ACCESS TO CAPITAL
for Emerging Life Science Enterprises in Tennessee:

The Most Important Element in Growing a Vibrant, Vertically Integrated Life Science Industry in our State
Life Science Companies and R&D Assets in Tennessee:

**EXECUTIVE SUMMARY**

The life science industry has experienced expansive economic growth across the globe over the past decade, and is expected to continue this growth well into the future. Today, the industry in the U.S. alone accounts for more than 1.6 million direct jobs paying nearly 80 percent more than the average worker in the U.S. Tennessee has a vibrant life science industry contributing significantly to the state’s economy and employing more than 40,000 citizens with an average salary of more than $79,000 a year.

Across the U.S., regional clusters that fully realize the industry’s growth have significant investment in programs that enhance the availability of the life science workforce, as well as focus on programs for life science entrepreneurs that can advance companies in the early and growth stages.

Successful growth of the life sciences in any region requires long-range planning and collaboration between governmental policymakers, private industry, and academic research institutions. These stakeholders each play a major role in developing technology from the first steps of development in the lab to bedside or home front.

Life science enterprises in the state are vertically integrated ranging from multi-billion research and development institutions such as Vanderbilt, Oak Ridge National Laboratory, the University of Tennessee, and St. Jude Children’s Research Hospital; to equally large medical device companies such as Smith & Nephew, Medtronic, and Wright Medical Technologies; to mid-sized biotech companies such as Aegis Sciences and Berg Pharma; to agricultural technology companies with R&D facilities in Tennessee including Bayer CropScience, Mars, Inc. and Tate & Lyle; to emerging companies and start-ups that, while small today, have great potential to grow into the next large corporations, or to enhance the growth of those large corporations via mergers and acquisitions.
The continued growth of the industry in Tennessee, however, has several challenges. This report from Life Science Tennessee, the state’s leading industry association, describes the opportunities and challenges in the growth of the life science industry in Tennessee. Based on extensive research, including surveying best practices by other states in the Southeast and dialogue with stakeholders throughout Tennessee, this report concludes with recommendations that we believe are not only good for our industry, but for all of Tennessee’s emerging high-growth technology sectors. In that respect, our recommendations below are written to be more broad in their support of Tennessee’s technologies, however, as an industry association we believe these also will make the greatest contribution to the growth of Tennessee’s life science economy.

Key Recommendations for State Support of Tennessee’s High-Growth Technology Industries:

1. Implement a SBIR/STTR matching program whereby the State of TN would match SBIR and STTR grants received by emerging Tennessee technologies from federal agencies dollar-for-dollar up to a maximum of $1.5 million per grant and $3 million per company. To foster more successful grant applications SBIR/STTR grant writing support should also be made available. A total of $40 million should be allocated to this program over 4 years.

2. Implement a venture matching program whereby the State of TN would match investments made by qualified venture and angel investors in emerging Tennessee companies on a 1:2 ratio ($1 from state for every $2 invested by venture fund) up to a maximum of $2 million per company. A total of $40 million should be allocated to this program over 4 years.

3. Support the implementation of programs that aid in the development of successful early life science companies including support for programs that build a statewide network of life science professionals and programs to aid emerging companies. This includes expanding the state’s current life science accelerator programs with additional depth and breadth, as well as targeting programs for stakeholders in the life science ecosystem — scientists, entrepreneurs, and venture funders. These programs should both assist in the development of young companies and raise both state and national awareness of investible Tennessee companies in the life sciences. This includes support for and synergy with the Governor’s Rural Challenge agricultural innovation program. A total of $5 million should be allocated to this program over 4 years.
Life Science Tennessee (LifeSciTN) is a member-driven association representing a range of Tennessee-based enterprises as well as educational and clinical research institutions engaged in a wide array of life science sectors, including biotechnology, pharmaceuticals, medical devices, diagnostics, agricultural biosciences, agritech, and bio-based products research and development.

LifeSciTN collaborates with State of Tennessee leadership, including the Governor’s office, Department of Economic and Community Development, and General Assembly, in a vigorous effort to determine statewide strategies that will encourage new investments in the life sciences in Tennessee.

Life Science Tennessee, and in particular its Economic Development and Entrepreneurship Development (EED) Committee, is charged with identifying critical components for fostering the life sciences in Tennessee. Due to the wealth of economic potential that the industry can bring, the State of Tennessee has created and should continue to seek out policies and programs that aid in the recruitment and expansion of the industry. In 2011, the LifeSciTN EED committee focused on the state’s competency in technology transfer and commercialization. In response, LifeSciTN developed a report, Technology Transfer in Tennessee: Comments on Current Commercialization and Technology Transfer and Recommendations for Improving Current Process (LifeSciTN 2011) that identified a number of challenges and opportunities at that time. As discussed in this report, a number of gains have been made since release of that report. In 2012, attention turned toward workforce development and the need to ensure a steady stream of qualified workers. The subsequent report, The Life Sciences Workforce in Tennessee: A Report by the Education and Workforce Development Committee (June 2012) identified a number of skills gaps in addition to the troubling fact that Tennessee is a net exporter of Ph.Ds.

While the association continues to focus its efforts on making improvements in the areas of workforce and technology transfer and commercialization, the EED committee recognized that the third leg of the life science ecosystem stool is capital. Adequate access to capital is perhaps the most critical of the three lynchpins to assure job creation and growth of life science enterprises since capital enables the other two challenges to be met.

