levels for a piece of the growing life science industry pie. As states and regions ramp up to attract this development they are putting together a significant amount of capital, infrastructure and facilities to create competitive advantages that will attract and retain life science industry related businesses, research and development.

Following is a review of (select) developments and facilities within the Midwest that show the breadth and depth of development in the industry. Many or most are focused on existing regional expertise and provide specialized infrastructure to meet the demands of these platforms.

**South Dakota**

In South Dakota, the State has provided resources to develop a research and development initiative focused on providing South Dakota-based businesses a competitive advantage in the life sciences. The Governor requested, and the Legislature approved, approximately $3.5 million for a Research and Development Initiative that is being undertaken jointly by state government and the SDUS Board of Regents. Almost $2.8 million of this amount was designated to fund a Research Centers Program. In 2006, the Legislature approved an additional $500,000 for 5 years to establish a fifth 2010 Research Center. Three of the four 2010 Research Centers focus on the biosciences.

The South Dakota Health Research Foundation (SDHRF) is a nonprofit, 501(c)3 organization formed by the University of South Dakota School of Medicine and Sioux Valley Hospitals and Health System. SDHRF is dedicated to research excellence through the work of its Cardiovascular Research Institute, Signal Transduction Institute, Oncology Research Center, and Women’s Health Center.

The Center for Infectious Disease Research and Vaccinology, South Dakota State University (SDSU) Department of Veterinary Science fosters research leading to the development of novel therapeutic and diagnostic technologies and products for infectious diseases in humans and domestic animals. Research targets include vaccines for diarrheal diseases of livestock and humans, an improved vaccine for porcine reproductive and respiratory syndrome, and improved diagnostic tests for transmissible spongiform encephalopathies, such as bovine spongiform encephalopathy in cattle and chronic wasting disease in deer.

The South Dakota Signal Transduction Center, University of South Dakota (USD) Cardiovascular Research Institute examines the pathways that regulate cell growth and differentiation, cell death, response to stress, and the maintenance of constant physiological conditions, leading to improved detection and treatment of a range of serious heart and cancer conditions.

The Center for the Research and Development of Light-Activated Materials, USD Department of Chemistry performs both basic and developmental research on materials with light-activated properties. The research relates to medical applications such as human tissue bonding, drug delivery, and anti-tumor agents and is important to developing phosphors for sensors.
Minnesota

The Minnesota Partnership for Biotechnology and Medical Genomics recently completed development of a new research facility, built on top of the existing Mayo Clinic Vincent A. Stabile Building in Rochester. The Partnership is a collaboration of the Mayo Clinic and the University of Minnesota and is focused on providing competitive advantages to Minnesota to advance medical genomics applications. In 2006, the state provided $15 million to fund research projects and to provide infrastructure support in the form of equipment, software, and other infrastructure needs.

Within the State, there are several incubators focusing on life sciences and biotechnology. In the Minneapolis metro-area, a review of incubators includes the University Enterprise Laboratories (UEL) that is a private, nonprofit life sciences incubator in St. Paul that opened in the summer of 2005. It is a key anchor facility in the St. Paul Bioscience Zone. The incubator is housed in a former warehouse purchased by the City of St. Paul and donated to the University Enterprise Laboratories. The laboratories occupy almost 50,000 square feet of space in the overall 125,000-square-foot facility, with the remaining space leased to post-incubator and established life science and biotech firms. The UEL has laboratories ranging from 750 to 1,050 square-feet and currently has nine tenant companies.

Elliot Park Life Science Institute is a private, for-profit, 60,000-square-foot life science incubator located in the Minneapolis Bioscience Zone, which includes three major hospitals. The institute added five new tenants in 2006.

Menlo Park St. Paul is a biotechnology office and laboratory facility located less than 2 miles from the University of Minnesota. This is a private business incubator facility that offers up to 50,000 square feet of office and wet-lab space and currently houses eight firms.

Manitoba

The University of Manitoba’s Faculty of Engineering will acquire state-of-the-art biomedical imaging and bio-sensing equipment to create an enhanced Bio-Engineering Facility. This new equipment will train and educate students and improve interaction between Manitoba’s life science and biotech firms and local research and clinical institutions. The biomedical engineering research laboratories will be located in the University’s new Engineering and Information Technology Complex. The system of equipment is unique and one of a kind in Canada. This variety of equipment creates a critical mass for researchers to study life science and biomedical problems, using a combination of scientific techniques that is critical to ongoing research and development.

Winnipeg is also home to the Institute of Cardiovascular Sciences, the Canadian Science Centre for Human and Animal Health (the first and only global center with level 4 bio-containment capability for the study of both human and animal diseases) and the National Research Council Institute for Biodiagnostics, the most state-of-the-art facility in Canada for studying and developing NMR (nuclear magnetic resonance) and MRI (magnetic resonance imaging) technologies.

