

West Michigan Science & Technology Initiative



PROOF^{OF} CONCEPT

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COVER PHOTO CREDIT: JAMES RESAU, PH.D., VAN ANDEL INSTITUTE, GRAND RAPIDS, MICHIGAN
2007 NIKON SMALL WORLD IMAGE OF DISTINCTION AWARD, HUMAN BREAST CARCINOMA (40X)
For more information about Dr. Resau's work with the Laboratory of Microarray Technology at the Van Andel Institute, visit www.vai.org.



Rich Cook
Venture Center Director, West Michigan
Science & Technology Initiative

Greetings!

Welcome to the fifth edition of Proof of Concept, the biannual newsletter of the West Michigan Science & Technology Initiative. I am very happy to have this opportunity to share with you the great work and wonderful ideas happening through our members, clients and allied organizations.

This edition features an innovative new company that may change the way Michigan school children interact with high-technology science topics such as DNA replication and identification. This new company, headquartered in our Venture Center, could play a very important role in helping to expose our youth to new scientific frontiers and ignite a passion for science and mathematics that may one day improve the lives of others in Michigan. For more information, see the New Company profile on Syzygy Biotech Solutions on page 6.

Also featured, Kalamazoo-based RealBio Technology, which has developed a new way to grow and culture cell and tissue samples for scientific study. The new system features a bioreactor that makes lab-grown cells develop in a similar fashion to how they act in the human body. This will allow for some exciting new research that could speed the discovery and development process for the drug industry. Turn to page 8 for more.

If advanced materials science is your thing, check out our feature on Barrier Technology—the Venture Center resident that is making big waves with its new lightweight and super-strong polymer. Details are on page 11.

Our clients also continue to grow. Kent Intermediate School District has expanded the Health Sciences Early College Academy for area high school students (page 18); ClinXus has added new members; and a new medical device company—Lithos Surgical Innovations—has been formed (page 22).

Plus, Fleetwood Group Electronics has joined the WMMDC and has two new products in development, and former Venture Center resident, Applied Security, Inc., continues to grow and expand. Check out the details on pages 15 and 24.

venture center director's note

There is much more inside, from how life sciences can be applied in Michigan's "four corridors" of economic development to insight and thoughts from our guest columnists, Mark Leahey, from the national Medical Device Manufacturers Association (MDMA), and Stephen Rapundalo of MichBio.

Our region continues to be a source of tremendous life science and technological activity, and we at the Initiative continue to be excited and energized by the regional collaboration and commercialization activity here in West Michigan.

Thank you for your interest, and please share your copy of this issue with colleagues and business partners once you are finished!

Best regards,

west michigan entrepreneur

Ryan Phillips

Ryan Phillips was a kid in a candy store. The only difference is that he ran the place. He had inventory, plenty of customers and a storefront inside his parent's Charlotte, Mich.-based business. He was 9 years old.

"I'm a serial entrepreneur," laughs Phillips, who is now president and owner of Magnum Engineering, LLC in Grand Rapids. "I've always been looking for opportunities, and never really wanted to work for anyone but myself for as long as I can remember."

According to Phillips, people are either entrepreneurs, or they aren't.

"It takes a certain tolerance of risk," he explains. "You can't become too personally invested in your product or idea—you'll get good advice along the way that may change your idea, or discard it altogether based on market and economic realities. But that risk is also what provides the payoff when you do succeed."

Phillips' current company appears to be a sure thing. Magnum Engineering has doubled its sales volume for three straight years since it was founded in 2007, and 2010 is on pace to double growth once again—despite a down economy.

"Adapting to changing realities has helped us to survive and even thrive," said Phillips. "I started Magnum Engineering to design, build and sell acoustic loudspeakers. But the market changed and a new opportunity came along."

That opportunity turned out to be the Evolution Scoring System (www.evolutionscoring.com)—a conversion system that allows bowling centers to upgrade CRT-based proprietary scoring system displays with inexpensive off-the-shelf LCD or projection monitor systems. Today, that system outsells all other competitors combined by a 2-to-1 margin.

The success of the Evolution Scoring System enabled Magnum Engineering to expand and modify its services and take advantage of yet another opportunity that Phillips identified.

"Today, Magnum handles product development for individuals and companies to help them drive their product to market quickly and efficiently," said Phillips. "We provide the engineering expertise while the inventor manages the sales and marketing."

The arrangement has been productive, considering a full 90 percent of Magnum's work is product development. They've developed a pathway that helps inventors generate funding and manufacture short runs of products at reduced pricing that is similar to mass quantity manufacturing. This approach enables young companies to manage product inventory, finances and capacity, but still compete with larger players in the market.

The growth of Magnum has also provided a pathway for Phillips to develop a product he and his engineering classmates started working on while he was an

Continued on page 4.



PHOTO CREDIT: CHUCK HEINEY PHOTOGRAPHY, © 2010

Ryan Phillips Continued.

undergraduate student at Grand Valley State University (GVSU). The University secured the product's patent.

Magnum licenses the technology of its torque measurement system for bicycles. This training tool helps riders monitor and improve efficiency and power output as they pedal by quantifying torque throughout the entire cycle stroke. The increased push-pull efficiency smooths the power and reduces fatigue for professional riders as well as competitive amateurs.

"The benefit of this product is that it is lightweight, portable and does not have any wires," said Phillips. "This product replaces the crank arms so it can be used on the road in actual training circumstances, helping riders maximize their performance without needing to ride a stationary bike."

Why did an innovative entrepreneur start and continue his company in Grand Rapids? According to Phillips, the quality of life and general atmosphere of the city has a lot to offer.

"I really didn't want to leave," he said. "We have access to employees and advice through the area's universities and the community has a strong history of local reinvestment—you can see by the construction along the skyline that there is a lot going on here." •

The West Michigan Science & Technology Initiative can help with ideas or projects in the life sciences and high-technology industries. Contact our offices today to learn more or to schedule an appointment.



PHOTO CREDIT: DAVID JACKSON

Understanding the Health Care Supply Chain

industry insight



Mike Zamora
Principal
Keystone Product Development

As the health care industry supply chain evolves, health care providers are seeking significant cost savings and revenue generating opportunities for themselves and their customers. Keystone Product Development Principal Mike Zamora shares insights on how to leverage the changing supply chain environment to drive results.

Q: To best understand what's happening today, it might be helpful to learn how we got here. How has the supply chain changed?

A: Hospitals began to pull purchasing resources together to enhance buying power. Today, Group Policy Organizations (GPO) and Integrated Delivery Networks are not only providing buying power

programs, they are diversifying product and service portfolios and are serving as the gatekeepers for vendors and service providers.

In fact, the average hospital in the United States has just two and a half GPO contracts—meaning that if your company doesn't have a contract to supply a GPO, you face an uphill battle. The reason for the small number of contracts is that hospitals are working to minimize the number of vendors they deal with, so they can maximize purchase power while lowering costs without negatively affecting clinical outcomes.

