The Life Sciences Voice
The Georgia Bio Industry E-Newsletter

Newsletter Issue: November 2017

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Georgia Bio Newsletter Credits

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National Life Sciences Partners
As 2017 comes to a close, we reflect on another year of milestones for Georgia’s bioscience industry. Rather than list our accomplishments and champions here, I invite you to join us at the Cobb Energy Performing Arts Centre on February 15 for our Annual Georgia Bio Luminaries Awards Gala. We have much to celebrate and hope you will be a part of that celebration.

Following another informative and successful Innovation Summit in October, we know from our survey results that networking remains the #1 priority for our members. We will continue to offer productive networking events in 2018 and are exploring more professional development offerings for you and your colleagues. Save the date for October 9, 2018 for our next Summit.

I’d like to also remind you to take advantage of all the benefits of your membership, including discounted event admission, access to your fellow members, and discounts on products and services via our BIO Business Solutions program. Our members have saved hundreds of thousands of dollars on these programs, and we invite you to reach out to us to request a savings estimate or analysis.

Finally, I remind you to engage with our team to discover all that your membership has to offer you and your team. Also keep an eye out for our new member orientation sessions beginning January 9th.

Thank you,
Russell Allen
President & CEO
2017 GaBio Innovation Summit Recap
JoAnna Pendergrass, DVM, Founder, JPen Communications, LLC

The 2017 Georgia Bio Summit, held at the Cobb Galleria in Atlanta, GA on Tuesday, October 24, was yet another successful representation of the life sciences industry in Georgia. Presentations and exhibitors from across the life sciences spectrum provided attendees with thought-provoking information on innovations and solutions to continue moving the industry forward.

Breakfast Keynote
To kick off the Summit, Dr. Jay Yadav, Georgia Bio Chairman and founder & CEO of MiRus, spoke of recent accomplishments in Georgia’s life sciences industry and emphasized the need for a larger industry footprint in the state. Russell Allen, president & CEO of Georgia Bio, highlighted some of Georgia Bio’s major components, including networking, business support, and advocacy.

Greg Simon, president of the Biden Cancer Institute, gave the breakfast keynote address. During his address, Mr. Simon continually stressed the need for health to be viewed as an asset, rather than a cost. Seeing health only as a cost, he said, can lead to denying drug treatments due to cost without realizing that allowing access can save lives and return more money to the economy.

Mr. Simon also emphasized putting patients at the center of clinical trial designs. For example, these designs can provide avenues for participants to send thank you notes and provide feedback during the trial. Overall, he said, pharmaceutical companies can lose sight of the patients who are looking to them for hope.

Remarking on his time as leader of the Cancer Moonshot program, an Obama administration initiative to fast-track cancer research and access to cancer therapies, Mr. Simon said the program “became a movement and more than just a government program...it was about saving lives.” Companies participating in the program were pushed to double their impact and focus on touching the lives of patients with cancer. As president of the Biden Cancer Institute, Mr. Simon is currently tackling the issue of physical hoarding of data by encouraging data sharing.

As he concluded his address, Mr. Simon referenced a Bible story in which fishermen were told to cast their net to the other side of their boat. He implored pharmaceutical companies to do the same because “all the patients are on the side where the net is not being cast,” he said.

Lunch Keynote and Panel Discussion
Kim McCleary, Managing Director of FasterCures, provided the keynote address at lunch. Her presentation, titled ‘Engaging for Success: Patient Centricity Comes of Age,’ highlighted the progression from limited patient involvement in healthcare to the development of a patient-centric healthcare system. She noted the FDA’s Patient-Focused Drug Development initiative, which puts increased focus on how patients perceive their medical conditions and available treatment options. Mrs. McCleary also mentioned organizations like diaTribe, which, in 2014, helped the FDA understand that the A1C blood test is not the only thing that’s important to patients with diabetes.

Following her presentation, Mrs. McCleary led a panel discussion with Robert K. Coughlin and Dr. Jason Spangler. Mr. Coughlin, who is President & CEO of the Massachusetts Biotechnology Council and a Cystic Fibrosis Patient Advocate, has a son with cystic fibrosis (CF). He is passionate about finding ways for academia, government, and industry to collaborate and find a cure for CF. He lauded the advances of precision medicine, yet remarked that precision medicine therapies won’t mean much if people can’t afford them. Coughlin mentioned that his son’s CF therapy, which doesn’t include the newest CF drug, costs $500,000/year.

