

THE LIFE SCIENCES VOICE

The Georgia Bio Industry E-Newsletter

Newsletter Issue: August 31, 2016

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National Life Sciences Partners

Letter from the President: Can Medical Innovation Survive?



Through my daily interactions with Georgia Bio members and partners I am constantly amazed, humbled and inspired. Amazed by the creativity and complexity of the medical innovations I see. Humbled by the brilliance and the dedication of bioscience researchers and professionals. And inspired by their universal commitment to improving and saving lives. Ours is an industry that creates great jobs and contributes disproportionately to our economy. But most importantly, it is an industry that exists because it must. Medical

innovation happens because it's the right thing to do.

Despite this obvious value of innovation, our companies face constant pressures that threaten their future and the future of further healthcare advancements. Research funding at our universities and young companies is increasingly difficult to obtain. For those fortunate enough to receive sufficient initial research funding, the next hurdle is to pay for the extraordinary costs of continued R&D, clinical trials and regulatory requirements.

“But most importantly, it is an industry that exists because it must. Medical innovation happens because it’s the right thing to do.”

Those costs run into the millions, and sometimes billions, of dollars before a bioscience product is approved and eligible to be sold. Then comes the necessity to fairly price the product so that doctors and their patients gain access while the company can repay its debts and its investors to continue to innovate and operate. Between mandatory rebates, Medicare reimbursement and insurance negotiations, this burden can take its toll on even the strongest companies.

Price increases for drugs and medical products has been a hot topic in the press recently. While the nuances of pricing decisions are often overlooked, the impact to patients is ultimately the concern. So how do we strike a balance and keep these life-saving products coming to the market? And if price controls are implemented, what will that do to R&D and future innovations in America?

I ask that those in industry come together with providers and patients to discuss possible solutions within our companies, and to encourage productive state and federal policies. We are launching a Patient Advocacy Network at Georgia Bio to further engage the patient voice, and I invite readers of this newsletter to join us in the conversation. Send me a message to me if you'd like to participate. And of course I hope you will join me and bring your ideas to the Georgia Bio Innovation Summit on September 28th. Hear from advocates, researchers, investors, patients, and executives at this one day conference and add your voice to the discussion. www.georgiabiosummit.org.

Thank you,

Russell Allen
President & CEO
Georgia Bio

Morning Keynote:

The Impact of Innovation



Gillian M. Cannon
President of North
American Operations
UCB, Inc.



James C. Greenwood
President and CEO
Biotechnology Innovation
Organization (BIO)



Parker H. "Pete" Petit
Chairman of the Board
and CEO
MiMedx Group



Mary Woolley
President
Research!America



Georgia Bio Executive Interview Series:

Courtney Smith, Director,
Business Development and
Licensing, Hovione

*By Ishaneka Williams, MBA
ELN Small Business Liaison*



How did you decide on a career track in business development and licensing?

I did not plan a career in business development and licensing. Actually, I started out in marketing communications and advertising, but always had an interest in the life sciences. One of my

marketing communication clients was developing a novel process for protein development and manufacturing in biotech. It was so cutting edge and innovative, it made me regretful that I had not followed my interest in life sciences through college and I decided to return for a degree in microbiology with a plan to work in pharmaceutical research. I was very passionate about people suffering from diseases and wanted to help bring therapies and solutions to the marketplace. As I got further into my degree program and learned more about potential career paths, I realized my strengths could be better utilized in a business capacity. I made an effort to network with professionals in the pharmaceutical industry and was given an opportunity to do an internship at Glades Pharmaceuticals. I embraced the opportunity and learned as much as I could about the business of pharmaceuticals. After spending time with the business development group, I realized that was the career path best suited for my interests, education and personality.

With Hovione being a Portuguese company, how does it influence your line of work? What are differences in United States licensing regulations and other global markets?

Hovione is a global company with its largest R&D and manufacturing facility in Portugal. I think being a global company helps in many aspects of business development and licensing. I am continually exposed to different cultures and ways of doing business, which helps when trying to build a partnership that could have global reach. There are differences everywhere you look, but to be successful in business development and licensing you have to acknowledge those differences and agree to compromise to find a path forward to bring new therapy options to patients.

What are the challenges and/or benefits you have faced within the industry and how is Hovione navigating them?

