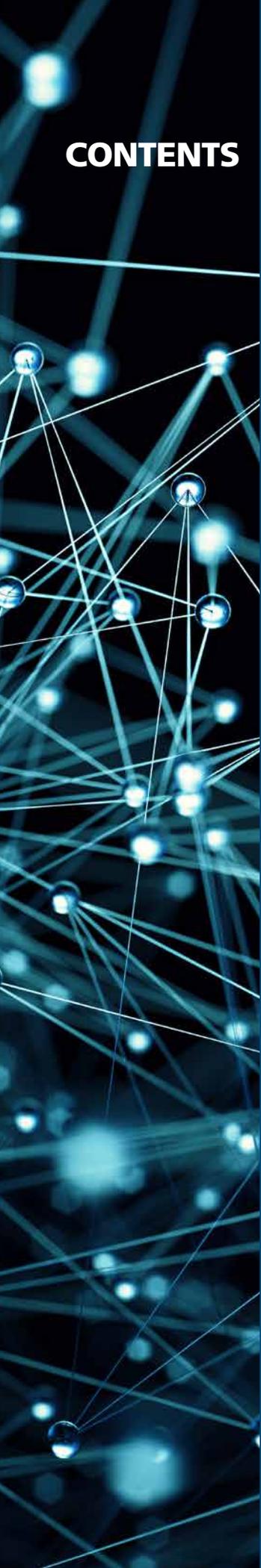




POWERING INDIANA'S LIFE SCIENCES COMMUNITY

# Profiles of Money, Molecules and Management



# CONTENTS

- 1 Prologue
- 2 Money, molecules and management
- 4 Michael Arpey: Indiana's reputation globally good, but life sciences funding remains a challenge
- 6 Joe Muldoon: Build it from scratch
- 8 Bruce Molitoris: Making kidney research cool and potentially profitable
- 10 N. Clay Robbins: Being intentional about developing life science as an economic driver
- 12 Claire Fiddian-Green: Developing, attracting and retaining talent is key to a thriving life sciences sector
- 14 Laura Lyons: The sound of airway technology, from Purdue to market
- 16 Kristin Sherman: Inject big-pharma knowledge to make fast, short companies
- 18 Mark Kelley: Mix one part molecules and one part venture capital, bake well
- 20 Anantha Shekhar: Harness the power of molecules to build Indiana life sciences
- 22 Darren Carroll: Using money strategically to build a life sciences culture
- 26 Derek Small: Building companies out of science, or what I learned from a failed effort
- 28 Richard DiMarchi: A Carl Sagan appreciation for the local life sciences cosmos

## Prologue



DAVID  
**JOHNSON**

Indiana's life sciences sector is unmatched throughout the country, offering both a high concentration of life sciences jobs and the second highest export volume in life sciences products, \$9.9B in 2015, in the United States. It is a significant driver of our economy, with an Indiana impact of over \$60 billion and accounting for one in every ten jobs—and in the process, driving significantly higher average wages than the Hoosier norm in nearly every occupational group.

BioCrossroads has tracked and monitored these promising statistics for well over a decade, in a series of detailed research studies marking trends and growth. Among other things, our reports on this sector have identified and continuously quantified our leading opportunities for growth across Indiana's pharmaceutical, medical device and diagnostic, agriculture technology, healthcare delivery and information technology sectors. Still, as impressive and diversely important as Indiana's life sciences economy has become, we are always reminded that it all comes down to people.

Truly, to understand what powers our life sciences success, the story must begin with the individuals who provide the vision, drive discovery, form and support new entities, and find the capital that sustains activity every day. Indiana has long benefited from a tradition of talented leaders who have turned innovations into thriving enterprises—such as the well-known examples of Colonel Eli Lilly and Eli Lilly and Company; Bill Cook and Cook Group; Dane Miller and Biomet; and Bill Eason, whose discoveries in his garage led ultimately to Roche Diagnostics. But there have been many more; and in fact, their numbers and contributions are increasing rapidly. Take a look at the dozen profiles that follow, and you'll see why our hopes are so high that Indiana's tradition of life sciences talent is alive and well—and winning.

Sincerely,

A handwritten signature in black ink, appearing to read "David L. Johnson". The signature is stylized and fluid, with a large initial "D" and "J".

David L. Johnson  
President and CEO, BioCrossroads

# Money, molecules and management

By John Ketzenberger

The following are a dozen stories of people critical to the development of Indiana's life sciences. These are some of the people who mind the money, the molecules and the management necessary to nurture arguably the state's most important economic sector.

Many migrated here for opportunity and stayed. Quite a few are natives who studied or worked elsewhere and then returned. All of them are high achievers, adaptable and always, always learning.

They take risks. Whether it's with money or their reputations, these folks aren't afraid to chase opportunities others either miss or are unwilling to pursue.

And they care. They care about their work and how it may help someone else. They care about a robust biotech business here. They want Indiana to succeed in a truly global and highly competitive sector.

What distinguishes them? Some are specialists, like private equity and venture investor Michael Arpey who invests all over the world from his perch as managing director and head of investor relations for Washington D.C.-based Carlyle Group. He's spent 15 years molding the investment climate here.

Joe Muldoon has made a career of leading local biotech companies, including FAST BioMedical, where he's raising money to take a promising kidney test into the final rounds of clinical testing.

Bruce Molitoris, whose research is the basis of FAST BioMedical's business, would rather spend his time on the bench at his

lab cracking molecules and wondering how they might be used to benefit sick people.

Then there are the combo players. N. Clay Robbins and Claire Fiddian-Green are examples. Robbins, the Chairman, President and Chief Executive Officer of Lilly Endowment, Inc., and Fiddian-Green, President and Chief Executive Officer of the Richard M. Fairbanks Foundation, Inc., represent organizations that have supported the deliberate development of the biotech sector here. Their foundations' grants have helped cultivate this increasingly vibrant industry.

Laura Lyons and Kristin Sherman have adapted to changing conditions throughout their management careers. Lyons, head of regulatory compliance for SonarMed, knows how useful the company's endotracheal tube monitoring device is because as a respiratory therapist she used to insert such devices in people. Sherman knows what it's like to spin-out a big device company and used that expertise to set up a couple of nimble companies that exited with big returns in just a few years.

Mark Kelley suspects his generation of scientist is the last to look askance on budding entrepreneurs behind the bench. Kelley's classic research has led to 11 patents and a company just now taking a pancreatic cancer treatment into clinical trials. Anantha Shekhar's got a load of patents, too, and treasures his time in the lab, in the clinic and seeing patients. But he's equally adept at helping others identify, patent and commercialize promising research.

Then there are those who in baseball would be called five-tool players, the ones with a knack for doing many things well. Darren Carroll's



an attorney by practice, but as the head of Eli Lilly and Company's global investment teams, he's good at identifying and assessing promising companies. When he's not traveling, Carroll's in Indiana pushing to improve the business climate, whether it is money, talent or the regulatory environment, so the state can compete in all the other places he does business.

Indiana's getting over its aversion to business failure and Derek Small's certainly exhibit A. The business maven cut his teeth on a promising but underfunded company that didn't make it, but has parlayed that into a well-financed effort with two lines of promising research ready to enter clinical trials.

Then there's Richard DiMarchi who retired at 50 as head of biological research at Lilly only to become a chemistry professor at Indiana University. His knack for identifying novel research has led to a string of successful company startups. It's also made a lot of people quite wealthy. Those companies have returned an estimated \$500 million to investors.

The life sciences sector here, as viewed through these examples, has evolved into an important slice of Indiana's economy. The incredible energy and wealth-building potential present in biotech across the globe is mind-boggling. Harnessing it in Indiana will ensure the state's prosperity and ensure it remains among the desirable places to live and work and raise families.

The stakes are high, the opportunity's great and Indiana's poised to be a player. "We've got a remarkable group of companies with leadership across almost the entire spectrum of life sciences, from ag to technology to therapeutics [and] diagnostics," observed Carroll, assessing

the state's attributes from a global perspective. Whether it is orthopedics, pharmaceuticals, medical devices, agriculture or diagnostic tools, there are major biotech players in Indiana and the benefits spread through the sector. Better yet, Carroll observed, the companies cooperate in a way that's not found in other places.

When it comes to molecules and management, Indiana's flush. The research centers at Indiana University, Purdue and Notre Dame are abuzz while the Indianapolis business center rapidly develops. Indiana needs more money, though. It's still tough to get venture capitalists clustered on the coasts to pass through, and the state's network of angel investors isn't as well organized as others. One strength many mention—the two seed funds established and managed by BioCrossroads. The funds have provided early unfettered cash with little dilution to many local companies. When asked to describe in one word what the seed funding meant, the answers included "life" and "existence."

Money, molecules and management.  
Mix them together and they make  
for mighty compelling stories.



## Indiana's reputation globally good, but life sciences funding remains a challenge

By John Ketzenberger

**MICHAEL  
ARPEY**

There are two centers of gravity in the life sciences realm, Boston and San Francisco, but there's no reason Indiana should suffer an inferiority complex.

"My experience in the state is that Indiana is probably more self-critical than it ought to be," said Michael W. Arpey, the managing director and head of investor relations for the Carlyle Group based in Washington D.C. "There's a lot more going right there than wrong."

For nearly 15 years Arpey has criss-crossed Indiana as an investor and a manager of the Indiana Future Fund, a \$73 million fund of funds BioCrossroads created in 2004 to spur investment in local biotech businesses. The money man sees Indiana's life sciences sector from an outsider's perspective, but clearly he has an affinity for the strides taken to compete with the coasts.

Arpey's quick to note every other region in the United States competes with Boston and San Francisco in life sciences, arguably the most potent economic sector going forward. Indiana's major assets—university research, established companies and organized promotion—stack up with any of those aside from the coasts, Arpey said, and that means the state is poised to capitalize.