Capital availability is predominately driven by favorable public economic development policies coupled with private sector successes. Although the economic recovery has been strong in Tennessee, many small businesses still struggle to access capital, and raising investment capital in the life sciences poses unique challenges. Investors typically need to have experience navigating regulatory hurdles and other specific life science dynamics. Investors from other sectors may shy away from sound investment opportunities in the life sciences because they lack that experience. Early stage life science companies often require more funding than other technology-related or service-related businesses due to a variety of factors. Life science technologies require years of research, additional state and federal regulatory requirements, and highly technical clinical prototyping in the bioscience space and field trials on the agricultural science space. These factors can limit the overall investment in the sector from sources looking for quicker returns.

Despite these challenges, Tennessee has made considerable improvements in increasing access to capital in recent years as evidenced by a large number of thriving new start-ups. This growth has been accentuated by state policies and programs, particularly the state’s investment programs TnInvestco and INCITE, which have provided $130 million in seed monies to emerging technologies in the last five years. Unfortunately, funding for these state incentive programs has been expended, and the likelihood of an additional injection of state support for similar incentives is not expected at this time. The impact of this change is expected to slow progress for life science startups.

This report overviews the current state of “access to capital” in Tennessee along with programs that have helped to foster that growth. The report makes three recommendations for sustaining and accelerating that growth over time. The report will also showcase a number of Tennessee’s emerging and established venture-backed life science companies.
OVERVIEW OF THE LIFE SCIENCES IN TENNESSEE

Life sciences, sometimes referred to as biosciences, are a diverse group of sectors and activities with a common link—they apply knowledge of the way in which plants, animals, and humans function. The industry spans different markets and includes manufacturing, services, and research activities. The life sciences industry includes companies in the fields of agriculture, biotechnology, pharmaceuticals, biomedical technologies, life systems technologies, nutraceuticals, cosmeceuticals, food processing, environmental biology, and biomedical devices. It also includes organizations and institutions that devote the majority of their efforts in various stages of research, development, technology transfer, and commercialization. By definition, the life sciences are a unique industry cluster and are constantly changing to incorporate the latest research and scientific discoveries. Broadly defined, the industry includes the following five sectors:

- Agricultural feedstock, chemicals and biofuels (5,605 jobs in TN)
- Drugs and pharmaceuticals (1,839 jobs in TN)
- Medical devices and equipment (7,549 jobs in TN)
- Research, testing, and medical laboratories (8,903 jobs in TN)
- Biologistics (16,514 jobs in TN)

Biologistics is a specialized sub-category, with a cluster of expertise in West Tennessee. The sub-sector focuses on logistics, warehousing, and distribution of biomedical products across the marketplace. Additionally, there is a range of agricultural innovations related to crop efficiency, new crop protection approaches, animal health, functional foods, and many others in which companies and jobs can be created in Tennessee.

**TENNESSEE BY THE NUMBERS**

- 1,200 life science businesses and organizations
- 40,000 employees in the life sciences industry

**Hubble Telemedical**

TNIInvestco Venture Capital Investments by MB Venture Partners

Chuck Witkowski has some experience seeking funding for life science start-ups.

The President and Chief Executive Officer of Hubble Telemedical founded a Knoxville-based company named Protein Discovery as part of a bold experiment to get an MBA and leave with a company.

After bootstrapping the start-up with Small Business Innovation Awards, Witkowski secured a $1 million Series A round from Memphis-based MB Venture Partners in 2003, a $5 million Series B led by the Oak Ridge-based Southern Appalachian Fund two years later, and a $10 million Series C led by Austin-based Santé Ventures in 2008. Protein Discovery was sold at the end of 2011.

“It was really tough, particularly in life science,” Witkowski says in describing raising capital. “In 2003, MB Venture Partners was the only life science-focused venture fund in Tennessee, at least that I was aware of. I was always looking outside the state and, for that matter, outside the region.”

Fast forward a few years, and Tennessee has four venture funds focused on the life science sector—MB Venture Partners, Innova Memphis, Limestone Fund, and Tri-Star Technology Ventures.

Witkowski is also still in the game, this time leading a unique company built on technologies coming from two of the state’s premier research enterprises—Oak Ridge National Laboratory and the University of Tennessee, specifically its Health Science Center.

Hubble Telemedical is focused on improving medical outcomes and lowering costs for healthcare consumers.
Entrepreneurs are drivers of growth and job creation. They are responsible for pushing forth new, often disruptive, technologies that lead to increased productivity, more competition to drive down prices, and better products that meet the needs of consumers. Life science entrepreneurs bring technologies to market that help better feed, fuel, and heal the world.

Access to capital is critical for entrepreneurs to be successful. Venture capital is particularly important in the life sciences as it funds ideas and technologies that could not be financed with traditional financing given the level of risk and often long product launch runway. Numerous successful life science companies began with venture funding—some even began or have strong connections to Tennessee—including CTI Molecular Imaging (now Siemens), BioMimetic Therapeutics (now Wright Medical), Advanced BioHealing, and Ironwood Pharmaceuticals.

Total venture capital funding in the United States in the life sciences in the first quarter of 2014 increased 15 percent from 2013. According to a PricewaterhouseCoopers (PwC) report, it is the “strongest start of a year since the recession.” (Venture Capital Investments in the Life Sciences Sector, 2014).