The Institute of Cardiovascular Sciences, at the St. Boniface Research Center, is studying the molecular and sub-cellular basis of heart dysfunction. The Institute is exploring two key problems: ischemic heart disease (blockage of the coronary artery), and congestive heart failure, particularly in connection to the regulation of calcium.
Montana

Through a grant program operated by the Montana Board of Research and Commercialization Technology, Montana has created the Montana BioScience Alliance; opened two wet-lab–capable incubators; and moved toward a venture-capital program supported by the Montana Associated Technology Roundtables, a multi-sector technology council.

Montana State University has opened a 40,000-square-foot Molecular Biosciences Building and has broken ground on a 73,000-square-foot structure for chemistry and biochemistry research. The University of Montana has broken ground on a 59,000-square-foot, $14 million research addition to the College of Health Professions and Biological Sciences. It has also received $12 million for a new Bio-Science Building.

Montana has developed two specialized life science/biotech incubators including “TechRanch,” a 10,000-square-foot facility in Bozeman at the Advanced Technology Park and the Montana Technology Enterprise Center, a 32,000-square-foot warehouse near the campus of the University of Montana at Missoula.

Montana State University’s Advanced Technology Park in Bozeman, currently housing 43 companies in 14 buildings over 74 acres, includes both academic and industrial bioscience tenants. Ravalli County, home to the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID) Rocky Mountain Laboratories in Hamilton, has begun planning a research park and incubator that could serve spin-outs from the laboratories.

Kansas

As home to Kansas State University, Manhattan is growing as a center of research activity in the biosciences. Manhattan is home to the $55 million, 130,000-square-foot Biosecurity Research Institute, a comprehensive biosafety level three facility that enables Kansas State University scientists to study pathogens that threaten humans, livestock, and crops, and develop intervention strategies to minimize impacts on the nation’s food supply and economy.

Manhattan has created a partnership between the government, business, and state to create the National Institute for Strategic Technology Acquisition and Commercialization (NISTAC). This entity serves as an incubator and a facilitator to create successful business opportunities coming from the university. NISTAC has experts that can assist with intellectual property issues (NISTAC holds a portfolio of over 1,100 patents) and has a strong working relationship with the Kansas Bioscience Authority. This partnership between the city, the university, and the Bioscience Authority is enabling Manhattan to construct a new $6.5 million headquarters facility at the K-State Research Park.

The first K-State spin-off technology company is Nanoscale Materials, Inc., makers of advanced materials like reactive nanoparticles that can detoxify the environment, control air pollution, and aid in water purification. They are housed in a 20,000-square-foot state-of-the-art facility at the K-State Research Park, with on-site manufacturing and quality control. As part of the University’s Grain Science & Industry complex, the Bioprocessing & Industrial Value Added Program (BIVAP) deserves special note. BIVAP has over 15,000 square feet of research space allocated to research in biomass conversion, fermentation, pre-fermentation processing, and extrusion.
Iowa

Clinton is in the heart of corn country. From ethanol to plastics, scientists have started using corn products to replace expensive petroleum-based commodities. In fact, the region already has Clinton County Bioenergy LLC, a biofuels producer, and three more biofuels and ethanol manufacturing projects are under development: Hawkeye Bio-Energy LLC, Fulton Ethanol LLC, and Thompson Ethanol LLC.

A joint venture has been established between Archer Daniels Midland Company (ADM), an agribusiness giant that already owns a wet corn milling plant in Clinton, and Metabolix Inc., a biotechnology company based in Cambridge, MA. The venture is set to make biodegradable plastic from corn-eating bacteria, and will begin production when the new plant is built by the end of 2009. This is a new generation of high-performance natural plastics that are eco-friendly and based on sustainable, renewable resources. The plant will make 110 million pounds of corn-based plastic a year at a value of $250 billion according to a source at Metabolix. Clinton was chosen because the wet milling corn plant was there, and because Iowa leads the states in corn production.
Nearly every community with a major academic medical center is targeting life science development as part of its economic development efforts. Due to the expected growth in the industry and the competitive nature of recruitment and retention of these businesses, states are now putting together extensive development packages and programs to spur development. Following is a brief overview of what other communities and states across the country are doing to build their capacity for life sciences and to attract, recruit and grow life science businesses.

**Specialized Infrastructure & Support**

The State of North Dakota has provided extensive support and resources in the development of specialized infrastructure and support.

Similar efforts, but at a much larger scale, include the State of Arizona. In 2002, Arizona’s public and private leaders raised $90 million to support the development of the Translational Genomics Research Institute (TGen), a nonprofit biomedical research institute whose mission is to make and translate genomic discoveries into advances in human health. In 2003, the Legislature and Governor approved $440 million to fund university research facilities, primarily in the biosciences.

Anticipating more than $500 million in increased tax revenue over the next decade from growth of the bioscience sector, Kansas passed an Economic Growth Act that authorizes creation of a Kansas Bioscience Authority with the capacity to provide funding for faculty recruitment, research collaboration, and additional facilities.