The missing link here, historically, is investment capital and that's improved dramatically over the last 20 years. "Money in the end is fungible," Arpey said. "To give people a reason to want to put their money someplace is beyond just kind of the simple funding need. In Indiana that reason is the tremendous connection

between what the government is doing, what the universities are doing and what the corporate community has done."

The Future Fund is just one effort to address the capital need here. The state has plowed money from its retirement funds into the technology sector, created a pair of venture capital pools to spur additional investment and BioCrossroads has generated two seed funds meant to ensure nascent biotech ideas have a chance to survive into clinical trials and beyond.

"A life science company in Indiana is competing against life science companies anywhere in the world," Arpey said. "The technology is ubiquitous. The hard part really is getting the companies past the Valley of Death so that they can see the light of day and be compared against similar companies from around the world."

Arpey, like most venture capitalists, has a Darwinian investment philosophy. In fact, he said, funding companies that don't deserve it can actually hurt a region's long-term efforts. "If you wind up funding a company that does not stack up well against a company someplace else, what you wind up doing is good people leave their jobs to join in anticipation of it being a going concern, only to find that it's not a going concern because it's really not what it was represented to be, and you end up doing more economic harm than good in the long run. It makes for a bad reputation for the state."

While Indiana's venture funds have had their hits and misses, the state has done a good job funding companies that can

“stand on their own two feet,” Arpey said, which has enhanced its reputation among investors nationwide. The two seed funds created and administered by BioCrossroads are especially good examples of showing the world Indiana’s serious about life sciences, he said. “Before the seed funds, the Valley of Death might prematurely kill things that might be able to stand on their own two legs,” Arpey said. “That’s why the seed fund is so important.”

Funding remains a critical challenge, though, especially early money to translate laboratory research into commercially viable treatments. Indiana needs more of the so-called angel investments, those made by wealthy people willing to risk their money early for potentially greater returns. There are plenty of potential investors, Arpey said, but efforts to unlock the money haven’t been as successful as they should be. “I think it is rough going within the state regarding angels,” Arpey said.

The key is to create networks of angels—those who have ties to a particular university or a niche within life sciences—and then leverage the money to help many young companies. Arpey met a lot of angel investors in his travels across the state, but said a lot of work remains to organize the networks to reach their greatest potential. “You can’t just show up once and think you’re done,” Arpey said. “You’ve got to create an environment where those people are interacting on a regular basis and then you understand what it is that they’re looking for and the things you’re bringing before them are apt for the appetite. I think getting it organized and getting it systematized is probably what’s needed.”

There’s one asset that Arpey said sets Indiana apart from its peers—BioCrossroads—and it’s more than just the work the not-for-profit does to secure money for life sciences companies here. “BioCrossroads is crucial,” Arpey said. “It acts as a repository, a clearinghouse for opportunities. A lot of times you have people coming out of larger places or educational contexts or other situations, and this is their first time to the rodeo. BioCrossroads can provide them with kind of an infrastructure that allows the germ of an idea to take hold and really be fostered.

“Absent that,” he added, “I think the amount of inertia that might exist wanting to make that leap of faith would be overwhelming.”

Inertia’s not a problem in Indiana’s life sciences, Arpey said, and no one’s overwhelmed either. “Indiana, in terms of what it’s done with its in-state investment activity, really has been a leader,” the investor said. “It’s not a perfect world there, but guess what, it’s a lot worse in other places. The fact that they’re being self-reflective is a sign of their confidence and their desire to continue to improve.”

Inferiority complexes are for others, not Hoosiers.

**A life science company in Indiana is competing against life science companies anywhere in the world.**



## Build it from scratch

By John Ketzenberger

### JOE MULDOON

There are many ways to build a company around promising research. FAST BioMedical chose to do it the old-fashioned way—from scratch.

“We really started with an idea and some initial discoveries that came out of Dr. (Bruce) Molitoris’s lab at the Indiana University School of Medicine,” said Chief Executive Officer Joe Muldoon.

FAST was founded in 2006 around promising research for a test to quickly quantify blood volume and kidney function, which are important factors for treating both acute kidney injuries and disease. If the research indications proved accurate, doctors in emergency rooms could learn in minutes what used to take hours.

The benefit was obvious—patients could receive better treatment faster if FAST’s technology panned out. The market for the test could be \$1 billion.

With patents and licensing agreements in hand, it was time to secure initial funding, but this is where building a tech company in life sciences is much different from, say, a tech company with an Internet search engine.

FAST faced a strict regimen of clinical trials over the course of several years to prove its concept worked and that it didn’t harm the people it was supposed to help. The cost: millions of dollars to develop the technology and millions more to test it.

There aren’t many investors with an appetite for that kind of risks in Central Indiana. BioCrossroads was one of them. “They were really one of the first groups to be able to intelligently assess the risk versus the

upside and then make a financial decision on investing,” Muldoon said. “When other people see that, then they’re more likely to invest as well because they see somebody’s sharing that risk with them.”

That early money, he said, was pooled with other early investments to show the solutions suggested by the research worked. “Without that initial early funding (the research) remains as an interesting idea that may or may not have had a market (and) that may or may not have been viable to actually get to work,” Muldoon said. “So it’s really critical.”

BioCrossroads invested twice for a total of \$530,000, funds Muldoon said were critical to pushing the company to the testing phase where the risk is even greater. At any point during the trials results could show FAST’s process doesn’t really work or, worse, it harms patients.

“In life sciences, if you make progress that means you don’t have to stop and you get to raise more money to take more risk to make more progress,” Muldoon said.

With great risk comes the potential for great reward. Survive the clinical testing process and investors are likely to receive tremendous returns.

“It’s so late in the game before you get to take any risk off the table,” Muldoon explained. “When you have a software idea that’s not in the regulated medical market, you (can) spend a little bit of time and some money early, and then see if anybody will buy it. If they do you can iterate and iterate and get more customers and more customers.”

“In the life sciences you have deployed so much capital before you can sell (the product) to one person,” he added, “and that is the real challenge of life sciences investing.”

So FAST was founded around Molitoris’s research, initial development went well and the company survived the recession thanks to timely investments from BioCrossroads and a few others. Yet the company’s greatest challenge was still before it—clinical trials.

It’s an expensive process. The company’s already spent about \$15 million to clear Phase I human trials in Europe and Phase II human trials in the United States. Another upshot: FAST learned its testing wasn’t limited to kidney function. It can be useful in nearly all major surgery or critical care circumstances, which boosts the market potential in the billions of dollars.

The new challenge is to raise an estimated \$25 million more for the final two stages of human trials. The first trial would include about 30 patients; the second, several hundred. The trials could be finished sometime in 2018 and, if all goes well, FAST could receive regulatory approval the next year.

Then FAST has to determine whether it will remain a company made from scratch and launch the test as its own product, or whether aligning with another company for the launch makes better sense.

“We’ve already got a lot of interest from (investors) that are sold on the unmet medical need (and) see it as a product in its own right,” Muldoon said, “but (some companies) see it as a strategic benefit to them because it could also help bring their products to market better.”

Before that decision is made, Muldoon will have to convince more investors to take more risk on the remaining trials, but he knows the opportunity wouldn’t exist without early help from BioCrossroads.

“A specialized (seed) fund in this area is so important because understanding product development risk in biology is very different than product risk in software,” Muldoon said. “In a regulated environment, just having experience with that and understanding all the variables is wildly important.”

Beyond initial funding, he said, it would be good to see more specialized later-stage investment funds that are either located in Indiana or have a desire to do more deals in Indiana. “We’re seeing some of that,” he said. “We look at hundreds of potential investors, but those that you can actually get a mandate out of, an increasing number of them are saying, ‘you know, we like the Midwest because deals aren’t overpriced, people work hard and they’re pretty honest.’”

“We need more people to invest based on that theory, be successful (and) get exits,” he added. “Then success drives success.”

For all of the challenges, there is an overriding motivation that drives Muldoon and the company.

“You get grounded in the reality of all the work you have to do. There are frustrations,” he said. “What keeps you going through them is it is more apparent every day that this can eliminate some human suffering and that is motivational in a way that is profound to everybody that works on it. During the tough days, you just remember that. You’re one day closer to literally changing somebody’s life.”

**In the life sciences you have deployed so much capital before you can sell... that is the real challenge of life sciences investing.**



## Making kidney research cool and potentially profitable

By John Ketzenberger

### BRUCE MOLITORIS

Epiphanies strike when they will and it's a good scientist who acts immediately. Just ask Bruce Molitoris, who obtained his first patent for a discovery that occurred with an epiphany at a research conference.

The presenter was talking about new imaging techniques and Molitoris, a medical doctor who has long engaged in basic scientific research, recognized a way to improve what he was doing and, at the same time, translate it into use on patients.

"It was really the imaging center here [at the Indiana University School of Medicine] that allowed us to do unique scientific experiments and have insights that limited people get to have," Molitoris said. "And we could see some of the things that needed to be done."

Literally.

Molitoris now holds six patents and his research is central to a pair of companies in central Indiana, FAST BioMedical and INphoton. His work has made him a leading authority in the understanding and treatment of kidney disease, an area that is ripe for advancement. "Nephrology is a field that hasn't progressed technically in developing procedures and tests," Molitoris observed. "Whereas cardiology, pulmonary and [gastrointestinal] areas have done that in spades, nephrology has not. So nephrology is a tremendous opportunity to move forward in that domain."

Here's how it's worked so far for Molitoris, who arrived at IU in 1993 and now heads the Indiana Center for Biological Microscopy. While winning his patents, Molitoris also has published more than 100 papers and received more than \$25 million in research

grants from the National Institutes of Health, the Veterans Administration, the American Heart Association and Lilly Pharmaceuticals. His work is central to opening nephrology and redefining the understanding of kidney disease, what causes it and better treatments.