Companies need to be able to adapt to changes and stay current with market trends to remain relevant. Hovione's Product Development and Licensing group is focused on developing differentiated formulations of approved molecules following the 505b2 regulatory path in the U.S. Our business model is to develop intellectual property and generate data to support an IND for Phase 2b human studies. One of the challenges we have faced is consolidation. Our lead product is in dermatology where there has been considerable consolidation within the past few years. This has created deeper pipelines and less of an interest to partner on early stage developments. We continue to listen to the market to identify opportunities that will add value for our partners while addressing needs of patients in dermatology, ophthalmology and respiratory conditions.

Do you have a vision and/or goals for your involvement with the organization?

[Hovione's] Product development and licensing also has an objective to work with start-ups who have innovative technologies in ophthalmology and dry powder inhalation - we invest in the R&D and manufacturing and the partner is responsible for clinical development and commercialization. Georgia Bio has insight into the industry trends in Georgia, and the companies developing innovation here in Georgia. Being a part of Georgia Bio offers the opportunity to connect with companies that may be interested in co-development partnerships. I think it would be great to partner with a Georgia-based company.

What opportunities do you see for Georgia Bio and the life sciences industry locally?

Opportunities are abundant, considering the leading research institutes and universities within our State. I believe Georgia Bio is in a unique position to cultivate entrepreneurship by providing "innovation stations" to start-up companies where they could have access to resources and knowledge, creating a sense of community. Several companies in large pharma have created innovation centers to give early stage ideas an environment where they can grow and evolve. I believe investing more in start-ups and creating an environment where start-up companies can grow and thrive will build upon the life science foundation in Georgia and help the state remain relevant in life science innovation moving forward.

Would you like to share any advice to young professionals who are early in their career or to those aspiring entrepreneurs in the pharmaceutical/healthcare industry?

Your network is a great resource for young professionals. It allows you to distinguish yourself, develop important relationships, and gain marketplace insight i.e. what companies are looking for in an employee and how you might be able to fill that need. The best advice I can give any young professional is to find a mentor, learn from that person, and learn the reality of how business is done. Most importantly, listen! We're all eager to be brilliant, but early

on in a career it is more important to listen and learn. It's possible to feel the pressure to demonstrate how smart we are but actions speak louder than words. Having a mentor, a seasoned professional, can help you think through professional matters. Someone who will take an active role, and champion you throughout your career. ELN is a great resource to network with professionals. Make it a point to meet someone new and learn from their experiences.

The University of North Georgia, Where Leaders and Innovators Are Born

By Steven Kronenberg and Donna Brazzell

The University of North Georgia (UNG), a regional multi-campus institution and one of six Senior Military Colleges in the country, provides a culture of academic excellence in a student-focused environment that includes quality education, service, inquiry, and creativity. As a state designated Leadership Institute, it develops students into leaders for a diverse and global society. With a student body of over 18,000, UNG is positioned in the fast growing region of north Georgia, with five campuses located in: Blue Ridge, Cumming, Dahlonega, Gainesville, and Oconee.

The College of Science and Mathematics teaches over 3,000 students enrolled as STEM majors, who will seek careers in biology, chemistry, physics, mathematics, or secondary education, or continue in professional programs or graduate school. The college offers B.S. degrees in these fields, pre-engineering courses for the Regents Engineering Transfer Program or the dual degree program with partner universities, and an Associate's Degree in Core Curriculum with pathway courses in

science or mathematics. Our faculty are committed educators invested in the success of our students, serving as teachers, advisers and mentors. Students receive a strong educational foundation in science and mathematics in the classroom and in lab courses. Many students participate in other learning opportunities such as internships, study abroad trips to Costa Rica and Belize, and undergraduate research projects with faculty, which often result in publications and presentations at professional conferences.

