Letter from the NJBIN President

In this special edition of the NBIA-NJBIN Chapter newsletter, we are taking a closer look at how the NJBIN and the entire New Jersey business development community are helping early-stage life science, pharmaceutical, and biotechnology companies to put down roots in New Jersey.

Early stage companies in these industries face unique funding hurdles. They are unlikely to be able to obtain funding from the Small Business Development Centers (SBDC) or Small Business Administration (SBA), because these loans require collateral such as hard assets on the balance sheet, something these companies generally do not yet have.

NJBIN helps these companies with grant applications, assistance in technology and business plan development, and completion of major milestones needed to attract investors and business partnerships. This assistance moves these companies to a level where they can take advantage of the many other people and organizations—including BioNJ, EDA, New Jersey State Legislators and Congressmen, angel and VC investors, and executives of established New Jersey companies—who focus on helping these companies.

I hope you enjoy this issue’s focus on the life science, pharmaceutical, and biotechnology community in New Jersey!

Most Sincerely,

Suzanne Zammit
President, NJBIN

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NJ Resources Enable Life-Saving Therapies

It all begins with a headache. Not just a routine headache, but the worst headache of your life. In the United States, someone suffers a ruptured brain aneurysm, a type of brain injury, every 13 minutes, and every 23 seconds someone is rushed to the emergency room with a brain injury due to trauma. Both can result in a brain hemorrhage, bleeding in the brain, and are shockingly common, disabling and deadly. In fact, head trauma is the signature injury in the Global War on Terror and a big concern of military doctors. Of the approximately 40,000 persons annually who survive their initial aneurysmal rupture, many die or are disabled from a secondary complication called delayed cerebral ischemia (DCI). DCI causes irreversible brain cell death and remains a leading cause of death and disability.

Edge Therapeutics, Inc., is developing treatments to reduce or prevent DCI. “We can’t stop an aneurysm from bursting,” said Brian Leuthner, president and CEO of Edge Therapeutics, “but we may be able to prevent this secondary complication. DCI typically begins around three days after the ruptured aneurysm and goes away after 10-14 days. This window of opportunity provides doctors a chance to change the course of outcome for a patient. The hope is high for an improvement in care since doctors know when DCI happens, and the patient is already in the hospital under the care of doctors. Today, current treatments are expensive, time-consuming, and only marginally effective.”

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Funding New Jersey’s Youngest Life Sciences Companies

2011 was a challenging time for emerging life sciences companies in New Jersey. These companies need a large infusion of cash prior to becoming commercially viable, but investors have not been in a position to invest. In addition, the larger pharmaceutical companies are currently focused on mergers and are not buying startup companies. Consequently, investors are not cashing out on current investments as quickly as they could in the past, and so have less money to invest in new companies.

However, investors are optimistic. “The window will open up again and investors will start to look,” said Kathleen Coviello, director of the technology & life sciences division of the New Jersey Economic Development Authority (EDA). “Another reason for optimism is that because pharma companies are so busy consolidating, they aren’t looking at discovery. We’re hoping that means they’ll be looking to small biotechs to address their new product pipeline.”

While the New Jersey life sciences community waits for the tide to turn, they have maintained a strong support system so that when investors begin to look for new investments, the state’s emerging companies will be ready.

Incubators help companies enter the funding pipeline

Often, life science companies learn about the state’s extensive support system and begin to experience it in a business incubator. There are six incubators that are nurturing 36 life sciences, biotechnology, and pharmaceutical companies. The largest concentrations of these companies are at the EDA’s Commercialization Center for Innovative Technologies (CCIT), which sits on the campus of the Technology Centre of New Jersey in North Brunswick, and the Enterprise Development Center (EDC) at the New Jersey Institute of Technology.

In addition to the many business support services provided by the incubators (See “Is an Incubator Right for your Life Sciences Company?” for more on incubator services), incubators prepare their companies to enter the funding process. The process generally starts with federal funding through the National Institutes of Health or the Small Business Innovation Research grants (SBIR/STTR). The incubators provide information sessions and one-on-one meetings with consultants to guide them through the process. The EDC

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Investing at the Intersection of IT and Pharma: An Interview with Donna Usiskin, Partner at Edison Ventures

Donna Usiskin has been covering the Pharma and Healthcare IT sector since joining Edison in 2002 as an associate. Her enthusiasm for companies that are blending information technology and healthcare was evident during a recent interview with her. "It's intriguing to see the science side of healthcare colliding with information technology," she said. "We can now take what we know about information technology to lay on top of what we are learning about healthcare. As a result, healthcare in seven years is going to be very different from what it is today."