Molitoris's career marks what may be a point of inflection in the arc of research-to-application. The research culture as he became a scientist still guided students and post-graduates toward mentors in their favored fields where they would work to extend the knowledge base and publish or perish. Over time, though, Molitoris and many in his age cohort became more directly exposed to the application of their research, guiding its advancement through startups or licensing agreements with established companies.

Molitoris has seen the fits and starts of the IU Research and Technology Corporation (IURTC) as it works to make the connections to unlock research for practical applications. He's seen younger researchers navigate the academic traditions through more patents and fewer papers and has witnessed the tensions created as a new balance is established. The realm is changing fast.

"It's like an epidemic. It's taking off," Molitoris said of translational efforts here. "Ten years ago? No. Five years ago it really got a good start and everyone is thinking, including the basic scientist, about translating what they do to the patient."

"The days of the one-hitter, doing something and then moving on, are gone," Molitoris added, "and if you really want to translate, it's many years of moving forward. People pick up the baton, so to speak, and move it forward."

The notion is as simple as renaming “acute renal failure” to “acute kidney injury” and as complex as understanding the myriad reasons for doing so. Molitoris is on the vanguard of that redefinition, doing research that seeds companies with a better understanding of what causes kidney injuries—whether it’s a physical injury or poisoning from medications used to treat other conditions like cancer. His imaging work led to FAST BioMedical’s testing procedure currently in clinical trials that could give doctors clear indications of kidney injuries in minutes instead of hours.

The research may lead to better treatments, too. Molitoris’s work is at the center of a recent licensing agreement through the IURTC with a California-based company to develop new derivatives of his patented antibiotic combination that may treat or prevent a variety of genetic diseases. The work is an off-shoot of research Molitoris was doing to better understand how other drugs, in this case a powerful antibiotic that can damage a patient’s kidneys, can be made less toxic while still effective. “The kidney takes up a lot of drugs and they can be toxic to it,” Molitoris said. “That’s about 20 percent of what we see in the hospital and what we call nephro toxins.”

The “we” is important. Collaboration is critical to quality research and Molitoris embraces some recent funding changes that encourage the range of researchers to work together more closely. “If you want to do science now, you have to have interactive groups,” he said. “No. 1, it’s more efficient. No. 2, I think it’s more creative.”

“The positive aspect of the limitation in NIH funding has been the requirement of working together and making dollars go further rather than one investigator trying to do everything with all the equipment you need to do everything,” Molitoris added. “Now you have to have four, five, six investigators working together, which creates a tremendously synergistic environment. It’s a lot of fun and it is why ... having a group of interacting MDs and PhDs is absolutely necessary. We see it in the hospital. We understand it from a physiology point of view. The PhDs primarily understand it from a molecular [and] cellular point of

view, and bringing the two together then gets you the total view of what’s going on.”

Molitoris is content to leave the business functions to those whose talents are better suited for it, but he doesn’t ignore that side of the business. “Yeah, I’m on the phone once or twice a week, primarily as an information source, not a financial source,” he said of quality time with the business side. “If people have questions, if they have concerns, if they have ideas, I’m there on the phone.”

His focus on research doesn’t mean his keen powers of observation are limited to the sterile lab setting. To compete, Indiana needs more early funding sources, whether it’s seed funds like those administered by BioCrossroads or more angel investors willing to take early risks. “The [medical] school recognized translation was very important, but had limited funds to put into that,” Molitoris said. “BioCrossroads and the state supplied a lot of needed money to get the process going and to get investors around the state to see the importance of developing some of these processes within their own state.

“You need a seed fund managed by a company that has experience, knows the territory and knows all the players within the state and can bring in the money from outside the state,” he added. “I think BioCrossroads has developed that kind of experience both within and outside the state. They’ve really done a commendable job to date.”

Still, there is more work to do. “Life sciences [in Indiana] is at a far higher level than is recognized by the venture capital world,” Molitoris said. “If you look at both coasts, unfortunately the Midwest is not seen as an area of great ingenuity and creativity. It really is, but the funds necessary to advance that aren’t here.”

Molitoris didn’t finish that sentence with the word “yet,” but you could tell it’s on the tip of his tongue and he intends to continue doing what he does to finish the story.

If you want to do science now, you have to have interactive groups...

No. 1, it’s more efficient.

No. 2, I think it’s more creative.



## Being intentional about developing life science as an economic driver

By John Ketzenberger

### N. CLAY ROBBINS

Lilly Endowment's ability to affect many aspects of Hoosiers' lives is the result of a family's success building a biotech company. It's not surprising then that the Endowment considers a thriving life sciences sector to be critical to achieving its aim of helping people in Indiana build better lives.

"We realized that if one of our key objectives is to help enhance the prosperity and vitality of Indiana, we needed to look at those clusters in which Indiana really could have excellence and build strength and capacity," said N. Clay Robbins, the Endowment's chairman, president and chief executive officer. "The life sciences offers some salaries and jobs that pay well above the average and that is what we're going to need more of to start to turn [the state's economy] around."

"We need to increase the state's average per capita income," Robbins added. "To do that, more investment will need to be made in some industry clusters that have higher wages. It's pretty clear the life sciences, when you think about Lilly, Dow, Roche, the Warsaw companies, Cook and when you look at their payrolls and the intellectual capital that comes from those institutions and the [Indiana University] Medical School and the National Institutes of Health funding that comes in, is an attractive cluster to invest in."

The Endowment was established in 1937 by descendants of company founder, Col. Eli Lilly, and has ranked as one of the nation's largest philanthropies with assets exceeding \$11 billion at the end of 2015. The Endowment is known for its deliberate investments and strong follow-up to ensure its grants are spent as intended. Its involvement in BioCrossroads began with a larger observation.

"There was a decision that with the loss of corporate headquarters and the reduction of clout that individual leaders had in their companies in Central Indiana, the region needed to have a more proactive organization that had professional staff at a very high level of quality and capacity," Robbins said. "The Endowment funded an analysis of the economic structure of the Central Indiana region. Not that anyone was surprised, but I don't think we fully realized how significant the life sciences cluster was. The report lifted up the life sciences as one of the strongest clusters that we had. Logistics and advanced manufacturing were the other significant ones. At the time [information technology] was registering as an enabler of both the clusters. It certainly has become its own cluster while also enabling the other two."

This work led to development of the Central Indiana Corporate Partnership, an umbrella group charged with fostering development in the various economic clusters. Lilly Endowment participated in CICP's development, as a corporate member and as a funder of its charitable and educational programs, and the Endowment remains one of its key supporters. BioCrossroads is one of six sector-specific initiatives that flowed from creation of the CICP.

"BioCrossroads set a standard," Robbins said. "It's the first one that got going. It's had very significant investments from the [Richard M.] Fairbanks Foundation and Lilly and the other life sciences companies. Certainly Purdue and IU and Notre Dame have been engaged as well in a significant way. It's been very effective and certainly it's been helped by having someone like David Johnson at the helm, but he has a really strong team around him and they've really been very intentional about what they do. I think they've tried to

rely on good research and analysis to test what they've done. A big part of their success is that they're thoughtful and reflective."

Most of the jobs and wealth in the economy will come from new startups, Robbins said. BioCrossroads has done a good job understanding the sector and developing programs to capitalize on strengths and address weaknesses, he said. Their study has led to new sector-specific efforts such as AgriNovus to capitalize on the state's robust agriculture-related biotech work and the development of the Indiana Biosciences Research Institute.

"One of the incidental benefits to BioCrossroads and then to all of the life sciences is the information and the contacts that Nora [Doherty, the Vice President of Finance and head of the seed funds] and her team gain by talking to all of these groups that are looking for funding," Robbins said. "That is a very good way for them to stay informed about what's happening out there. Who are the people doing exciting things? They can assess capacity and talent, creativity in people who play in this space. It might be that a particular company is not one that they want to invest in, but often they are impressed with the people and know there could be other things down the road that they could be involved with that could be successful. It's a really good way for BioCrossroads to stay engaged and understand what's going on. They also do a lot of connecting and building the social capital in the sector through these kinds of efforts. When you combine that with what they do outside the investment side of BioCrossroads, it can be pretty yeasty."

Aligning the efforts of Indiana's institutions of higher education and the business community remains a critical challenge, Robbins said. "I think there needs to be more improvement in the communication channels between higher education institutions and the business community so that students know what the opportunities are in Indiana in the life sciences," he said. "We have a number of jobs in the life sciences that don't require a bachelor's degree. There is manufacturing in the life sciences. That's important and there's a lot to be done to make sure that people who want that are adequately trained to be able to take those jobs. That's important to the overall sector."

"We also need to continue to build up the PhD and master's level scientists and engineers who are part of the sector and to make sure that we have the climate and the support and encouragement for these kinds of businesses to have more of these jobs available here in the state," Robbins added. "That's going to require a lot of different things to get there. BioCrossroads can be really helpful in providing information [and] knowledge about what's happening across the country to policy leaders so that they'll be open to doing what it takes to foster those types of jobs."

BioCrossroads also is well-situated to help direct the state's public policy discussions in a way that boosts biotech and, as a result, the state's economy and its citizens' well-being. "It's important for BioCrossroads to continue, in a very effective collegial way, to work with state policy leaders, particularly around how we provide investment support and capital for emerging businesses," Robbins said. "There are certain kinds of very early seed capital that are hard to come by. State funding can play a critical role in helping emerging businesses get to the point where venture capital firms will invest."