Dr. Spangler, who is Amgen’s Executive Director of Value, Quality and Medical Policy, spoke about the need for pharmaceutical companies to develop innovative approaches to reimbursement and payment, such as insurance designs that incentivize the use of high-value medical services. He said that the pharmaceutical industry must think of how patients are going to pay for the therapies and realize just how many costs, like transportation, aren’t even factored into current healthcare costs.

Looking forward, Mr. Coughlin is excited about seeing the pharmaceutical industry’s image improve and become more appreciated. Yet, he would like to see changes to the payer system changed that benefit everyone, along with more focus on fixing brokenness in the healthcare system. Dr. Spangler is excited about the power of precision medicine in determining therapies on an individual basis. However, in a memorable catchphrase, he described precision medicine as “Star Wars medicine but Flinstone delivery.” “If we don’t move forward,” he said, “all of the innovation will be for naught.”
Innovation Stage
Throughout the day, the Innovation Stage provided companies an avenue to pitch their novel approaches to persistent problems in medical diagnostics and treatment. Oculus Prime, for example, described an outpatient procedure for glaucoma that could replace current eye pressure-lowering treatments. Lunula Health presented a smartphone app that would meet the need for a noninvasive and inexpensive tool to diagnose anemia. Centizyme pitched a new treatment for severe asthma that would use functional gold nanoparticles to target inflammation.

Concurrent Sessions
Presentations during the concurrent sessions covered many life sciences topics. In the ‘Research & Innovation’ session on the fight against infectious diseases, the presenters touched on several key areas, including the value of basic science research in preparing for epidemics, the need to simplify vaccine storage and delivery, and the importance of having quickly-scalable vaccine manufacturing processes.

A ‘Company Investors Presentation’ session featured Intent Solutions, a company that has developed a tamper-resistant device called tadTM (“take as directed”) to improve patient compliance. This session also featured the company Covanos, which has developed a noninvasive diagnostic technology called C-Heart for diagnosing heart problems.

Participants in one of the ‘Quality Management Systems’ discussed the Medical Device Single Audit Program (MDSAP), which was developed by a consortium of 5 countries (USA, Australia, Brazil, Japan, Canada). MDSAP’s goals include eliminating auditing redundancies and reducing influence of auditor subjectivity. Current obstacles to MDSAP participation, the session’s presenters noted, include cost and lack of interest in participation.

A roundtable session on pre-commercial PR & Marketing covered such topics as the goals of pre-commercial PR, difficulties in accessing busy private practice physicians, and on-site training sessions as a PR strategy. Roundtable participants also discussed what companies need to do before beginning their PR efforts, including compiling all clinical trial information, knowing where the company’s brand will land in terms of serving an unmet need, and building relationships with key stakeholders.

Ed Schutter (President & CEO, Arbor Pharmaceuticals), and Daniel White (President & CEO, Clearside Biomedical) were panelists for a ‘Life Science Leader Chats’ session on achieving success. Mr. Schutter attributed his success to being in Georgia while Mr. White spoke about his commitment to caring for his employees and paying it forward. For recent graduates looking to raise money to start a company, Mr. Schutter and Mr. White advised graduates to work with a good mentor and build a strong management team. When asked to provide characteristics of success, the panelists described such traits as curiosity, fearlessness, and loving what you do.

To close out the Summit, Dr. Stacy Williams Shuker of Down South Innovation presented the Anthony Shuker Scientific Poster winners in honor of her late husband. Summit attendees then enjoyed a Casino Night and silent auction, whose proceeds benefit the GeorgiaBioEd institute.