Tennessee has made considerable gains in the past few years. According to the Milkin Institute, Tennessee’s success can be attributed to improvements in its risk capital infrastructure. This finding comes from the institute’s 2012 State Technology and Science Index which “tracks and evaluates every state’s tech and science capabilities—and their success at converting those assets into companies and high-paying jobs” (Klawden, 2012). Tennessee was recognized as one of three movers and shakers in the report making the biggest gain from 41st to 35th. The growth was largely driven by the number of companies receiving venture capital and growth in IPO proceeds.

On Milkin’s risk capital and entrepreneurial infrastructure composite index Tennessee gained 26 spots to rank 19th with significant growth in venture capital and in the number of companies receiving it. Tennessee leaped from 20th to third in IPO proceeds.
Charlie Brock, President and CEO of LaunchTN, an entrepreneur support organization, believes Tennessee should likely be ranked higher due to the fact that a number of deals were not disclosed to the primary reporting agencies. LaunchTN estimates the discrepancy to be as much as $100 million in undisclosed deals per year. This paints an even more positive picture of the state of venture capital funding and the entrepreneur ecosystem in Tennessee.

According to LaunchTN data, more than $200 million of venture capital investment goes to Tennessee-based companies across a variety of industries annually.

In 2013 approximately $42 million venture capital dollars went into life science companies, representing 19 percent of all venture capital investments (all VC investments totaled more than $222 million). Life science investments include companies with products ranging from medical device to diagnostics, biotechnology, agricultural innovation, and health care technology companies. The health care technology companies included have diagnostic or patient care-specific capabilities. Health care management technology companies are not included in these numbers. This is notable given Nashville’s prominence in the health care management sector. 2013 showed a slight increase from 2012 with a total $41 million in venture capital investment in the life sciences.

### VENTURE CAPITAL INVESTMENTS IN TENNESSEE

<table>
<thead>
<tr>
<th>Year</th>
<th>Total VC Investment in TN</th>
<th>Life Science VC Investment</th>
<th>Life Science VC Investments as percent of all VC Investments</th>
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<td>2013</td>
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**Cagenix**

**TNInvestco Venture Capital Investments by Innova Memphis**

“Every round of capital is critical,” Daryl Newman, Chief Executive Officer of Cagenix, says while quickly adding that the funding through Innova Memphis came at a particularly important time for the Memphis-based company.

“We were revenue positive, but pre-profit,” he explained. “I’m not sure we would have gotten to where we are today without those dollars.”

Similar to a number of start-ups, Cagenix existed in the early years on investments from “friends and family” and eventually some other investors.

A pivotal point in the start-up’s history occurred in late 2011 when Innova led a Series A round that included monies through the TNInvestco program. It allowed the company that markets dental prostheses to move into its own facility, hire people, and promote its product.

Cagenix, which employs 12 people, was founded in 2005 to research and develop new dental implants. Its founders were Carl Schulter, a DDS; his son Drew; Dr. Denis DiAngelo, professor of BioMedical Engineering at UTHSC; and local business executive Earl Yanase. They collaborated on new ways to manufacture and distribute dental frameworks and bars.

Cagenix entered the market with a fixed denture product in 2010, about a year after Newman joined. During the ensuing years, the company has made several enhancements to the product and is now poised to raise a Series B round.

Like other life science companies, Newman cited challenges beyond funding such as access to talent. He also noted how important the involvement of Innova’s two Partners – Ken Woody and Jan Bouten – and Memphis Bioworks Foundation have been to the company’s success.

For more information on Cagenix, visit its webpage at http://www.cagenix.com/.
A 2010 National Bureau of Economic Research paper on the effects of government sponsored venture capital found that companies with a small amount of government sponsored venture funding in addition to private capital performed better than companies without (Brander & Hellmann, 2010). Large amounts of government funding, which is often synonymous with more government control, led to weaker performance. The authors conclude that when government funding is disciplined by private funding the additional money has a positive effect. Governments use a variety of tools including matching funds, tax credits, fund of funds, and other policies to support venture deals.

On a national level, the Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR) programs grant federal R&D monies into U.S. companies that have high potential for commercialization.

Additionally, in agricultural innovation, the USDA has a sponsored program called the Rural Business Investment Program (RBIP), which provides support to help start rural based investment funds in partnership with the national Farm Credit System. Tennessee companies are working to take advantage of this program to ensure that innovation-based investments benefit the rural community.

Tennessee currently has two programs that have had a substantial impact in fostering an increase in early stage life science companies in the state—The TNInvestco program and the INCITE Co-Investment Fund.

Chuck Witkowski of Hubble Telemedical, a TNInvestco portfolio company, noted, “TNInvestco has been a tremendous catalyst for new company starts and growth.” The first round of funding is often the most difficult to secure. He credits the TNInvestco program with making the decision easier for local venture capital firms to invest in his company.

**TNInvestco Support of the Life Sciences**

The TNInvestco program was started in 2009 under then Governor Phil Bredesen as way to fuel the creation of start-up companies.

According to the 2009 press release, “the goals of TNInvestco […] are to develop Tennessee’s entrepreneurial infrastructure, to bring additional capital into the state, to diversify the state’s economy and to create ‘anchors’ or ‘clusters’ of business innovation which can result in new companies being created or spun off and new talent being attracted to Tennessee” (Tennessee Department of Economic and Community Development Press Releases, 2009).

The program funded 157 companies as of April 2014, allocating $200 million dollars in tax credits to a cross section of venture capital funds with broad experience in developing new companies in Tennessee. Four venture capital firms in Tennessee that participated in the program focused predominately on investing in life science companies. They are TriStar Technology Ventures, Innova Memphis, MB Venture Partners, and Mountain Group Capital/Limestone Fund.