The Endowment has made some grants directly to universities for this purpose, but philanthropic restrictions and tax laws narrow how those funds can be used, Robbins said. "The state doesn't really have those same restrictions," he said. "I feel like there could be some good leveraging from such investments if we get some really smart people to sit with public policy leaders and do this in a way that makes sense. BioCrossroads is in a position to help convene the right leaders to sit around and think through that."

Consistent, deliberate efforts to improve economic vitality for widespread benefit. Characteristics of both Lilly Endowment and BioCrossroads.

**We realized that if one of our key objectives is to help enhance the prosperity and the vitality of Indiana, we needed to look at those clusters in which Indiana really could have excellence and build strength and capacity.**



**CLAIRE  
FIDDIAN-  
GREEN**

## Developing, attracting and retaining talent is key to a thriving life sciences sector

By John Ketzenberger

Richard M. Fairbanks Jr. got his start in media by selling classified advertising for the Indianapolis News. By the 1950s he'd created a juggernaut in radio led by WIBC.

Fairbanks Communications tied the community together with its large news operation and popular disc jockeys. His legacy, through the Richard M. Fairbanks Foundation, Inc., is to advance the vitality of Indianapolis and the well-being of its people.

The Fairbanks Foundation, which has awarded grants of more than \$200 million since its inception, sees BioCrossroads' efforts as critical to achieving one of its three focus areas: the economic vitality of Indianapolis. It's one reason Fiddian-Green cited for the Foundation's long-time support of BioCrossroads. The Fairbanks Foundation has provided grants totaling \$8.6 million to support the life sciences not-for-profit's operations, she said. "The life sciences industry is the major economic driver for Central Indiana. Formation of BioCrossroads was seen as central to our goal as a foundation to strengthen the Indianapolis economy," Fiddian-Green said.

A recent reassessment of the Fairbanks Foundation's priorities conducted as part of her first year on the job "reaffirmed that we should continue to focus on life sciences. It is essential to our economy to develop, attract and retain talented people, who in turn are employed by life sciences companies in Indiana. In addition, the life sciences sector helps foster innovators who seek solutions to health, science and business problems that today seem unsolvable."

She named several large companies, the state's major universities and a bevy of research

scientists as the foundation for Indiana's life sciences strength. "We have tremendous assets in central Indiana," Fiddian-Green said. "BioCrossroads works because it is a catalyst to bring all these assets together."

Creating that connective tissue is critical, she added, and sustaining consistent efforts by BioCrossroads' staff is just as important. That experience allows ideas to reach fruition more efficiently.

"BioCrossroads sits outside of the different sectors in the life sciences and is able to see the bigger picture. It is also able to serve as a catalyst and convener," Fiddian-Green said. "They are an ecosystem enabler, helping to ensure that different sectors collaborate and work together." The Fairbanks Foundation also supports The Mind Trust, an education-related not-for-profit established to provide every Indianapolis student – regardless of income – access to high-performing schools. "In my view, BioCrossroads and The Mind Trust play a similar role in their respective fields," she said. "They create a larger vision and then work to coordinate related organizations and cross-sector partners, with the ultimate objective of better outcomes for kids and adults."

Talent recruitment and retention are critical elements to the region's continued success in life sciences.

"Where we continue to see a need is in the area of talent, whether we are developing it ourselves or attracting and retaining it in Indiana," Fiddian-Green said. "This applies in particular to teaching Science, Technology, Engineering & Math (STEM) subjects in schools, colleges and universities,

and in workforce development training programs, to ensure Indiana is creating a robust supply of skilled talent for the life sciences jobs of today and tomorrow.”

In addition to supporting BioCrossroads’ general operations, the Fairbanks Foundation has invested in both BioCrossroads’ seed fund programs and the BioCrossroads-sponsored INext venture capital program. “Venture capital funds tend to focus on later stage investments, so there is a short supply of early stage capital,” Fiddian-Green said. “That’s understandable because it’s riskier, and it’s more difficult to tell what the return on investment will be, but it remains an important need.”

Early stage funding is even more critical because of the success in attracting later stage venture capital. A 2014 report prepared for BioCrossroads by the Battelle Technology Partnership Practice demonstrates Fiddian-Green’s point. “Indiana has made substantial gains in life science venture capital investment over the past decade,” noted the report, “Reexamining the Need for Innovation Capital to Advance Life Science Development in Indiana.”

Thirty-nine companies attracted \$349 million in 100 deals between 2003 and 2013. That compared with \$80 million in 26 deals involving 14 companies in the decade 1993 to 2002.

The increase “has raised (Indiana’s) visibility on the national scene,” the report noted.

While it’s still a fraction of the action across the nation, the improvement gives reason for hope.

For Fiddian-Green, fostering entrepreneurial activity in the life sciences is the key to future economic success, whether it’s a big-pharma company like Eli Lilly and Company or a startup like Calibrium. “Failure is par for the course when it comes to innovation,” she said, “and sometimes failures become the seeds that sprout successful new ventures. But you need a sufficient supply of early stage capital to support the generation of good ideas that have the potential for implementation and positive longer-term impact.”

Richard M. Fairbanks, Jr. wanted to use the fortune he amassed in radio to strengthen the city of Indianapolis. BioCrossroads helps to do so by promoting the growth of the local economy. “An important role that BioCrossroads plays is to align and coordinate life sciences activities in Indiana,” Fiddian-Green said. This helps ensure some consistency for economic development efforts when there are changes of administration in the public sector and changes of leadership in industry, she added. “BioCrossroads plays an important sustaining role when it comes to the success of the life sciences in our state.”

**It is essential to our economy to develop, attract and retain talented people, who in turn are employed by life sciences companies in Indiana. In addition, the life sciences sector helps foster innovators who seek solutions to problems that today seem unsolvable.**



## The sound of airway technology, from Purdue to market

By John Ketzenberger

### LAURA LYONS

Laura Lyons was preparing to leave the company where she'd honed her skills as the person to navigate federal regulatory and compliance requirements for medical devices. At one time Lyons had been a respiratory therapist, a person who spent a lot of time putting tubes through patients' airways.

So it was a serendipitous moment when she saw that SonarMed, a company then about to launch a novel monitoring device for artificial airways, was looking for someone with regulatory and clinical experience. "I went, 'Oh, my gosh, this device would have changed the way I treated my patients,'" Lyons said. "I would have been more successful treating my patients if I'd had this device."

When Lyons was a clinician the only way to really know what was happening with a breathing tube was to take X-rays. It was inconvenient and time-consuming, so the market was ripe for a better solution.

SonarMed's device looks deceptively simple. A coupling that hooks into the artificial airway is connected to a small monitor. It generates sound waves and then measures them to immediately show more definitely the positions of breathing tubes, whether they've moved or if they're clogged. It eliminates a lot of the guesswork clinicians like Lyons used to face and it does so in real time, which is especially useful since most of their patients can't communicate.

How the device made it to market is a classic need-meets-research tale. A trio of Purdue University professors, Jeffrey Mansfield, Eduardo Juan and George Wodicka, had conducted extensive research in acoustic reflectometry. A neonatologist found out about

the research, according to Lyons, "and said, 'If you can use sound to probe tubes, what can you do with endotracheal tubes, especially with neonates [babies]?' It's a real problem. These tubes can come out and they can get clogged, and then the baby's life is at risk."

SonarMed was formed in 2005 and the application of the research to help babies spurred development of what's now called the Airwave, but it would be several years before it got federal approval for use in babies.

"Look at the process of getting a product to market and then things have to change a little," Lyons said. "Start with investment. Look at the size of the adult market. It's much greater than the size of the neonatal market, and I don't mean the physical size. It's easier to attract investors to a larger market than to this tiny little niche neonatal market."

"Also from a regulatory standpoint, when bringing a new device to market, it's a whole lot easier to get clearance and approval for your device from FDA and other regulators if you're trying with an adult than these tiny, most fragile little babies," she added. "So the process then was to create a product, do all the testing that needed to be done and submit it to the Food and Drug Administration for the larger-size tubes. Then, once that was there, make sure the product worked like we thought, make any changes that were necessary, then miniaturize it for the neonates."

Nearly five years after marketing its initial Airwave, SonarMed earned approval in January 2016 for use with the smallest endotracheal tubes. "Needless to say we've had a lot of interest in this product, but we're

doing a very limited launch and are now up and running in hospitals,” Lyons said.

The process of converting research to medical device wasn’t easy—or cheap. Lyons said SonarMed spent about \$10 million to get the device to market. The big money from venture capitalists and government programs that SonarMed used to develop the Airwave and gain regulatory approval was made possible by a much smaller initial investment, the first ever made by BioCrossroads’ first Indiana Seed Fund. The \$6 million fund risked \$250,000 of its stake on SonarMed in 2006 when the company’s only tangible asset was a mailbox at Purdue.

The early money was important, Lyons said, because, “it helped leverage other money and people see that Indiana has put some skin behind it. Also the fact that it can be used however the company needs to use it. We did have grants from the National Institutes of Health as well, but those are very specific in how they can be used. There are a lot of things that need to be done that can’t be done with that grant money.”

The BioCrossroads money came with something else—Nora Doherty, the organization’s Vice President of Finance and Managing Director of its seed funds. Lyons said Doherty’s presence on the SonarMed board was “extremely beneficial. The measured attention that she gave us, the consistency in it,” Lyons said. “It wasn’t what [BioCrossroads] was going to get out of us, it was a very unbiased, helpful business approach. No drama, just great support.”

The return, beyond the investment, is apparent. While SonarMed ramps up its newest application of the Airwave, a contract manufacturer in the state is making the devices. Dozens of well-paying jobs exist that support families while the tax dollars that flow from those jobs help support the state’s economy. It’s a real-life example of how biotech innovation occurs.