With 5,500 hospitals in the U.S. market, most organizations that do land a contract and implement a marketing plan have greater opportunity for sales revenue through products or services to member hospitals.

Q: As hospitals and health systems look to integrate and more closely align systems to meet provider needs, what are the opportunities for vendors or service providers?

A: First, we need to understand how the supply chain works. High-quality clinical outcomes remain the priority for health care systems and their patients. If your product or service can be directly tied to improved patient outcomes, you should have fewer barriers.

For those whose products or services are not tied to clinical outcomes, focus on cost reduction and efficiency

improvements, or address critical quality improvements and how they can be tied to cost savings or improved performance in how care is delivered.

Also, new technology continues to entice health care providers to evaluate current needs and determine if there is a better way to achieve outcomes or reduce cost.

Q: How can companies strategically prepare to meet the needs of hospitals and health providers leveraging technology and tools to streamline spending?

A: The supply chain is unique. A typical supply chain partner has 2,000 or more vendors. Companies looking to partner with health providers must understand the marketplace they are targeting. Who is the competition and who is the clinical decision maker? What are the clinical needs of the facility? What are the current and future trends of the market? What are the acceptable price points? Can your manufacturing capacities and capabilities meet fulfillment and regulatory requirements? What are the sales channels? What makes your product unique? Is the marketing plan funded and well defined? Launching new products is not a quick process!

Answering these and other questions will help you develop a strategy to meet the needs of health providers and suppliers, and drive demand for your product and the growth of your company.

Syzygy Biotech Solutions LLC

Polymerase Chain Reaction (PCR) is a common and indispensable technique used to amplify a single or a few copies of a piece of DNA, generating thousands to millions of copies of a particular DNA sequence for use in medical and biological research labs.

Syzygy Biotech Solutions LLC produces biological agents for PCR applications. Through economies of small scale, local advantages and proprietary production methods, Syzygy is able to sell DNA polymerase for a fraction of the price charged by industry leaders. As a result, it's poised to translate that cost savings into a meaningful advantage for Michigan.

"In research, medical diagnostics and especially education, cost has long been a barrier to access and progress," said Barry Nowak, COO at Syzygy. "Our goal is to help support a lasting advantage for Michigan by providing biological reagents at a very low cost to researchers, diagnostic laboratories, universities, and local elementary and secondary schools."

Founded in 2010 by five native Michiganders, Syzygy—committed to being the world's most effective producer of heat-stable DNA polymerase—is headquartered in the labs of the Grand Rapids-based West Michigan Science & Technology Initiative. Syzygy credits the Initiative with making its dedication to discovery a reality.

"We wouldn't have a viable product without the resources, equipment and support we receive from the Initiative," said Nowak. "We're eager to pay that assistance forward by making life science education affordable and giving Michigan students an advantage in the global market through programs and equipment that allow every student a 'hands-on' experience as early as elementary school."

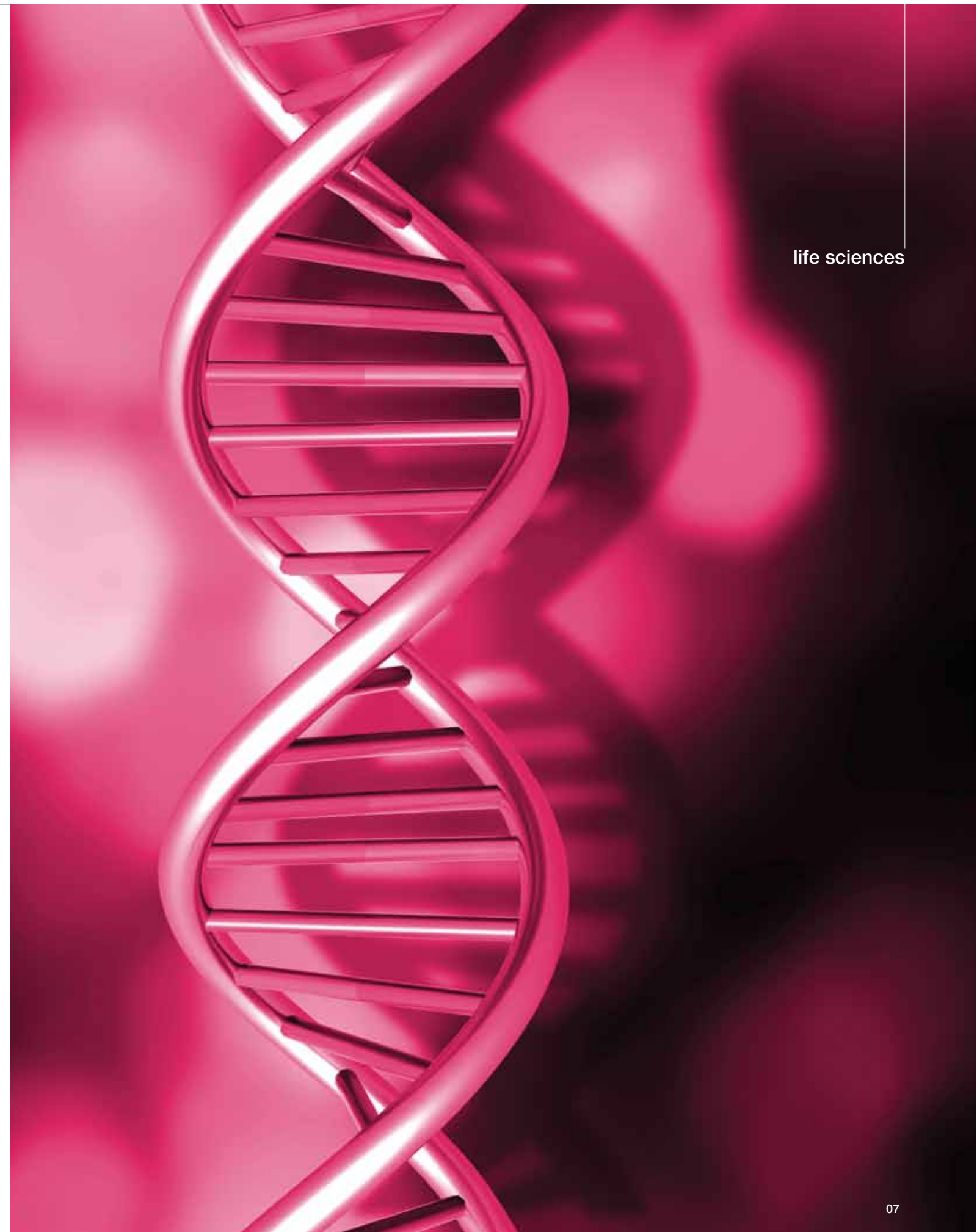
Currently, equipment is set at price points that make it difficult for most schools to offer individual students an

educational experience with related technology. Syzygy has a provisional patent pending on a low-cost apparatus suitable for educational use. For the cost of a textbook, the apparatus will make it possible for every student to have access to equipment and educational materials that enable them to understand the applications of PCR in the fields of agriculture, forensics, anthropology, biomedicines and more.