Study Abroad with UNG
The University of North Georgia (UNG) prepares students with a solid educational foundation in the life sciences by offering learning experiences in the classroom and laboratory, in research, on study abroad trips, or at professional conferences. These opportunities provide our students with the best overall education, leading them to excel and win scholarships, grants and awards. Megan Andres (left), a biology major, was selected as a 2016 National Institute of Health (NIH) undergraduate scholarship recipient. She plans to be a pediatric oncologist and will have the opportunity to work one year at the NIH upon graduation. This is the third consecutive year a UNG biology student has received this nationally competitive award. Katie McCullough, a biology graduate (’17), received a prestigious Fulbright scholarship to study microbiology in Poland this fall. Katie interned at Los Alamos National Laboratory in New Mexico this past spring and plans to pursue a PhD in microbiology at the University of Tennessee in 2018.

The College of Science and Mathematics faculty offer undergraduate students many research experiences. These freshman biology students (right) are participating in a research lab experience isolating and identifying novel bacteriophages from soil and streams. Their results from this “SEA-PHAGES” research will be published and contribute to the Howard Hughes Foundation Science Education Alliance. Dr. Miriam Segura-Totten, recently awarded the prestigious University System of Georgia’s 2017 Regent’s Award for Excellence in Teaching, and colleague Dr. Ryan Shanks (above far right) manage a grant for this research project. For more information about UNG biology programs and ways to support life sciences at UNG, contact Donna Brazzell at donna.brazzell@ung.edu

Study Abroad with UNG
The US government and industry spends nearly equal amounts of money on research. If the focus is only on government grants, then half of the money being spent on research is missed. In industry, most of your work is solicited. In government, most of the work is unsolicited, meaning you submit for the grant. If a company solicits you to write a proposal, then odds are in your favor- 1:3, 1:2, or maybe more. How do you get to the point where the odds are in your favor? Build your reputation over time. You must build credibility and a strong a strong background. How does the company know you can do the job as opposed to someone else? Having the reputation. While a research project may still be risky – you are probably the best person to do it. Government and industry grants have this in common. A researcher can be good at both government and industry proposals, but learning that translation takes time. Things are not done the same way in industry as they are in academia. The way industry assesses research and the people doing research is different. The researcher must learn the difference. Much of the fundamental research is hypothesis-driven and much of applied research is not. A great deal of the research done in industry is fundamental. You need to understand something before you can apply it in many cases. You need to have fundamental understanding before applying it.

What motivated your transition from industry to academia?

Something I’ve always wanted to do. Thought it would be closer to the end of my career, but it was not. Research comes down to people. So where do you get the people? How do you work with the best people? In industry, you get people out of university and develop them from there. In the university, you start earlier on in the development process.

What kind of training and mentoring did you see in industry?

The company had 10 interns per year for 10 years. At the time, this put them at the higher end of companies that had robust intern programs. Universities like these collaborations because they can say to students: this is what you can expect. They also like to announce that this is where our students go after graduation. They build a lot of hard data from these collaborations. Senior people and vice presidents would remark anytime they were asked- that an internship was the deciding factor in their career and that it gave them direction and focus. High-level people always supported internship collaborations. Students would be put on meaningful projects so they could go back and tell about their experience. Internships also facilitate hiring and visibility for the company.
The Bio/Med Investor Network is an Atlanta-based investor network that focuses on emerging health innovation technologies in the therapeutic, medical device, diagnostic and digital health fields. Since I joined this organization in January this year, it seemed appropriate to do a year-in-review for the network. Only three years old now, the Bio/Med network has had a very active 2017. The allure of a health innovation-focused investor network has attracted the attention of many folks in the angel investment community.

I represented Bio/Med at the Angel Capital Association (ACA) conference in April connecting with other angel groups that invest in the health innovation field. I was also invited to represent Bio/Med on two panels this year at the RESI Investor Forum at the BIO International Convention in San Diego, CA last June and at the SEBIO Investor Forum in Pinehurst, NC this month. The crowd at both events and the follow up showed a large interest in the network.

Investors from the Bio/Med network also participated at the Georgia Bio Innovation Summit this past October as mentors for the Company Showcase presenting companies sharing their insight with the CEOs prior to presenting at the Summit.

Lastly, the Bio/Med network added two more portfolio companies this year so far from dozens of applicant companies and from the efforts of a very active screening committee. Fortus Medical (Minneapolis, MN) and Nephrogen Sciences (Atlanta, GA) received funding from members of the network this year. There were also a number of other highlights in 2017.