By way of example, Usiskin explains that due to differences in people's metabolism or presence of certain biomarkers, some drugs are ineffective more than 50 percent of the time. "But eventually we'll be able to take a cheek swab and know that of the 10 drugs available to treat a certain disease, only three would work for this individual at a unique dosage for that person. That is great healthcare," she said.

Following is more from the interview:

What types of companies do you invest in?

Electronic records and patient data analysis are two primary target markets. Building on our prior Pharma IT successes, such as Dendrite, POMS and Marcam, we have recognized promising market opportunities in Bioinformatics, personalized medicine and predictive modeling. We've also been active within claim submission, eligibility verification and payment.

At what stage of an emerging company's growth are you most likely to consider investing?

Edison Ventures focuses on expansion stage companies that are bringing in $5-20 million in revenue and are typically growing over 30 percent.

What rate of return are you looking for?

We expect 3-5% returns, with a higher side of 10%.

Has this changed in the current economic climate?

It hasn't changed our philosophy. We've stayed steady. But there is a lot more scrutiny in working with companies to make sure they can still do those types of ventures.

What are the things that are most important to you when you are making a decision of whether or not to invest in a company?

Right now I'd say it's about 3 years from the first time we talk to a company until we invest in them. We hear about their forecasts and watch to see that they're meeting their projections.

Having the right team in place and a good product in place are key. Also they need to understand what their revenue model is, because due to this economy we need to make sure that there is value perceived by the market. It's pretty significant to us if we see 30 percent growth month after month, even if it's a smaller amount of dollars.

How involved are you in the companies in which you invest?

Each of us at Edison has a lot of experience. I have a sales background, which is a skill set that contributes to companies. So It's a partnership between us and the entrepreneurs and they should look at us as a resource. We become as involved as they like us to.

Another resource that's available is the Edison Director Network, which is a community of professionals that have been in our portfolio in the past. They will take board seats on our companies and are otherwise available for consultation. The network is an incredible group of people that is extremely valuable to our portfolio companies. Edison makes a huge commitment to the group: we spend an entire day with entrepreneurial professors and they speak to our network, so that they are as current as they possibly can be, and be the best board members that they possibly can be to our portfolio companies.

What is the best way for an entrepreneur to approach you about investing in their company?

Our website has a submission page, so companies can send a plan online. We do review them. We may say “we're aware of you, but reach out again in the next six months to a year when you're closer to our parameters.”

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Life-Saving Therapies

The seeds of the partnership that would become Edge Therapeutics were planted in 2005 at the International Stroke Conference in New Orleans. A mutual friend and neurocritical care doctor introduced Leuthner to R. Loch Macdonald, M.D., Ph.D., now chief scientific officer of Edge Therapeutics. “This friend told me Dr. Macdonald was one of the most accomplished researchers in the world looking at secondary brain injury,” said Leuthner. “He introduced me to Dr. Macdonald as a brilliant mind in the commercial marketing of medicines in critical care. Together, he thought we would be a good combination to create medicines that someday might save patients’ lives. Little could he have imagined that several years later, Edge would be close to putting one of their potentially life-saving medicines into patients.”

Dr. Macdonald believed that in order to help people that had suffered from a brain hemorrhage, physicians had to deliver the drugs differently than through the standard routes, by mouth or intravenously. For brain hemorrhage patients, these routes of administration had proved suboptimal in delivering therapeutic concentrations of effective drugs to the brain. The higher doses needed in the brain, delivered by mouth or intravenously, would cause harmful side effects outside the brain and mitigate any benefit for the patient. The answer Dr. Macdonald thought of was to encapsulate known drugs into a microparticle, implant the microparticles directly into the brain at the site of injury, and allow the microparticles to release the drug over several days. With the vision of developing such a treatment, Leuthner, Macdonald and a third partner, Carl Soranno, Esq., who is a practicing lawyer and ex-Wall Street executive, formed Edge Therapeutics in February 2009.

Leuthner wanted to locate in New Jersey and, in April 2009, moved into the Enterprise Development Center (EDC) at NJIT. “The incubator staff—in particular, Jerry Creighton, Yvonne Drakes, and Judith Sheft—were excellent in providing the resources for a solid foundation in which to start, providing us with outreach and resources to help nurture our company,” said Leuthner.