**TriStar Technology Ventures**

Tri-Star was founded in 2009, specifically to take advantage of the TNInvestco opportunity. The company has since raised approximately $25 million in a second fund. Approximately 50 percent of the firm’s portfolio is in the life sciences. The other half is in health care IT. Six of 15 of its portfolio companies are based in Tennessee.

According to Brian Laden, Ph.D., Tri-Star Co-founder and Partner, “The life sciences are a great place to be investing right now. The landscape is changing rapidly, particularly the regulatory and reimbursement environments. However,
if you can assemble a team who understands how to navigate through the uncertainty, there is a tremendous amount of value to be unlocked.”

Now that all of the TNInvestco funds have been committed, Tri-Star uses the INCITE Co-Investment Fund to “extend the runway” for companies that need more time to meet regulatory or other milestones. Public support of their ventures is an important part of their strategy for success.

**Innova Memphis**

Innova Memphis announced in September 2014 the completion of its third venture capital fund, Innova Fund III, offering $20 million in capital commitments.

Innova was founded in Memphis in 2007 by the Memphis Bioworks Foundation. Given the concentration of medical device expertise in Memphis (the 4th largest medical device cluster in the U.S.) Innova, along with Memphis Bioworks, developed the ZeroTo510 accelerator, the country’s first medical device accelerator program. While the fund focuses predominately on medical device companies, its portfolio includes companies across the life science spectrum. Innova invested over $15 million in 36 startups, attracting over $50 million of outside capital, for a total annual impact greater than $90 million and supporting more than 150 direct jobs.

**MB Venture Partners**

MB Venture Partners is a Memphis-based venture capital firm that provides capital and strategic direction to life sciences companies. The firm invests in medical device and biotechnology companies at all stages of development and are especially interested in funding product solutions for musculoskeletal disease. The first hosts the annual Musculoskeletal New Ventures Conference in Memphis, and this year will be the 12th annual event.

MB Venture Partners is arguably the first venture capital firm dedicated to life sciences in Tennessee.
The Firm was founded in 2001 and has since raised four Funds totaling more than $120 million in committed capital under management. In total, we have invested in more than 40 start-ups, more than half of which are in the state of Tennessee. MB Venture Partners has funded some of the state’s most successful life science companies including Memphis-based GTx and Nashville-based BioMimetic Therapeutics, which was recently purchased by Wright Medical.

MB Venture Partners is one of the ten firms selected for the TNInvestco program. The firm has collaborated with Innova Memphis on the ZeroTo510 accelerator, the country’s first medical device accelerator program.

**Limestone/Mountain Group Capital**

In 2003, Joe Cook Jr., founder and past chairman of Ironwood Pharmaceuticals and former group vice president of Eli Lilly and Company, moved from San Diego, California to Nashville to start Mountain Group Capital, a venture capital investment firm specializing in the life sciences. The initial fund was made up almost entirely of capital from high net worth individuals. Mountain Group launched Limestone Fund to take advantage of the TNInvestco program. The fund was successful enough that the group was encouraged to raise another fund. In March 2013, Mountain Group closed on an approximately $34 million fund.

Cook says the TNInvestco dollars helped his firm bring additional money to the table that helped to keep high-potential companies moving forward. But, perhaps most importantly, it served to connect investor groups together and to expose the firm to opportunities across the state.

**The TNInvestco Catalyst**

The TNInvestco program linked together the venture capital firms with expertise in the life sciences. They continue to jointly study companies and, at times, rely on each other’s due-diligence for investment opportunities.

As of the end of 2013, TNInvestco funds allocated $108 million to Tennessee companies (TNInvestco Annual Report, 2013).

The TNInvestco fund is credited with getting a number of companies off the ground that might not have been launched otherwise. The first round of funding is often the hardest to secure. The funds moved many companies from the proof-of-concept stage to the commercial stage. Perhaps most importantly, as Diagnovus Founder James Stover noted, “[This] gives companies the credibility needed to secure future investments.”

Attracting additional private investors was a key goal of the program and one they’ve been largely successful at achieving. The TNInvestco portfolio companies have received $221 million in “follow-on” capital (additional private investment).

Increasingly firms outside of the state are investing in Tennessee companies. Hatteras Venture Partners for example has partnered with Tennessee’s Limestone Fund, and has invested in numerous early stage companies including Device Innovation Group and Pathfinder Therapeutics.

Many credit the program for creating a spark in the venture capital community that not only gave firms the confidence to launch a new fund but that facilitated the creation of networks across the state and beyond which helped get industry expertise where it was most needed. These partnerships have played out time and time again through programs such as the LaunchTN Southland Conference and Health Care Connection programs, as well as programs at Tennessee’s accelerators and mentor networks.
To summarize, the program was important for fostering three components critical for any entrepreneur ecosystem to thrive. The program:

1.) attracted companies (talent) to Tennessee;
2.) established a network for mentorship and expertise sharing; and
3.) attracted additional private investment.

**INCITE Co-Investment Fund**

If TNInvestco was the spark, then INCITE is the fuel to keep the flame burning.

The INCITE Co-Investment Fund matches a portion of investments in Tennessee-based companies. The program is administered by LaunchTN a public-private partnership focused on supporting entrepreneurs and the development of high-growth companies in Tennessee.

The INCITE Co-Investment Fund is a key component of Governor Bill Haslam’s INCITE initiative to drive growth and create knowledge-based jobs in Tennessee by encouraging investment in the state’s developing small businesses.

