BIOLOGICAL QUARTERLY

SUMMER 2014

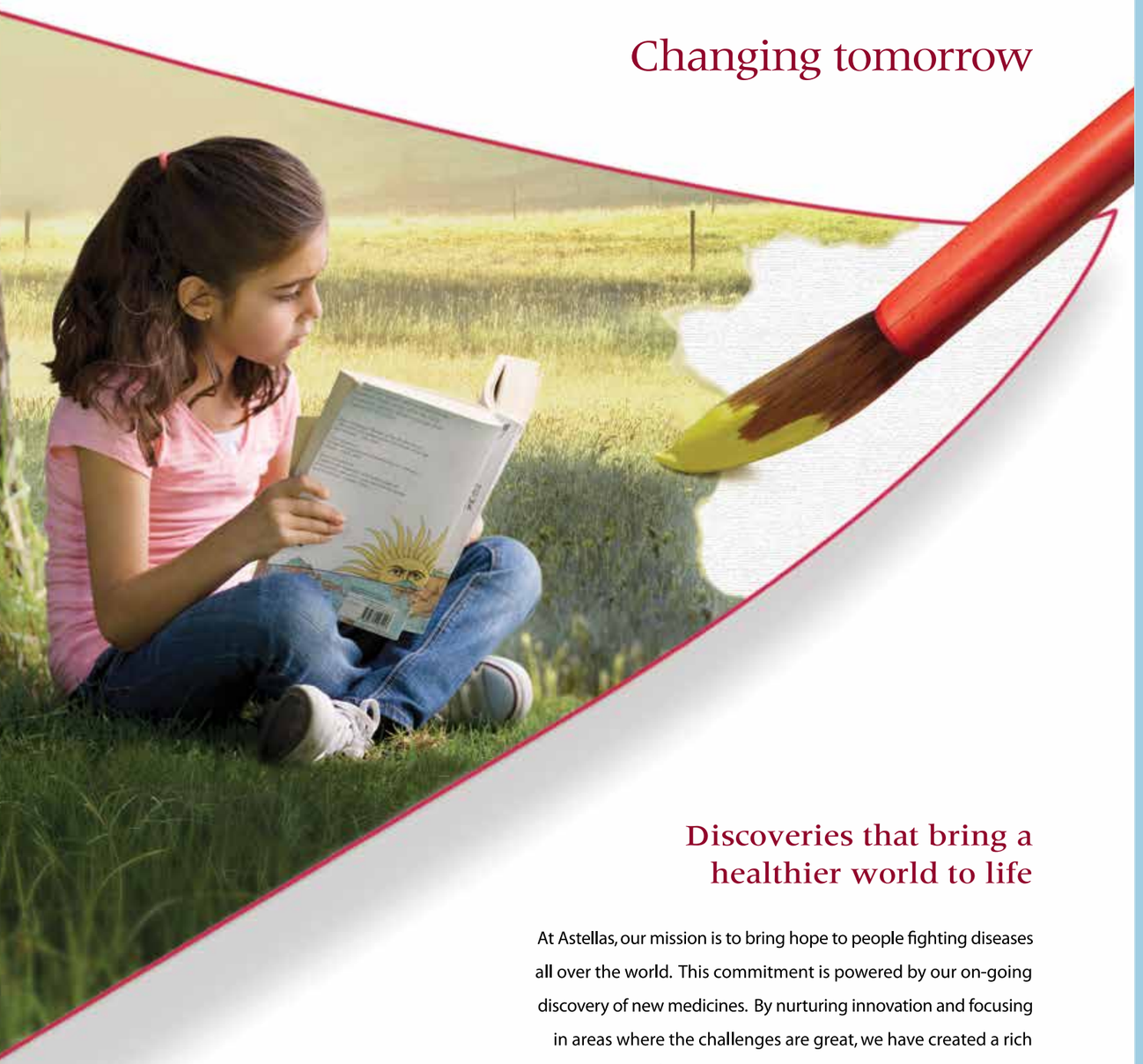
Q&A WITH ILLINOIS GOVERNOR PAT QUINN ON *MATTER* (COMING THIS FALL)

VETTER AND "SWEET HOME" CHICAGO

THE ROLE OF RESEARCH INSTITUTIONS IN BIOTECH

Governor Pat Quinn

ALSO INSIDE



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The purpose of *BioLogical Quarterly* is to promote community building and open discussion through awareness of the leadership displayed by Illinois life sciences organizations.

Cover photo courtesy of Illinois Governor Quinn's Office.

MATTER

COMING THIS FALL TO CHICAGO: MATTER!

Governor Quinn and the MATTER Board at the February 2014 press conference announcing MATTER.

Q&A with Governor Pat Quinn and Tim Walbert

On February 6, 2014, Illinois Governor Pat Quinn and Horizon Pharma, Inc. President & CEO Tim Walbert joined other leaders from the Illinois life sciences community to announce the launching of MATTER, a co-working space and hub for the commercialization of healthcare technology in Chicago.

The governor announced that the State of Illinois will be investing approximately $4 million to assist with MATTER's buildout and startup operations. MATTER will be modeled after 1871, the Chicago hub for digital startups that state officials say created about 800 jobs in the first year. MATTER is a community hub of healthcare entrepreneurs, academic and industry leaders, and prospective investors working together in a shared space to individually and collectively fuel the future of healthcare innovation. Located in the heart of Chicago at the Merchandise Mart, MATTER will open its doors in the fall of 2014.

Following the press conference, Governor Quinn and Tim Walbert, a board member of iBIO and MATTER, sat down to discuss how MATTER will impact the Illinois community.

Tim Walbert (TW): Governor, thank you for taking the time to sit down with me and discuss the launching of MATTER. You are a long-time and passionate supporter of Illinois' life sciences community. You were the BIO Governor of the Year in 2011-2012, and you spearheaded policy changes to help promote R&D in our state and investment into new technology ventures. And now your administration has made a large investment into a center for the life sciences community to promote the commercialization of new ventures. Why is this industry so important to Illinois?

Governor Pat Quinn (PQ): Tim, thank you. In many ways, Illinois is already a leader in the life sciences industry. We have world-class research institutions, national labs, large global corporations and top entrepreneurial talent like you. Horizon Pharma is a great success story for Illinois. But we can't rest on our laurels; we need to continue to make investments to help this community grow and flourish in Illinois.

The life sciences community is a major contributor to Illinois' economy, providing $98 billion in economic output. The life sciences community is also the highest paying industry in Illinois, and for every life sciences job created, it also creates an additional three to four indirect jobs to support the industry. Investing in the growth of this community attracts a highly paid and educated workforce to Illinois. For every dollar we invest in this industry we can expect to receive $3 in economic output.

Last year, iBIO commissioned Ernst & Young to conduct a study on the industry in Illinois and the Midwest. As part of this study, Ernst & Young provided us with key areas for future investment. Our investment in MATTER directly addresses three of these areas: infrastructure, entrepreneurial education and attracting investment in Illinois.

TW: Governor, you just referenced iBIO. In our community we have a number of existing organizations that are running effective programming to help increase the success rate of new ventures, either through services or by attracting investment and resources for the community. How do you see the State's investment in MATTER in comparison with these existing programs?

PQ: Our investment in MATTER is additive to these existing resources. It will directly benefit organizations like the Illinois Biotechnology Industry Organization, PROPEL at the iBIO Institute, Chicago Innovation Mentors and Health 2.0. MATTER will provide resources and support to these already successful programs. It will also provide economies of scale, share resources and help provide additional marketing for each of these organizations.

The State provided some of the seed investments in PROPEL, and we have seen a great return provided to the life sciences community. In February PROPEL announced that its companies have raised over $100 million since the start of their programming in 2007. These are very small, very early-stage companies where failure is more likely than success. Reaching a milestone like they did is a testament to what can happen when we invest in this community. We see our investment in MATTER as a continuation of our support for PROPEL.

Tim, you are a seasoned entrepreneur with a very successful Illinois company. What are the main benefits provided by MATTER that you wish were available to you when you were starting up Horizon? What are the main benefits that MATTER can provide to Horizon now that you are a publicly traded company?

> **"The State provided some of the seed investments in PROPEL, and we have seen a great return provided to the life sciences community."**

TW: I would have liked to have had a place like MATTER when Horizon was starting up. We were working out of a Panera and Starbucks, anywhere we could sit down and plug in. Having a space where we could work together, hold meetings and meet with other members of the community would have been a great resource. In addition to the physical space, MATTER will create an instant community, providing startups with support and services. We also would have benefited from economies of scale on services, reducing our business costs.

Now that Horizon is an established company, what interests me about MATTER is its promise to break down barriers between different parts of the healthcare industry. Working closely with universities, doctors and patient groups is a big value-add for the more-established companies. MATTER will also increase the pool of talent available to larger companies like Horizon. We are always looking for great entrepreneurial talent.

Governor Pat Quinn greets Tim Walbert at the February 2014 press conference.

PQ: That is an area where we think MATTER can make a big impact in this community. We need to look at the full spectrum of the healthcare industry and find areas where we can improve collaboration, building stronger connections between doctors, companies, researchers, universities, students, patient groups and entrepreneurs. MATTER will serve as the hub for all of these stakeholders and build stronger connections between each group.

Illinois' universities are home to some of the top engineering, business and legal grad programs in the country. We want to retain this diverse and highly educated workforce here in Illinois. We believe MATTER will help cultivate that Illinois entrepreneurial spirit.

Here in Illinois we are also home to world-class hospitals, research institutions, medtech, pharma, insurance and service companies. We need to stop looking at each of these groups as separate entities, but look at where they interact, and how we can build stronger connections between them. MATTER is where these groups are going to come together; it is where we are going to solve some of the largest problems facing our state.

Tim, what other impacts do you see MATTER having on our startup ecosystem here in Illinois?

TW: MATTER is a great marketing opportunity. It will shine a spotlight on our most promising startups and their founders. We have already seen the success that 1871 has brought to the digital community in Illinois. MATTER will do the same for the healthcare community. It will attract investment in our community, which will attract seasoned entrepreneurs to start up new companies.