Additionally, Syzygy has discovered a new species of *Thermus* bacterium capable of producing novel polymerase. They plan to launch in 2011 once its properties have been characterized. It is designed to allow researchers to do more in less time with better results. Syzygy anticipates that in three to five years, its "full catalog" of products will be ready globally.

"There is an opportunity in the production of DNA polymerase," said Nowak. "And it's an opportunity that can help support a local advantage in life science research, medical diagnostics and education." •

Syzygy is led by its five founders: William Ziehler, Ph.D., Brent Nowak, Ph.D., Christopher Eusebi, Barry Nowak and Blane Hansknecht. Together, they are working to discover, invent and produce a portfolio of intellectual property and products that will benefit Michigan today and for future generations. For more information on Syzygy, visit www.syzygybiotech.com.



technology

Revolutionary Research Tool Mimics Natural Micro-Environments in a Laboratory

The world of laboratory research and pharmaceutical testing might never be the same, thanks to Kalamazoo-based life sciences startup RealBio™ Technology, Inc.

For decades, researchers and pharmaceutical testing scientists could either grow cell cultures in a Petri dish or use animal subjects to generate relevant data. Petri dish-grown (in vitro) cells don't develop the same as tissue in the human body. Tissue grown in animal subjects (in vivo) has added costs and is not representative of the human body.

Part of the expense and high rate of failure in pharmaceutical small molecule development is due to the challenge of finding good in vitro models of human tissue that exhibit key characteristics of normal in vivo tissue organization and function. Researchers are in a race to identify the compounds that will fail in the development cycle, so critical resources can be channeled to the most promising product candidates.

The RealBio D4™ Culture System allows scientists to cultivate tissues and cells in an in vitro environment while mimicking the natural composition, configuration and function of human tissues. In the drug development

setting, the system enables researchers to observe and detect adverse or toxic effects of drug compounds at very early stages in the development process—helping speed the identification and elimination of drug candidates with unacceptable safety profiles before they advance to human trials. Other scientists may use the system to mimic diseased or healthy tissue for their research.

“The secret is in the design of the culture system, which combines an open, three-dimensional tissue scaffold with the ability to independently control nutrient flow and gas exchange,” said Paul Neeb, president and CEO at RealBio™ Technology. “The result is a system that promotes growth and maintenance of tissues that are more like the tissues grown in the human body.”

The new, patented technology opens doors for researchers and scientists to approach how they use cell cultures. Because the sources of gas and nutrients are separated (vs. infused in the Petri dish medium), researchers can slow down delivery of nutrients or gases, replicating conditions in diseased human tissue. Researchers could also isolate tissue in the D4 Culture System to evaluate compounds and variables that can't be ethically tested on humans or in animal models.

“This system provides researchers with flexibility,” said Neeb. “If research involves subsets of individuals with genetic or environmentally specific characteristics, those conditions can be replicated in the lab setting to quickly and efficiently identify safety profiles that should closely resemble real-life effects.”

The design ensures that cells can be cultured with an ideal mixture to promote healthy, consistent growth, improving the culture quality.

“Our system allows researchers to remove dying or dead cells, which can help the culture remain viable for an extended period of time. There is no other technology available today that can do that,” Neeb added.

Because accurate comparisons are a critical step in the scientific method, the RealBio D4™ Culture System could become an important tool to reduce the donor-to-donor variability often found in primary cell cultures grown

for research. The system is closed, so the possibility of contamination is greatly reduced and introduction of foreign compounds is the result of study protocols, instead of natural processes in animal subjects or contamination. Reducing variability helps researchers make decisions about the effects on human health with greater confidence.

Currently, the RealBio D4™ Culture System is being developed using bone marrow cells; however, the company is working to develop partnerships that would enable the system to be used in the culture of many different types of primary tissue. The most promising new application may be an in vitro cancer tumor model.

Grand Rapids-based MedBio Inc., also a member of the Initiative, manufactures for RealBio. •

For more information, please visit www.realbiotechnology.com.



RM+D

Reagan Marketing + Design (RM+D) is a Virtual Company ally providing full-service strategic marketing to the Initiative and its clients.

As West Michigan's life science and health care industries continue to grow, strategic marketing helps startups and established companies achieve results.

"We understand the unique challenges that the life sciences and health care industries face—from both a business-to-business and consumer perspective," says Mary Reagan Shapton, owner and founder of RM+D.

RM+D understands that sometimes a client needs help with a specific project and other times may need RM+D to serve as an extension of the organization, to be its virtual marketing department.

"We partner with companies to first listen to their needs, then formulate a strategic plan," says Reagan Shapton. "But we hardly ever stop there—most clients count on us for flawless execution with attention to detail."

With a client list that encompasses health care, life sciences, retail and

manufacturing, RM+D brings together a laundry list of in-house services to deliver results, drawing upon a team of nearly 30 professionals.

"Based on the project, we leverage the talents of our strategists, project managers, coordinators, designers and writers," says Reagan Shapton. "I would describe our approach as 'intrepid.' We problem-solve and deliver solutions."

RM+D tackles traditional tactics such as branding, identity, print, motion graphics, events, product launches, meetings and trade shows. Beyond traditional tactics, the team has unique expertise in opening new facilities, developing educational materials for internal audiences, guerilla marketing, social media and archiving.

"It's important that individuals find the right fit with a marketing firm," advises Reagan Shapton. "Budgets, personalities, timelines and experience should all be taken into consideration.

"Companies today have to be focused on creativity as it relates to productivity and results to the bottom line—there is a real need for market differentiation through a cohesiveness of carefully developed strategy and purposeful design," adds Reagan Shapton.

Entrepreneurs and established companies that will survive and thrive in this economy need results-driven marketing now more than ever.

"Like the Initiative, we are a resource," says Reagan Shapton.

RM+D has served clients from its West Michigan location since 1991. For more information, check them out on the Web at reaganmarketing.com or at facebook.com/reaganmarketing.

For more information about Virtual Company benefits, please call the Initiative at 616.331.5840.

Barrier Technologies

Need a tough, sturdy material for a competition-racing sailboat? Add Kevlar to reinforce the hull. Want a stronger, lighter material for a new passenger airplane to save fuel and increase payload capacity? Add carbon fiber to the fuselage.

Researchers are continually developing new materials to meet demands. The progression of engineering, architecture and aerospace design relies on pushing the limits of what is possible with available materials.

The limits are being tested at Grand Rapids, Mich.-based Barrier Technology. Barrier is developing a composite in wafer-thin, extremely strong sheets that can be used in a broad range of applications from aerospace to health care. This new material provides nearly twice the strength of similar materials by weight. It opens the door for new designs that can withstand greater heat and won't conduct electricity or degrade or decompose when exposed to chemicals or UV. This breakthrough could change the way many people look at designs for airplanes, buildings, bridges, and medical devices and equipment.