The fund was created in 2011, using $29.7 million of federal funding awarded under the State Small Business Credit Initiative.

The fund matches between 15 and 25 percent of venture capital investment made by approved investment firms based in Tennessee.

In its first two years of operation, the Fund augmented investments in 31 companies, leveraging $50 million in outside capital into $75 million. These INCITE portfolio companies range in size from one-person operations to businesses with up to 40 employees.

Of the 31 INCITE portfolio companies, four are in the life sciences: Molecular Sensing, Diagnovus, Pathfinder Therapeutics, and Advanced Catheter Therapies.

**INCITE by the Numbers**

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<td>Jobs</td>
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THE ENTREPRENEUR ECOSYSTEM IN TENNESSEE

The success of venture capital is dependent upon a good flow of science, motivated entrepreneurs, protection of intellectual property, and a skilled workforce.

Money Follows Technology
While not solely in the life sciences, a significant amount of research money comes into the state through institutions like Oak Ridge National Laboratory, Vanderbilt University, St. Jude’s Children’s Research Hospital, University of Tennessee, and others.

In 2013 NIH funded $456 million in research in Tennessee. The state ranks 8th in the U.S. for public sector expenditures as a percentage of GDP.

Since the writing of LifeSciTN’s commercialization report, significant gains have been made in moving research out of the lab and into the market. The University of Tennessee Research Foundation (UTRF) and Vanderbilt conducted competitive nation-wide searches to make key hires with substantial experience in commercialization. As a result, Vanderbilt has increased its startup launches from one in fiscal years 2009-2011 to 15 in fiscal years 2012-2014. UTRF launched 16 in 2012-2014 compared to 15 in years 2009-2011. Although this represents an increase of only one start-up launch, this accompanied an increase in its invention disclosures from 86 to 147.

St. Jude Children’s Improvements in Technology Transfer and Commercialization

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<tr>
<td>UTRF</td>
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NuSirt Biopharma
TNInvestco Venture Capital Investments by Mountain Group Capital/Limestone Fund

“The TNInvestco program was critical in funding a study that led to our recent pivot,” says Barbara Cannon, Chief Operating Officer of NuSirt Biopharma, Inc.

Now, thanks to that earlier funding, the start-up has just begun clinical trials on a new drug for type 2 diabetes patients that could be prescribed in lower doses while potentially reducing negative side effects.

The story begins with the founding of NuSirt in 2007. Based on the research of Dr. Michael Zemel at the University of Tennessee, the company was focused on the positive effects of energy metabolism.

The business plan called for selling nutraceuticals at health stores and online, but all of that changed last summer when NuSirt discovered the potential of combining leucine with metformin, one of the most commonly-prescribed medications for diabetes.

Fast forward to this August when about 100 patients at eight research sites, including two in Nashville, began participating in a clinical trial that should be completed by the end of 2014. If the results are as positive as Cannon and others believe they will be, the drug could be approved for commercial use by 2017.

The team recently presented its work thus far in two papers at the American Diabetes Association’s “Scientific Sessions.”

NuSirt, which has a total of six employees located in Nashville and Knoxville, has also completed two rounds of external funding with its partners — Mountain Group Capital as a major investor along with Limestone Fund, TriStar Technology Ventures, and Tennessee Community Venture Fund.

“We would not have been able to raise the Series A funding without the TNInvestco program,” Cannon said.

That funding has also allowed NuSirt to file 11 patent applications. Two patents have issued thus far.

Cannon is experienced in the entrepreneurial space as well as human clinical trials on a national and international basis. She applauded the vision that “allowed this unique and useful program (TNInvestco) to happen in Tennessee.”

For more information on NuSirt, visit its webpage at http://nusirt.com/.
Research Hospital increased its disclosures over the same time period.

While these numbers are across all sectors it is evidence of the large amount of research activity and intellectual property creation in the state. Every sector benefits when a state is seen as a hub for intellectual property creation.

**Money Follows Talent**

As a major research center, the state cultivates talent dedicated to science and research. Having adequate capital resources will allow those researchers and entrepreneurs to follow their dreams and create companies here in Tennessee.

Vibrant networks of researchers, entrepreneurs, and venture capitalists create catalytic effects. The bioscience industry is one of the world’s fastest growing and important economic engines. Jobs employed by the life science industry are some of the best paid, highly skilled positions in today’s economy. Our state’s research institutions are leading the way in training and attracting these skilled workers. Vanderbilt University is a top institution for the generation of life science Ph.D.s according to the National Science Foundation, Tennessee has produced an average of 200 life science Ph.D.s each year since 2007. Tennessee State University’s College of Agriculture, Human and Natural Sciences recently opened its agricultural biotechnology research center and has dramatically expanded its Ph.D. program from three Ph.D.s in 2008 to 26 in 2014. The college has also added 75 masters level students during the same time period growing the program from 11 to 86 over the last six years.

While some Tennessee companies often have to reach well beyond state borders for the deep experience needed to bring a life science company to market, progress is being made. Tennessee has a high quality of life and a low cost of living compared to the east and west coast life science cluster regions.

Nashville has achieved national press as a great place to live and work. Other Tennessee communities enjoy similar reputations. Once qualified people get to Tennessee, they tend to stay and tell others. More than one investor noted that having one or two major successes will have a big impact on companies’ ability to recruit and retain talent in Tennessee.