“Innovation typically is going to come from the smaller companies that really need the seed money,” Lyons said. “It’s hard these days for the large manufacturers to truly innovate. The cost to them is actually

higher. What might have been an \$8 million project for us might have been a \$100 million project for a large manufacturer.

“A smaller innovative design shop can also be nimble. It can move a lot faster,” she added. “The seed money is really important that way and understanding that if we in Indiana really want to be a great medical device manufacturing state, then we also need to promote these small companies. It’s often then that you get to keep the project here in Indiana.”

Lyons, the expert in navigating the regulatory environment, also thinks Indiana would benefit from three things. The first is in her bailiwick. “Very often a small, innovative company does not understand the regulations and the magnitude of those regulations,” she said. “For a small, innovative company, it’s expensive to get that expertise. If there was a way to have, early on with the seed fund, a consultant come in and say here are the things you need to think of right now before you take any further steps, I think that could speed the innovation and the time to market up a little bit.”

Secondly, Lyons would like to see “universities through their medical schools make clinical research easier and less expensive. That is also a very expensive part of innovation and it’s cumbersome. Finding a way to streamline that and have the Indiana universities get involved in helping with technology would also be very beneficial. Maybe that comes in some kind of incentives from the state if they’re helping because they have their own revenue to earn. But if there could be some working together there, that could probably speed the time toward innovation.”

Finally, she said, the state needs to do more to assist the transfer process from idea to company. “I run into people out there with new ideas who are starting their companies and they’re fresh and they haven’t a clue of where to start,” Lyons said. “I would love to see Indiana write a road map to show how here’s the way to do it. Share the success stories. We don’t need to hold it tight. Let’s help people become successful. That is good for Indiana.”

**Innovation typically is going to come from the smaller companies that really need the seed money.**



## Inject big-pharma knowledge to make fast, short companies

By John Ketzenberger

### KRISTIN SHERMAN

Kristin Sherman knows what it takes to build companies big and small. She's spun out a publicly traded medical device company from Eli Lilly and Company and helped found two quick-exit life sciences companies that reaped millions of dollars for investors.

And she's hungry for more.

"I think we're always looking for new opportunities," said Sherman, who's collaborated with others twice to commercialize research by Dr. Richard DiMarchi. "It is very much driven by the science and that's what makes it a little hard to predict if and when. You want to wrap money and the team around the science that you feel confident has an opportunity to succeed."

What sounds like a simple formula is not. Sherman's wisdom comes from experience gained because she wasn't afraid to take a risk.

The DePauw economics graduate had a nice gig at Lilly crunching numbers when she made a common-sense decision to earn her MBA at Dartmouth. Two years later she returned to Lilly, where she was placed in charge of the company's MBA recruiting program.

This is when Sherman short-circuited her comfortable career to take a flyer on Guidant Corp., the company Lilly spun out to produce and market cardiovascular devices. She was among a dozen or so people who decided starting a company from scratch sounded like fun.

"We were charged with figuring out how (to) take these different medical device companies and create what became Guidant," Sherman recalled. "They were autonomous,

decentralized and had been functioning truly independently and now they had to operate under a new parent umbrella."

She was assistant treasurer when it started in 1994, so she helped set up the core components of the company's treasury and accounting system. What wasn't obvious was the implications these systems would have on Guidant's corporate culture.

"We had to be very cognizant of culture because we were taking different companies with different cultures and trying to create what ultimately would become the Guidant culture," she said. "So the beginning was blocking and tackling, and from there we started obviously to begin growing and expanding, which required people, bring on lots of people, expanding with all the challenges that come with more people."

Guidant grew rapidly and in 2006 it was acquired by Boston Scientific in a deal worth \$27 billion. By then Sherman, steeped in the company's history, had become its treasurer and vice president of finance.

It wasn't long, however, before Sherman and others who'd started up Guidant reconvened. They were drawn to DiMarchi's research on ways to treat metabolic diseases such as diabetes and obesity.

This startup of Marcadia Biotech felt similar to that of Guidant with one very different exception. Instead of adding employees as the company grew, Marcadia used contracted research. "Marcadia was a virtual model," Sherman said. "That was a conscious decision. It was, 'Let's run a very, very tiny staff of actual employees (11 at its sale) and let's outsource everything we need.'"

The company otherwise followed Sherman's formula for success—wrap money and good management around solid science—and succeeded beyond expectations. Early money from the state, \$2 million from Indiana's 21st Century Fund, gave Marcadia a chance to prove itself to other investors, who responded with \$16 million in two rounds of venture capital.

"Our model was, basically, a quick yes or a quick no from a drug development perspective," Sherman said. "We had no intention of being a large Phase III clinical organization. That requires a different infrastructure, different talent and different size."

Marcadia got some quick yesses on compounds to treat complications of diabetes and obesity, and that caught the attention of others, including Swiss pharmaceutical company Roche. The Swiss company paid \$287 million for Marcadia in 2011, a sale that brought some validation to Indiana's life sciences efforts.

It wasn't long before Sherman and the others rallied around more of DiMarchi's research, this time on insulin. Calibrium leveraged DiMarchi's track record and Marcadia's success to raise \$1.7 million to get established. Along the way DiMarchi regained control of the molecules Marcadia sold to Roche, which decided to give them up after struggles with other compounds in clinical trials.

Last September, about 18 months, after Calibrium was founded, the Danish pharmaceutical giant Novo Nordisk came knocking with an undisclosed offer to acquire the startup and MB2, the company that held the former Marcadia compounds.

Now what?

"I can tell you my circle of folks that I have conversations with, that I interact with has definitely expanded," Sherman said.

So has the local life sciences effort.

"How we support the life sciences start-up community is getting larger both physically with these incubator spaces (and) that creates more critical mass in terms of people working in the space, having similar experiences and

creating that community," Sherman said. "I think there is a journey that we're on and the more successes we have, that creates more of a pool of individuals to help with that effort of taking the intellectual capital out of the lab and moving it into a commercial environment."

While the growth is encouraging—and real—it's still fragile. Funding remains the biggest challenge, Sherman said, especially early stage money.

"An active angel community is vital in terms of supporting life sciences," she said. "There is a lot of science, there is a lot of technology that is out there that needs just a small amount of initial funding to perhaps get to that next proof of concept or that next study."

The financial success Sherman and others have had helps grow the angel community, but she noted there are less tangible improvements evident.

"This is about connecting people, connecting assets and connecting access to capital," she said. "The role BioCrossroads plays in terms of facilitating is very valuable."

The early validation from BioCrossroads' seed funds helps turn on the tap for venture capital, too, but Sherman would like to see Indiana change a few policies to help with financing life sciences ventures.

She'd like the 21st Century Fund, or a similar state-level pool of capital, to participate in life sciences funding again. The fund moved away from funding life sciences ventures several years ago. Sherman would like the state to use common tools like training grants more often and, especially, wants legislators to boost the state's early venture investment credit as an incentive for angel investors.

"It is hard to attract a venture capital firm or some big money if you haven't created your base, done your homework, built your core team with just a little bit of that seed startup money," Sherman said. "You have to walk before you run and being able to walk by offering someone a tax credit is a nice feature."

A nice feature just like Sherman's hard-won experience building life sciences companies.

This is about  
connecting  
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capital.



## Mix one part molecules and one part venture capital, bake well

By John Ketzenberger

### MARK KELLEY

Mark Kelley's taking aim at pancreatic cancer, one of the deadliest forms, and he means to boost the miserable 7 percent survival rate over five years.

A researcher by training and a business founder by chance, Kelley's ApeX Therapeutics recently received approval to conduct human clinical trials for a compound they call APX3330. It's a molecular treatment for cancer that indicates it can shrink pancreatic tumors more effectively than current chemotherapy and that it can help stop the cancer's spread.

ApeX is a case study in translating research into products that can affect lives and Kelley is exhibit A in scientists' changing career arc. "I'm still doing basic science down in the weeds," Kelley said, "but we're always looking out of the corner of our eye [thinking], 'is this [research] applicable in cancer?' As new things come along you think, 'how can I work and put that together to make it better?' A lot of people now think that way. You have to think that way."

The company started as a conversation more than a decade ago in Kelley's small office on the campus of Indiana University-Purdue University at Indianapolis. John Barnard had dropped by after hearing from former dean of the medical school, Craig Brater, that Kelley had some promising research. Barnard is a veteran executive at Eli Lilly and Company who runs Pearl Street Venture Funds and has helped launch several local biotech companies.

"My goal is really to move the science to the patients," Kelley said, "and that brings me to why seed funding is so important to the state and to investigators. In academia we're about discovery, new and novel ideas. We're

probably not that great on [establishing] companies, marketing all this sort of thing."

It is a simple recognition, but one that often is difficult to realize given the high risk and high cost of developing drugs, not to mention the long lead time. ApeX has spent more than \$5 million to get its initial treatment to clinical trials and will spend two or three times that just to clear the initial hurdles. It's been a long slog, Kelley said, to get to this point.

Several prominent figures in the biotech business here have contributed to the company's success so far. Another Lilly alum, Homer Pearce, came aboard early and remains on the board of directors. David Broecker, who left Lilly to help manage another biotech startup, is the chief executive officer. He took over from yet another Lilly ex-pat, Martin Haslanger, who also remains on the ApeX board. They're all part of the network of business talent that, when well-funded, can translate scientific research into something that will benefit sick people. "It's somewhat rare to take a drug from bench to clinical trials and I think I'm very fortunate," Kelley said. "I work with wonderful folks and I've learned a lot about the development side and the marketing side."

Kelley's resume reads much more like a scientist than it does business person. He's the associate director of both the Herman B Wells Center for Pediatric Research at Indiana University and the med school's Pancreatic Cancer Signature Center. He's the Betty and Earl Herr Chair in Pediatric Oncology Research and holds three professorships: biochemistry and molecular biology, pharmacology and toxicology, and pediatrics. He runs a lab next to his office near Riley Hospital for Children and spends most of his days in a lab coat.