I am also interested to see how different industry sectors will interact through MATTER. I agree that it has the potential to build strong collaborative partnerships between different parts of the Illinois economy. When I look at the trends in the medtech industry and even with the promise of personalized medicine, Illinois has a great opportunity to bring together the digital minds of 1871 with the scientific minds of MATTER.

PQ: MATTER is where all of these industries are going to connect and where the next great innovations are going to be born. We have large pharma companies like Takeda, Astellas and AbbVie. We also have large medical products companies like Abbott, Baxter, Siemens and Hospira. We have Google, Motorola and a very strong and vibrant digital startup community housed in 1871.

We are changing the narrative of Illinois. We are investing in new innovative areas like biotechnology, medtech and digital manufacturing. We are building the framework to ensure a long and prosperous economy for our children and their children. In 10 years, when we look back at what we have accomplished this year, we are going to be amazed at how far Illinois and this community have come. Ten years ago, we had never hosted the BIO convention, now we have hosted it three times.

> **"We are building the framework to ensure a long and prosperous economy for our children and their children."**

TW: Since the first BIO show in Chicago, we have built successful programs like PROPEL and Chicago Innovation Mentors (CIM) to help entrepreneurs. We have attracted leading international companies like Takeda, Lundbeck, Astellas and Fresenius Kabi to build their U.S. homes in our state. Illinois is on the map; now it is time to show the world what we are really made of.

PQ: Well said, Tim. With you and your peers in industry partnering with government and our academic centers of excellence, I'm confident that the world will indeed learn about, and benefit from, our collaborative and entrepreneurial culture. **BQ**

START. STAY. GROW.

THE ILLINOIS MEDICAL DISTRICT IS COLLABORATION IN ACTION

By Warren Ribley
Executive Director, Illinois Medical District Commission

Success in healthcare and life sciences requires both collaboration and action.

The Illinois Medical District (IMD), the largest urban medical district in the country, is proving how collaboration between–and action among–industry, academia and government helps cultivate and grow healthcare and life sciences innovation. This model of diverse organizations partnering to create new incubators, labs, technologies and products is advancing healthcare and life sciences, driving economic growth, adding higher-paying jobs and increasing global competitiveness in our region and throughout the country. Above all, research is evolving and patient care is improving as today's healthcare and life sciences innovation leads to tomorrow's patient care.

By fostering this collaboration, the IMD has entered a new era of economic growth, job development and medical advances. Within the next 10 years, the IMD expects to generate between 2,000 and 4,500 permanent jobs, spur business development resulting in $300 million in new revenue, drive research innovation and improve healthcare delivery and outcomes.

To achieve this growth, and with the help of our IMD stakeholders, we created a new strategic plan in which four key priorities are used as benchmarks when evaluating new projects:

1. Community Health

2. Translational Research

3. Clinical Data

4. Infrastructure and Development

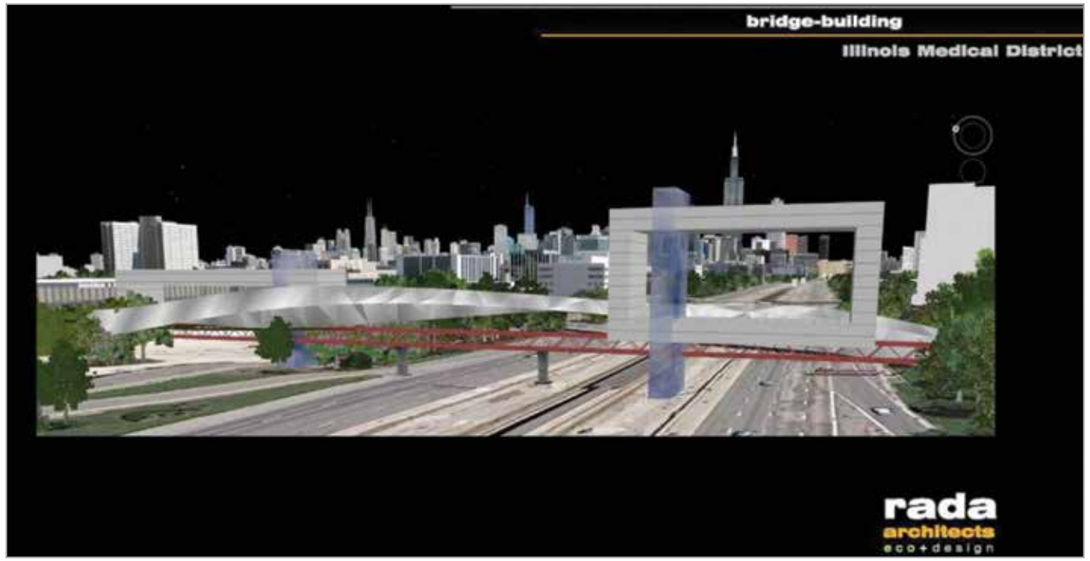
The Illinois Medical District Commission (IMDC) has made significant progress in the year since the strategic plan was adopted, making the IMD an ideal location for life sciences and healthcare and life sciences companies to start, stay and grow their businesses by leveraging a unique combination of assets that these entrepreneurs could not find anywhere else in the country.

Community Health and Clinical Data: Access to Patients

Many U.S. medical districts offer premier healthcare, but according to the Boston Consulting Group, the IMD has the most diverse patient population in the country. The 560-acre IMD is home to Rush University Medical Center, University of Illinois Hospital and Health Sciences System, John H. Stroger, Jr. Hospital of Cook County, and the Jesse Brown Veterans Administration Medical Center. These public and private institutions serve a patient population that is 45% African-American, 30% white, 15% Latino, with the remaining patients comprised of Asian and other ethnicities.

> **"Success in healthcare and life sciences requires both collaboration and action."**

In December, the IMDC and the Chicago Community Trust began a partnership with 10 Chicago-area hospitals and health systems, pooling their vast talent and resources to study rare and common diseases. The effort, made possible from a $7 million award from the Patient-Centered Outcomes Research Institute (PCORI), allows researchers from the Chicago-based team, named the Chicago Area



Sample rendering of the bridge that would connect the IMD to its neighbors north of the expresswway.

Patient-Centered Outcomes Research Network (CAPriCORN), to establish a regional clinical patient data research network, facilitating patient-centered outcomes on a national platform.

This collaboration is designed to change how medical researchers approach developing research studies and how the results of these studies are shared with frontline clinicians, voluntary health organizations, patient advocacy groups and the general public. Unlike traditional medical research, where investigators generate research topics, the team is creating a Patient and Clinician Advisory Committee that will work in conjunction with the CAPriCORN investigators to generate research questions that are relevant to those impacted by several common and rare diseases being studied under this award.

CAPriCORN members and Illinois Senator Dick Durbin.

Participants will also advise investigators on how to prioritize research that takes place within the CAPriCORN network, evaluate requests from external investigators seeking data from CAPriCORN and promote the sharing of research findings within professional societies, hospitals, voluntary health organizations and patient advocacy groups.

One of the most striking features of this area-wide partnership is that investigators who normally compete with one another will collaborate across institutions to investigate the health questions that matter to patients and their healthcare providers. Apart from the four IMD hospitals, participating organizations include NorthShore University HealthSystem, Northwestern University, University of Chicago, Loyola University, The Alliance of Chicagoland Health Centers and the Hines VA hospital.

Translational Research and Entrepreneurial Development

The IMD has 500 NIH-funded principal investigations and conducts more than 700 clinical trials each year, drawing $392 million in research funding annually. In addition, Quintiles Transnational Holdings Inc., one of the world's leading firms that conducts clinical trials for the pharmaceutical industry, is in discussions with District hospitals to assist with research.

The two enterprise centers of Chicago Technology Park (CTP): the Incubator Laboratory Facility (ILF) and the Health, Technology and Innovation (HTI) Center.

Wet and dry labs will open in the fall of 2014 at 1701 W. 13th Street in Chicago.

The IMD Gateway development, estimated to open in 2016, will include retail and lab space, a hotel and medical offices.

To drive more of this activity, the IMDC is investing in collaborative programs to create and grow the healthcare and life sciences companies of tomorrow.

The Chicago Technology Park (CTP) is at the heart of this effort. The CTP, which has been home to more than 150 early-stage companies in the past 25 years, spans 56 acres within the IMD and hosts the nation's oldest healthcare and life sciences incubator. The CTP's facilities, services and decades of experience in healthcare and life sciences incubation help to meet the needs of growing tech-based companies today. It is where companies such as Amgen, MedChem Partners, Litholink and STAT Analysis all got their start.

Last year the Health, Technology and Innovation (HTI) Center, a hybrid incubator-research center focused on accelerating the healthcare and life sciences startup environment opened at CTP. The HTI provides wet and dry labs, validation, proof-of-concept and meeting space for healthcare and life sciences entrepreneurs.

Start. Stay. Grow.

To highlight and expand these assets and support entrepreneurial development, the IMDC recently launched a campaign "Start. Stay. Grow. at IMD." (SSG@IMD). The program is designed to provide innovators aiming to commercialize their technology with well-coordinated, critically needed resources that will enable launch, sustainability and growth of their companies. The IMD's spectrum of assets supports companies at the earliest, proof-of-concept stage, as well as companies looking for permanent stand-alone facilities.

Leveraging the close proximity of the two academic medical centers, four hospitals and numerous other health institutions, SSG@IMD will help bridge the gap between academic research and private industry by providing access to seed and venture capital, state-of-the-art laboratory facilities and a peer network of dedicated professionals.

For companies at the incubation ("start") stage, SSG@IMD will help entrepreneurs secure access to high-quality, low-cost laboratory and office space in the CTP. While there, startups or spinouts will receive project-management assistance and learn from leaders in academia, the healthcare and life sciences industry and government. In this supportive environment, new entrepreneurs will be able to exchange scientific, academic and technical ideas that lead to discovery, development and commercialization of new life sciences technologies and attract investor opportunities.