- Dozens of Applicant Companies
- 24 Companies Presenting to the BioMed Screening Committee Meetings
- 8 Companies Presenting at Quarterly Investor Dinners
- 7 Syndication Requests from Other Angel Networks
- 8 New Members
- 2 New Sponsors

…and a partridge in a pear tree. Fantastic!

A huge thanks to the support of our sponsors The Georgia Research Alliance, McDaniel Law Group, King & Spalding, Meunier Carlin & Curfman, BradyWare and our host sponsor The Northern Trust. The Bio/Med network is constantly soliciting applicant companies in the health innovation field, accredited investors to join the membership, and sponsors eager to support this exciting group. Please contact me if interested. Wishing you a great holiday and amazing 2018 from the Bio/Med Investor Network Board of Directors!

**Vaccines: Powerful Simplicity**

*Emily Burke, biotechPrimer*

**VACCINES: ELEGANT, POWERFUL SIMPLICITY**

Anyone who’s suffered the aches and fever of influenza has good reason to value the simple flu shot. In fact, millions roll up their sleeves and literally take their medicine. The US Centers for Disease Control (CDC) (Atlanta, GA) estimates that about 146 million doses of influenza vaccine went to doctors’ offices, health departments, and the corner drugstore among other places, to help keep us flu-free during 2016-17. Drug companies keep up with this high demand by manufacturing these vaccines well in advance—six to nine months before the start of flu season in October.

The influenza vaccine is one of many life-saving vaccines that keep people healthy. This week, we look at different types of vaccines and how drug companies manufacture them.

**JENNER’S NEEDLE IN THE HAYSTACK**

Vaccines have been around a long time—dating from the late 19th century during the smallpox pandemic. This deadly disease killed or disabled hundreds of thousands of people just in England! In 1796, an English doctor, Edward Jenner, noticed that local milkmaids were immune to smallpox. Jenner observed that these women
had all suffered from cowpox, a related but harmless virus. Jenner hypothesized that the cowpox imparted some type of immunity, so to test his theory Jenner took pus from a cowpox blister and inoculated his gardener’s small son, James, with the virus through shallow scratches. James developed a slight fever afterward, but when intentionally exposed to smallpox later, the little boy never became ill.

Jenner’s methods were a little rough (not to mention unethical by today’s standards), but his thinking was spot on. The idea behind vaccines is simple. First expose someone to a harmless version of a disease-causing microorganism, or pathogen. Amazingly, this “trains” their immune system to recognize and fight the germ. Exposure to the disease forces the body to create special white blood cells, known as memory cells, which combat any further exposure to the disease.

**COCKTAIL FODDER: 40,000 SAVED!**
According to the CDC, flu season runs from October through May in the US. The organization’s latest study estimates that the flu vaccine saved 40,000 lives in the US during a nine-year period.

**TYPES OF VACCINES**
Vaccines come in different varieties including: inactivated whole, live attenuated, and subunit vaccines. Each necessitates different manufacturing requirements.

Inactivated whole vaccine. Made with dead microorganisms (viruses or bacteria), these stimulate an immune response. Among the most famous is Dr. Jonas Salk’s polio vaccine, developed in 1955.

Live, attenuated (weakened) vaccine. These are created by reducing a pathogen’s strength so that they become harmless. Live vaccines tend to produce the strongest immune reaction.

Subunit vaccine. These vaccines use only one part of a pathogen, an antigen. The antigen provokes an immune response. One method of making subunit vaccines involves isolating a specific protein from a virus and administering only this protein.

Scientists are also currently developing DNA-based vaccines. These consist of a gene encoding a pathogenic protein as opposed to the protein itself.

The Whole Story

Most whole pathogen vaccines protect against viruses, such as rabies, not bacteria. But making any vaccine means first growing lots of virus. This “virus-farming” involves selecting and obtaining a strain of a particular virus, the seed strain, and choosing what to grow it in (the medium). Where do manufacturers buy a pathogen in the first place?

They come from one of two sources. Viruses (and other microorganisms and biological materials) are produced and housed in well established “culture collections,” such as the American Type Culture Collection (Manassas, VA.) Some companies or academic institutions also develop strains of particular viruses “in-house.” For the flu vaccine, new strains are selected annually based on the World Health Organization’s assessment of the virus’s evolution over the previous season.