The College of Health Sciences & Professions is the newest addition to UNG and encompasses some of our greatest programs. Within the College we host three main programs: Nursing, Physical Therapy, Counseling as well as certificates Interdisciplinary Healthcare. The interdisciplinary components consist of Health Information Technology, Population Health and Healthcare Administration. **The RN-BSN Nursing Program was recently ranked 10th overall in the U.S. and 4th in affordability.** Recently the Physical Therapy Department partnered with GA Tech for the second summer in a row on a program called cREAtE (Creating Rehab Engineering & Assistive Technology Experiences). The program combines the knowledge of Physical Therapists from UNG and Industrial Engineers to solve clinical issues for clients in the community. We also offer two pro-bono clinics to the public in Counseling and Physical Therapy, both located in Dahlonega. The College of Health currently offers the only doctorate program at UNG (Physical Therapy) and will soon add a Doctor of Nursing Practice (DNP) where UNG will be the lead institution. **The College of Health also hosts two global engagement trips each year to Bolivia and Dominican Republic where our students and faculty get hands on medical experience. In 2016, our teams helped over 1,500 men, women and children in need. We'll add Belize and Uganda to our global engagement trips this coming year.**



Savings Now Available to Members on Nikon Instruments Inc. for Research Grade Microscope Systems

BIO Business Solutions®, BIO's cost-savings program, has announced a new partnership with Nikon Instruments Inc. The Nikon Instruments Research Grade Microscope Systems Program is available to BIO and Georgia Bio members, and offers a wide selection of research instrumentation and digital imaging solutions for microscopy for direct purchase. Nikon Research Grade Microscope Systems enable researchers fully integrated microscope systems for expediting discoveries to commercialization at a cost savings.

Member benefits include select discounts on microscope packages, individual items, free installation, 1 Year Warranty on Systems, 5 Year Warranty on Microscopes, 15% off Warranty Extension Programs and free on-site customized training. Full program benefits can be found at <http://bbs.bio.org/content/nikon>.

Nikon Instruments Inc. is a world leader in the development and manufacture of optical and digital imaging technology for biomedical applications. Now in its 99th year, Nikon provides complete optical systems that offer optimal versatility, performance, and productivity. Cutting-edge instruments include microscopes, digital imaging products, and software. Nikon Instruments Inc. is one of the microscopy and digital imaging arms of Nikon Inc., the world leader in digital imaging, precision optics, and photo imaging technology.



Regional Assets, Global Impact: Health Connect South 2016

By Russ Lipari, Founder & CEO, Health Connect South 2016



As we prepare for the third edition of Health Connect South's flagship conference, we have been talking to several of our colleagues about the value of, and needs for, effective collaboration among our regional health assets capable of delivering global impact. Here's what a few had to say:

"Together we have proven it's possible to not only understand certain correlations, but it is also possible to build new tools that bridge the interoperability gap. Thanks to I3L's innovation in EMR platforms, we have a single set of algorithms that can predict some outcomes for epilepsy patients. We have more than a signal, we have reason to believe we can positively impact patient care. By using the predictive analytics and skills of I3L and their FHIR (fast healthcare interoperability resources) platform, we are on the cusp of delivering new tools that we believe can help shorten the periods from diagnosis to the optimal therapeutic approach for epilepsy patients of all ages. This would not have happened if not for the introduction to Georgia Tech and the I3L team made through Health Connect South."

- [Chris Clark](#), Portfolio Strategy and Intelligence - Epilepsy, UCB

"Change takes a village. Healthcare problem solvers working collectively in an intentional way is what is most needed. The trigger has been pulled on the move to value-based care, but the metrics to judge success and the pathway(s) to this goal are unclear at best. Now more than ever, healthcare leaders of all types will need to work with a unified purpose, engaging with members of the continuum they may not have been accustomed, or motivated, to until now."

- [Sidney Welch](#), Healthcare Innovation Practice Lead, Polsinelli, P.C.

"The CDC, the WHO, WebMD, Health Connect South, and so many others need to work together: parties public and private, researchers, chemists, data analysis, physicians, and entrepreneurs. At the points in which we all intersect, we can make healthcare better, including prevention, for the global population. Conferences like Health Connect South help push that forward."

- [Dr. Hansa Bhargava](#), MD, Medical Editor and Pediatrician, WebMD

In the first two years of our conference, we proved that we can connect, and demonstrated the power of those connections and capabilities – at least in a reactive way as it related to Ebola. In year three, we are shifting to collaboration's proactive potential to affect positive change amongst the world's top disease states. The assets are here. What's needed is the connectivity among those assets to spark new partnerships that otherwise would not exist if not for our collective work. We cannot do it alone. But together we can accomplish almost anything.

Ready to be part of the solution? Ready to discover your next partner with whom you can change healthcare for the better on a global scale? Then you are ready to register for [Health Connect South 2016](http://www.healthconnectsouth.com): Regional Assets, Global Impact, September 21, 2016 at the Georgia Aquarium in Atlanta. Visit www.healthconnectsouth.com.