Kelley joined the faculty at IU in 1993, coming here from a stint at Loyola University in Chicago. A Huntington native, Kelley did his undergrad at DePauw University before earning his master's and PhD at Louisiana State University. He did post-doctoral work at Rockefeller University. He's conducted research at the Oak Ridge National Laboratory and studied fruit flies on a National Institutes of Health grant. He's authored or co-authored 166 papers for peer-reviewed scientific journals.

Somewhere amid all this science Kelley started obtaining patents on novel research. The patents seed his entrepreneurial spirit, whether it's starting ApeX or licensing a patent to another company to develop. As universities start to recognize the value of commercializing research, they're beginning to reward scientists for filing patents on discoveries as well as publishing papers. "We have policies that a patent and a disclosure now kind of counts as a grant or a publication [toward tenure], so there's value added and it counts as an academic step forward," Kelley said. "Frankly we could be even a little better about it to make sure you do get the full recognition. I don't think sometimes maybe a tenure and promotion committee or others understand how much work it is to move these things along and how much time it takes."

Another major change: the Indiana University Research and Technology Corp. (IURTC), which is the university's tech-transfer arm. "The whole tech transfer/intellectual property process has improved, I don't know how many orders of magnitude since I came here," Kelley said. "I work very well with the group over there at the IURTC, so I think it's all been a kind of moving together, a perfect positive storm if you will."

The changes have meant more of his colleagues are thinking more about applying their research than they used to. "People are more aware of it, they're more amenable to doing tech transfer and interacting with business," Kelley said. "When I was coming up and training, it was kind of us vs. them and now we're all one. People also see if you're successful, you have licensing or you have a start-up company, they'll say, 'I'd like to do that,' or 'I have a great idea, why can't I do that too?'"

Kelley jokes the world has changed a lot since he was studying fruit flies. "We used to joke when I worked with fruit flies, it's the National Institutes of Health, not the National Institutes of Fruit Fly research," Kelley said, "and yet things discovered in fruit flies are a major target in cancer research. So it applies, but sometimes you have to do the basic science for the basic science's sake, which is still going on. Sometimes you have to say, I'm doing this, but what pathway does it impinge upon and that sort of thing. It makes it even more exciting because you get to collaborate with a lot of clinicians."

Kelley senses he may be the last of his kind, "where you have five years of grad school, one post doc and then you've got an assistant professor job. Now it's longer in grad school, maybe two post docs that may be longer and so it's extended out. We were of that [era] where you grew up and you were going to be like your mentor. Now there are a lot of options. There is science writing. There's intellectual property, you can be a lawyer with a science background, you can do biotech in large pharma, any number of pathways. That's now part of our training too, as our students come through. We're not saying this is what you have to be. There are a whole lot of options."

Kelley's realm has changed a lot since he arrived in Indianapolis. The state's research compares well with any other and funding is beginning to improve. "If you're in Boston and you have an idea, you have a lot more people looking at it and there are a lot of companies based there, so they have people retiring early with a lot of money saying they want to do a startup," Kelley said. "At times there may be a lot of opportunity on the coasts because there is more money, more churn. I think maybe they are more willing to take risks at times. If you don't have quite as much [in Indiana], then sometimes you have to be more careful in your [funding] choices. But it's getting better. We're getting more interest."

We'll know in the next 18 months or so whether Kelley's ApeX treatment will progress into the final clinical trials. Meantime, you'll find him at the lab looking for ways to help sick people.

**My goal is really to move the science to the patients and that brings me to why seed funding is so important to the state and to investigators.**



## Harness the power of molecules to build Indiana life sciences

By John Ketzenberger

### ANANTHA SHEKHAR

Economic development pros like to talk about clusters, places where ideas and opportunity merge to foster companies. Over time successful clusters self-perpetuate to become economic forces.

Think Boston and San Francisco in the life sciences, for instance.

Anantha Shekhar understands these clusters, but as a primary force in trying to develop Indiana's life sciences he sees it differently. Shekhar, a medical doctor who also has spent 27 years in the lab, sees these clusters as molecules.

He's thinking of the new life sciences incubator at IU Health's Methodist Hospital campus where he's attempting to mix the business savvy necessary to start-up companies with young scientists interested in translating research to medical treatments.

"It has room for 15 start-up companies and most of it is full now," said Shekhar, who is also director of the Indiana Clinical and Translational Sciences Institute. "What I'm hoping to do is take the next subset of scientists, people who don't necessarily want to be academics or work for (big companies), but are entrepreneurial in spirit, and give them one- or two-years of post-doctoral training in the incubator so they can actually learn the ropes."

In other words, let them bounce around like molecules to mix and match with others to develop into a new class of scientist/entrepreneur capable of building the life sciences cluster in Indiana.

"Hopefully they will become the next generation of CEOs for future companies here,"

Shekhar said. "It's a workforce development program, essentially, to create a small group within our academic environment."

Like molecules at the heart of all matter, for Shekhar this is the essence of building Indiana's life sciences cluster. And Shekhar's got his hands on a lot of molecules, literally and figuratively.

As a psychiatrist he still sees patients. As a lab researcher he's still teasing out treatments in neuroscience and brain disorders. As an entrepreneur he's building Anagin, a company developing treatments for post-traumatic stress disorder. As an academic he's IU's executive associate dean for translational research, and the August M. Watanabe Professor of Medical Research and a professor of psychiatry, neurobiology and pharmacology in the IU School of Medicine. And as an administrator, Shekhar shepherds ideas from the IU School of Medicine's laboratories into the marketplace.

"A lot of it was working behind the scenes, working in the lab, working to help others get their ideas moving forward," Shekhar said.

Here are three examples of the many ways Shekhar works to bring ideas out of the lab and into the market.

We'll call the first one the Clinical and Translational Sciences Institute's Idea Fest.

The institute is a collaboration among IU, Purdue University and the University of Notre Dame, which has built momentum for life sciences statewide. A primary way to do this is an idea-vetting process that's easy to access and quick to respond.

Shekhar has developed seven teams of six to eight people—scientists and business types. These teams review ideas from the lab to determine whether they're market-worthy. They'll do one of three things after the review: fund the idea up to \$20,000, offer advice and expertise if it's close to ready for funding, or suggest ways to rethink the idea so it could become market ready.

Ideas are regularly encouraged, Shekhar said, and welcome whenever the scientist is ready to share it. "Send us a paragraph, send us a one-pager, whatever you've got, and we'll set up a one-to-one meeting with our project development teams," Shekhar said. "We will convene the team quickly, usually in a couple weeks."

The teams—four in Indianapolis and one each in Bloomington, West Lafayette and South Bend—have reviewed more than 750 ideas over the last eight years, he said, and funded more than half. About 30 companies have emerged from the process and a couple have led to products now on the market, like a device for patients with Parkinson's Disease that helps them hear better and, as a result, speak better.

There's a less obvious benefit to this process, too. "We've involved something like 90 or so senior researchers and business people across the state in these research teams," Shekhar said. "There have been a lot of interesting conversations and collaborations among them as a result."

Shekhar also helps bolster the life sciences effort through his own company, actually working through the processes he's helping others traverse. Shekhar co-founded Anagin with Yvonne Lai, a scientist in IU's Department of Psychology and Brain Institute. It's an extension of his research into treatments for Posttraumatic Stress Disorder and traumatic brain injuries.

Working through the IU Research and Technology Corp., the university's arm for commercializing research, Anagin has shown real promise. The company won BioCrossroads' 2014 New Venture Competition, which is part of the \$950,000 in grants and investments Anagin has already attracted.

In June the IURTC recognized Shekhar as its inaugural winner of the Outstanding Innovator Award. The award was presented by IU President Michael McRobbie, who also was instrumental in the third example of the Shekhar effect on life sciences in Indiana.

The Precision Health Initiative is a collaboration among the IU School of Medicine, IU Bloomington's College of Arts and Sciences, School of Informatics and Computer, Fairbanks School of Public Health, the Kelley School of Business and the School of Nursing. Shekhar will lead the collaboration.

It won a competitive process to become the first effort selected under McRobbie's Grand Challenges Program, which will spend \$300 million for as many as five initiatives over the next five years. The Precision Health Initiative will work on cancer, childhood disease, chronic illness and neurodegenerative disease.

"We want to reach for something bigger and make a difference," Shekhar said. "In that sense it inspires people. It makes people think beyond their own project in their own labs. I think that's probably going to be the biggest gain."

Collaboration seems to occur naturally for Shekhar, who believes Indiana's life sciences sector stacks up to any in the country outside Boston and San Francisco. The willingness of people here to cooperate is encouraging, he said.

"The handful of people who have experience are always ready to help," Shekhar said. "There is a sense that we have to do this for our city or our state, (and) that kind of positive support has been very gratifying."

It's also the biggest frustration, because building expertise takes time and a lot of effort. "We need to grow our own through our business school and our incubators," Shekhar said.

Progress, like molecules, is hard to see until there's a critical mass, and then it's hard to miss.

**We want to reach for something bigger and make a difference... it inspires people. It makes people think beyond their own project in their own labs.**



## Using money strategically to build a life sciences culture

By John Ketzenberger

### DARREN CARROLL

Money's one of the tools that Darren Carroll uses to build life sciences companies all over the world. He's invested Eli Lilly & Company's money on the American coasts, all over Europe and heavily in Asia.

Lilly's senior vice president of corporate business development invests a lot of money across Indiana, too. Some of it is Lilly's and some of it is a combination of state and private money invested through funds he's advised as a board member.