Choosing the seed strain is only the first step of vaccine manufacture. Although dangerous and often deadly, viruses are powerless without a host—someone or something to grow on. Two of the most common “host-cell platforms” are chicken eggs and animal cell culture.

Chicken eggs? Yes, the incredible edible egg provides a fantastic growth medium for influenza and other viruses. (Side note: The CDC recommends that most people with egg allergies be vaccinated. However, it also suggests that those with severe, life-threatening allergies receive only certain vaccines.)

Some viruses thrive in certain types of animal cells. Two of the most commonly used in vaccine production include one from the kidney of the African green monkey—known as Vero cells, and one derived from the kidney cells of a cocker spaniel (MDCK cells). Though it is easier and quicker to scale up animal cell culture vaccine production, it is much more expensive than egg-based vaccine growth.

Regardless of medium, once there’s enough virus, the manufacturer needs to separate or isolate it from the host material. Isolation involves centrifuging and filtering to divide virus particles from the host cells.

Production of whole pathogen or inactivated vaccines involves the critical step of inactivation. This means disabling a virus’s ability to infect without eliminating the parts of the virus that trigger an immune response. Inactivation involves a variety of strategies, including detergent treatment, heat treatment, or exposure to UV light.

- Detergent-treated: Specific for envelope viruses, detergents break the chemical bonds that hold the virus’s envelop (outside surface) together disabling its ability to invade a host.
- Heat, chemical, and pH-treated: Viruses use proteins on their surface to infect host cells. Altering their shape destroys their ability to recognize and infect cells.
- Ultraviolet light-treated: A virus’s basic building blocks—their DNA or RNA—are destroyed by UV light. With no genetic code, viruses cannot make more of themselves. The last step in making vaccines is formulation. The inactivated virus gets mixed into a sterile water or salt solution along with stabilizers and preservatives. Some vaccines also contain adjuvants
at this point. An adjuvant is a substance that boosts the immune response to a vaccine. Vials are then filled, inspected, labeled, and shipped. Most vaccines require refrigerated storage and shipping.

**ALIVE, NOT KICKING**
Producing a live, attenuated vaccine follows similar steps, without inactivation. In addition, it starts with a seed strain that has been rendered harmless. The new organism continues to grow but produces immunity without causing illness. Attenuated vaccines produce stronger, usually longer-lasting, immune responses than inactivated vaccines because they more closely mimic actual infection. Attenuated vaccines should not be given to people with weakened immune systems, such as cancer patients or the elderly.

Safe, attenuated vaccine strains are produced in a few different ways. Sometimes, it may simply be a related, but harmless virus that kicks in the immune response. Jenner’s vaccine, which was essentially the cowpox virus, is a classic example. Today’s smallpox vaccine uses a related virus, vaccinia. Another common method to produce vaccines is raising several generations of a clinical isolate, or a laboratory-pure version of a pathogen. Growing in non-human cells, it adapts to its new host, becoming less infectious over time. Examples include the measles, yellow fever, and poliovirus vaccine strains. Scientists can also use recombinant DNA technology to delete the portions of a virus’s genome that cause infection.

Vaccines have a simple premise, but the science and manufacturing that make them possible is complex. Different microorganisms require individual approaches. Through trial and error, microbiologists, virologists, and other scientists determine the best formulation.

In part two of this series, we’ll discuss other kinds of vaccines, including virus-like particle (VLP), polysaccharide, and further discuss subunit vaccines. We’ll also give an overview of how vaccines are tested and approved.

New at Morehouse School of Medicine

**Dr. DeQuan M. Smith, Morehouse School of Medicine; Dr. Angelita Howard, Morehouse School of Medicine**

In an effort to expand the number of high paying, advanced career opportunities in the Bioscience and health arena, and enhance student achievement in science education, Morehouse School of Medicine (MSM) partnered with strategic collaborators to build comprehensive offerings to diversify the scientific workforce. Over the last several years, MSM has researched best practices to reshape traditional course offerings utilizing technology to create a more robust pipeline in the health sciences.