Companies that are slightly farther along in their growth plan will be encouraged to "stay" in the IMD with access to space and business development resources within the IMD.

"It is where companies such as Amgen, MedChem Partners, Litholink and STAT Analysis all got their start."

Collaboration is integral to the SSG@IMD program. Entrepreneurs in every stage of development will receive education through seminars, mentorships, pitch coaching, regulatory guidance and counsel delivered by stakeholders throughout the IMD

ecosystem. The program will also provide access to funding workshops, consultations and networking opportunities where entrepreneurs can interact with venture capitalists and other investors.

SSG@IMD not only has the support and involvement of IMD stakeholders, but also from corporate venture capital partners, growing biopharmaceutical companies such as Horizon Pharma, Durata and Paragon, and established biopharmaceutical companies such as Takeda, AbbVie, Astellas, Baxter and Hospira.

Infrastructure and Development

To effectively exchange all of the data throughout the IMD and beyond, the IMDC is installing a high-speed fiber-optic-network infrastructure that will operate as much as 100-times faster than commercially available services. All IMD stakeholders will be able to securely connect to the network at a lower cost and a much higher quality than what commercial providers offer.

The Illinois Medical District (IMD) is located less than two miles from Chicago's central business district.

One of the most transformative infrastructure projects in the works within the District is the IMD Gateway real estate development project, located at the northern entrance of the IMD and consisting of approximately 9.5 acres of land.

The IMDC has issued an RFP for real estate development to develop the IMD Gateway into a signature, urban mixed-use project. The project's goal is to provide the IMD and its stakeholders with a cohesive mixed-use development containing a combination of retail, hotel and dining establishments; conference space; high-rise residential housing; medical, professional and life sciences laboratories; office space; and parking structures. The IMD Gateway is integral to the "grow" phase of the SSG@IMD program by creating amenities that do not currently exist within the IMD, allowing it to truly serve a 24/7/365 environment. The project is expected to be completed in late 2016.

"All IMD stakeholders will be able to securely connect to the network at a lower cost and a much higher quality than what commercial providers offer."

A newly completed infrastructure project in the IMD includes the 8,000-square-foot expansion for GreatPoint Energy (GPE). The glass-and-brick extension completed GPE's relocation from Cambridge, Mass. GPE produces clean, low-cost natural gas from coal, petroleum coke, and biomass utilizing its bluegas™ catalytic hydromethanation process.

The Anatomical Gift Association (AGA), a former IMD tenant, is returning to the IMD and will locate its headquarters in an energy-efficient, retrofitted 31,000-square-foot building. The AGA is a not-for-profit corporation that manages the willed-body donor program for medical, research and educational institutions in Illinois and around the world.

More infrastructure projects are in the works around the IMD, further expanding the diversity and quality of its collaborations. For example, the Eisenhower Expressway creates a physical divide between the IMD and institutions such as Crane Medical Preparatory High School and Malcolm X College. Many of the students from the high school matriculate to the college and ultimately join the IMD through internships and employed positions in fields ranging from health technology to nursing. To bridge this divide, the IMD is working with transportation leaders from the state and city to find an innovative way to connect the communities.

Access to these developments will be improved with a significant upgrade to the Chicago Transit Authority's (CTA) Blue Line train at Damen Ave., which will undergo a $23 million renovation to improve accessibility for pedestrians, as well as visitors and residents in wheelchairs and with other special needs.

Collaboration and Action Prove Successful

The IMD is growing at an unprecedented rate and has received tremendous support from Illinois Governor Pat Quinn, who recognized two years ago that the IMD needed to be reinvigorated and sought new leadership, not only for my position as Executive Director, but with a new board of directors. While we have already made some headway, there is much more that needs to be done in advancing healthcare and life sciences, which cannot be sustained without attracting the next generation of scientists, physicians and entrepreneurs. It is no coincidence that the successful technology-oriented regions around the country are always located near major research universities with attractive residential and lifestyle amenities that help retain this top talent.

"It is no coincidence that the successful technology-oriented regions around the country are always located near major research universities...."

Collaborations are working—and the proof is in the numbers. A recent Economic Impact Study completed by the UIC Center for Urban Economic Development shows IMD adds $3.4 billion annually to the Chicago region's economy, is responsible for more than 18,000 jobs and contributes more than $75 million to the tax revenue of the state and region. The study also reported that the IMD is responsible for $3.1 billion in annual employee compensation in the region—including IMD employees' earnings and the positive impact that the IMD has on the region's salaries overall.

"Collaborations are working—and the proof is in the numbers."

While much of the current economic impact cited in the study derives from the educational institutions and associated medical colleges and hospitals, it is anticipated that a large portion of future growth will occur thanks to new biomedical innovation initiatives being undertaken in the IMD.

By continuing to collaborate with organizations and government entities that share the IMDC's vision, and by fostering innovative ideas and action, the IMD will emerge nationally as a recognized leader in healthcare and life sciences. **BQ**

As executive director of the Illinois Medical District Commission, Warren Ribley is responsible for spurring business development to drive research innovation, economic growth and improved healthcare for the community. To learn more about the IMD or to join our monthly IMD & U email list, please visit www.imdc.org.

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VETTER AND "SWEET HOME" CHICAGO

By Claudia Roth, PhD
President, Vetter Development Services USA, Inc.

Everyone, it seems, loves a good "before and after" story. This is particularly true when the story involves a win-win situation for an individual, company or institution. We especially enjoy learning about how a particular problem or opportunity was analyzed and addressed, and how it turned out in the end. Most often, we can learn valuable lessons from these stories and apply them to our own situation. What follows is one such "before and after" story involving the contract development and manufacturing organization (CDMO) that I represent wanting to have a greater presence in the U.S. market by building our first-ever facility outside of Germany.

The company I work for, Vetter, is a global leader in the aseptic filling of syringes, cartridges and vials, servicing the top 10 pharma/biotech firms in the world, as well as smaller biotech companies on the brink of creating innovative drugs. Headquartered in Ravensburg, Germany, our company decided in early 2009 that the time was right to establish a physical manufacturing presence in the United States to better serve our U.S. customers in their drug development process. The new facility would be an expansion of Vetter Development Services, which has a large infrastructure in Germany, and has supported drugs in development for more than 10 years.

The Vetter team at the ISTP works with biopharmaceutical firms from preclinical development through Phase 2.

Being part of the injectable-drug market for around 35 years, we are well aware that, while expertise is essential to the business of sterile manufacturing, it is change that drives action. And, with nearly two-thirds of Phase 1 and Phase 2 drugs coming out of U.S.-headquartered companies, Vetter needed to take action to better support the entire product-development cycle of its customers earlier. With the new location, we could sharpen our focus on clinical stages and early-phase manufacturing, working with biopharmaceutical firms from preclinical development through Phase 2. And, the facility would provide a seamless and streamlined product transfer to Vetter's large-scale manufacturing facilities in Germany for Phase 3 and subsequent commercial manufacturing.

After looking at numerous locations, we decided to build the site in the Skokie-based Illinois Science + Technology Park (ISTP), a state-of-the-art facility centrally located between downtown Chicago and Lake County, Ill. The technology park, once home to the pharmaceutical company Searle (Pharmacia), was first developed in 2005. Since then, more than 20 companies have located at ISTP, which occupies about 23 acres of property.

At the time, some thought this choice of location for a manufacturing site for a company like Vetter to be unusual. Would New Jersey, Boston, or the San Francisco


Vetter dedicates its first facility located outside Germany.

Bay area, home to numerous large pharmaceutical and biotechnology companies, perhaps make better sense?

"Chicago Fit Like a Glove"

"We came to Illinois to build our first facility outside of Germany because Chicago fit like a glove," stated one of our managing directors, Peter Soelkner on December 1, 2009, the day of the ribbon-cutting ceremony for the Chicago-area site. He explained that the central location of the ISTP within the United States would enable Vetter to travel easily to all of its North American customers, and they to Vetter. And the manageable difference in time zones enables convenient communication among Chicago and German facilities.

"Illinois is considered a ´hot spot´ in biotechnology, and that was important for Vetter," said Michael Rosen, senior vice president of New Business Development at the ISTP. "But the possibility of locating their facility at the Illinois Science + Technology Park was a significant added benefit because the park is centrally located among top-flight academic institutions, and gives Vetter access to cutting-edge science and a highly skilled employee pool. The park also afforded Vetter management the opportunity to customize their space and create a facility that not only anticipated their current needs, but their future needs as well. Since arriving at the ISTP, Vetter has had the need to expand significantly, and we have been able to accommodate them."

> **"Illinois is considered a ´hot spot´ in biotechnology, and that was important for Vetter."**

Work on the site to retrofit the new area to Vetter's exacting specifications began immediately. The facility had to be ready for materials preparation, compounding and aseptic filling of injectables, followed by visual inspection. Working in unison with the Development Services operation in Germany, the 24,000-square-foot structure, which had been empty since 2003, had to be gutted and customized for the intensive laboratory and small-scale production necessary for development work. This included implementing new microbiology and chemical analysis labs for performing functions such as incoming compound-specific testing and active pharmaceutical ingredient (API) concentration testing.

Investments over the next two years included specialized filling equipment housed in three Class 100/10,000 area cleanrooms that were constructed to handle the clinical batches we produced. In one cleanroom, we installed a flexible semi-automated filling unit capable of filling a variety of packaging materials, including syringes, cartridges and vials with a capacity of up to 500 units per batch.

A second cleanroom contains the first-of-its-kind automated vial filler, designed specifically for early clinical-stage, high-value biopharmaceuticals capable of running up to 10,000 liquid or 6,000 lyophilized vials per batch. A third cleanroom will expand current operations and provide fully automated filling of syringes. All filling units are integrated in a restricted access barrier system (RABS), which mitigates risk of contamination by minimizing human contact with products during manufacture.