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**Restore Medical**

TNInvestco Venture Capital Investments by MB Venture Partners and Innova Memphis

The co-founders of Restore Medical were trying to bootstrap the start-up while holding full-time jobs in Atlanta when they heard about the “ZeroTo510” medical device accelerator run by Memphis Bioworks Foundation with support from Innova Memphis and MB Venture Partners.

“It was a once-in-a-lifetime opportunity,” Co-Founder and President Shawn Flynn says. So, the two business partners – Ryan Ramkhelawan is Chief Executive Officer – quit their jobs and relocated to Memphis in 2012 to join the inaugural cohort in the 90-day accelerator program.

Their company has developed a patent-pending approach to sterilizing instruments used in surgical procedures. Not only does the Restore™ Modular Sterilization Tray System lessen the touch points within the surgical sterilization continuum, it does so in a way that increases the efficiency of a process, meaning a reduction in surgical delays.

“We could have bootstrapped our company, but it would have taken us longer to get to market, and time to market is critical,” Flynn explained.

By being selected for the “ZeroTo510” program, Restore Medical received an initial seed round of $50,000, courtesy of the two venture funds.

“The seed money was needed and appreciated, but the mentoring and connections were most valuable,” Flynn notes. That’s the hallmark of “ZeroTo510” and the other accelerators that are part of a statewide network funded partially by Launch Tennessee.

When the “ZeroTo510” program ended in August 2012, Restore Medical secured $2.5 million in funding from MB Venture Partners and Innova.

The company started pursuing its 510(K)
Accelerators and Incubators

Tennessee has a state-wide network of accelerators that are linked together through LaunchTn. That network ensures that each has access to a growing network of mentors and investors. Each of Tennessee’s nine regions is home to an accelerator. The Memphis accelerator, Zeroto510, as noted earlier is focused on medical devices.

The accelerators play an important role in attracting talented entrepreneurs to Tennessee and in providing much needed support to local companies. They are also important tools for vetting new companies and for making efficient use of venture capital dollars. The Zeroto510 program, for example, invests $50,000 in each cohort company and then runs the company through a rigorous boot camp. At the end of the program, the venture capital firms have a better sense of the companies’ potential. From the 2014 cohort, Compression Kinetics and EndoInsight each received $100,000 in follow-up funding.

Tennessee Department of Agriculture and USDA are currently funding the development of a strategic ag innovation strategy that are modeled on the successes of programs such as Zeroto510 to help agricultural entrepreneurs start and grow companies. This is part of the Governor’s Rural Challenge 10 Year Strategy for Agriculture released in December 2013.

Accessible and affordable incubator space is a necessary component of life science technology development. Tennessee has promising life science research parks in our state including Agricenter International, Memphis Bioworks, the Cool Springs Life Sciences Center in Franklin, Cumberland Emerging Technologies in Nashville, Cherokee Farms in Knoxville and the ETSU Innovation Lab in Johnson City.

In agricultural innovation, in addition to the traditional incubators, UT Institute of Agriculture and Tennessee State University have a network of experiment stations, research farms, and extensions service across the statewide which is being organized to better serve the development and growth of startup companies. These are joined by applied research assets at University of Tennessee at Martin and Middle Tennessee State University. For success, the incubators need to have a network that helps emerging companies attain capital funding as well as a network of life science professionals to guide their companies through growth.

Strategies for Attracting More Capital

In the early 2000’s, MB Venture Partners was essentially the only venture capital firm funding life science companies in Tennessee. Today, there are at least six Tennessee-based venture capital firms and a handful of non-Tennessee based firms that are active investing in life science in the state.
The word is getting out that Tennessee is the place to find opportunities at a great value. Many investors have noted that it is much less expensive to fund a start-up in Tennessee than in Silicon Valley or Boston, for instance. The life science entrepreneur ecosystem is thriving with support from organizations like Life Science Tennessee, Memphis Bioworks and LaunchTN.

More can be done, however, to ensure that venture capital continues to be available. While INCITE continues to fuel the flame sparked by the TNInvestco program by providing additional funds, some investors worry that the private sector may not sufficiently fill the gaps without a concerted public and private sector response.

Below are recommendations that Life Science Tennessee advocates for continued and increased access to capital in the state of Tennessee.

**INTRODUCTION TO RECOMMENDATIONS**

The TNInvestco program, once all funds are distributed, will have infused close to $150 million into Tennessee companies over five years. The program has dramatically changed the investing landscape. A gap will surely be felt by the investment and start-up community. To continue to attract investors and companies, a program of similar size and scope should be implemented.

**Kentucky SBIR Matching Fund**

The Kentucky Science and Technology Corporation, through the Kentucky Cabinet for Economic Development and Office of Commercialization and Innovation matches funds of up to $150,000 for Phase I and up to $500,000 for Phase II to Kentucky companies participating in the Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Since the program’s inception in 2007 and as of January 2013, there have been over 155 grants awarded totaling over $37 million dollars in state funding. (BIO 2012)

Fund matching mechanisms are used by many states to ensure a constant flow of money into new technology start-ups. Matching programs help ensure that the private sector has fully vetted the technology and company. This makes initial investments more likely to succeed and perform.

Venture firms investing in the life sciences understand that they face particular challenges with long return times, heavy, and often unpredictable regulation. These firms often take advantage of programs like the INCITE program to extend the runway for companies and/or to decrease the risk associated with an investment that must get through several regulatory hurdles. Given the high-risk nature and the long time-to-market typical of many life science companies, public funds are disproportionately important to the life sciences sector.