"We are providing an opportunity for engineers, designers and others to re-imagine what might be possible," said Stephen Looman, Ph.D., project manager at Barrier Technology. "This product could unleash the creativity and ingenuity of the design and engineering communities."

For two years, researchers at Barrier Technology worked to combine very strong fibers with a binding agent in a way that would result in a "technical paper"—the wafer-thin sheet of super-strong fibers—that can be molded into many different products.

"We were developing the product with very little progress," said Robert Smart, Ph.D., founder and president of Barrier Technology. "Then one day, Stephen modified the process we were using to combine the binder and fiber in a way that caused the fibers to flow, which allowed us to make the technical paper that is the basis for this new product."

The rest is research and development history.

Barrier is now tweaking the material and process to maximize efficiency and strength, and is seeking manufacturing partners. Even though there are a lot of positive attributes that make the material attractive for use, it's unlikely you'll see the product on store shelves anytime soon.

"Just like carbon fiber use was very limited when it was first developed, our material is also likely to be limited to use by high-tech and government-level applications—at least for the near-term," said Smart.

Barrier Technologies was located in the West Michigan Science & Technology Initiative incubator, and recently graduated from the facility. •

For more information, please contact the West Michigan Science & Technology Initiative (www.wmsti.org).

west michigan medical device consortium member profile

Creative Foam Corporation

Forty years ago, native Michigander Peter Swallow started a company specializing in a new material developed with Dow Chemical. Today, Swallow is vice chair of Creative Foam Corporation, boasting 600 employees, seven manufacturing plants and an engineering facility across four states. Sales this year will approach \$100 million but it's the next 40 years that may prove to be the most exciting.

The company, which defines itself as having materials development "as part of its DNA," works with more than 300 kinds of materials and an international base of suppliers and clients in the development, and production of thousands of products. And if this year's achievement of an anticipated 20 to 25 percent growth rate wasn't enough, Fenton, Mich.-headquartered Creative Foam is looking at a projected 50 percent growth rate over the next five years—primarily the result of its rapidly expanding medical systems division.

"As with so many Michigan-based manufacturing operations, Creative Foam began as a supplier to the automotive industry," said Wayne Blessing, president of Creative Foam. "Over the last several years, we've been working to strategically position ourselves as a

materials solutions provider across a broad spectrum of diverse industries, including the booming medical field, and more recently renewable energy. Our materials innovation, engineering and design expertise have applications nearly everywhere, and we're excited to see where it takes us."

Creative Foam diversified into the medical industry more than 15 years ago. Most materials applications are used for increased patient comfort. Products include the specialized padding on the tables of computed tomography (CT) scanners and magnetic resonance imaging (MRI) equipment. About 18 months ago, Creative Foam joined the West Michigan Medical Device Consortium (WMMDC).

"The networking opportunities have been phenomenal," said Blessing. "There are so many good, innovative, Michigan-based companies we've connected with, and now are partnered with as both customers and suppliers to one another. The expansion opportunities for all of us are really exciting."

Blessing and the Creative Foam team also are excited by their growing industry recognition. In 2008,



Corp! Magazine named Creative Foam a "Best of Michigan Business" and this year the publication named the company a "Science and Technology Leader in Michigan."

"Creative Foam strives to be best-in-class in everything that we do," said Blessing. "It is extremely gratifying to have the hard work, dedication and commitment of our team recognized and rewarded."

Unlike the majority of its competitors, Creative Foam is not merely a "part-to-print" foam dye-cutting operation. Rather, companies bring product ideas or challenges to Creative Foam. The team works with customers to develop unique material engineering and design solutions. And don't let the name fool you. Creative Foam works with a huge variety of materials, including non-wovens, cloth, lamination, rigid materials, thermoplastics and many more. "We're definitely not just a foam company," says Blessing.

Creative Foam continues to diversify its operations and multi-industry expertise, while capitalizing on new opportunities in the alternative energy industry, supplying customizable materials for the inner core of wind turbine blades to a global network of customers.

"In addition to the medical arena, renewable energy definitely is contributing heavily to our current corporate growth," said Blessing. "And just as we have for the last 40 years, we're finding ways to be innovative and solutions-oriented in this new industry. After all, 'creative' is what we do best." •

For more on Creative Foam, visit www.creativefoam.com.



west michigan medical device consortium member profile

Fleetwood Group Electronics

Fleetwood Group Electronics recently joined the West Michigan Medical Device Consortium in advance of its entry into the medical device marketplace. The Holland, Mich.-based company brings more than 35 years of expertise in radio frequency (RF) systems and product development and manufacturing expertise that includes 12 U.S. patents and 14 patent applications in the RF/wireless electronics category.

Fleetwood Electronics pioneered wireless audience response and polling systems, and continues to dominate that market today, improving how systems operate within the changing electronic environments found in K-12 schools, on college campuses, convention centers, hotels and corporate conference centers around the world. In fact, the company developed a proprietary communications protocol that enables its devices to communicate in the presence of increased RF interference. That improvement has helped the company's product remain reliable

and effective without interfering with other wireless systems located in the same facility—something that ensures functionality and delivers a better user experience.

“The company has the depth of product development and manufacturing expertise that make it a natural fit for medical device development,” said Don Beery, director of new business development at Fleetwood Group Electronics. “We have a proven, quality-oriented manufacturing process that is highly automated and utilizes the latest in optical inspection systems technology to ensure quality control.”

Fleetwood is currently involved in the production and design of two products intended for use in health care. The first is in co-development with Versus Technology, Inc. (www.versustech.com), another Michigan-based technology company focused for over 20 years on health care applications. Versus delivers

context-aware real-time locating systems (RTLS) to health care, enabling precise communication of location and automated patient flow, bed management and asset tracking. Fleetwood and Versus combined their respective talents to enhance the RTLS hardware product offering.

Fleetwood, an employee-owned company, teamed with Versus on the product design (firmware and hardware) and was responsible for the mechanical development. Fleetwood will also manufacture the device, with production beginning in October 2010. Additional details about this product and specific applications will be announced in the fourth quarter of 2010.

The second product currently in development is a handheld Electronic Medical Record (EMR) reader. The portable device features a color LCD touch-screen display and can

Continued on page 16.

Fleetwood Group Continued.

decode data from multiple smart card formats. The device is purpose-built for reading EMR smartcards and does not run additional applications, so the cost is lower and the device is very functional. The reader is capable of two levels of functionality—it can read data and display it to the LCD screen, or caregivers can enter additional information that will be encoded and stored on the EMR for use by other medical professionals at a later date.

“Fleetwood Electronics has a tradition of working as a complete multi-disciplinary design team to move projects from concept through

manufacturing,” said Beery. “This fully integrated approach assures that all facets of the process clearly anticipate the capabilities and trade-offs in a timely fashion. The results are faster product development, optimized manufacturing efficiency, and competitive overall costs. We believe these are some of the qualities for Fleetwood.”