Significant Progress by 2011 and More to Come

In April 2011, we revealed that our ISTP facility was ready to accept client projects. Approximately six months later, we were pleased to announce that our state-of-the-art facility was fully operational. We were now ready to begin working with biologics companies to prove the effectiveness of a product, and then supporting our customers from our German sites to get the product through the necessary later-development stages and approval processes, and establish the drugs' commercial viability.

Since becoming fully operational in October 2011, the facility has performed very well and has already released several customer batches for clinical trials. We have generated revenue through a mixture of customers that serve U.S. and ex-U.S. markets, including companies located in South Korea, Israel, the Netherlands and Austria. Drugs under development by our customers include treatments for blood cancer, muscular dystrophy, wound healing and dwarfism.

Meanwhile, the facility has already expanded analytical and microbial testing, added 2,000 square feet of good manufacturing practice (GMP) storage, and built out its business office to accommodate more than 20 additional work spaces.

"Since becoming fully operational in October 2011, the facility has performed very well and has already released several customer batches for clinical trials."

All filling units are integrated in a RABS (restricted access barrier system), which mitigates risk of contamination by minimizing human contact with products during manufacture.

Three years ago our site employed 12 people, all German expatriates, highly trained technicians and professionals, including scientists with advanced degrees, many of whom speak multiple languages. Today we have grown to 50 employees—three are expatriates and the remaining are local Illinois hires.

In keeping with our strategy of creating a presence in the country's heartland, we moved our new sales office to the ISTP. The office, officially known as Vetter Pharma International USA Inc., is responsible for Vetter's North American sales and key account management business.

And to give back to the community that so quickly embraced us, we are proud to be able to contribute to the success of others in Illinois. In January I had the honor of being named a member of iBIO's board of directors.

Vetter is proud to be a member of the Chicago community and, clearly, Chicago has embraced our presence. **BQ**

TEACHERS OFFER PERSPECTIVES ON EDUCATE PROGRAMS' VALUE

By Ann Reed
Vice President, EDUCATE Center of the iBIO Institute

For nearly eight years, with funding from Abbott Laboratories, AbbVie, Archer Daniels Midland, Baxter, DuPont Pioneer, Hospira and Takeda Pharmaceuticals, the EDUCATE Center of the iBIO Institute has provided TalentSparks programming for Illinois teachers. TalentSparks provides teacher professional development workshops focused on novel, standards-aligned curriculum that inspires student achievement by encouraging hands-on, inquiry-based exploration of real-world problems. Independent external evaluation data show TalentSparks programs create statistically significant average content gains of nine percentage points in science and math for teachers and their students. More than 700 teachers and 60,000 students have benefited from TalentSparks programming.

Recently, through a grant from the Astellas USA Foundation, EDUCATE developed the Stellar Girls after-school STEM (science, technology, engineering, mathematics) program for girls in grades four through eight, based on published research demonstrating that girls begin eliminating STEM fields as career choices in the third and fourth grades. More than 200 girls have participated in this program in the past two years. Fifth- and sixth-grade girls who participated in Stellar Girls showed statistically significant gains for science and math content. Although the sample size was small, these girls showed 16 percentage-point gains from pre- to post-tests.

"More than 200 girls have participated in this program in the past two years."

While these metrics are impressive and demonstrate high-quality programming, just like any statistic seeking significance, they can only describe what is common to all. They are unable to define the seismic impact a subtle shift in teaching practices can have for a teacher and the scores of students that benefit from this shift.

We invited four teachers involved in EDUCATE Programming to reflect on how TalentSparks or Stellar Girls programs have transformed teaching and learning in their classrooms and impacted their students.

Sharon Churchwell, Science Teacher, Lincoln Hall Middle School, Lincolnwood, Ill. Stellar Girls Program School Leader.

I feel that the Stellar Girls programming is engaging girls who for one reason or another loved science when they were younger, but who felt that they were not as capable at science and math as they should be as middle-schoolers. In Stellar Girls, they engage with the STEM projects enthusiastically and apply math and critical-thinking skills excitedly. They

also have their own unique way of recording their observations in very artistic but still appropriately scientific ways. The girls offer their ideas and hypotheses without worry or self-censure. We had a co-ed after-school robotics club that was very exciting, but no girls participated in it. It seems to be very important to have an all-girls space for STEM education.

Adie Slaton (Evanston High School) performs bomb calorimetry during TalentSparks.

As far as my own teaching goes, I find that the Stellar Girls program is helping me to overcome the inertia I feel from years of training in traditional teaching methods. The Next Generation Science Standards, as well as the realities of our rapidly changing world, necessitate that we teach students how to tackle large, open-ended problems. Unfortunately, our texts and classroom materials are often very traditional and therefore limited in how much real problem solving they engender from our students.

> **"As far as my own teaching goes, I find that the Stellar Girls program is helping me to overcome the inertia I feel from years of training in traditional teaching methods."**

The very engaging lessons collected for Stellar Girls take seemingly simple activities and open them up to problem solving in the context of meaningful scientific concepts and applications of math. They also invite the use of the design and redesign concepts of engineering. For instance, a typical lab activity might ask students to explore yeast metabolism by examining the gas production of yeast with and without the presence of sugar. But the Stellar Girls lab asks the girls to explore a variety of situations: sugar vs. sugar substitutes, amount of sugar, acidity of liquid, temperature of water. The girls choose their variables, collect data and present their analyses to each other. They can then relate all of the data back to an intriguing question, such as recipe creation. Many science concepts can be leveraged from this lesson, such as cellular respiration, environmental factors affecting organism survival and climate concerns. And this energizes me as a teacher.

In another Stellar Girls activity, the girls made sugar water of increasing, known sugar concentrations and used that as a scale to rate the sweetness of different varieties of apples. They graphed the data and used interpolation to add the known sugar contents of the apple varieties. One of my seventh-grade girls then applied the ideas learned in this lab to convince me to let her do a science fair project that was aimed at high school level and too involved for her to carry out by herself. She had fellow students use the concentrations of sugar water to help her rate the sweetness of different formulas of smoothie recipes. She saw an opportunity to extend what she had learned in Stellar Girls to conduct an investigation that she cared about. The level of engagement and excitement that Stellar Girls promotes is wonderful.

Kelly Kleinertz, Science Teacher, Grades 4-6, Skinner North Classical School, Chicago, Stellar Girls Program School Leader.

The Stellar Girls program has been part of our after-school academic programs at Skinner North for two years. This program has empowered our students both socially and academically. In an all-girls setting, students take risks, ask questions, form peer relationships and develop team-building skills in a space that is free from judgment. The lessons provided in the program are aligned with the Next

Generation Science Standards and are rooted in science and engineering practices. My students have had opportunities to plan and carry out their own investigations, develop models, construct explanations and analyze and interpret data.

Throughout the program, I have seen firsthand the growth in my students' confidence in science class. The girls often share ideas and discoveries learned in Stellar Girls with the rest of their peers during whole-class discussion. They seem more comfortable asking questions about science concepts and taking leadership roles within the classroom. Almost daily, they make connections with the curriculum using knowledge gained in Stellar Girls.

The greatest benefit I have seen from this program is the love for science Stellar Girls has fostered. My students are excited to come to Stellar Girls every week and show enthusiasm to learn about science and how it connects to their lives. The girls have taken a great interest in the process of doing science as well as the content gained from the thematic units.

Karen Wolfe, Science Instructor,
Instructional Coach, Maine East High School,
Park Ridge, Ill.
TalentSparks Math-Science Partnership Grant Project in partnership with Monroe Randolph Regional Office of Education.

TalentSparks

The TalentSparks program profoundly impacted my practice by introducing me to thinking routines, by fostering the implementation of the Obesity and Global Climate Disruption Problem Based Learning (PBL) units, and by encouraging me to change my approach of simply "pushing content" and instead emphasize 21st century skills with my students.

The value of those skills became evident when a student, while presenting her culminating obesity solution, became excited not by the content of her project, but by her ability to integrate three multi-media formats to create a presentation. By including graphs, photos, data and interviews from experts in nutrition and fitness, she effectively communicated her ideas while clearly owning the content because she cared about finding a solution to the problem.

Since implementing the PBL approach and thinking routines in my teaching, I cover about half as much content, but I strongly believe that my students learn twice as much. Most importantly, they know why they are learning key concepts and why those concepts are relevant.

(Left to right) Aide Slaton (Evanston High School), Mark Casey (Dunbar Vocational Career Academy), Ellen Fierer (Evanston High School), and Karen Wolfe (Maine East High School) examine gel electrophoresis during ag-bio exploration.

For example, students have always been able to memorize the structure and function of fats, carbohydrates and proteins; however, through the obesity PBL they also learn the nuances of social, political and economic factors that impact the obesity epidemic. Through the PBL approach I have been able to draw students' attention to real-world issues, to explore solutions and to feel empowered to act. One student's interest in Global Climate Disruption's impact on policy allowed him to make connections to transportation options in his community. As a result of his project, he served on a community task force to implement biking and walking paths throughout the city.

> "... I cover about half as much content, but I strongly believe that my students learn twice as much."

The "thinking routines" I learned in TalentSparks encourage my students to ask their own questions, seek out answers using varied sources and formulate explanations. These techniques build a culture of inquiry in my classroom. Once students begin to ask their own questions, they want the answers. I discovered this when using a thinking prompt on gene expression; students were so engaged they began exploring various sources in pursuit of answers and then spontaneously and enthusiastically shared what they learned with classmates. Without even being aware of it, the students identified several major concepts for our upcoming unit and began to form their own ideas and explanations for how genes may be expressed. In addition, these routines provide me with a bird's-eye view of my students' thinking, which in turn helps me identify their misconceptions. These teaching tools have also led to a more student-centered classroom, as the students are identifying what they would like to further explore and leading their own class discussions.

> "Once students begin to ask their own questions, they want the answers."

These days when the bell rings I frequently hear, "What, it's over, already?" Now I have reason to believe that not only are they engaged in class, but that they will be finding connections to my content long after they head out the door.

Kelly Kleinertz (Skinner North Classical School) coaches one of her Stellar Girls during wind turbine design activity.