Purdue University’s Gateways Program assists their researchers and other Indiana entrepreneurs in the commercialization of intellectual property. The program provides a range of services including business plan development, test marketing, and financial and technical advice. The Gateways Program uses a methodology that is often employed by high-performing firms in growing industries to identify, evaluate, and assist commercial business opportunities. Their “stage-gate” process includes matching clients with market-specific mentors, helping clients identify a clear pathway to development, developing early-stage gap financing resources, and assisting with the formation of a management team.

**Business Planning and Financial Support**

The Oklahoma Technology Commercial Center (OTCC) plays an important role in Oklahoma by positioning Oklahoma entrepreneurs to grow viable businesses. One key way is by helping start-ups focus on their business plans and strategies through hands-on educational and training support and detailed consulting. OTCC also helps entrepreneurs secure angel financing and other early-stage funding (including a state seed fund program that it operates). OTCC has helped organize 44 angel investor groups across Oklahoma, involving 300 investors with a net worth of $2 billion.

The most important contribution of OTCC is its activities in helping to stimulate investment deal flow, as well as improving the quality of deal flow to private investors. In its first 2 years of operation, OTCC served 467 clients, of which 268 have received detailed project assistance and 74 have been presented before angel investor and other financing sources with nearly $15 million in hard-to-find pre-seed and seed capital dollars raised, leveraging more than four times the amount of state investment in OTCC operations.
The Wisconsin Alumni Research Foundation’s (WARF) mission is to support scientific research at UW by moving inventions to the marketplace and investing licensing proceeds to fund further research. It has been highly successful, and each year more than $1 billion of products are sold under license from the organization. WARF receives 360 disclosures annually and accepts 60 percent for patent applications. WARF licenses 100 to 120 technologies per year and returns $40 million to $45 million back to the university.

WARF’s influence extends beyond the Madison campus as the organization also manages the WISys Technology Foundation, which provides patent and licensing services to the entire UW System. WISys, established in 2000 as a pilot project, is a wholly owned subsidiary of WARF. The foundation is currently handling disclosures for 12 of Wisconsin’s 13 four-year universities, and their portfolio includes some exciting technologies from campuses in Milwaukee to Eau Claire. WARF’s “What’s IN It For Wisconsin Business” campaign is designed to make the Madison-based foundation more accessible to companies throughout the state, as well as to educate them about the wealth of home-grown product potential—in the form of patented UW discoveries. Since 1993, WARF has taken an equity position in 29 start-ups, many of them in Wisconsin.

**Education & Training Support**

Montgomery College, the Community/Technical College for Montgomery County, Maryland, has developed relationships with the Montgomery County Public Schools and the universities at the Shady Grove Life Science Center to offer a 2+2+2 program of technical education. Beginning with the last 2 years of high school, the program continues with 2 years and an associate’s degree from Montgomery College and offers the option of completing another 2 years for a bachelor’s degree. The first phase, the Montgomery County Public Schools Tech Prep Program, allows high school students to receive college credits for grades of B or better if they major in the corresponding program at Montgomery College.

Students are eligible to receive credit in one of 22 college programs, including biotechnology. The high school biotechnology program is housed at the Thomas Edison High School of Technology and offers intensive laboratory experience, interaction with scientists and technicians from local research facilities and firms, and leads for summer and college internship opportunities. Once the student completes the second phase and earns an associate’s degree from Montgomery College, they may choose to continue working toward a bachelor’s degree at the Shady Grove Center. Eleven University of Maryland System institutions are involved in the partnership.

**Commercialization Support**

The Montana Board of Research and Commercialization Technology, a unit of the Department of Commerce, offers matching grants or loans to encourage university/industry collaborations with a clear path to commercialization. The program functions over multiple disciplines including the biosciences. Projects must be matched at least 1:4, but the average match has been 1:3. The typical grant is $100,000 per year for up to 2 years, with a range of $20,000 to $500,000. As of October 2005, the cumulative total awarded was $22.3 million, and the current year program is funded at $2.6 million. Private laboratories or research centers are defined as eligible applicants, making them eligible for the same grants and loans as college- or university-based centers.
Endowed Chairs

As noted, the University of North Dakota currently has provided funding for endowed chairs. The current effort by the UND Foundation, with funding through the Engelstad Family Foundation, has funded an endowed chair in medicine and another in engineering, through gifts of $2 million each.

Endowed chairs are extremely important to the overall mission and strategic plan of the University. They bring with them a great deal of prestige, highlighting the excellence of faculty on campus. Funding for endowed chairs enables the University to attract dynamic educators and researchers in the face of stiff competition.

The State of Missouri will fund an endowed chairs program beginning in FY 2007 requiring both a non-state commitment of a $2 million endowment or $100,000 per year for 20 years, and a university and state commitment of $100,000 per year for 20 years.