“In addition to the staff, another important tool the EDC offered us was access to consultants from the New Jersey Small Business Development Center (NJSBDC), such as Randy Harmon,” said Leuthner. “Harmon is an expert on the sources of grant funding and provides suggestions on ways to write grant applications. He and the other consultants provided us with strategies for financing science and technology businesses.” With Harmon’s guidance, Edge wrote and submitted an application for a New Jersey Commission on Science and Technology Grant (NJCST). In November 2009, Edge Therapeutics was the final recipient of a $500,000 grant from the NJCST. In December 2011, Edge was honored by the NJSBDC as a recipient of its 2011 Success Awards, which recognize companies for their commitment to the growth of small businesses. The 2011 awards recognized 13 New Jersey-based companies from the approximately 5,000 companies that the NJSBDC assisted in 2011.

“The NJCST grant was an important event for us,” said Leuthner. “$500,000 in financing allowed us to advance our business to the next level, and just as important, provided validation for our business strategy. This validation allowed Edge to quickly match the grant with financing from outside investors. We also received a $100,000 loan from the New Jersey Economic Development Authority and received $244,000 from the Qualifying Therapeutic Discovery Project Program (QTDP), which was championed by Senator Robert Menendez. These funds were crucial.”

To date, Edge Therapeutics has raised about $4 million from private investors and over $1 million in grants.

Leuthner gives credit to the state’s wider biotechnology community for the success of Edge. “We are very blessed in that there are so many people in New Jersey that support what we are doing. Without that, we really wouldn’t be here,” he said.

New Jersey’s biotechnology community includes Debbie Hart, president of BioNJ; Dr. Sol Barer, a founder of Celgene, chairman of BioNJ and member of the Edge Therapeutics Board of Directors; and Dr. Geert Cauwenbergh, past-chair of BioNJ and one of Edge’s business advisors. One of BioNJ’s programs, funded through a federal grant (Bio-1), allowed Edge to hire four MBA interns from the Rutgers MBA program. “The MBA’s helped in a number of ways, including updating the Edge website and product forecast models used in meeting with potential investors, said Leuthner. Of the four interns, one was our first hire, another was hired by Merck, another was hired by Johnson and Johnson, and the last one is still helping us while awaiting graduation. This program was really a ‘win-win’ for Edge, the students, and New Jersey.”

Brain Aneurysm Foundation

For additional information about brain aneurysms, visit http://www.bafound.org/
The company has also gotten support from current and former New Jersey legislators, including Congressman Bill Pascrell, Jr., co-chairman and founder of the Congressional Brain Injury Task Force; Senator Robert Menendez, who sponsored the QTDP; Congressman Leonard Lance, who is very active in the orphan drug and rare disease community and former New Jersey Congressman Mike Ferguson, a former member of the House Energy and Commerce Committee, where he served as Vice Chairman of the Health Subcommittee.

The support of the biotechnology community is paying off: the company now manufactures a human-grade drug that is ready for use in human trials. People suffering from brain aneurysms may soon start benefitting during clinical trials scheduled to commence in 2012; FDA approval is expected in 2016.

“The New Jersey Business Incubation Network and the biotechnology community have been very supportive to Edge, and we are truly blessed that people recognize the need for us to develop our life-saving therapies” said Leuthner. “They are really instrumental in helping people succeed.”

What are the alternatives for life science, biotechnology, and pharmaceutical companies that decide not to locate in an incubator?

I would say that every university in New Jersey is willing to look at collaboration opportunities with start-up companies. There are opportunities for sponsored research programs and SBIR/STTR collaborations, even if those companies are not associated with an incubator. In addition, start-ups can look to the universities as a source of talent—our graduates are potential new hires for these companies. And of course companies should participate in the wide range of entrepreneurial and life science events within the state. Also, for someone who is working on their business part-time, it might not be appropriate for them to be located in an incubator. Some incubators such as the NJIT EDC have a virtual program that allows an individual to explore start-up opportunities. For foreign companies, we offer additional soft-landing services to help them get established in the U.S. market. Both NJIT EDC and the CCIT incubator have been certified by the National Incubation Association as soft landing facilities. They have relationships, as well with some incubators outside of the US, so that if some of our companies are looking to enter foreign markets, we can help through our relationships with those other incubators.

Who are the companies that are NJBIN’s biggest success stories?