Carroll knows, then, that it takes more than money to build a strong life sciences industry. "The money is a critical element, but I like to talk about this as a three-legged stool," he said. "As one leg of that stool, investing in life sciences requires risk capital in the right amounts with the right kind of guidance and the right risk calculus.

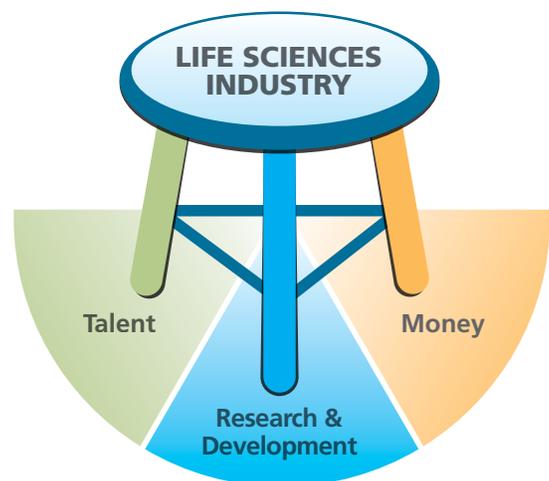
"Second, you've got to have really talented people," he added, "both to do innovation and to lead companies—two very different kinds of people by the way—and number three, you have to have the substrate of innovation to invest in."

The stool must have three strong legs, he said, or else the stool will fall over. "The good news about Indiana is that at various times we have had all three," Carroll said. "So we know it's possible to build a three-legged stool here that is strong. But we've got to have a commitment to all three legs of the stool, and to do so for a long enough period of time that people are going to

be willing to sit down on that stool and take the risk of being in this market."

So what does Indiana have to work with? Let's start with the last two legs of the stool, talent and substrate, the term commonly used in biotech to refer to the product of research and early development. "We've got a remarkable group of companies with leadership across almost the entire spectrum of life sciences, from agriculture and technology to therapeutics and diagnostics," Carroll said.

Think of companies like Lilly, Dow Agro Sciences, Cook Group and all the orthopedics companies in Warsaw, Ind. "Those companies work together in profoundly different ways than you can find anywhere else in the world. There is no other place quite like this, because we have leaders in different industry



segments, which allows them to leverage each of their strengths to better drive innovation in their respective segments. It's just luck, really, that we have so many leaders in different industry segments."

Indiana's government gets high marks, too. "There is a government here that has historically wanted to find a way to work with industry," Carroll said. "Looking across different industries, there's a natural reluctance to pick a winner. That's a classic philosophy -- you don't bet on winners, but rather let the market sort things out. But in the case of life sciences, the market has already sorted out this industry as a winner in Indiana."

The importance of life sciences to Indiana's economy correlates with its importance in the rest of the world, Carroll contended. Better yet the United States, and Indiana in particular, enjoy a distinct and substantial competitive advantage in life sciences. "But anyone who believes that competitive advantage must endure is mistaken," he said. "We've seen too many examples of industries where the United States had a compelling competitive advantage that should have lasted for decades, and now the United States is just part of the pack."

"We don't have some sort of natural right that says the United States must always be the leader in life sciences," Carroll added. "For example, anyone who tells you that China can't take that lead away from us has not been to China. There are some very talented people there working very hard to try to catch up and surpass the U.S.."

Money, the third leg of the stool. Again, Indiana's got a hit-and-miss record. There's not enough angel funding, venture capitalists are still loathe to spend much time here and the decision to stop funding biotech out of the 21st Century Research and Technology Fund all concern Carroll. Even the successes, like BioCrossroads' two Indiana Seed Funds, give pause.

"The Indiana Seed Fund has been carrying too much of the weight in the last five or

six years," Carroll said. The Indiana Seed Fund program has been operating 10 years or so and it's done a good job. We've gotten a lot of companies up on their feet. We're starting to see some liquidity events.

"We need to find a way to attract some more diverse sources of seed stage capital," he added. "It is available in places like San Francisco and Boston. Their academic institutions are deeply involved; culturally and institutionally, academic scientists in these cities find support to get technology outside the walls of the institution."

The culture is changing at Indiana's universities, Carroll said. The major research universities have boosted their efforts to translate research into the marketplace, but the culture needs to change even more to actively encourage faculty who are pursuing patentable inventions.

"This is something that you have to pay attention to," Carroll added. "You have to nurture it. You have to make sure you're doing things that support the faculty and the post-docs and the doctoral students who are driving this innovation. Because these people are the energy source for the creation of new companies in our industry."

"I know it can be frustrating when a university recruits a top talent, only to see that person leave a few years later to start a company. But that creates a virtuous cycle: other really bright people are attracted to places that provide options," Carroll said. "That's an important advantage in the global market for talent."

Carroll's experience mirrors that model. A lawyer by training, Carroll left his practice in New York to work for Lilly about the time it acquired a pharmacy management business. He later became part of Lilly's legal team for Prozac. Carroll left for a top job at Real Med in anticipation of its initial public offering, which didn't happen after the market crashed.

He rejoined Lilly with a unique assignment: build companies around research done by

...investing  
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Lilly scientists. "These were mostly one- and two-person companies," Carroll said. "We started more than a dozen and about 10 survived to the point where they still exist or were sold to someone. Only two went out of business. We got lucky, of course, but we also worked hard to be lucky."

He led one of the companies he started, and he did so from Boston. InnoCentive was built to bring the concept of open innovation so common in software development into biotech. "Other people had attempted to do this and concluded it was impossible," Carroll said. "We didn't know that people had attempted it, so I guess we were too ignorant to realize it was impossible --- until we did it."

InnoCentive attracted customers all over the world and created a network of 175,000 scientists. "We built the network just as the first wave of globalization was occurring. So what I like to tell people is that thanks to InnoCentive and the path-

breaking work we were doing, I had a front row seat to globalization," Carroll said.

Globalization. The United States still enjoys a dominant share of the global biotech market, but as Carroll noted earlier it will take even more work to maintain the advantage. "The city of Suzhou, China, about an hour's drive outside of Shanghai, has built an incredible capability to support large life science companies," Carroll said. "The city makes available low-cost or zero-cost credit for companies that want to build big facilities and then they actually make that debt forgivable, so it doesn't even come into the capital structure. But they do it only if other investors are willing to come in. So they've been able to attract large investment syndicates and great talent.

"Their problem is, they can get talent and money but they can't always get substrate," Carroll added. "So they're going to struggle. What I'm saying is: different areas around the world view the





life sciences as one of the most important areas to invest in. It produces very high quality jobs. It produces very little of the negative effects we sometimes associate with some other industries like pollution, etc. These companies pay high salaries and buy goods and services from other employers. These companies are great for the tax base and their surrounding communities.”

Investing in life sciences creates an energy that flows through a place, whether it's Indianapolis, elsewhere in the United States or anywhere in the world. “It has made the

life sciences an incredibly competitive space,” Carroll said. “If you don't think Indianapolis is competing with Suzhou, you're wrong. How do I know that? Because every day, at companies around the world, people like me and my colleagues are deciding where to put capital. So what we have to recognize here is, we are no longer in the Midwest, OK? Because for the purposes of risk capital, there is no such thing as the Midwest.”

Three-legged stools, it seems, are found all over the world.

**You've got  
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innovation  
to invest in.**



## Building companies out of science, or what I learned from a failed effort

By John Ketzenberger

### DEREK SMALL

There are many ways to build a company out of scientific research and Derek Small's experience runs the gamut. It is proof, too, that non-scientists with a business background are more than useful in the life-sciences equation.

The story begins with Semafore, a company that started life as ComChem in 2000. The company's name changed in 2004 and, as part of its new logo, used signaling flags to spell "hope." Small was its head of business development and directed regulatory and clinical affairs and ushered research by a scientist at Indiana University into clinical trials for a drug to combat cancer.

Along the way Semafore raised about \$20 million, including more than \$2 million from the 21st Century Research and Technology Fund and a second venture capital round of \$9.5 million. What sounds like a lot of money, though, is barely enough to keep the lights on when translating research into medicine.

"My first experience in Indiana was a company that we didn't have the resources to have a big team," said Small, who carried two official titles and many unofficial ones. "In my first four years of my five years there, we never had more than three-months cash on hand. It was very much hand-to-mouth and we all did what we had to do. We made progress. We got the first indication into clinical trials and I developed a lot of respect for what goes into it and how we have to all work together, the scientists [and] the business people in that kind of cycle."

The drug didn't make it past the clinical trials, though, and Semafore eventually wound down in 2010. The failure hurt, but it also put Small squarely in the midst of Central Indiana's life sciences community. "I was fortunate to be

forced into this world of a lot of important science with this target that the Semafore guys got me into," Small said. "I was really introduced to a lot of people all over the world that created an access for me into both pharma and academia, so now it's been easier for me to identify people who can develop our drugs."

In the years after Semafore's failure Small pooled investments from people in the biotech world and invested in several companies, but in 2013 he started work on a venture that, in terms of funding, is much different. Assembly Biosciences is a public company out of the combination of a couple others that now has two promising and very different treatments being readied for clinical trials—and plenty of money to do it.

Three years ago Small and other investors honed in on research conducted by Indiana University scientist Adam Zlotnick around treatments for hepatitis. This was about the time new treatments for Hepatitis C were driving cure rates up to 90 percent, but Zlotnick's research indicated a new way to treat Hepatitis B, a strain that affects more people worldwide but has cure rates of 5 percent or less.

The new company raised \$1.5 million in relatively short order, including \$500,000 from BioCrossroads' second seed fund and \$1 million from Johnson & Johnson. As the money from this initial funding was put to work, Small became aware of a public company that had just experienced the failure of two drugs in clinical trials. The timing was fortuitous.