Morehouse School of Medicine desires the interest of new and existing professionals to provide a pathway for knowledge and skill enhancement to become innovative problem-solvers who can identify problems and seek new solutions in the industry. By creating offerings accessible all over the world, MSM is thrilled to assist in increasing the number of students who will gain the adequate experience to improve the health of people, animals and the environment. This is an exciting new method for Morehouse School of Medicine to expand its curricula through technological advances. Students will engage with classmates and faculty in regular synchronous and asynchronous online sessions, virtual office hours, study sessions, group projects, collaborative assignments, and networking.

As the Division of Biomedical Sciences in Graduate Education moves forward to employ new strategies to meet the needs of the emerging scientific workforce, this new educational track will offer coursework that will lead to an Executive Master of Science degree in Biomedical Technology (eMSBT). It is the intent of the division that this new distance-learning program will assist in the preparation of future biomedical technologist to support the scientific workforce. Within the Graduate Division of Public Health, the Executive Master of Public Health (eMPH) is designed for working professionals with a community health policy-focused approach. The eMPH consists of a community health and policy curriculum coupled with additional program requirements to ensure students obtain the practical skills necessary to advance and further as leaders in the public health profession.

Morehouse School of Medicine looks forward to working closely with Georgia Bio to continue to the development collaborations to meet the Bioscience needs, wants, and deficiencies.

**Executive MPH pending approval from Council on Education for Public Health**
**Biomedical Technology Certificate pending approval by the Southern Association of Colleges and Schools Commission on Colleges**
Looking for a way to globally market your startup organization at a discounted rate?

Exhibit in the Georgia, USA Pavilion at:

The 2018 HIMSS Conference & Exhibition, March 5-9 in Las Vegas, brings together 40,000+ healthcare IT professionals, clinicians, executives and vendors from around the world. Enjoy the exceptional education, world-class speakers, cutting-edge products and powerful networking opportunities that are hallmarks of this leading conference.

***RECEIVE DISCOUNTED EXHIBIT SPACE***

The Georgia Department of Economic Development and Innovation Crescent Regional Partnership invite you to exhibit in the Georgia, USA Pavilion at HIMSS 2018. As the first and only state exhibitor at HIMSS 2015, the Georgia, USA Pavilion will again offer a PRIME LOCATION for exhibiting and networking at the 2018 convention. Georgia’s Innovation Crescent is offering four spaces to early stage companies inside the Georgia Pavilion at a discounted rate of $2,500. Travel and hotel accommodations are not included.

All exhibitors are expected to staff their booths during exhibit hours and submit print-ready artwork/logo for their pedestals.

YOU’LL RECEIVE:

- Exhibit space in the Georgia Pavilion with your company’s logo on the front of your individual pedestal.
- Meeting space within the Georgia Pavilion. Sign-up required prior to show.
- Attendance at the in-booth reception.
- Company listing in HIMSS Show Directory.
- Up to three exhibitor passes providing access to entire exhibit hall, conference sessions and all HIMSS has to offer.
- The opportunity to promote your products and services to national and international decision-makers in health IT.

Contact Kristin for more information. kboscan@georgiainnovationcrescent.com
Upcoming Events

**Careers in Life Sciences Series**
December 5, 2017

**WIB-Atlanta 2017 Holiday Potluck**
December 10, 2017

**Intellectual Property Professional & Practitioners Holiday Party**
December 14, 2017

**Biotech Showcase**
January 8-10, 2018

**Digital Medicine and Medtech Showcase**
January 8-10, 2018

**BioGeNe 2018**
February 8-9, 2018

**BIO CEO & Investor Conference**
February 12-13, 2018

**Georgia Bio Life Science Luminaries Gala Celebration and Golden Helix Awards 2018**
February 15, 2018

**Georgia Clinical & Translational Science Alliance Statewide Conference**
February 22-23, 2018

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**BIO Asia International Conference**
March 19-20, 2018

**BIO Executive Training Programs**
June 2-4, 2018

**2018 BIO International Convention**
June 4-7, 2018

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Welcome New Members

- Cambium Medical Technologies LLC
- Chemily, LLC
- Flow-Medtech
- Haldeman Homme
- OncoLens
- One-World Inc.
- Plasma Surgical, Inc.
- Recro Pharmaceuticals
- RW Sullivan Consulting
- The Pipette Solution
- WSP USA
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