Adriane Slaton, PhD, AP Biology
and Chemistry Teacher,
Evanston Township High School, Evanston, Ill.
TalentSparks Math-Science Partnership Grant Project in partnership with Monroe Randolph Regional Office of Education.

For me, the first summer program focusing on the hormonal, genetic and epigenetic causes of obesity provided a chance to re-conceptualize possibilities in pedagogy and what it means to create and deliver guided-inquiry units. The TalentSparks program instructors allowed us, the teachers, to put on our "student hats" and experience what guided-inquiry units feel like. They then provided the time and space to think about what such units would look like in our classrooms. Upon reflection, I feel like I was unwittingly holding on to many misconceptions about what inquiry-based teaching looked like in practice.

TalentSparks demonstrated *how* a teacher could be both clear in focus and allow students to push the daily agenda. Specifically, the idea that student questions drive each day (vs. a standard learning objective) was a very powerful conceptual change in my teaching. The TalentSparks units consider teaching to be more like Next Generation Science Standard (NGSS) unit storylines, in which the teacher's role is to guide students to specific "experiences" (a lab, a data set, a question, a problem). These storylines then play out as students ask for more data or more information to answer the question. TalentSparks showed how to make the incentive for learning clear for students.

> "The TalentSparks program instructors allowed us, the teachers, to put on our 'student hats' and experience what guided-inquiry units feel like."

Sharon Churchwell (Lincoln Hall Middle School) and her Stellar Girls preparing to make hydrogels.

> "The hard part of teaching this way is that it takes more time—but the experiences are longer-lasting."

The hard part of teaching this way is that it takes more time—but the experiences are longer-lasting. For example, several students from the TalentSparks project are in my Advanced Placement Biology classes; each time questions on homeostasis, cell receptors, epigenetics, or on the specific hormones leptin and ghrelin come up—they know how to tackle the questions. And their knowledge on how to tackle them is genuine—they did not just memorize meaningless factoids and definitions—instead, we created a strong foundation for learning. It has been really fun and cool to see their retention and excitement for knowing these ideas. BQ

Teacher feedback offers important insight on how programs for teachers, like TalentSparks and Stellar Girls, impact students. EDUCATE greatly values these teachers' efforts providing quality learning experiences that inspire student interest and create the next generation of STEM innovators.

THE ROLE OF RESEARCH INSTITUTIONS IN BIOTECH

By Lawrence B. Schook, PhD
Vice President for Research, Edward William and Jane Marr Gutgsell Endowed Professor
University of Illinois

Universities and industry have partnered on research endeavors for more than a century. Collaborative research activities have evolved over time, growing beyond the sponsorship of distinct research projects to longer-term strategic partnerships. These public-private partnerships have resulted in life-changing discoveries, particularly in the area of biotechnology. Research that was once inconceivable has led to innovative medical treatments and therapies and cutting-edge technologies that are now part of our everyday lives.

Public research universities are powerful drivers of innovation and discovery. The University of Illinois, a world-class research university and one of the top 10 sources of patents in Illinois, is having a profound impact on the biotechnology industry through the delivery of scientific breakthroughs. The application of the life sciences, physics, chemistry and engineering to biomedical research promises to improve human health and create dynamic new technologies that will forever change the way we think, work and live.

Today the biotechnology and biomedical domains extend beyond academic researchers and scientists. They include local entrepreneurs, startup companies and any individual with a "big idea." As industry dynamics shift, universities must be flexible and willing to adopt new research models that foster innovative thinking and reward active collaboration with corporate partners if they are to remain competitive.

> "Public research universities are powerful drivers of innovation and discovery."

With an aging population and an increasing number of medical treatment centers, the demand for bioengineering and biomedical innovations continues to rise. Biomedical research is a critical part of the University of Illinois' mission to improve the health of the communities and citizens we serve. Researchers and scientists are continuously working to enhance patient care and to develop lifesaving treatments and therapies.

For our part, the University of Illinois graduates more engineering students than the top four engineering schools in the nation combined. We are also home to the country's largest medical school. Collectively, we have generated an expansive repertoire of bioengineering and biomedical patents, license activity and startup companies.

The majority of health-related research funding at the University of Illinois at Chicago (UIC) supports biomedical research, while the University of Illinois at Urbana-Champaign (UIUC) leads the nation in National Science Foundation (NSF) funding. Both our Chicago and Urbana campuses experienced a surge of biotech activity and achievements in the past year, driving the growth of our local, national and global economies. In fiscal year 2013, the University of Illinois approached nearly $1 billion in federally sponsored research expenditures. By placing a significant investment in scientific research, the University is positioned to join forces with the best and most advanced industry partners.

> "In fiscal year 2013, the University of Illinois approached nearly $1 billion in federally sponsored research expenditures."

The University of Illinois places a strong emphasis on interdisciplinary research and corporate partnerships. Combined, these synergic activities support a collaborative approach to solving some of the world's most pressing problems. A significant amount of research, commercialization, startup activity and collaborative endeavors between universities and private industry have been developed in the biomedical and bioengineering disciplines.

Elevating Ideas

The Office of the Vice President for Research at the University of Illinois is responsible for advancing the economic development mission of the University by elevating ideas and innovations into sustainable technologies. Through our innovation pipeline, we protect, fund and support ideas prior to launching as viable business solutions.

The EnterpriseWorks incubators support faculty and community entrepreneurs with new ideas seeking to start companies. Located on the Chicago and Urbana-Champaign campuses, EnterpriseWorks offers a broad range of services and programs designed to launch technology-based startups into sustainable businesses. These incubators have played a significant role in the development of biotech companies and are the cornerstones of the entrepreneurial ecosystem in their respective communities.

Author Dr. Larry Schook on the "DNA" staircase at the University of Illinois at Chicago (UIC).

EnterpriseWorks Chicago

A "startup for startups," EnterpriseWorks Chicago (EWC) is charged with creating a robust entrepreneurial community to nurture commercialization and accelerate viable high-technology startups throughout the Chicagoland community. EWC coordinates and fosters five pillars of vibrant entrepreneurial ecosystems—infrastructure, innovation, talent, networks and capital.

The flagship initiative of EWC is the Health, Technology and Innovation (HTI) facility, a proof-of-concept center for therapeutics, devices, diagnostics and information technology. Located in the Illinois Medical District, the nation's largest urban medical district, HTI is the first shared laboratory space for early-stage entrepreneurs in Chicago. It brings scientists, clinicians, engineers and industry together in support of an interdisciplinary approach to drug, diagnostic, device and information technology development.

> "The EnterpriseWorks incubators support faculty and community entrepreneurs with new ideas seeking to start companies."

ENHANCING EDUCATION

HTI provides both physical space and support services to validate technology, translate innovation into products and accelerate projects to venture readiness. By focusing on the fundamentals of technology and market feasibility, HTI increases the viability and sustainability of life sciences research-based startups. It serves University faculty, staff and students; Chicago-area research institutions; and the broader entrepreneurial community as a nexus of biotechnology commercialization.

HTI offers access to shared wet- and dry-laboratory space for proof-of-concept work, and access to University resources and our innovation pipeline. Entrepreneurs ready to test their ideas before formally launching a business take advantage of HTI's short-term leases and access to investors.

IllinoisVENTURES, the University's venture capital firm, is located within the facility, connecting innovators to the seed investments necessary to jump-start their businesses. IllinoisVENTURES has funded numerous biotech startups that have become viable companies.

AbbVie, a global pharmaceutical company, is a flagship sponsor of HTI and participates in entrepreneurial workshops and programming in order to have access to the entrepreneurs and technologies coming out of HTI. AbbVie's involvement brings industry closer to the discovery-driven academic culture, and is an example of a mutually beneficial university-industry partnership.

Shared laboratory space in the Health, Technology and Innovation (HTI) Center.

In less than a year, numerous biotechnology companies have established residence in HTI, including:

- Benecure, a new venture that is developing a cardiac emergency alert system with an integrated user-interface application to predict and prevent cardiac events.
- Novalex Therapeutics, founded by a medicinal chemistry and pharmacognosy professor, that is developing new classes of antibiotics, including an antibacterial compound to treat staphylococcal infections and an antiviral compound to treat hepatitis C, a viral infection of the liver.
- Vivacelle, a startup company that has developed an intravenous fluid to treat hypovolemia, a condition that occurs when there is inadequate fluid volume in blood vessels.

HTI was made possible by a $3.4 million investment by the Illinois Department of Commerce & Economic Opportunity (DCEO) and the University of Illinois. Additional grant funding provided by DCEO to entrepreneurial support services has resulted in the formation of 10 new startup companies.

EnterpriseWorks

At our Urbana-Champaign campus, EnterpriseWorks and the University of Illinois Research Park provide an environment for technology-based businesses to work with faculty and students, and take advantage of collaborative research opportunities and easy access to the University labs and services. Research Park is home to companies of all sizes from multiple sectors, including Abbott Laboratories and Sony Biotechnology.

The Phi Optics CellVista Q1000 provides real-time, label-free and quantitative imaging of live cells and tissues with nanoscale sensitivity.

ENHANCING EDUCATION

EnterpriseWorks is located in the heart of Research Park and is the business incubator for the Urbana-Champaign campus and local community. With more than 40 startup companies spanning from biotechnology and chemical sciences to software development, EnterpriseWorks' clients have obtained more than $267 million in investment capital. The following biotechnology companies have experienced success and growth in a short time:

- **BioAnalytics** is an early-stage biotechnology-student startup company focused on designing the next generation of immunoassay technology. BioAnalytics has developed a novel technique, which reduces the number of assay steps required for protein quantification, resulting in faster and more accurate multiplexed assays.
- **Diagnostic Photonics**, founded by two electrical and computer engineering professors, developed an imaging technology that generates diffraction-corrected images of tissue microstructure by solving the mathematical equations governing the physics of light at high speed, transforming defocused images into in-focus ones. This technological approach brings imaging to the point of care and places the power of optical imaging in the hands of the physician.
- **Exalt Diagnostics**, founded by a bioengineering/electrical and computer engineering professor, developed FluoroBoost™, a technology that measures the presence and concentration of dozens of proteins circulating inside the human body. The technology utilizes a nanostructured photonic crystal surface to increase the output of any surface-based fluorescence assay by more than 500 times.
- **GlucoSentient**, founded by a chemistry, biochemistry, materials science and engineering and bioengineering professor, developed a technology that transforms personal glucose meters into devices that quantitatively and conveniently detect non-glucose targets.