Not only is the State of Missouri putting together funding for endowed chairs, they have the Research Alliance of Missouri (researchmissouri.org) and the Stower's Institute. These are serious commitments by the state government and private individuals to support life science research.

In South Carolina, Clemson University will tap into state lottery funds set aside last year by the General Assembly for an endowed chairs program. BMW Manufacturing Corp. pledged $10 million, with another $5 million to be raised by suppliers, for the state to match. Clemson will use the funds to recruit engineers and scientists to the school's new graduate program in automotive systems integration.

Georgia has invested more than $300 million over a 10-year period to build core research facilities and to attract Eminent Scholars, the majority of which are in the life sciences. To complement these efforts, the state has created a $1 billion Georgia Cancer Coalition that is designed to make Georgia a national leader in cancer prevention, treatment, and research.

Conclusion

Best practice suggests that there is a technique, method, process, activity, incentive or reward that is more effective at delivering a particular outcome than any other technique. Best practices can be defined as the most efficient (least amount of effort) and effective (best results) way of accomplishing a task, based on repeatable procedures that have proven themselves over time for large numbers of people. What is obvious in the life science industry is that access to innovative researchers and ideas is tied to several key “practices” including access to infrastructure, capital and a skilled and/or educated workforce.
LIFE SCIENCES MARKET ASSESSMENT FOR GRAND FORKS

A competitive life sciences sector requires a sophisticated and adaptable innovation pipeline. The life sciences innovation pipeline is the support and process infrastructure that drives the production and creativity in a region’s life sciences industry. Under this definition, a strong innovation pipeline plays a critical role in the growth potential of a region’s life sciences industry. The pipeline consists of five components:

1. R&D (knowledge assets).
2. Risk capital and entrepreneurial infrastructure.
3. Industry infrastructure (the industry’s hard infrastructure and supports).
5. Innovation output.

Based on these five criteria, a review of the Grand Forks market shows mixed results. The community and region have considerable R&D knowledge assets based primarily at the University of North Dakota. Recently these assets have been augmented by new and emerging business concerns that are partnering with University researchers to develop new ventures. The UNDRF is integral in facilitating this process, working with UND faculty and staff to build successful strategic partnerships between the university and private companies.

Access to risk capital is a potential gap locally. While there are newly established RAIN funds in the state and in Grand Forks, the overall capacity to provide a level of equity required to spur growth and support startups, locally and regionally, is viewed as problematic. The lack of pre-seed and seed capital resources is viewed as limiting entrepreneurship at UND and reducing the number of innovation-based companies locally and regionally.

Industry infrastructure in the region is fairly robust, especially with the development of the REAC and the availability of cGMP labs and a BSL 3 research lab. Other infrastructure includes The Basic Sciences Imaging Center, which consists of two facilities including the light microscopy core and the electron microscopy core. The Center for Biomedical Research offers a state-of-the-art animal research facility.

Additionally, The USDA Human Nutrition Lab, adjacent to campus, adds to the existing infrastructure with an 80,000-square-foot building that contains state-of-the-art facilities for research with humans and animals, plus multiple chemical and biochemical laboratories. While there is considerable existing (public) infrastructure, there is a lack of labs and space for private life science businesses as they mature and spin out of the REAC facility.

UND’s various schools and departments provide education and training in a myriad of disciplines and professions but there is a lack of key professions required for a vibrant and sustainable life science industry. In particular, microbiologists, biomedical engineers, biochemists and biophysicists were identified as lacking in number, or critical mass, to sustain high levels of growth in the region.

Innovation output is growing here in the region. UNDRF has experienced new growth in partnerships with “outside” private industry to capitalize on intellectual capital and research being conducted by the UND. Over 50 people on campus now have disclosed patents in play.
The market potential for driving economic development initiatives is focused on core platforms that the region has proven expertise in, and has the potential to build on regional synergies in defining new business opportunities. As noted previously, the region has concentrated expertise and specialty infrastructure in:

- Infectious diseases
- Nutrition & food
- Medical devices
- Rural health
- Neurosciences
- Biodefense
- Biofuels

These platforms are aided by regional and demographic trends. There is significant growth in the Fargo in platforms related to the purification of biological materials (both protein and DNA), cell-based assays and products and services to the DNA vaccine and gene therapy community. The Manitoba life science sector is strong in biodefense, immunology and related platforms mirroring local strengths.

Demographic trends play an important role in developing and enhancing the local and regional market potential. The pending boom of seniors on a national and world-wide basis portends an increase in neurodegenerative diseases, including Alzheimer’s disease and could lead to growth opportunities in addressing the identification and management of these diseases.

**Conclusion**

Grand Forks is strategically positioned geographically, centrally located in a very capable life science region (Minneapolis, Winnipeg, Fargo) of the Great Plains of the USA and Canada. This geographic location, coupled with strong and unique applications and platforms developed at the University, affords the Grand Forks region with the opportunity to leverage capabilities and resources to develop businesses and research focused on both services and products.