Edge Therapeutics, which is developing a new treatment for delayed cerebral ischemia (see related story on page 1); Amicus, which is developing therapies for rare diseases; Genewiz, a DNA services provider; Mensanna, which is developing a portable breath collection apparatus that can collect breath samples for highly sensitive laboratory analysis; and Uro Valve, which has developed a bladder management system.
Incubator News

Following are a few of the news stories regarding NJBIN Life Science, Biotech, and Pharmaceutical Companies from the past year.

Burlington County College High Technology and Life Science Incubators

On April 8, 2011, Dr. Ashok Rao Tunoori opened AV Square Chem Inc. at the Life Science Incubator at Burlington County College (BCC). AV Square Chem Inc. is servicing national and foreign pharmaceutical, bio-technology and agro-chemical industries by providing specialty products essential to these firms’ research and development programs. Read about this company at http://www.nbia.org/njbin/may11/av_square.php.

Commercialization Center for Innovative Technologies

Aestus Therapeutics Inc. (Aestus), announced in February 2011 that it had initiated screening of patients for a clinical trial to evaluate the efficacy of its novel pain therapeutic, ATx08-001. This placebo-controlled, two-dose level study will test the efficacy of ATx08-001 in reducing the pain following an outbreak of shingles. To read the full press release, go to http://j.mp/jygYQF.

On April 11, 2011, New Jersey’s Lt. Governor Kim Guadagno led the ribbon cutting ceremony for the opening of a new 5,000 square-foot headquarters for Sophion Bioscience Inc. at the Technology Centre of New Jersey’s Biotechnology Development Center. The ceremony marked the successful transition of Sophion, a biotechnology research device company, from incubation at the Center for Commercialization Center for Innovative Technologies (CCIT) to self-sustaining company. It also marked the success of an international company expanding into the U.S. market by locating a subsidiary in New Jersey. Read the full story at http://www.nbia.org/njbin/may11/sophion.php.

Enterprise Development Center

BioNeutral Group Inc. a specialty life science technology-based company, has received approval and registration from the Environmental Protection Agency (EPA) in response to the Company’s regulatory application for its YgieneTM 206. This regulatory approval represents the addition of a significant new weapon being deployed in the ongoing effort to combat hospital acquired infections (HAIs). HAIs account for a high number of illnesses each year, resulting in what could otherwise be avoidable fatalities. Coupled with appropriate infection control programs, YgieneTM is expected to help reduce infections thereby not only potentially saving lives, but also redirecting scarce healthcare resources to overall improved medical care. As an industrial grade antimicrobial, YgieneTM also has applications in homeland security, as well as the hospitality, transportation and mold remediation sectors, to name just a few critical uses. Read the full press release at http://j.mp/jiuupB.

Funding New Jersey’s Youngest Life Sciences Companies

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and other incubators provide companies with access to Randy Harmon, a technology commercialization consultant from NJSBDC who not only helps companies with the federal grant process, but also analyzes the company and helps them find the right solicitation to pursue.

In addition to assistance with grant applications, the incubators prepare their companies for the formal investment stage by training them to effectively pitch to investors. “A venture pitch is a different presentation from one given at a scientific meeting. A venture pitch focuses on the questions of ‘So What–Who Cares” said Judith Sheft, associate vice president of technology development at the New Jersey Institute of Technology. “Once our companies are ready, we can introduce them to angel investors and venture capitalists. We’ve heard from angel investors that if someone is coming to them through a referral from a business incubator, they know the company has been vetted. So it’s really very valuable for both the entrepreneur and the investor.”

Entering the Formal Investment Stage

Once a company has revenue coming in, they are ready for the formal investment stage. The EDA helps increase available capital for NJ life sciences companies by investing as a limited partnership into venture capital firms that invest in New Jersey companies. EDA has formed partnerships with several investment firms, including the Edison Venture Fund, which invests in application software, communications, financial technology, interactive marketing, healthcare and pharmaceutical IT companies (see page 3 for an interview with Donna Usiskin, principal at Edison Ventures) and NewSpring Health Capital, which invests in pharmaceuticals, healthcare services, and medical device companies. NewSpring Health Capital is the most recent life sciences fund to receive an investment from the EDA: they received a commitment for $5 million, with the requirement to match it
with an additional $10 million to fund New Jersey companies. The Garden State Life Sciences Fund, managed by Quaker BioVentures, has received $10 million of investment from the EDA and invested in three NJ life science companies: Amicus Therapeutics, Celator Pharmaceuticals, and EKR Therapeutics Inc.