FluoroBoost is a trademark of Exalt Diagnostics Inc.

- **ImmuVen Inc.,** founded by a biochemistry professor, is a biotechnology company with novel technology to discover and develop new biotherapeutics to treat cancer, infectious disease and autoimmune disorders. Based on proprietary technology developed in the laboratory of its scientific founder, ImmuVen's platform allows rapid selection and optimization of T-cell receptors with high affinity to targets in cancer, infections, and autoimmune pathways.
- **InstaRecon**, founded by a bioengineering/electrical and computer engineering professor, developed algorithms for image reconstruction that are inherently more efficient than conventional algorithms. The technology is used in medical/biomedical imaging, industrial imaging and security imaging. InstaRecon's technology can simultaneously improve image quality, increase reconstruction speed and reduce reconstruction engine cost.
- **Midasyn Inc.** is commercializing a technology platform that will enable the automated synthesis of small molecules. The company will provide services as well as the sale of molecules, chemical libraries, reagents and small-molecule synthesizers.
- **Oracle Biosciences** is developing a single gene-based clinical assay for diagnosis and prognosis for basal-like breast cancer for use in clinical diagnostics and subtyping. The company has collaborated with Carle Foundation Hospital and multiple departments at the University of Illinois.
- **Phi Optics Inc.**, founded by an electrical and computer engineering professor, is an optical microscopy company that developed a disruptive technology—Quantitative Phase Imaging—that provides highly accurate, fast and inexpensive imaging of live cells and tissues. The company was selected to participate in the Innovation Corps Program (I-Corps), an NSF initiative that fosters entrepreneurship leading to the commercialization of technology previously supported by National Science Foundation (NSF)-funded research.
- **Vanquish Oncology**, co-founded by a chemistry professor, is a drug-development company focused on targeting unexploited molecular defects in cancer cells to create personalized therapeutics for unmet or underserved cancer markets.

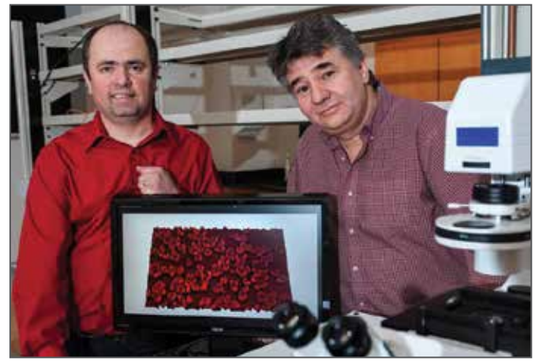
Federal Support

In addition to strong support from the State of Illinois, the biotechnology industry is fortunate to have strong champions at the federal level. Senator Richard J. Durbin recently addressed a crowd of researchers, staff and students on the UIC campus regarding the *American Cures Act*. This act seeks to preserve the nation's role as a global leader in medical innovation by establishing a mandatory trust fund for biomedical research at the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and health programs at the Departments of Defense and Veterans Affairs. Biomedical research funding has been lagging for years, and Senator Durbin's bill would help close the gap. The University of Illinois is grateful to Senator Durbin for his efforts to prioritize federal research funding to advance innovation and drive economic growth.

Conclusion

The University of Illinois and other research institutions play a vital role in the rapidly growing biotechnology and biomedical industries. Through continued collaboration and investment in university-industry partnerships, universities are well equipped to meet the needs of society through revolutionary research discoveries and the creation of cutting-edge technologies. With countless life-changing scientific breakthroughs and new innovations continuing to emerge from universities, it may be difficult to imagine, "What's next?" However, we have only scratched the surface and the possibilities are endless. BQ

A complex gene expression heatmap picture of human breast cancer patient samples, a human breast cancer tissue sample showing the expression of a Forkhead Box C1 *(FOXC1)* gene; product box in which the test is projected to be marketed; and the proposed Prognostic Mammotype™ Score Report.



Phi Optics COO Catalin Chiritescu and CEO Gabriel Popescu behind the CellVista Q1000 system.

Director Kapila Viges presents during one of HTI's "Startup Series" events, a series of events geared toward Chicagoland entrepreneurs.

The Diagnostic Photonics Imaging System places a live view of tissue microstructure at the physician's fingertips, providing immediate insight into tissue microstructure.

THE MEDICAL DEVICE TAX: REAL-WORLD IMPACT IS A WAKEUP CALL FOR POLICYMAKERS

By Steve Ubl
President and CEO, Advanced Medical Technology Association (AdvaMed)

Today's medical technology industry is a success story for both patients and the economy, especially in states like Illinois where it supports more than 40,000 jobs. Unfortunately, the medical device excise tax instituted in 2013 has had an unprecedented negative impact on medical technology jobs, R&D and U.S. investment, underscoring the need for policymakers to address this burdensome tax and repeal it.

A recent AdvaMed survey examining the first-year, real-world impact of the medical device tax showed that approximately 33,000 medical technology industry jobs have been lost nationwide as a result of the tax—including cuts of about 14,000 and forgone hiring of 19,000. Up to 165,000 jobs have been lost if you factor in indirect employment among industry suppliers.

The survey also found that almost one-third of respondents had reduced R&D as a result of the tax.

Nearly 10% of respondents said they had relocated manufacturing outside the United States or expanded manufacturing abroad because of the tax.

"Up to 165,000 jobs have been lost if you factor in indirect employment among industry suppliers."

In terms of investment dollars, three-quarters of respondents said they had taken one or more of the following actions in response to the tax: deferred or cancelled capital investments, deferred or cancelled plans to open new facilities, reduced investment in startup companies, or reduced or deferred increases in employee compensation. In addition, some small companies reported more difficulty in raising capital.

These survey results confirm and underscore what AdvaMed has been hearing from medtech CEOs for a long time now—that this job-killing device tax is taking a heavy toll that will only grow over time. Indeed, looking forward, 58% of survey respondents said they would consider future employment cuts and 50% said they would consider future R&D cuts if the device tax is not repealed.

Simply stated, the device tax is bad for patients, it's bad for jobs and it's bad for innovation.

Contrary to the claims of some, companies are simply not anticipating a windfall from expanded coverage under healthcare reform. At a time when unemployment is high and there is bipartisan interest in growing high-technology manufacturing jobs in America, these survey results should serve as a wakeup call for policymakers at the state and national levels.

AdvaMed
Advanced Medical Technology Association

Overwhelming bipartisan majorities in the U.S. Senate and House have already openly sided against the device tax. This includes a majority of the Illinois delegation in the U.S. House of Representatives. On the Senate side, Senator Dick Durbin (D-IL) has expressed concerns with the tax and Senator Mark Kirk (R-IL) is a cosponsor of device tax repeal legislation. We are hopeful that mounting evidence of the tax's destructive effects will help spur definitive action by Congress and the president before more harm is done.

AdvaMed will also continue to work with its coalition partners in the State Medical Technology Alliance, a consortium of state-based trade associations that includes the Illinois Biotechnology Industry Organization (iBIO), to encourage action on the device tax.

"We are hopeful that mounting evidence of the tax's destructive effects will help spur definitive action by Congress and the president before more harm is done."

America's medical technology companies support nearly two million jobs nationwide and currently lead the world in developing lifesaving and life-enhancing treatments and cures, but that leadership is in peril. Instead of punishing the American medical technology industry through poor tax policy, our government—at the federal and state levels—should be encouraging it.

It is time to allow medical technology companies to continue to innovate, for the good of America's patients, for the sustainability of America's healthcare system and to support American job creation and economic growth. **BQ**

COMPLIANCE ISSUES?
FIRST, DON'T PANIC

By Greg Kain
Regional Operations Manager, Integrated Project Management Company

A hurricane is coming. You heard about it on the radio. Everyone in the family jumps to it. You rush to the grocery store and pile as many cans of Chef Boyardee as will fit in your cart. Your spouse nails boards across the windows. The kids run around the house collecting candles. But when the storm hits, you realize you have plenty of ravioli but no drinking water, windows that are protected but a neglected leak in the roof, and candles but no matches.

It would have been far better to stop. Take stock. Make a well-coordinated plan based on the requirements and realities of your situation. *Then* take action.

The same goes for addressing a regulatory compliance issue. Whether a 483, a warning letter, a recall or a consent decree, it's all hands on deck, to be sure. But a rigorous process-driven approach helps secure the outcome you want, and ultimately provides the fastest path to get you there.

Storm clouds are symbolic of the turmoil that a crisis can cause.

Rule #1: Take a Deep Breath

When a regulatory compliance issue is identified, especially a serious one, everyone leaps into action. But speed without structure can make things worse than they already are. Although the clock is ticking, to prevent missteps and redos, it's important to spend the time to thoroughly examine the issues raised by the regulator and build a rock-solid plan to address them—*before* the "go, go, go."

Rule #2: Dedicate a Full-time Project Manager

A dedicated, experienced project manager is a must for regulatory compliance programs when it's absolutely essential to hit the mark. He or she knows how to guide the development of an airtight project plan based on objective analyses to make sure the web of activities remains coordinated and to facilitate rapid problem-solving when the team hits the inevitable speed bump or two.

> **"Make a well-coordinated plan based on the requirements and realities of your situation. *Then* take action."**

Rule #3: Fully Understand Your Regulatory Requirements

It's not unusual for a company faced with a compliance issue to seek a swift remedy and misunderstand the true depth and root cause of the problem. The result? The fix doesn't fully address the agency's requirements. Then you've *really* got a problem. For a successful outcome, make sure you thoroughly understand the regulator's expectations. Then build into the project plan regular oversight by your regulatory group as the project progresses to ensure that every activity ties back to agency requirements.