**Recommendation #1 Tennessee should allocate state funds to an SBIR Grant Matching program**

Implement a SBIR/STTR matching program whereby the state of TN would match SBIR and STTR grants received for emerging Tennessee technologies from federal agencies dollar for dollar up to a maximum of $1.5 million per grant and $3 million per company. To foster more successful grant applications SBIR/STTR grant writing support should also be made available. A total of $40 million should be allocated to this program over 4 years.
There are several ways that states utilize matching fund dollars to support emerging technologies. More than 25 states support emerging companies through some level of matching public funding although some programs are stronger than others. The options for matching program include such things as matching federal small business research grants, called SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) programs.

Other states have programs that place additional capital in emerging technologies through the use of tax credits to raise capital. Through the generation of these funds states make investments directly in companies, invest in private funds, and match private funding. The degree of involvement and ease of funding access vary wide by state and program.

Numerous states including Kentucky, North Carolina, South Carolina, Virginia, and Florida have implemented matching programs where state funds are awarded to companies that have received funding from one of two federal funding programs—SBIR or STTR.

Companies that receive state funds in addition to the SBIR funds have been more successful at securing additional federal funding for phase two (prototype) and phase three (commercialization) funding. Also, states with matching programs increased substantially the number of grants coming into the state (Chapman, 2010).

More than 1,200 companies have received SBIR or STTR funds in Tennessee. Tennessee ranks 26th in the total number of awards and in total dollars awarded (SBIR/STTR Awards Reports, 2014).

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**Diagnovus**

*TNInvestco Venture Capital Investments by Mountain Group Capital/Limestone and TriStar Technology Ventures; INCITE Fund Recipient*

“*It takes a lot of money to get from nowhere to somewhere in the life science space,*” James Stover, President of Diagnovus, LLC says.

The former Vice President of Operations for the organization now known as Launch Tennessee saw the needs firsthand while helping accelerate the number of technology-based start-ups in Tennessee. As a co-founder of three-year old Diagnovus, he has also seen how important access to adequate capital can be on the early success of a life science company.

“There has to be some form of venture capital or risk capital to advance anything in the life science sector,” Stover says. Nashville-based Diagnovus was in a fortunate position to already have initial capital, thanks to Mountain Group Capital and TriStar Technology Ventures. Both are part of the TNInvestco program.

“TNInvestco got us off the ground,” Stover says, adding that the funding helped “move us from proof-of-concept to commercial stage with three products in the clinic, de-risk potential future investment from outside investors, and align with strategic partners.”

This fact was particularly important for the molecular diagnostics company that was paving new ground as it focused on making an impact in diseases where there are tough clinical decisions that have to be made. In essence, the TNInvestco dollars provided important credibility.

Stover has also seen the value of the INCITE Co-Investment Fund run by Launch Tennessee. Diagnovus’ Series A included $500,000 from the fund.

The company is generating revenue, thanks to these early investments, and will soon complete a Series B round that will fund commercial sales and growth.

As Stover looks to the future, funding is not the only challenge the company faces. Others include finding management and scientific talent as well as affordable and available lab space, and addressing “things that we cannot control.” The latter includes regulatory issues and reimbursement.

For more information on Diagnovus, visit its webpage at [http://diagnovus.com/](http://diagnovus.com/).
Our neighboring state to the north, Kentucky, boasts the Kentucky SBIR Matching Fund and has awarded $5.6 million to 21 companies since Jan 2014.

LaunchTN administers a FAST grant awarded by the Small Business Administration that is designed to help entrepreneurs secure SBIR and STTR funding. While an important part of the process, the addition of a state matching program could ultimately increase the total number of companies receiving awards as well as increase participating companies’ chances of success.

Recommendation 2: Expand matching mechanisms to support emerging life science companies

Implement a venture matching program whereby the State of TN would match investments made by qualified venture and angel investors in emerging Tennessee companies on a 1:2 ratio ($1 from state for every $2 invested by venture fund) up to a maximum of $2 million per company. A total of $40 million should be allocated to this program over 4 years.

Venture and angel fund investing continue to bring needed capital that advances technologies from the lab to the marketplace for companies in the bioscience field. With the growth of global demand for better health care and more efficient use of resources, through the development of life science technologies in Tennessee, we have an opportunity to be a leader in bringing solutions to the market place.

Tennessee’s two venture funding initiatives, TnInvestco and INCITE, are coming to a close. It is perhaps too early to tell the direct impact of these program on Tennessee, but we know these program have considerably advanced the momentum for the life sciences industry as evidenced in a stronger network for startups across the state.

A venture matching program represents a collaborative approach by key stakeholders in Tennessee’s early-stage companies to leverage capital and create a continuum of high tech entrepreneurs in Tennessee.

Tennessee’s INCITE fund is a model for a continued venture matching program. The fund has matched between 15 and 18 molecular sensing

Molecular Sensing  
TNInvestco Venture Capital Investments by MB Venture Partners; INCITE fund recipient

This is not Bill Rich’s first life science rodeo, as the old saying goes, so it’s important to take note when the Chief Executive Officer, President and Chair of Molecular Sensing Inc. says the start-up opportunities in Tennessee for companies like his outweigh the challenges.

“Vanderbilt is like a gold mine for scientific talent,” the Chattanooga native says. That fact clearly offsets what Rich calls the infrastructure challenge. “Engineering and manufacturing for diagnostic and med device instruments are in California and Massachusetts.”