Fleetwood Group was founded in 1955 and has a long and stable history. Recently, the company has grown more aggressively, recording a nearly 50 percent growth over the past five years. In 2006, Fleetwood was named the number one

employee-owned company in the U.S.A. More recently, the company was named a finalist for The Wall Street Journal’s Top Small Workplaces of 2009 Award. Also in 2009, Business Review West Michigan named the company one of the Most-Philanthropic Small Businesses in West Michigan, recognizing the company for significant donations last year to 501(c)(3) organizations. •

For more information on Fleetwood Group Electronics, visit www.fleetwood-electronics.com.

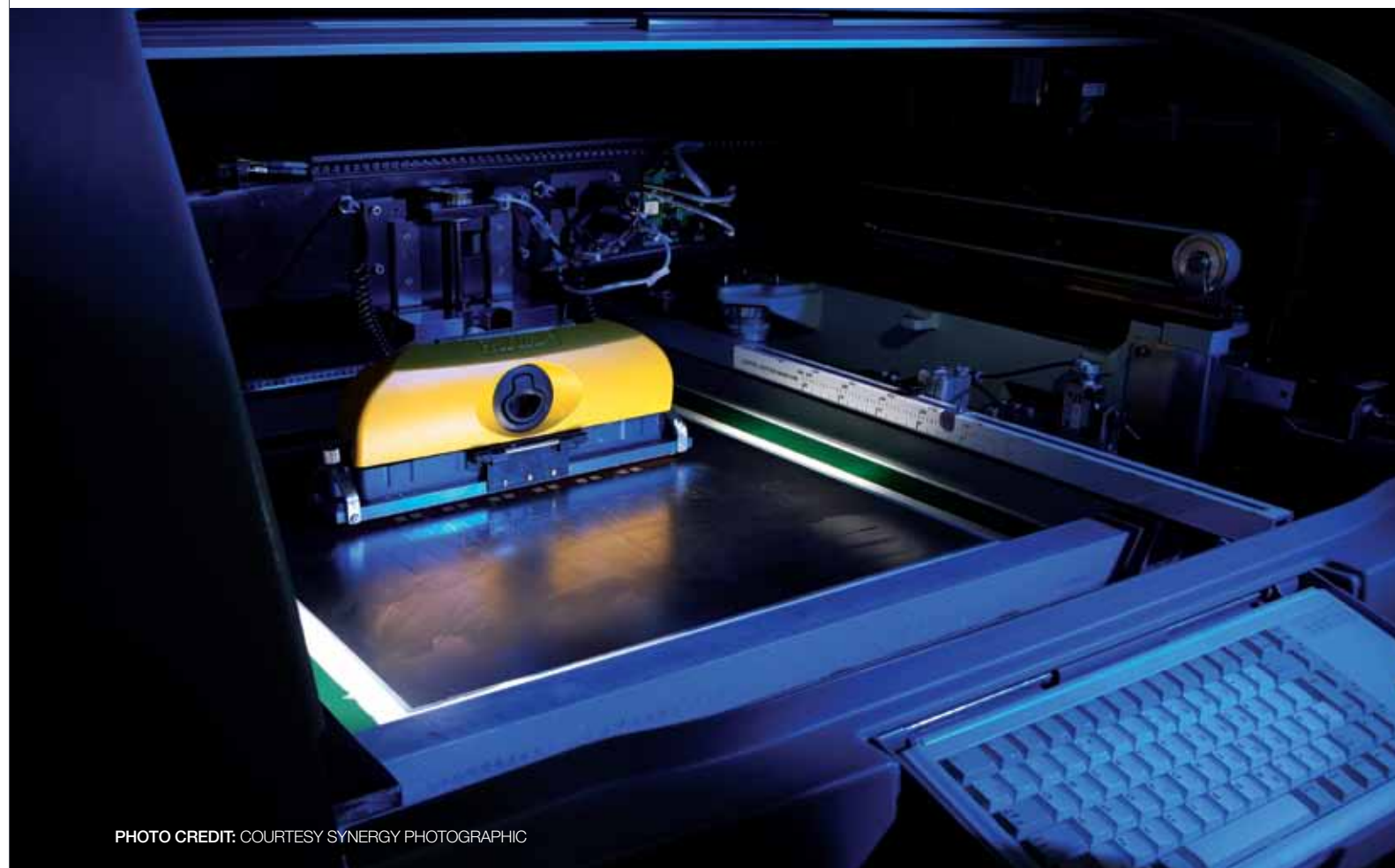


PHOTO CREDIT: COURTESY SYNERGY PHOTOGRAPHIC

west michigan medical device consortium member profile

Rose Technologies

For nearly 12 years, Grand Rapids, Mich.-based Rose Technologies has been designing, manufacturing and assembling components for finished medical devices. Today, efforts are focused on several core competencies to give this specialized company an edge in the medical device manufacturing world.

Rose works with fellow West Michigan Medical Device Consortium member Avalon Laboratories (www.avalonlabs.com) to form smooth plastic tips for its Elite™ brand of catheters and cannulae that make it easier for health care providers to place these devices in the human body.

In fact, forming smooth plastic tips for dilators and catheters is one of the company’s most important competencies, and an important area of growth.

Rose also developed a technique to manufacture wire-reinforced tubing for use in cannulae and catheters.

The wire reinforcement prevents kinking or collapse of the tube during flexing and bending. Rose manufactures wire-reinforced tubing from silicone or thermoplastic, depending on the needs of its customers.

Additionally, Rose has special expertise in dip-molded products, including customized designs. The custom-built dipping machine and experienced staff together offer a wide range of capabilities—from extremely thin wall requirements to smooth or textured surfaces.

“We are a company that is dedicated to our core values and work hard to earn the trust and respect of our business partners,” said Todd Grimm, president of Rose Technologies. “By being tenacious and innovative, we’ve managed to find a strong niche in the cardiovascular and bariatric surgical markets, of which we are very proud.”

But Rose isn’t just about established products and markets. The firm has targeted medical device development

clusters across the country, including California, where Rose works with developing companies to provide contract manufacturing and design and development services to venture capital groups seeking a high quality development and manufacturing partner for new and innovative products.

Rose provides partners with short-term pilot runs or long-term production in one of its class 10,000 clean rooms, and works with partners to design, build and automate production.

“We take pride in our ability to help our customers from start to finish,” said Grimm. “No matter where they are in the product development cycle, from prototype to product and process validation, we can provide assistance.” •

For more information about Rose Technologies and its services, please visit www.rose-technologies.com.

Education: The Missing Link

In 2002, the West Michigan region was buzzing with talk of a new, diversified economy anchored by the health science industry. Plans were developing for a “Medical Mile” on Michigan Street, old-line manufacturing companies were shifting to medical device manufacturing and other life-science related developments were in full swing. The activity held the promise of health science-related jobs and prosperity for the region.