"The idea was to get [our company] public quickly anyway, so here was an opportunity to reverse merge with a company that has almost \$30 million in cash when we were going to do

a \$30 [million] to \$35 million offering anyway, so it worked out," Small said. "We could have raised money right at the close [of the reverse merger], but within a few months raised our first financing \$16 [million] to \$17 million from really good public investors. The stock traded up nicely, so then we raised \$86 million in public financing in March last year. Pretty quickly we went from \$1.5 million seed financing to \$120 million we raised to advance the company."

As a result Small has more than three-months' of cash in reserve as Assembly Biosciences prepares for its clinical trials on the Hepatitis B drug as well as advancing its microbiome research to develop biologic treatments based on human bacteria strains. He's also created a company with responsibilities distributed across three regions, Indianapolis, San Francisco and New York. More than 100 people work for Assembly, including about 35 in Indianapolis who are mainly responsible for directing the company's business and administration. Zolotnick maintains a lab in Bloomington, but much of the research and development is done in California.

"I've always looked at this virtual model and I've really looked for the best people that can help a particular project at any given time," Small said. "The investors appreciate that you get the best people to do the work. The focal parts of the company are here, but the whole team isn't here. We manage this virtually."

Assembly's potential is enormous if either treatment works; it's gigantic if both come through. There are more than 300 million people worldwide with chronic Hepatitis B, Small said, so if Assembly's drug works and makes it to market, a cure rate double or triple the current 5 percent would make the company.

Its research into the human gut—the so-called microbiome—could yield treatments for a plethora of gastrointestinal ailments that currently are difficult to effectively treat. Assembly's already developed and tested a delivery system, so if its research pans out this, too, could make the company.

"Theoretically if we resource the company appropriately and find the right partners for the microbiome program, we will be

able to advance five or 10 completely non-[Hepatitis B virus] clinical trials with these products rapidly right into patients," Small said. "It's a really interesting platform. That wasn't what we had envisioned [originally]. When we merged the company [microbiome] was a really minor part. Even in our investor meetings, we disclosed it but we never did get to those last couple slides. But now at this point they're essentially equal weight in the company. Half of our investment goes to HBV and the other half goes to microbiome."

With the money in hand and promising technologies ready for clinical testing, Assembly stands at threshold of success that was hard to imagine in the Semafore days. A lot has changed in Indiana's life sciences community, too.

We're learning failure isn't fatal and that selling a company can mean the beginning of new ones, not necessarily the end of an era. "Selling companies is not a bad thing," Small said, "especially if you're recycling that resource."

And that brings us to funding. Small knows what it's like to lack funding and he's working in a well-funded environment now. One constant, he noted, is BioCrossroads' seed funds, which he calls "refreshing." By that, he means BioCrossroads invests without taking too much equity and the money comes with the group's collective expertise. "Having the right investors early is really important and super hard to do, especially in Indiana," Small said. "That can be the bridge in life sciences, you need a lot of capital and getting to that larger plateau is important. BioCrossroads has been smart about what they do and they've been a good early investor."

He likes where Indiana is on its development curve. "It's more important for us to be patient and continue to take the steps we're taking," Small said. "It's important and it's difficult to convince Indiana that working with people outside Indiana is just as beneficial if not more beneficial than working just inside Indiana."

Having  
the right  
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hard to do.



## A Carl Sagan appreciation for the local life sciences cosmos

By John Ketzenberger

### RICHARD DI MARCHI

Few people in the state's life sciences realm can match Richard DiMarchi's experience or his success, but what makes him truly unique is the scientist's ability for observation coupled with the professor's gift for relating it in meaningful terms.

DiMarchi thoroughly understands the process of translating research into medical treatments and he has done so in big companies, start-ups and universities. Here's how DiMarchi discussed his decision to retire from Eli Lilly and Company, as head of biotechnology research at age 50 and begin a stint as chemistry professor at Indiana University: "One matures and titrates to a point where there is a level of confidence to function independently," DiMarchi said. "There is a personal need for more autonomy and diversity than a single large company can provide. It's just a stage of life when you recognize if you don't act, you will miss the window of opportunity to do so."

He acted, all right. Thirteen years and five start-ups later, DiMarchi's still up to the challenge. These days you'll find him at the Purdue Research Park near Indianapolis International Airport ramping up a laboratory for Novo Nordisk, the Danish company that acquired DiMarchi's startups Calibrium and MB2. Novo Nordisk's local lab is extending research on the potential diabetes and obesity treatments that were central to the companies.

DiMarchi clearly enjoys what he does. "I'm having a helluva lot of fun," he said. "I feel as if we're making a difference scientifically and I just have my fingers crossed that these lead drug candidates really live up to expectations."

Investors like getting close to the products of that research, too. The *Indianapolis Business Journal* estimated investors have earned more than \$500 million by backing DiMarchi.

"When I look at the biotech sector we are dramatically different from where we were when I exited Lilly, but we're still operating on a relatively small scale," DiMarchi said. "We can identify a handful of successes, but more importantly I think the substrate exists here for doing what was uncertain when I first left Lilly and it needs to be exercised."

The region is beginning to exercise its biotech management muscles. DiMarchi started his first company, Ambrx, in California, because that was where he could learn biotech's business side. "Despite having led biotechnology at Lilly I knew nothing of what it was like to live in biotechnology, to be in what I call the sell side as opposed to the buy side," he said. "Much like a college student I needed to go off to get an education in how it's done in the world-class centers and then, once having those relationships and education, I can come back home and do it and do it as well as anyone elsewhere. I think we have proven that."

Others have emerged. DiMarchi named Fritz French and Kent Hawryluk, who've led the business operations of more than one of the companies built on his research, and Derek Small, the CEO of Assembly Biosciences who has worked on several investments with him. "Where we are today is so much more mature and there are more capabilities than existed just a decade ago," DiMarchi said. He warned, however, constant vigilance is required. "In the absence of creating the substrate those capabilities will atrophy or move to other locations because you can't expect the people to sit and wait indefinitely to see if these things are going to materialize."

"So that's the key role that BioCrossroads plays here. Trying to help everyone appreciate what they have, what they don't have, minimizing competition where there shouldn't be competition and looking for ways to stimulate productivity," DiMarchi

added. "I can't tell you how many days I have wondered how many more people are there in the likes of Lilly, Merck and Roche that should be equally as successful as I have been having been provided the opportunity that I have been provided. I suspect it's a fair number, right? If I'm right, then it's a damn shame that that has not been unleashed in some way that would benefit large companies and the entrepreneurial community and obviously, also the local geography."

It's critical to always look over the horizon, DiMarchi said, and not get lost in the present. Following the life sciences continuum enforces the discipline to look beyond. That continuum begins with exploration, the work of scientists working in labs to discover new potential. The effort to realize that potential begins during the experimentation phase, when the idea and initial outside capital are mixed for the purpose of teasing out new treatments. If that succeeds, then comes exploitation of that research, turning it into a product that will help patients, in DiMarchi's case, with problems related to diabetes.

"I've had a wonderful set of experiences in seeing what large organizations can do," he said. "Despite all of the rhetoric about how different they are from one another and how one is superior to the other, they're more alike than they are different. They, to a large extent, are applied research organizations. They are suited for doing what I call the exploitation. I don't mean that in a negative sense. Someone has to have the resources, the capabilities to take a mature idea that has been field tested, to all of the things that the regulatory environment demands of us, that the pricing environment demands of us to demonstrate that this is worthy of being marketed at a premium price that justifies the investment. That's what large companies are designed to do and there is no substitute for it."

Then there's the process of exploration. "In a field that is as immature as life sciences, despite everything we say about being as high-tech as we are, we're bloody inefficient," DiMarchi said.

"The inefficiency is a manifestation of how young we are. This isn't an engineering science where you can just write on a blackboard how to do this. It requires a tremendous amount of trial and error. It's largely dependent upon individual observation, serendipity and that is as much art as it is science. Therefore the ability of an individual to constitute an observation and formulate it into a hypothesis is best done in isolation.

"You don't need committees assessing or micromanaging what needs to be done," he added. "Just go and do the experiment and be wise enough to recognize of the many observations, which are the valid ones worth pursuing and which are the ones that should be trashed. The majority of them should be trashed. And it take someone with sufficient experience and sophistication about what end product might constitute being able to do this. That is why in the breadth of brilliance that you find in academics you see so little that translates into the commercial realm because there is no context, no history, there's no relevance for, 'what do I do with this?'"

Just as there are more business people who understand biotech's vagaries, there are more people who know how to link the exploration to the exploitation, but in between is where universities are most useful. "There is this middle space that I refer to as the experimental phase," DiMarchi said, "where you really do field test, pressure test and advance something from an individual in an academic laboratory to a handful of individuals, 10 people, who are willing to stake their reputations, their careers, their finances on the likelihood that one of these early signals can be advanced in larger animals in early clinical studies and prove itself to be something worth being commercialized."

Money is a tool in DiMarchi's construction, one that's historically been tough to find in Indiana. It's no secret venture capitalists don't spend much time venturing too far from the coasts where they're congregated, so the critical money tool is harder to find here. BioCrossroads has established a pair of seed funds to provide early capital and has helped foster a native venture capital community. "High quality venture capitalists bring more than what I just defined as commodity cash," DiMarchi said. "They bring connections, they bring education in terms of how to use those dollars, how to hire people. All of that is part and parcel to getting an appropriate return on the investment.

"It's a long journey," he added. "Even the fastest routes to success are still measured in more than a few years. If you could do this in five years, that would be equivalent to the three-minute mile, right? So you know it's going to be five years, and it's more likely to be 10 years."

There's an observation worth translation: It's a good start, now keep it up.

**High quality venture capitalists bring more... They bring connections, they bring education in terms of how to use those dollars, how to hire people. All of that is part and parcel to getting an appropriate return on the investment.**

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