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**Figure 6: Regional Innovation and Its Outcomes**

![Diagram showing Regional Assets, Discover, Develop, and Deploy phases with Regional Outcomes](image-url)
LIFE SCIENCE DEVELOPMENT STRATEGIES FOR THE GRAND FORKS REGION

The Grand Forks region’s assets and capabilities in the life science industry sector are significant. Several life science disciplines present here hold substantial potential that can be leveraged to "jumpstart" life science economic development. Nonetheless, significant challenges exist to advance the life science industry sector as a key driver of the regional economy.

For the life science sector to fully realize its potential as a major economic engine for Grand Forks, the region must simultaneously strengthen existing research drivers and facilitate the efficient translation and development of commercial enterprise from research innovations. Four strategies and sixteen specific actions have been identified to further develop the Grand Forks region’s life science research base and build a critical mass of bioscience companies.

Strategy One: Build Grand Forks’ life science research and business development capacity around already strong and emerging research and technology platforms.

The focus here should be on the infectious disease work at REAC and in the Medical School, the Center of Excellence for Medical Devices, neurosciences, nutrition and food and biodefense.

- The EDC, in collaboration with the UND Research Foundation and the Red River Valley Research Corridor, should develop and implement a marketing plan for the recruitment of businesses and talent that will strengthen or complement the core areas of expertise and specialized infrastructure located at the University of North Dakota. These key platforms currently have the most local momentum and bolstering their support can and will prove beneficial in the development of new opportunities.

- The EDC, the UND Research Foundation and others should actively participate in activities and events held by the Life Science Association of Manitoba (LSAM) and Minnesota’s LifeScience Alley. These regional organizations hold tremendous potential to identify new technologies, learn about new development strategies, find potential partners and identify emerging business or funding opportunities.

- The UND Research Foundation, the UND Alumni Foundation, private industry and the Grand Forks Region EDC, should encourage and support the Endowed Chair Program at UND, specifically to attract world-class research talent in one or more of the core life science areas of expertise.

Currently the UND Foundation, with funding through the Engelstad Family Foundation, has endowed a chair in medicine and another in engineering, with gifts totaling $2 million.

Endowed chairs are extremely important to the overall mission and strategic plan of the University. They bring with them a great deal of prestige, highlighting the excellence of faculty on campus. Funding for endowed chairs enables the University to attract dynamic...
educators and researchers in the face of stiff national competition.

- The EDC and the UND Research Foundation should meet on a regular basis with North Dakota’s Congressional delegation to partner with them in identifying and acquiring federal funding for existing and new research centers and for specific project support. An immediate objective should be for the BRIC to pursue the possibility of significant funding for an institute in therapeutics for infectious diseases.

- The EDC and the UND Research Foundation should advocate for funding support from the City of Grand Forks and the North Dakota Department of Commerce to market the regional life science sector and the Red River Valley Research Corridor on a national level.

- The feasibility of an industry-university matching grant program should be researched. This program could fund work in life science specialty areas that now exist at the University of North Dakota and at COELSAT. The Grand Forks Growth Fund may be a possible resource for this program.

**Strategy Two: Promote and encourage the commercialization of life science research to enhance opportunities for start-up companies and existing firms in the region that wish to expand and/or enter new markets.**

- The EDC should work collaboratively with the new Manager of Science & Technology Business Development at the Economic Development & Finance Division of the ND Department of Commerce to provide support for life science initiatives at UND and in Grand Forks. This should include work with UND to develop new proposals for North Dakota’s Center of Excellence program.

- UND’s Center for Innovation should promote participation by undergraduate and graduate students in science, technology, engineering and math (STEM) and life science related disciplines to participate in course offerings delivered by the Entrepreneurship Program at the University of North Dakota School of Business.

- The University should continue to develop and implement policies and procedures that actively encourage faculty involvement in developing and disclosing intellectual property and subsequent commercialization activities.

- The University, working hand-in-hand with the EDC, should nurture and provide incentives for the talent that currently exists on campus – focusing on researchers and disciplines that are already leading in cutting edge research and successfully competing for federal research grant dollars.
Strategy Three: Support and develop Grand Forks life science talent and expertise.

• The EDC should spearhead the local organization and deployment of the Plus Experience, a North Dakota EPSCoR program. This is a customized business and technology course that enriches the skills and career success of students and graduates. Plus it provides businesses with team members who can produce industry-specific results quickly. The Plus Experience is a series of six- to twelve-week courses, available to students with at least two years of college. Teaching and demonstration is be done by a combination of university and industry personnel at sites relevant to the course material.

• The EDC should work with the UND Alumni Association to help reach out to and attract former UND graduates that are currently life science professionals, including entrepreneurs and mid-management professionals with life science experience.

• The University should explore additional opportunities and funding to develop co-op and internship programs for life science and business students, particularly those in STEM disciplines.