Rule #4: Prioritize and Pressure Test

Complex issues require complex remedies. But trying to do too much can be as detrimental as doing too little, resulting in confusion, errors and missed deadlines. When building your project plan, identify each activity required to get the job done. After squeezing out slack time and bottlenecks, can you meet your regulatory deadline? If the answer is "no," can you identify any "nice to haves" that you can drop from your to-do list? If still "no," you know it's time to add or reallocate resources, or appeal to the agency for more time. Then retest your plan.

Rule #5: Be Vigilant but Flexible

Stick to the project plan but maintain flexibility. If the schedule starts to slip, find out why. Problem with one of the personnel? Major holdup in one area freezing the entire project? Investigate, fix it, then adjust your project plan to match the new reality.

Rule #6: Make Sure It Doesn't Happen Again

Once it's all over, debrief. How did you get into this mess in the first place? Problems can stem from a failure to keep up with rapidly changing regulations or from the mindset that "we've always done it this way." It's common nature after a major stressful push to want to quickly get back to work as usual. But taking the time to evaluate what went wrong is well worthwhile. You'll raise the quality of your operations and strengthen your organization overall.

To illustrate some of these principles in action, read the case study of:

How a Global Biopharmaceutical Company Faced Doom and Emerged Unscathed

It wasn't a good day. Management had received a warning letter citing nearly 90 observations at one of their manufacturing plants, ranging from contamination problems due to faulty aseptic procedures to inadequate document storage. The plant told the corporate office not to worry; they had it covered. They'd been operating for decades. It would turn out fine. But the facility's track record on delivering had not been stellar. Management assigned a seasoned project manager to assess the facility's plan and progress.

The pressure was on. The corporate quality manager had invited the FDA to visit the plant in a couple of months. After issuing the warning letter, the agency could show up again anytime. Management decided to take some control over the timing by inviting them back proactively.

Making a List

Upon arrival, the first step taken by the project manager was to create a list of projects, not just of those related to the warning letter, but of all projects facility-wide, to get a handle on the full scope of activity at the plant. For the first month and a half, the project manager met with every single person who was leading a project. "Project" was defined as anything with a definite start, definite end, that required resources. The resulting list—of nearly 40 items—was far bigger than expected. Though he'd sensed it, the facility manager was taken aback at how much was under way at his plant, which, until all documented in one place, had not been apparent.

Prioritizing

With the list in hand, it was now possible to prioritize projects based on how critical they were to address the warning letter. The project manager worked closely with the corporate QA group, comparing the list of observations against the plant's current project list. Line by line, which projects were compliance-driven? Where were the gaps? What current projects could be cancelled or postponed in order to reallocate staff and budget to compliance projects? In the end, about a quarter of the less-than-critical projects were put

on hold, such as the relocation of a lab support facility and balanced scorecard implementation. The compliance projects to address the warning letter were then themselves prioritized.

When the FDA came for their follow-up site visit, management now had a list of projects demonstrating *exactly* how they would address every one of the agency's concerns.

Recipe for Disaster

During his initial interviews with the team, the project manager quickly realized they were all rushing toward a cliff. The bulk of the compliance work was planned to take place during the facility's usual summer shutdown. The plant would cease operations to replace several systems and make other major fixes, so the timing was ideal. But the scope of each project was enormous, comprised of huge lists developed in concert with the corporate regulatory and quality groups. The project manager asked the facility team if they'd be able to get all activities done in the time allotted. The answer: an unequivocal "no." But the corporate message had been "get it done." No excuses. So the team committed to doing it, and they'd give it their best shot.

Evidence-based Solution

To skirt catastrophe, the project manager worked with the facility team to develop three scenarios:

- **Scenario #1:** The "schedule" scenario assumed the facility must complete as much as its compliance work within the designated summer shutdown period as possible. Given the current project scope, what activities would the team have to remove to provide 100 percent confidence they could meet the schedule? Result: They would have to eliminate so many activities and thus would accomplish so little that they'd meet none of the regulatory objectives. The FDA could shut them down.
- **Scenario #2:** The "full scope" scenario was at the other end of the spectrum. If the team were to perform every single activity on the project list, how long would it take? Result: As expected, it would take many months more than the FDA would accept and than the business could maintain supply continuity.
- **Scenario #3:** The "balanced" scenario was prioritized based on the regulatory viewpoint. What were the absolute "must haves" that would satisfy the FDA's requirements and prevent a plant shutdown? What could they wait to do later? The team assembled that list, and projects were prioritized into tiers. Next: How long would it take to perform these projects? Calculations showed that the shutdown would start slightly later and last slightly longer than the original summer shutdown timetable, but the facility could build up adequate inventory in advance, and they'd meet the FDA's timetable.

Building the three scenarios took almost a full month: gathering data, developing detailed schedules and identifying resource requirements. It was time well spent. All scenarios were presented to corporate management, with the third "balanced" scenario as the team's recommendation. The official corporate response: "It's a no brainer."

Tightly Integrated, Fully Orchestrated

To stay within the "balanced" scenario schedule, every activity had to be carefully coordinated. The original plan had included four projects. They were integrated into a single program, led by one program leader and four sub-project team leads. The overarching plan had to be extremely detailed in terms of timing, handoffs and sequential and parallel activities. Otherwise, at some point, 20 people would suddenly converge into a five-by-five-foot space to work.

> "To stay within the 'balanced' scenario schedule, every activity had to be carefully coordinated."

During execution, the program leader and project managers stayed close to their teams to ensure they had what they needed to meet the schedule every day, problem-solving as necessary to keep the projects on track. Due to frequent communications, facility and corporate management remained fully in sync throughout.

Outcome

The facility met its targets, the warning letter was lifted and a shutdown was avoided. The organization as a whole improved its ability to plan and execute complex projects. And the corporate culture evolved to keep more ahead of the curve on regulatory compliance.

Tackling difficult compliance issues is not easy. But a process-driven approach provides an objective framework for regulatory success. No missed deadlines. No failed requirements. Plenty of matches. **BQ**

Implementing IPM's principles can have a calming effect on your organization.

> "The facility met its targets, the warning letter was lifted and a shutdown was avoided. The organization as a whole improved its ability to plan and execute complex projects."

Editor's Note: This article originally appeared in PharmaVOICE.

BioLogical Quarterly thanks PharmaVOICE for permitting the republication of Greg Kain's essay.

Integrated Project Management Company (IPM) is a project management consulting firm that specializes in the life sciences industry. Areas of company expertise include product development, alliance management, business process improvement, technology transfer, regulatory compliance and quality assurance. Headquartered in Chicago, IPM has offices in San Francisco, St. Louis and Boston. Visit ipmcinc.com or call 630-789-8600. Contact Greg at gkain@ipmcinc.com.

GROWING THE ENTREPRENEURIAL LANDSCAPE:
MORE THAN $110 MILLION STRONG

By Kate Anderson
PROPEL Community Member

"A garden requires patient labor and attention. Plants do not grow merely to satisfy ambitions or to fulfill good intentions. They thrive because someone expended effort on them."
– Liberty Hyde Bailey

In the entrepreneurial garden, each startup is a seed that needs the best soil, plenty of water and the right amount of sunlight to grow into a strong and healthy business. And it is a gardener's duty to make sure the plants are in the right environment to grow. Over the past seven years, the **PROPEL Center of the iBIO Institute** has been an attentive gardener cultivating Illinois' life sciences sector for startups and early-stage companies by providing entrepreneurs with access to education, specialized resources and expertise to prepare them for early-stage funding.

The hard work has paid off. The garden is thriving as PROPEL companies have now raised more than $110 million, including $23 million in 2013 alone. Today the life sciences industry in Illinois includes world-class research, management talent, an educated and trained workforce, state-of-the-art facilities, easy access to markets and scientific collaboration and advanced services infrastructure. And since 2007, PROPEL has worked to further develop these attributes into a thriving entrepreneurial community. With MATTER due to open later in 2014, this will only strengthen the ecosystem. PROPEL companies receive access to specialized coaching and mentoring, technical assistance, workshops, networking events, mock investor pitch sessions, grant and award programs, business plan competition and several publications—and much more. Since PROPEL's launch, it has awarded more than $550,000 in grants and awards and held more than 70 workshops.

It is, in part, due to these nurturing activities that PROPEL companies have been issued more than 70 U.S. and international patents and had two liquidity events, in addition to the $110 million in new capital. To acknowledge the significant achievement of the success of PROPEL's work, the Searle Funds at the Chicago Community Trust made a 2014 gift of $500,000, increasing its total donations to PROPEL to $1.5 million. Gifts like this and the community of volunteers have helped PROPEL reach such major milestones. Its programs greatly depend on the time and expertise of volunteer local life sciences experts, serving as coaches, technical experts, subject matter experts and panelists. With this support, PROPEL has developed a colorful and lively startup landscape.

Yet, it's the individual flowers that make the garden come alive and show its beauty. What startups are blooming in the PROPEL "garden"? Of the active PROPEL companies, 27% are medical device, 29% pharma/therapeutic, 13% medical diagnostic, 16% life sciences tools, 11% ag or industrial biotech and 4% represent a combination. Each has a unique story and an opportunity to disrupt its market. Endotronix, Prevail Health Solutions, Advanced Cooling Therapy, DeNovX and Sintact Medical Systems are just a handful that represent this growing community. Here is a brief glimpse into the "fertilizing" process of these companies and how PROPEL is helping them to succeed.

Endotronix

As a PhD student, Harry Rowland was looking to spin out his research into a medical device startup company when he met cardiothoracic heart surgeon, Anthony Nunez, MD. Realizing that both had family members who suffered from congestive heart failure, the two decided to move forward and form a company called Endotronix in 2007.

Rowland and Dr. Nunez had a burning desire to create digital health solutions that would enhance the quality of life, improve outcomes and lower costs for the 20 million people in the world who suffer from congestive heart failure. Their plan to accomplish this huge undertaking was to develop, integrate and apply advanced biosensors, telehealth technology and clinical services into new care delivery paradigms. But the biggest challenge they faced was obtaining the resources necessary to execute this plan.