Golf and Gamble for Good!

*By Jordan Rose
Executive Director, GaBioEd*

Get your poker face on for the Casino Night Gala & Auction on **September 28, 2016** at Cobb Galleria, and go golfing at the Swings Fore STEM Golf Outing on **October 3, 2016** at the Country Club of Roswell. Proceeds from both events support the education and workforce development initiatives of the Georgia BioEd Institute.

The Casino Night Gala & Auction, presented by UCB, features a live band, gaming tables, hors d'oeuvres,

premium open bar, and silent auction. Eat, drink and play for free; raffle tickets and additional playing chips are available for purchase. The Casino Night comes at the close of our Georgia Bio Innovation Summit, where over 500 industry professionals come together to see Georgia's bioscience innovation showcased. Tickets are free with Summit registration, and \$50 for those not attending the Summit.



REGISTER & SPONSOR TODAY!



Join us for fun, food, and networking at the Swings Fore STEM Golf Outing, presented by Kilpatrick Townsend & Stockton. There will be great food, contests, and an exceptional golf experience for pros and novices alike. Become a sponsor, get a foursome together, or register as an individual.

Don't miss either of these fantastic opportunities to have fun while supporting tomorrow's STEM workforce! You can help by registering for the events, donating an auction item for the Casino Night, and by becoming a sponsor here: <http://www.georgiabiomed.org/events>.

Join us for our next Bench to Business, A Commercialization Workshop Series

By Byron Lee, BioBitWorks

Having a patent does not guarantee protection – legal issues involved in commercializing your invention.

"It depends." This standard answer shifted to the top of most questions at the informative Georgia Bio workshop with industry guests Lauren Fritts, Brian Giles, and David Stern. Session 3 of the Bench to Business series, sponsored by Meunier Carlin & Curfman law firm, continued an intense learning experience for a range of industry leaders, professionals, entrepreneurs, and those interested in how to tackle the complex task of starting a biotech business in Georgia, the U.S. and the world. The third session's topic was how to obtain a patent and how it related to licensing.

Brian Giles, a patent attorney at Meunier Carlin & Curfman LLC, provided the standard answer to most patent questions up front during a discussion with Lauren Fritts, the Director at Emory's Office of Technology Transfer. Patent law can get complicated, fast. David Stern, Contego Medical's COO with 30 years of biotech business experience, provided insight regarding how narrow profit margins can get when a company doesn't take into account this complexity.

Hopeful inventors learned that the timing of decisions early in research and development can be crucial to the success of receiving a utility patent. In order to receive a patent application approval, their invention must be novel and nonobvious. Especially, if you are enhancing prior art. Inventors must show that their invention works by collecting quality data. To strengthen a provisional application, inventors need to have diverse data models and comparative data sets within the scope of their claim. Having done just a little more research may increase profitability during licensing negotiations or inhibit infringement litigation later on.

Leaving the U.S. immediately complicates business decisions regarding intellectual property, commercialization, manufacturing, and licensing. Brian Giles taught a lesson about how important it is to consider patents in relation to your invention. A previous client patented a new drug in multiple markets throughout the world before bringing it to market in just one. This reduced the promising researcher's cash reserve to the point where they couldn't bring their novel drug to market. It was a lesson on how important intellectual property is to a burgeoning biotech business that wants to change the world.

Ultimately, participants learned another important step taking them from the bench to a business to the biotech industry. Georgia Bio's commercialization series continued their offering by providing powerful insight from industry leaders in an interactive learning experience and discussion. With this new knowledge, inventors can take charge of their future success by reducing risk during the oncoming onslaught of paperwork, legal jargon, and crucial business decisions.

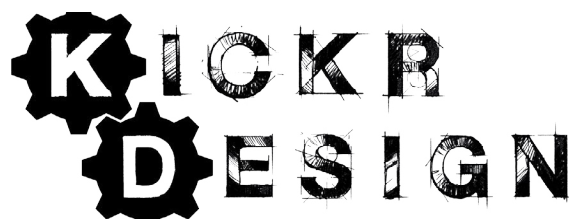
The next Bench to Business Workshop: Session 4 will be held [September 16, 2016](#).