• The University should develop and implement a microbiology focus and degree to ensure a trained workforce and provide employment opportunities for students/graduates.

• The EDC, the University and technology companies should encourage and support the Grand Forks Public School District in implementing innovations in science, technology, engineering and math (STEM) education for k-12 students.

• The EDC should support efforts in the North Dakota legislature to provide incentives for students to enroll in science, technology, engineering and math (STEM) fields. It should also support initiatives to encourage science and math graduates to stay, work, innovate and grow businesses in North Dakota.
**Strategy Four: Develop a business culture and environment that supports and sustains the growth of new and emerging life science industry and business in the Grand Forks region.**

- The EDC should spearhead the organization and operation of a life sciences roundtable comprised of leaders and innovators from research, business and government that meets regularly to discuss regional needs and emerging opportunities in the life sciences sector. By involving a diverse group, it is more likely that those emerging opportunities found at the intersection of multiple disciplines, technologies or markets will be identified as early as possible.

- Steps should be taken to involve Altru Health System in regional life science initiatives on a more regular basis to leverage their contacts and networks with pharmaceutical and medical device companies that may be interested in research related to infectious diseases, clinical trials and other related activities.

- The EDC should work proactively with the UND Research Foundation and the Medical School to plan for future research, development and commercialization facilities. A second REAC may be needed to accommodate future growth and the Medical School could significantly expand its scientific research with a $10 to $12 million facility to be used by faculty.
Increasingly the ability to track leading edge research, development, academic articles, up-to-date information regarding niche areas of the life science industry sector and the ability to interact with other professionals (via the Internet) in real time are critical in capitalizing on existing opportunities locally and regionally. To help establish a shared resource, an assessment of web-based resources has been developed with input from local and regional life science industry and development specialists. Focusing on some of the key platforms located at the University of North Dakota and others from within the region, this list will provide for follow-up and interaction for, and between, industry and development specialists locally and regionally.

**Life Science Related Blogs and Websites (Select).**

http://www.undrf.com/ is the portal for the University of North Dakota Research Foundation. This site outlines breaking news regarding advances within the Research Foundation’s new building, business partners and technology commercialization efforts associated with the Foundation and the University of North Dakota.

http://www.med.und.nodak.edu/cobre/ COBRE, an acronym for Centers of Biomedical Research Excellence, was designed by the National Institutes of Health to cultivate research expertise among junior faculty and strengthen the research infrastructure of states that do not receive as much NIH funding as some large states.

http://ndinbre.org/ site for the IDeA Network of Biomedical Research Excellence that aims to build biomedical research capacity in North Dakota by serving public universities and tribal colleges within the state.

http://www.dnavaccine.com/ provides the latest information about new technologies, upcoming conferences, and general information and resources related to dna, genomics and vaccines that are useful in providing background and general information for ongoing experiments.

http://www.ruralhealth.und.edu/ provides resources and knowledge to strengthen the health of people in rural communities. The site provides information regarding upcoming conferences, health related news and (federal) funding opportunities.

http://www.nih.gov/ is the official portal for the National Institute of Health and provides general health information, reviews of ongoing medical research initiatives and links to funding for research, clinical trials and research highlights specific to life and biosciences.

http://www.ncrr.nih.gov/ is the website for the National Center for Research Resources (NCRR) which provides clinical and translational researchers with the training and tools they need to understand, detect, treat, and prevent a wide range of diseases. NCRR connects researchers with one another, as well as with patients and communities across the Nation, to harness the power of shared resources and research.
http://www3.niaid.nih.gov/topics/BiodefenseRelated/default.htm The Biodefense Web site of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), includes biodefense-related information for biomedical researchers, the public, and the media.

http://www.ssti.org/ provides resources for those involved in technology-based economic development. The State Science & Technology Institute is a national nonprofit organization that leads, supports and strengthens efforts to improve state and regional economies through science, technology and innovation.

http://www.nrc-cnrc.gc.ca/clusters/winnipeg_e.html is the portal for the National Research Council (NRC), which is the Government of Canada’s premier organization for research and development. The site provides online resources for researchers, scientists, academics and business related to R & D, general information regarding areas of research, links to NRC institutes and programs and information regarding contract research.

http://ndsuresearchfoundation.org/ is the North Dakota State University’s research foundation portal and provides information regarding Commercial opportunities, technologies available for licensing, benefits to business and industry in participating with the Foundation and related technologies and general information including NDSU’s patent disclosure policy.

http://www.jimmunol.org/ is the Journal of Immunology’s portal that provides access to articles and reviews of ongoing academic and private sector research, development and experiments in the field on immunology.

http://blog.aesisgroup.com/ independent commentary on emerging trends in the life sciences, often with a Midwest slant.

http://www.venturemidwest.com/ is a portal established to provide unifying themes for tech professionals and enthusiasts throughout the loosely defined “Midwest” region.