Knowing that they needed assistance, Endotronix paired up with PROPEL in 2008. PROPEL helped Endotronix increase its exposure locally, introduced the team to new vendors and assisted in finding office space and bringing on financial advisors. In the last year, Endotronix has transitioned from a virtual company with one Illinois full-time employee to a full-time operation and almost a dozen employees in the Chicagoland area. Endotronix also took advantage of the mentoring program that PROPEL helped start, Chicago Innovation Mentors, and found the connections to be of great value because "…without that you can't make the connections that are unplanned that help grow the company," says Rowland. "PROPEL has been the essential piece in Chicago to create a positive ecosystem. If we can't obtain the resources to execute, we can't execute. It is essential to our success. PROPEL helped put Endotronix in a position to succeed. And it helps companies like ours compete on the global scale."

Recent Milestone:

During 4Q 2013, Endotronix was issued IP, won the 2013 PROPEL Business Plan Competition and raised additional capital.

Harry Rowland, Endotronix's CEO and Co-Founder, giving the winning pitch at the 2013 PROPEL Business Plan Competition Finals during the Chicago Innovation Showcase.

Prevail Health Solutions

After returning from Iraq, former U.S. Navy pilot Richard Gengler wanted to address high-profile behavioral health issues in the veteran and military populations. His unique experiences in the Navy, combined with the desire to help out, moved Gengler to form Prevail Health Solutions in 2008. The same year, Prevail joined PROPEL to take his Chicago-based healthcare technology company and its systematic online behavioral health programs to the next level.

Since the company's formation, Prevail has received Phase I and Phase II SBIR grants from the National Science Foundation (NSF), funding from the Robin Hood Foundation and the Bristol-Myers Squibb Foundation, as well as recognition from the Chicago Innovation Awards. Gengler and his team are proud of what they have accomplished and are excited for the future as their product offering expands to include iPrevail, Students Prevail and Moms Prevail.

"PROPEL has been the essential piece in Chicago to create a positive ecosystem. If we can't obtain the resources to execute, we can't execute."

After receiving several grants and awards from PROPEL, Rich Gengler is now giving back to the entrepreneurial community by serving as a PROPEL workshop speaker.

Recent Milestone:

Prevail Health Solutions was awarded a 12-month contract by the U.S. Department of Veterans Affairs.

Advanced Cooling Therapy

Erik B. Kulstad, MD, MS, is an emergency room physician who experiences firsthand the challenges associated with traditional patient temperature management. Looking at the bulky blankets, expensive machines and invasive catheter procedures traditionally used, Dr. Kulstad saw an opportunity for innovation and developed a device to safely and effectively modify and control patient temperature. With the aspiration to bring this approach to commercialization, he formed Advanced Cooling Therapy (ACT) and invented the patented Esophageal Cooling Device™ (ECD). This biomedical device provides a novel approach to control patient temperature in the operating room, recovery room, emergency room or intensive care unit.

This spring, Chicago-based ACT reached an exciting milestone–receiving both CE mark approval as well as Canadian approval for its first product, the ECD, which is now available to medical professionals in Europe and Canada. ACT achieved the CE marking milestone with guidance and support from PROPEL.

ACT participated in many PROPEL educational workshops and has received more than $50,000 in grants, awards and competition prizes from PROPEL since 2010. "PROPEL helps startup companies like ACT develop game-changing technologies and medical products," says Dr. Kulstad. "PROPEL educational programs have been instrumental in [our] success,… support that has resulted in the accomplishment of numerous value-enhancing milestones."

Recent Milestone:

Advanced Cooling Therapy recently received the CE mark for its ECD product in Europe and its license for Canada.

Erik Kulstad, MD, presenting Advanced Cooling Therapy at the MidAmerica Healthcare Venture Forum in April 2014.

DeNovX

DeNovX is a pharma-sciences company providing innovative products and services that overcome the challenges posed by the crystallization of active pharmaceutical ingredients (APIs). Because predictable performance is critical for pharmaceuticals, more than 90% of APIs are crystalline so that they can be manufactured, stored and used with confidence. DeNovX's patented R&D products are "slot-in" solutions that accelerate drug development timeframes by making the search for API crystal form variants more efficient. The company's service offerings will target the custom application of its crystallization products for strategic partners in the pharmaceutical markets.

> **"PROPEL helps startup companies like ACT develop game-changing technologies and medical products."**

DeNovX became a PROPEL company in 2013 and has already received three grants and awards from PROPEL, in addition to regularly attending PROPEL events. "PROPEL's depth and quality of services, educational functions and networking opportunities make it a valuable resource for entrepreneurs that cannot be overlooked or understated," says Andrew Bond, Chief Business Officer of DeNovX.

Recent Milestone:

DeNovX won the Best Pitch presentation at the American Chemical Society Entrepreneur Showcase East in April.

Andrew Bond (center) of DeNovX won the Best Pitch Award at the American Chemical Society Entrepreneur Showcase East in Waltham, Mass., after presenting to judges from the American Chemical Society, Yale University and Empiriko Corp.

Sintact Medical Systems

Sintact Medical Systems mission is to develop non-resorbable films that separate adjacent organs from adhering to each other after surgery by preventing postoperative surgical adhesions. Internal scar formation, commonly referred to as surgical adhesions, cause adjacent tissue and organs to adhere to one another due to surgical trauma.

Sintact's film acts as an adhesion barrier separating these surfaces to significantly reduce the likelihood of adhesion formation and associated postoperative complications. Complications from adhesions can often lead to major pain, bowel obstruction, and infertility while adding almost $3 billion in U.S. healthcare costs. Sintact anticipates publishing data that have shown its film achieved an 86% efficacy in reducing adhesions performed on an *in vivo* adhesion model.

Sintact became a PROPEL company in 2013 and has already received two grants and awards from PROPEL.

> **"Sintact anticipates publishing data that have shown its film achieved an 86% efficacy in reducing adhesions performed on an *in vivo* adhesion model."**

"The educational training and entrepreneurial ecosystem that PROPEL provided us has accelerated our early-stage medical device concept and management team skill set into an investable startup company," says Gali Baler of Sintact Medical Systems.

Recent Milestone:

Sintact was selected to present at the 2014 InvestMidwest, received a Stage 2 National Collegiate Inventors and Innovators Alliance (NCIIA) grant and was selected as a finalist at the Chicago Challenge Cup by DC-based 1776.

Creating a beautiful "garden" for startups takes a lot of digging, weeding and watering. By removing some of the obstacles involved, PROPEL has catalyzed the cross-pollination of ideas and expertise in the life sciences startup environment. As a result, Illinois is seeing flowers in the form of thriving startups and an increase in resources of grants and investments. And it doesn't stop there. With recent initiatives across Chicago to support local startups, such as MATTER, University of Illinois' HTI, University of Chicago's CIE and Northwestern University's Garage, the sun will be shining on Chicago scientists and entrepreneurs for quite a while, with PROPEL providing critical educational resources to life sciences entrepreneurs.

> **"Creating a beautiful 'garden' for startups takes a lot of digging, weeding and watering."**

We should appreciate how far the Chicago ecosystem has come in terms of engagement with entrepreneurs, and celebrate the major milestones that PROPEL and its companies have accomplished over the past seven years, exemplified by the raising of more than $110 million. In other words, it's time to stop and smell the flowers. **BQ**

2014 iBIO IndEx
RECAP

On April 24, 2014, iBIO held its 10th iBIO IndEx (Industry Expo), an intimate forum for sharing innovative ideas with other life sciences professionals.

The 2014 IndEx started with a morning keynote by John J. Castellani, President of the Pharmaceutical Research and Manufacturers of America (PhRMA), who offered his perspectives on how legislation impacts innovation.

John Castellani, president & CEO of PhRMA, talks with IndEx attendees before his keynote address.

Zoe Hoeppner and Amy Conn visit the exhibits at the 2014 IndEx.

Illinois Medical District Executive Director Warren Ribley addresses the attendees at the 2014 IndEx.

During the 2014 sessions, attendees learned about novel uses of big data to drive clinical trial optimization. They also gained insight into some of the industry's most notable medtech companies during AdvaMed CEO Unplugged, a session that featured the leaders from some of our global medtech companies. In the afternoon, attendees learned how the recent biotech boom is changing deal structures. Experts on the closing panel discussed how Chicago's startup ecosystem is changing in Illinois, with an eye toward the impending launch of **MATTER**, an incubator designed to fuel the future of healthcare innovation.

Nadeem Ali-Khan from the British Consulate General in Chicago asks a question during an IndEx panel.

Lester Knight, founding partner and co-chair of RoundTable Healthcare Partners (L), and Norbert Riedel, president & CEO of Naurex Inc., talk before the AdvaMed CEO Unplugged panel.

Andrew Cittadine of Diagnostic Photonics answers a question during the AdvaMed CEO Unplugged panel, which also included John J. Greisch, Hill-Rom (R) and Thomas Kapfer, Beaver-Visitec International (L).

The opportunity to network with IndEx attendees is always a highlight of the annual conference in Chicago.

iBIO held its 2014 IndEx at the UIC Forum, located just west of the Chicago Loop.

Cristal Thomas, deputy governor of Illinois, John Conrad from iBIO, Nancy Sullivan from IllinoisVentures and John Pletz from *Crain's Chicago Business* (L to R).

Jeff Malehorn from World Business Chicago gave a presentation on Chicago's global status during the lunch panel covering international issues.

John Pletz from *Crain's Chicago Business* (far left) moderates the closing panel, Chicago's Life Sciences Startup Ecosystem, with Illinois Department of Commerce and Economic Opportunity (DCEO) Director Adam Pollet, Norbert Riedel from Naurex, Nancy Sullivan from IllinoisVENTURES, Michael Liang from Baird, and Tim Walbert from Horizon Pharma (L to R).

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