At the same time, the Kent Intermediate School District (KISD) was working on an idea to help bridge the gap between secondary and post-secondary educational preparedness for Kent County high school students interested in health sciences careers.

Fast forward eight years, and qualified area high school students can attend KISD’s new Health Sciences Early College Academy (HSECA). Students in the program receive up to 11 tuition-free college credits. They have access to professional, hands-on facilities and equipment, practicing medical professionals and laboratory researchers, and focused instruction on three health sciences pathways.

“We developed the Early College Academy to provide students interested in health sciences an opportunity to get a firsthand look at what a career in the industry might look like,” said Jarrad Grandy, assistant director of Regional CTE Programs at KISD. “Our program attracts some of the region’s best and brightest students who have proven that they can handle the academic and hands-on rigor.”

Students with a strong interest in a health science career qualify for the program with a minimum GPA of 3.0, and completion of math and science prerequisites. Students are strongly encouraged to be also enrolled in chemistry and physiology/anatomy coursework.

The HSECA program offers three pathways for exploration at three Grand Rapids-area campuses: Therapeutic Services pathway for Grand Rapids Community College (GRCC) course credit at GRCC; Diagnostic Services pathway for up to 11 college credits at GRCC and Ferris

State University; or Biomedical Technology pathway for six college credits at Grand Valley State University.

HSECA students explore genetics, phlebotomy, ultrasound, and EKGs, among other health science technologies, and build a solid foundation in core subjects including anatomy and physiology, medical terminology, safety and infection control, and medical mathematics. The curriculum is also designed to help students hone their communication and employability skills.

To develop the program and curriculum, KISD turned to an advisory board of industry and educational professionals—including some of the region’s top physicians—and input from KISD’s top educational consultants. Rigorous oversight and guidance ensure that students receive instruction using the latest in outcome-based and proven techniques. Instructors have plenty of hands-on, real-world industry experience.

“We really worked to provide an experience that closely resembles the post-secondary environment,” said Duane Kiley, regional career technical education supervisor at KISD. “Students are exposed to college students as well as working professionals, which we hope will help translate into strong rates of college enrollment and completion for these students after they graduate from high school.”

Today, the “Medical Mile” build-out is nearly complete, hundreds of health sciences jobs have been created, and area universities and institutions are attracting leading scientific researchers and entrepreneurs. Plus, area students have an educational pathway that can take them from high school through college to jobs in the health science industry, right here in West Michigan. •

The HSECA program is available to all juniors and seniors in the KISD service area. For more information, please visit: www.tinyurl.com/kisdhseca or call 616.365.2253.



PHOTO CREDIT: CHUCK HEINEY PHOTOGRAPHY, © 2009



A Venture with Rich

Q&A WITH RICH COOK, VENTURE CENTER DIRECTOR

The Initiative answers questions about how inventors, entrepreneurs and small business owners can access capital to support the growth and development of their ideas and products. In our last issue, we asked Rich about the ways in which Michigan provides capital support for entrepreneurs. This issue investigates how the state categorizes investment opportunities, and how life science entrepreneurs can work with the Initiative to rethink how their business or idea may fit into these categories to access capital for growth.

Q: Michigan has identified four “corridors” of investment. What are they?

A: The four investment corridors are broadly defined as life sciences, alternative energy, homeland security and advanced materials. Often, entrepreneurs do not even take time to seek capital from the state because they think their business or idea doesn’t fit within the investment categories. Life science technology and applications are pervasive throughout our culture and many developments do fall into these categories. The Initiative can work with you to carefully analyze your situation with the state guidelines to help you access funds.

Q: How do life sciences companies qualify for “Advanced Materials” funding?

A: One example in West Michigan is a company called RealBio™ Technology, Inc. RealBio has licensed a specialized material from the U.S. government that is

particularly effective as a media to continuously grow cells or cellular structures. Rather than using a batch method like a petri dish, they have developed a continuous process by inventing a unique life science/medical device made by MedBio, Inc. in Grand Rapids. Be sure to read more about this technology in this edition’s “Emerging Technology” feature (page 8).

All sorts of materials technologies are being used in support of life science and health science endeavors. Here are a few examples of how advanced this has become:

- Specialized materials that make substrates for burn patients so they can grow their own skin for grafts.
- Biodegradable and resorbable glasses and ceramics for bone repair allowing bone regrowth.
- Precise delivery of pharmaceuticals using nanomaterials and nanotechnologies.

Q: What is considered under “Alternative Energy?”

A: Many fuels are now derived using living materials (plants or algae). As the energy balance (energy generated less energy used) is very small for most of these methods, research teams are using genetic engineering methods to improve the ability to use cellulose (the main component of wood or switch grass for example). Only with modern life science techniques do we have a hope of being successful.

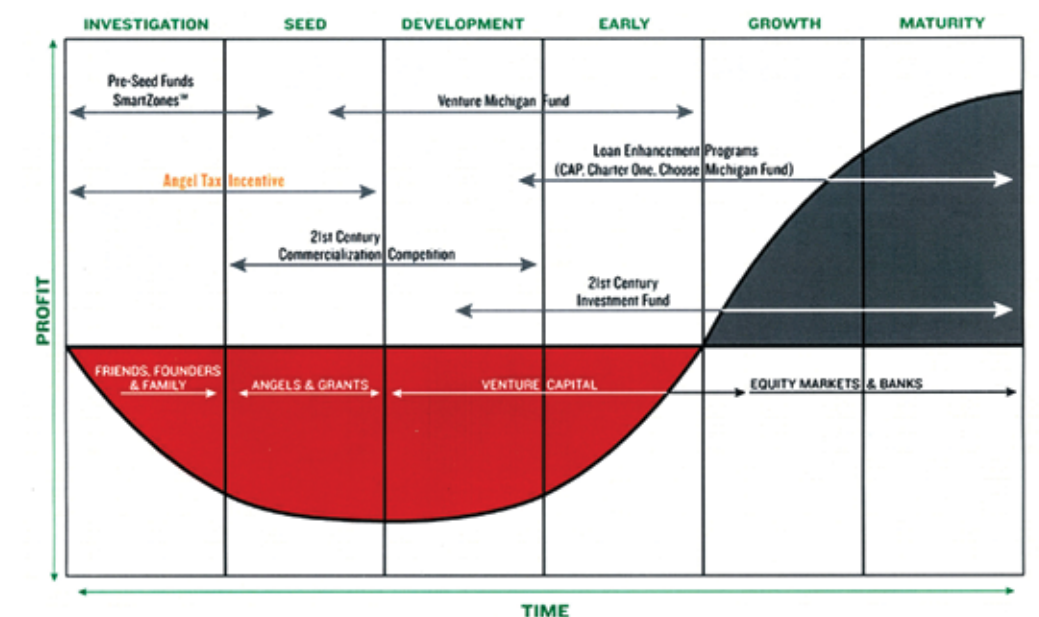
Closer to home, take a look at what a Calvin College Senior Project accomplished in 2010. The BioVolt mission is “to create a means of electricity production that is both portable and sustainable.” A small device, a microbial fuel cell (MFC), takes in the fuel and creates clean water and electricity. Check out the 2009-2010 BioVolt team at: https://knightvision.calvin.edu/bbcswebdav/orgs/ENGR/senior-projects/2009_10/team01/web/index.html.