Featured New Member: **Kickr Design**

Kickr Design is a unique product development firm that places an emphasis on engineering and entrepreneurship founded by Stanford alumnus Addison Shelton. Their services range from product conceptualization and industrial design, all the way through prototyping and manufacturing. Located in the Upper Westside of Atlanta, Kickr Design's capabilities include: mechanical, electrical, and materials engineering, as well as industrial design. Their diverse team represents Georgia Tech, Southern Poly, Vanderbilt, Virginia Tech, and others to create a friendly, professional, and accessible product design and engineering team. They offer class I and class II medical device designs and prototyping compliant with all FDA Good Manufacturing Practices, as well as design and prototyping of consumer products and industrial equipment.

Some areas of expertise include: IoT device design, mechatronic assemblies, advanced computer-aided modeling, sensor integration, embedded electronics, PCB design, software development, and design-for-manufacturing. In their prototype shop, Kickr has 3D printers, laser cutters, CNC mills, silicone molding equipment, welding and sheet metal equipment, and a full electronics workspace for electronics prototyping and embedded software programming. The in-house capabilities allow for rapid prototyping and iteration leading to an expedited pathway to commercialization. In addition to product design and engineering, entrepreneurs may also seek legal guidance from an in-house patent attorney. Kickr Design is an all-in-one resource for entrepreneurs and startup product companies to bring their ideas to life as well as gain an education in product development, engineering, market testing, and customer discovery for future endeavors. Check them out at www.kickrdesign.com.



Welcome New Members

Hydro Service & Supply	rPeptide, LLC
Kickr Design	Saol Therapeutics
Marsh	Slamcoll
NSF Health Sciences	Video Medicine
Osborne Healthcare Consulting	Witowski CMC Consulting, LLC
Peak Serum Inc	

Kennesaw State University STEM Career Fair
[September 20-21, 2016](#)

University of Georgia Fall Career & Internship Fair
[September 21, 2016](#)

Health Connect South 2016
[September 21, 2016](#)

2016 Georgia Bio
Innovation Summit
[September 28, 2016](#)



Casino Night
[September 28, 2016](#)

Trans-Pacific Health Sciences Dialogue
[September 28-29, 2016](#)

Mercer University Fall Career Expo
[September 29, 2016](#)

Swings Fore STEM Golf Outing
[October 3, 2016](#)



BioNetwork West-
Partnering Made Easy
[October 5-7, 2016](#)



Careers in Life Sciences Series:
Finance, Consulting and Business
[October 6, 2016](#)

The Southeast BIO (SEBIO)
Investor & Partnering Forum
[October 11-13, 2016](#)



BioJapan
[October 12-14, 2016](#)

AdvaMed 2016
[October 17, 2016](#)

Bench to Business: A Commercialization Workshop
Series: Session 5
[October 21, 2016](#)

Upcoming Events

GSU - GaBio/ELN Info. Session
[September 6, 2016](#)

T3 Labs Industry Tour
[September 8, 2016](#)



Viacyte Industry Tour
[September 12, 2016](#)



BioPharm America™ 2016—9th Annual International
Partnering Conference
[September 13-15, 2016](#)

Biotech Startup Day 2016
[September 14, 2016](#)

12th Annual Georgia Tech Biotechnology Career Fair
[September 15, 2016](#)

Digital Medicine Connect 2016
[September 15, 2016](#)

Bench to Business, A Commercialization Workshop
Series: Session 4
[September 16, 2016](#)

2016 ISPE Annual Meeting & Expo
[September 18-21, 2016](#)

Careers in Life Sciences Series - Athens, GA
[September 19, 2016](#)

Continued on next page...

International BioFest 2016
[October 24-27, 2016](#)

**International
BioFest²⁰¹⁶**

Celebrating life sciences
with 3 events in 1 week



IP Career Showcase
[October 26, 2016](#)

BioBasics: Biotech for the Non-Scientist
[October 27-28, 2016](#)

Medtech Women@SEMDA
[October 27, 2016](#)

BIO- Europe 2016
[November 7-9, 2016](#)



Drug Development Boot Camp 2016
[November 16-17, 2016](#)

Bench to Business: A Commercialization Workshop
Series: Session 6
[November 18, 2016](#)

Biolatam® 2016
[November 29-30, 2016](#)

Careers in Life Sciences Series:
Entrepreneurship
[December 1, 2016](#)

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