http://www.biotech-weblog.com/ Corporate and industrial news regarding diagnostics, methodologies and instrumentation; drugs, vaccines and therapeutics; energy, environmental and ecology; food and agriculture; gene therapy, genomics, proteomics and bioinformatics; microbiology, nanomedicine; and news regarding patents and intellectual property rights.

http://www.who.int/topics/infectious_diseases/en/ The World Health Organization has an extensive website that covers infectious diseases that are caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi - the diseases can be spread, directly or indirectly, from one person to another. Zoonotic diseases are included too and are infectious diseases of animals that can cause disease when to transmitted humans.

http://www.fda.gov/CDER/ provides information regarding the FDA’s Center for Drug Evaluation and Research, including drug information and regulatory guidance.

http://www.medicaldevices.org/ Medical Device Manufacturers Association (MDMA) is a national trade association, based in Washington, D.C., that represents independent manufacturers of medical devices, diagnostic products and healthcare information systems.
http://www.devicelink.com/ Offers medical manufacturers free information on industry suppliers, regulatory affairs, industry events, and job opportunities.

http://www.nsi.edu/ Independent scientific research institution dedicated to increasing knowledge of the biological basis for brain function.

http://www.nrel.gov/learning/re_biofuels.html Information about the National Renewable Energy Laboratory, including general information about the lab, how to locate NREL Employees, how they operate and do business, and how one can do business with the NREL.

http://www.lsam.ca/ the Life Science Association of Manitoba website provides a forum for members to improve as individuals/companies through training, the creation of local, national and international networking opportunities, Government liaising and an awareness of the local and global marketplace. LSAM represents members from Manitoba’s biotechnology, pharmaceutical, medical device, and health research industries as well as related service providers/suppliers.

http://www.lifesciencealley.org/ LifeScience Alley™, a Minnesota-based trade association serving more than 500 member organizations, provides access to top industry leaders, opportunities to build your business through education and networking, insights into current trends, regulations, research and emerging technologies, and the power of a collective voice at the state and federal levels.

http://www.siteselection.com/ provides research for economic developers and service providers in attracting, retaining and identifying key components in the site selection process.

http://www.ndsu.edu/cnse/ North Dakota State University’s Center for Nanoscale Science and Engineering, conducts large-scale, multidisciplinary research for government and industry. CNSE is a Defense Microelectronics Activity (DMEA) Center of Excellence (COE) for design and prototype fabrication of microsensors and miniaturized wireless communication devices. CNSE also includes two State of North Dakota Economic Development Centers of Excellence, the Center for Advanced Electronics Design and Manufacturing, and the Center for Surface Protection, a joint program with the Department of Coatings & Polymeric Materials in which CNSE personnel lead efforts in hard coatings.

http://www.ndsu.nodak.edu/cobre/ The Center for Protease Research is a multidisciplinary research center whose aim is to help combat diseases including arthritis, diabetes and cancer. Research is focused on a class of enzymes called matrix metalloproteinases (MMP’s), which play vital roles in biological functions.
ATTACHMENT B: LIFE SCIENCE CONFERENCES

With the growth of the life science/biotech industry the need, or desire, to attend and participate in professional conferences is driven by many issues and elements that are key to developing and maintaining a competitive advantage in the market place – regardless of the industry. Many go to glean market and/or product intelligence and information specific to a project or platform. Other key elements include the growing need to network with peers and (other) experts in the specific field/conference, to share ideas with industry leaders and to develop an increased or higher profile within the community of life science professionals and peers. Again, focusing on the interests, expertise and platforms located at the University of North Dakota and within the region, this list will provide insight to key conferences for industry and development specialists locally and regionally.

Selected Life Science Conferences

Dakota Conference on Rural and Public Health: Addressing Health Care Challenges
March 26-28, 2008
Fargo, North Dakota
http://ruralhealth.und.edu/projects/sorh/dakotaconf.php

A conference to provide continuing education to health and human service administrators, managers, researchers, and clinical providers, to create an environment of learning that is informative and educational to an inter/multidisciplinary audience of health and human service professionals, to provide participants with the opportunity to informally network with others to share skills and strategies meant to address access, financial, and quality of care issues found in rural and public health and to foster an environment that is conducive to collaboration between different organizations, health/human service disciplines, and communities.

Forging New Partnerships: How to Thrive in Today’s Global Value Chain
April 3, 2008
St. Louis Park, MN

Learn how to better develop and serve global markets, harness innovation, finance investments, and build skilled worker pipelines. An overview of best practices of small and mid sized manufacturers. Learn the obstacles and risks of participation in today’s global value chain versus the supply chain of the past and gain an understanding of how leading manufacturers have turned this challenge into opportunities.
Allergy and Clinical Immunology
April 4, 2008
Minneapolis, Minnesota
http://www.clinimmsoc.org/related/

This conference will highlight the importance of allergic and immunologic disease in the practice of medicine. An overview of new clinical strategies for diagnosis and management will provided practitioners important tools to identify the mechanisms and basis of the treatment of allergies and other adverse immune reactions and provides a practical interpretation of pulmonary functions.