Q: How about “Homeland Security?”

A: Anyone with a number of doctors has had the experience of manually filling out personal information and medical histories for every doctor and perhaps every medical laboratory visit. This is a result of the Health Insurance Portability and Accountability Act (HIPAA), meant to protect our personal data. But if, like me, you feel less secure with all of this paperwork and scanned copies of your insurance card and your driver’s license at multiple locations, you can appreciate the need for a single card that would transmit all of that data quickly and securely to the professionals who help you. One of our business incubator graduates in the Initiative’s Venture Center, Applied Security Inc., is working to make this a reality. The German parent company is the leading company providing the security measures for informational ID cards used in Germany. We could do it here in the USA! <http://www.apsec.us/index.html> •

There are various resources to assist with the expenses of developing a new business. Most resources are located at either the Michigan Economic Development Corporation (www.michiganadvantage.org) or the Michigan Small Business & Technology Development Center (www.misbtcd.org). Resources are available at different stages of business progression. In the chart, we have matched the best resources for the stage that your business currently inhabits. A short overview is provided to briefly explain what the service encompasses and a path for further review. The stages included within this toolbox include: Investigation, Seed, Development, Early, Growth and Maturity stages.

Stages of Business Progression



Generated from www.michiganadvantage.org

Minding Our Own Businesses

Keystone Solutions Group Forms Partnership for New Medical Device Company, Lithos Surgical Innovations

WMMDC member, Keystone Solutions Group, has announced the formation of a new medical device company, Lithos Surgical Innovations, which will develop and manufacture products for national distribution. Headquartered in Kalamazoo, Mich., Lithos Surgical Innovations is the result of a partnership between Keystone Solutions Group and inventor and medical device entrepreneur, Adam Keilen. After partnering with Keilen on numerous products in the past, Keystone Solutions Group formalized the relationship in order to not only develop and manufacture new products, but also to establish a sales organization to promote them.

The new company is bringing new job opportunities as well. Lithos Surgical Innovations is anticipating a national sales force of 50 employees, of which nearly half have already been hired. In addition, product development and manufacturing requirements will add several more positions in Kalamazoo and Grand Rapids.

Keystone Solutions Group provides development, supply chain management and contract manufacturing for the medical device, automotive, aerospace and specialty products industries. For more on Keystone, visit www.keystone-pd.com.

MarketLab Introduces New Products

MarketLab has two new products. The PathOS Pathology Organizing System—developed in cooperation with the

University of Michigan Technology Transfer Group—provides a better and safer way to transport pathology materials from the lab to the pathologist's office, or elsewhere, and makes specimen retrieval easier than ever. A molded plastic tray separates slides from specimens so lab workers can transport individual slides, blocks and paperwork together. Trays fit together so workers can more efficiently move multiple samples from one part of the lab to another. Please visit <http://www.path-os.com/> for more information.

A new and innovative point-of-care cart system showcases the expertise and superior quality of West Michigan design and manufacturing. The Medscape Agility cart features a stable, five-point stance with a functionally and ergonomically correct platform for improved mobility and efficiency in the hospital. The cart is made of composite and recycled materials that are easily cleaned and sterilized. A full line of accessories easily mounts to the unit, improving productivity, safety and aesthetics.

For more information, visit www.marketlabinc.com.

WMMDC Adds New Member

KI-Med, a contract medical device manufacturer specializing in prototyping and development services as well as process documentation recently joined the West Michigan Medical Device Consortium. They are located in Holland, Mich. Visit wmmdc.org for more information or to learn how to join.

Continued on page 24.



PHOTO CREDIT: COURTESY MARKETLAB © 2010

Minding Our Own Businesses Continued.

Oliver-Tolas Wins Packaging Industry Awards

Oliver-Tolas was recognized for two packaging innovations by the Flexible Packaging Association (FPA). The company took home Silver Flexible Packaging Achievement Awards for the Dispos-a-vent™ barrier pouch and the Isotech Bag®. Both products help ensure sterility and patient safety through innovative developments in design, materials and sustainability.

The Dispos-a-vent™ barrier pouch helps reduce waste by eliminating the need for a secondary package during chemical sterilization procedures and providing a puncture-resistant, oxygen-free and moisture-controlled environment for improved safety and prolonged shelf life.

For customers that need to transfer packaging components into a barrier isolator or automated filling line, it is imperative that those components do not come into contact with the outside of the transfer bag. Oliver-Tolas' Isotech bag® maintains sterility and offers a protective barrier for the easy transfer of products, such as stoppers, caps and pistons.

For more information about these and other award-winning products, please visit www.oliver-tolas.com.

ClinXus Adds Members

ClinXus added two new members in Michigan: Metro Health Hospital of Grand Rapids and MPI Research of Mattawan. The collaborative alliance now boasts 10 member companies working to benefit human health through participation in early phase biomarker and molecular-based clinical and preclinical trials.

Metro Health Hospital (www.metrohealth.net) is a 208-bed general acute-care osteopathic teaching hospital that serves more than 130,000 patients in Kent and surrounding counties. Its services include inpatient and outpatient care, emergency, surgery, intensive care, rehabilitation, wellness and community education.

MPI Research (www.mpiresearch.com) provides discovery, safety evaluation, bioanalytical and analytical services to the biopharmaceutical, medical device, animal health and chemical industries.

The two organizations further enhance ClinXus' collective expertise for trial sponsors. ClinXus' diverse and broadened member portfolio also gives the region a significant competitive advantage when attracting new research activity. *For more information, please visit www.clinXus.org.*

Applied Security Adds Staff to Meet Demand

Applied Security US Incorporated announced an addition of staff to meet demand for the company's fideAS security software.

The company also announced partnerships with Ohio-based executive security and risk services firm Echelon One, and the California-based Monterrey Technology Group to provide information technology security software and services.

Applied Security provides privacy and security data protection solutions to meet regulatory requirements, while efficiently and effectively securing information through encryption and access control to facilitate information workflow. For more information, visit www.apsec.us.

SmartZone Award Has Local Ties

Last June, Great Lakes Entrepreneur's Quest (GLEQ) hosted its Statewide Business Plan Competition Awards Ceremony with partner organizations Automation Alley, Michigan Economic Development Corporation and the Michigan SmartZones.

Each participating company needed to submit a letter of recommendation from its local SmartZone. The West Michigan Science & Technology Initiative (WMSTI) was chartered to support and vet the West Michigan companies being considered.

Throughout the competition, in the SmartZone category, WMSTI provided support, coaching services and endorsement to member companies Ascribe and Syzygy Biotech Solutions. WMSTI also offered consultation services to all GLEQ teams from West Michigan, in all competition categories.