Molecular Sensing is commercializing a new, game-changing molecular interaction biosensor technology called Back-Scattering Interferometry (BSI). The technology addresses unmet needs in pharmaceutical drug discovery and development, biomedical research, and diagnostics by overcoming the limitations of SPR and ITC, while combining their advantages in a single, synergistic platform.

Rich returned to the state in 2012 to take the top positions at the Nashville-based start-up that was founded in 2007. With four start-ups under his belt, he clearly understands the investment challenges that life science companies face and made adjustments.

“We set-up our business plan to be consistent with the capital available here,” Rich explained. “Companies in our market segment usually take $50 to $60 million. We believe we can reach profitability with $10 to 12 million in equity capital and NIH grants.”
The strategy appears to be working well for the TriStar Technology Ventures portfolio start-up. Molecular Sensing recently completed its Series B round that is expected to sustain the company, which has been generating revenue since 2009, as it moves into a commercial growth phase later this year. Rich says that some debt financing is likely as additional working capital will be needed.

For other entrepreneurs considering a life science start-up in Tennessee, Rich says they should not be deterred by the perceived lack of available capital in the region.

“I’ve found it to be better here,” he says of the investment community. “On the coasts, they are only interested in billion dollar companies. Out here, the venture capitalists are much more pleasant to deal with as well as provide professional assistance to guide the company to profitability and liquidity for shareholders.”

For more information on Molecular Sensing, visit its webpage at http://molsense.com/.

25 percent of venture capital investment made by approved investment firms based in Tennessee. To date the fund has leveraged $22 million into nearly $75 million of investment.

**Recommendation 3: Raise support and awareness of Tennessee’s life science community**

Tennessee should seed programs that aid in the development of successful early life science companies, including support for organizations that will continue to build the statewide network of life science professionals and programs that aid emerging companies. This includes expanding the state’s current life science accelerator programs with additional depth and breadth, as well as targeting programs for stakeholders in the life science ecosystem—scientists, entrepreneurs, and venture funders. These programs should both assist in the development of young companies and raise both state and national awareness of investible Tennessee companies in the life sciences. This includes support for and synergy with the Governor’s Rural Challenge agricultural innovation program. A total of $5 million should be allocated to this program over 4 years.

Along with capital, it is important for Tennessee to cultivate an ecosystem for life science entrepreneurs, as well as attract new companies and promote international life science investors to our state.

This recommendation will encompass all efforts by LifeSciTN and its partners to promote opportunities in Tennessee and leverage the following:

- Tell the stories of successful life science companies, programs and academic research institutions currently located in Tennessee
- Participate in the recruitment of new life science companies to Tennessee
- Promote new programs that would successfully bring additional investment in the life sciences to Tennessee including venture or SBIR match programs
- Distribute company profiles and other information to policy makers for promotion across the country

The purpose of this recommendation is to better tell our story, build on the life science ecosystem in Tennessee, and expand opportunities for the industry.
In this age of technology nearly every state has access to breakthroughs in the life sciences that have the potential for monumental economic impact. However, the states that answer the call for capital and support of early stage technologies that will have distinct competitive advantages.

Tennessee’s strong hold in life science research is an opportunity that should be seized and further built. Most states that are competitive in the field of life sciences not only have strong research, but they have strong public access to capital to support entrepreneurs and encourage investment. These states also have programs that foster the development of emerging technologies through workforce training, entrepreneur programs and accelerators specific to the highly regulated field.

Below are a few examples of state-sponsored programs from BIO’s Bioscience Economic Development publication referenced at the end of this report.

CONCLUSION
Texas: Emerging Technology Fund

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


North Carolina

In 1984 the North Carolina General Assembly founded the North Carolina Biotechnology Center in Research Triangle Pak as the first state-sponsored biotechnology center in the U.S. Since then the center has worked with state government, academic institutes, and the private sector to support biotechnology research investing more than $187 million in state funds to support the industry across the state.

Today, North Carolina boasts more than 600 life-science companies with 350 research and development; 130 contract research and testing; 110 production and manufacturing 60,000 highly-skilled employees, 2,000-plus additional companies that specialize in supporting life sciences. For more information, visit www.ncbiotech.org.

In 1999, the North Carolina legislature approved a law in 1999 that placed tobacco settlement payments into three separate trust funds. One of the trust funds created is the Golden LEAF (Long-term Economic Advancement Foundation). In 2003, The Golden LEAF Foundation’s board committed $60 million to create a statewide training program for bio-manufacturing workers. A portion of this grant, combined with $4.5 million from the North Carolina Biosciences Organization, provided the North Carolina State University in Raleigh with $36 million to construct a bio-manufacturing facility to train workers.

For more information: http://goldenleaf.org

Virginia

Virginia’s 2012 Special Session budget provided $5 million over two years to establish a research consortium comprised of six universities that contract with private entities, foundations, and other government sources to capture and perform research in bioscience. The fund provides a matching dollar-for-dollar investment from the state in approved bioscience research. http://lis.virginia.gov/122/bud/budsum/HB1301re.pdf

Michigan

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

The initiative’s Competitive-Edge Technologies Program invests qualified private equity funds, qualified mezzanine funds, and includes qualified venture capital funds as a commercial enhancement program to assist small companies. http://www.medc.org/about/index.htm.
Ohio

Ohio’s Third Frontier program has become an important part of the state’s successful efforts to build a strong, technology-based economy. Started in 2002, the $2.3 billion initiative supports research, commercialization, entrepreneur programs, capital formation, and workforce development. The program has provided new investment leverage outside state government, along with supporting industry growth. www.thirdfrontier.com

REFERENCES