As companies progress beyond the angel funding stage, they have access to a full range of services provided by the EDA, including its Edison Innovation Matching Loan Fund Program, Business Employment Incentive Program, and tax incentives, most notably, the Technology Business Tax Certificate Transfer Program, also known as the NOL program.

“The NOL program is a terrific way for a company to raise capital on an annual basis,” said Coviello. “It allows a biotech company to incur losses—as they always do early in their life cycle—and sell the NJ portion of that loss to a profitable New Jersey company for cash. Governor Christie has allocated $60 million in this year’s budget for the program.”

A Boot Camp with Capital and Mentoring

The EDA is currently providing funding for a private sector group to lead a new initiative to create a technology accelerator program for New Jersey. The initiative will aim to provide a competitive environment for technology-focused entrepreneurs to showcase their products, ideas and business acumen in a mentor-driven program for an opportunity to receive funding.

The accelerator program, which is modeled on existing accelerators in New York and Pennsylvania, will leverage EDA monies with private matching dollars. “The accelerator will provide seed capital for companies that go through the selection process,” said Coviello. “This initiative would provide a boot camp with capital.”

The Bottom Line

The bottom line is that, despite economic challenges, there are opportunities for early-stage life science companies in New Jersey. “There are resources available for the best companies,” said Coviello. “It’s not as broad or deep as it used to be, but as the private sector and government look to be fiscally responsible, for the best companies there is still cash available.”

Interview with Donna Usiskin

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We get to know most entrepreneurs through industry events, and our proactive outreach. Our industry teams are immersed in the industry events, and they follow up and interact with the companies they meet at a certain time. We also do our own research and investigation into the industry.

What general advice would you give to companies looking for investors?

So often you get a call or email and they have not looked at our website at all to see that we only invest in East Coast, that we invest in information technology, and that we have four big industry outlets that we invest in. Make sure you know the investor and what their parameters are before you call them. They should know that the investor that they’re seeking money from understands their industry.
New Jersey:

The Right State for Entrepreneurs and Business Venture Development

Are you a visionary entrepreneur with an awe-inspiring business plan? Do you have the technical know-how to be competitive? If yes, an incubator in our network could be the next home for your business. To find out more, send an email inquiry through the “contact us” form on our website (www.njbin.org), or call NJBIN president Suzanne Zammit, at suzannez@camden.rutgers.edu or 856-479-9044.

Burlington County College High Technology and Life Science Incubators assist entrepreneurs with commercially attractive technology and science ideas to start and grow their companies.

Contact: Ketan N. Gandhi 856-222-9311 x2801 Website: http://www.bcc.edu/pages/131.asp

The Commercialization Center for Innovative Technologies assists start-ups to become successful companies that will strengthen the economy by commercializing technologies and creating jobs.

Contact: Donald Shatinsky 732-729-0022 Website: http://www.njieda.com/

The Enterprise Development Center at NJIT is NJ’s oldest and largest incubator for technology and life-sciences companies, having graduated over 79 successful businesses since its start-up in 1988.

Contact: Jerry Creighton, Sr. 973-643-4063 Website: http://www.njit-edc.org/

The New Jersey Meadowlands Commission Business Accelerator provides a unique opportunity for entrepreneurial companies focused on alternative energy and green technologies and services.

Contact: Michel M. Bitritto, PhD 201-438-1245 Website: http://www.njmcaccelerator.com/

The Rutgers-Camden Business Incubator encourages businesses to locate in Camden and assists them with low-cost technical support and mentoring for successful startup.

Contact: Suzanne Zammit 856-479-9044 Website: www.rutgersbiz.com

The Rutgers Food Innovation Center is the university’s Environmental Research and Extension Center dedicated to moving science from the lab to real-world applications in our state’s businesses and industries and to promoting NJ as a center for innovation in alternative energy and environmental technologies and enterprises.

Contact: Serpil Guran, Ph.D. 609-499-3600 x225 Website: ecocomplex.rutgers.edu

The Rutgers Food Innovation Center provides business and technology expertise to food and agribusinesses in NJ and utilizes its outreach capacity to reach the food industry throughout the nation.

Contact: Margaret Brennan, Ph.D. 856-459-1900 Website: http://www.foodinnovation.rutgers.edu

The Rutgers Meadowlands Business Accelerator is an independent nonprofit incubator that focuses on developing, launching, and growing sustainable technology businesses in central New Jersey.

Contact: Jonathan Cloud 908-306-9075 Website: http://sustainablebusinessincubator.com/

The Rutgers EcoComplex

The Sustainable Business Accelerator

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