While neither Ascribe nor Syzygy took home the grand prize \$100,000 SmartZone Award, both made a strong showing in the competition amidst a group of very well-deserving entrants. Congratulations to both companies for proudly representing our region.

GLEQ, now in its tenth year of continuous operations, is a nonprofit 501 (c)(3) educational program designed to accelerate the formation of high-growth companies in Michigan. The 2011 GLEQ Business Plan Competition opened for registration on August 23, 2010. For more information, visit www.gleq.org.

Extol Introduces a Purpose-built, Cleanroom Application Hot-plate Welder

WMMDC new member, Extol, Inc., now offers a cleanroom version of its Rapid Conductor, hot-plate welder. The product was developed for a client who will be installing the plastics-joining machine in a class 7 cleanroom. Upgrades to the standard, servo-controlled welder include materials and coatings changes in addition to clean room-approved bearings, lubricants, and fasteners. Multiple pneumatic reclassifiers are integrated to keep exhausted air quality within specifications. •



Unsung Heroes Need Transparent Predictable Regulatory Process

guest column



Mark Leahey
President and CEO
Medical Device
Manufacturers Association

As America crossed into the 20th century, the average life expectancy was 47 years. Today, with cutting-edge technologies and medical advancements, the average American can expect to live to 78.

Credit for this enormous medical achievement can be attributed to several factors: increased quality of care, growth of the pharmaceutical industry and better access to health care. The medical device industry is perhaps one of the greatest unsung contributors to increased life expectancy. Research has shown that since 1980, death rates have declined 16 percent, life expectancy has increased four percent, and Americans spend 56 percent fewer days in the hospital, due in part to medical devices.

The United States is the global leader in medical technology innovation, but this position is currently being threatened. Over the past couple of years, there has been confusion and concerns over regulatory developments at the U.S. Food and Drug Administration (FDA), which is in charge of determining which medical devices are permitted to enter the marketplace. The FDA is currently examining the 510(k) review process, one of the methods by which medical

device manufacturers apply for and receive product marketing approval. In order to balance the priorities of increased patient safety and innovation, we believe the FDA should focus its review on bringing more predictability and transparency to the regulatory process.

A predictable and transparent review process is vital to Michigan's medical technology community. Michigan ranks fourth in the Midwest in the number of medical device establishments with 448 facilities, according to the West Michigan Medical Device Consortium. In order for manufacturers to continue developing cutting-edge products, we need a clear picture of the playing field and a clear understanding of how regulatory guidelines will be instituted. Without it, patient care and innovation suffer.

Who makes up America's medical device industry? Chances are it includes your neighbor or a friend who identified a need in the marketplace or a way to adapt existing technology. They are doctors, engineers and entrepreneurs working to improve patient care and add value to society. According to a U.S. Department of Commerce study, the medical device industry employs more than 350,000

people, and is directly responsible for generating an additional four and a half jobs for every one that exists, constituting nearly two million total jobs. The average salary for workers in the medical device industry is \$70,000, which is 49 percent more than the average private sector job and 18 percent more than the average manufacturing job. Michigan is all too familiar with the decline of the manufacturing sector, but the medical device industry provides a shining example of an area that is growing and expanding, even in these tough economic times.

While many observers are familiar with the industry leaders in medical technology such as Johnson and Johnson or Medtronic, more than 80 percent of medical device companies employ fewer than 50 people. Each and every day in Michigan, medical device start-ups are being formed. According to a recent Kauffman Foundation study, new companies in the United States add an average of three million jobs in their first year of operation, providing the largest source of job creation in the country. While it is important that industry leaders continue to help shape medical advancements, small start-ups often are where innovation and job creation occur. These companies

are the backbone of a dynamic and growing small business community that is central to our economy's recovery. At a time when everyone is rightly concerned about jobs, it is all the more vital that a clear and predictable regulatory environment exists to support patient care and innovation.

Organizations such as MichBio and the Medical Device Manufacturers Association are consistently advocating for entrepreneurial medical technology companies. They are committed to promoting innovation and improving patient care through outreach, education and the grassroots efforts of members. As policy makers and elected officials debate the future of health care and innovation, it is vital that stakeholders in the medical device industry get involved in the process, and share their stories. Getting involved with these types of organizations strengthens the collective voice and common goals of the medical technology community.

All stakeholders in the med tech field are working toward the same goal: an environment where patient care and innovation can thrive. This will improve quality of life, drive down health care costs, and continue to provide good

jobs across the country. But this cannot be achieved in a vacuum. All parties must continue to communicate and share ideas on how to retain the United States' position as the global leader in medical device innovation, while making sure that patient safety is the utmost priority. Together, entrepreneurs, doctors, manufacturers and policy makers can ensure that the cutting-edge technologies being developed today will deliver on the promises of a better tomorrow.

About the Medical Device Manufacturers Association

The Medical Device Manufacturers Association is a national trade association based in Washington, D.C. that advocates for entrepreneurial medical technology companies. They are committed to promoting innovation and improving patient care through outreach, education and the grassroots efforts of their members.

About MichBio

MichBio is the biosciences industry trade association and the official Michigan affiliate of the Biotechnology Industry Organization (BIO), which represents biotechnology companies across America and in 33 other nations. Formed in 1993 as the Michigan Biosciences Industry Association, MichBio is headquartered in Ann Arbor.

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- Affordable rates
- Office and meeting space available

For more information contact:

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Photos left to right:

Michigan Street Incubator standard laboratory for resident occupancy.

Michigan Street Incubator biosafety hoods.

(2) Representative labs at Monroe Avenue Incubator with biosafety and fume hoods available.

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SUM¹⁰mit
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September 28, 2010
Loosemore Auditorium

Richard M. DeVos Center
Pew Grand Rapids Campus
Grand Valley State University
401 Fulton Street West
Grand Rapids, MI 49503

Registration 7:30 am to 8:30 am
Program 8:30 am to noon
Luncheon begins at noon
Cost: \$35 per person

This year, SUMmit10 will explore the impact of Health Care Reform on innovation and entrepreneurship in the areas of drugs, diagnostics and devices. While the law is still being debated, interpreted, and reduced to regulations, the impacts on innovation, product development and conducting business are becoming clear for these three areas of interest. Join us to hear a keynote address on this topic and presentations from three regional companies and a regional law firm on how this new massive law will likely affect them in the future. Speakers include:

Keynote Roger S. Newton, Ph.D., Founder, CEO and President, and Director of Esperion Therapeutics, Inc.

Drugs Robert A. Beardsley, Ph.D., MBA – Chief Executive Officer, Metabolic Solutions Development Company

Diagnostics Kevin McCurren, President, Intervention Insights, LLC

Devices Justin Adams, CEO and President, mHealth Innovations, Inc.

Legal Overview Kathrin E. Kudner, Dykema

To learn more about or register for this event visit our website at wmsti.org/events or call or email us at 616.331.5840, wmsti@gvsu.edu.