Design of Medical Devices (DMD) Conference
April 15-17, 2008
Minneapolis, Minnesota
http://www.dmdconf.org/

The conference goals are to promote the medical device industry, and provide a forum to bring medical device designers, manufacturers, researchers, and representatives from the public sector together to share perspectives on medical devices.

10th Annual Alzheimer’s Disease Conference
May 1-2, 2008
Boston, Massachusetts

Bringing together leaders from industry, academia and government to learn novel advances in discovery, therapeutics and clinical trials. Key elements will include: latest developments in AD targeted therapies, new advances and accomplishments with imaging in AD, bridging cutting-edge research to clinical developments, case studies providing in-depth look at various components of AD research and progress with biomarkers and the future of AD diagnosis.

Eleventh Annual Conference on Vaccine Research
May 5 – 7, 2008
Baltimore, Maryland
www.nfid.org/conferences/vaccine08

Research on vaccines and associated technologies for disease prevention and treatment through immunization. This is a venue for cutting edge topics and issues. International experts will lead seminars and panel discussions on topical areas of basic immunology, product development, clinical testing, regulation, and other aspects of vaccine research. Opportunities for networking and scientific collaboration critical to advancing vaccine science and development will be available through audience discussions.

A Midwest Framework for the Advancement of Molecular Diagnostics & Personalized Medicine.
May 21, 2008
Minneapolis, MN
http://www.lifesciencealley.org/programs_events/detail.aspx?id=213

Explore what it will take for the Midwest region to become a powerhouse in leading the future of medicine. The focus will go beyond pharmacogenomics (what most people
think of, when they hear personalized medicine), and consider other critical areas of research and product development.

3rd Annual Frontiers in Biomedical Devices
June 18-20, 2008
Irvine, Irvine, CA
http://www.asmeconferences.org/Biomed08/

Leading authorities in the commercial and academic arenas will focus their expertise in eight technical topics including: imaging & anatomic interaction, simulation & modeling, device technology & innovation, bio-sensors & diagnostics, device testing, therapeutic devices, device design & development and clinical regulatory issues.

2008 Annual Conference on Antimicrobial Resistance
June 23-25, 2008
Bethesda, Maryland

The conference provides an interdisciplinary scientific forum to present, discuss, and address the science, prevention and control of antimicrobial resistance, and to define issues and potential solutions to the problem of antimicrobial resistance. Program includes presentations on drug resistant Mycobacterium tuberculosis, the evolution of rapid diagnostic technology, resistance and public policy, behavioral and social issues related to inappropriate antibiotic use, superbugs and severe infections, the synergies between veterinary and human resistance issues, and the potential influences of therapy duration on resistance.

Alzheimer’s Association International Conference on Alzheimer’s Disease 2008
July 26-31, 2008
Chicago, Illinois

This international conference serves as a catalyst for generating new knowledge about dementia and fostering a vital research community. Major topics will include overviews on genetics, epidemiology and risk factors, cellular and animal models, Neuropathology of amyloid, tau, protein misfolding, lipid biochemistry, signal transduction and other disease mechanisms, early detection and diagnosis, neuroimaging and biomarkers and current interventions and future therapies.

6th Annual ASM Biodefense and Emerging Diseases Research Meeting
February 24-27, 2008
Baltimore, MD
http://www.asmbiodefense.org/

The purpose of this meeting is to bring together individuals who are carrying out research to defend against the growing threat of bioterrorism; and decision makers shaping the future biodefense research agenda, recognizing that emerging infectious diseases serve as a paradigm for handling the public threat of bioterrorism.
Attachment C: UND Student Organizations: Life Sciences Related

American Medical Association-Medical Student Section
American Medical Student Association
American Medical Women's Association
Anthropology Club
Biology Graduate Student Association
Christian Medical and Dental Association
Doctors Ought to Care
Forensic Science Club
Graduate Resource Alliance for Students in Psychology
Indians into Medicine (INMED)
Medical Laboratory Science Club
Medical School Student Council
National Student Speech, Language & Hearing Association
Neuroscience Club
Nursing Students Association
Occupational Therapy Club
Physical Therapy Club
Physicians for Human Rights
Pi Theta Epsilon (Occupational Therapy)
Rehab Club, UND
Student Assn of Nutrition & Dietetics (SAND)
Student Athletic Trainers Organization
Student Dental Club
Student Psychological Association
Student Social Work Association
Undergraduate Medical Association
ATTACHMENT D: INTERVIEW PARTICIPANTS

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Mike Chambers, Aldevron
David Bradley, Avianax
Jerry Finken, CSM
James Carlson, PRACS
Brian Walters, FM Economic Development
ATTACHMENT E: REFERENCES


www.researchtriangle.org/lifesciences.