



connections newsletter



**MARCH 2020
UPDATE**

**Serving the NC Life
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NCBIO This Month

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NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on [LinkedIn](#) and on Twitter at [@ncbio](#).

NCBIO Links

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IP Lifeblood of Bioscience Industry



Panel: Julie Meigs, Shawn Glidden, Gary Pace, Mike Penn and Tim Wilson.

Intellectual Property protection, drug pricing and artificial intelligence are key topics for people working in the life science intellectual property space according to the panel discussion for the NCBCIO Life Science Luncheon and Forum on February 19. Moderator Julie Meigs of Womble Bond Dickinson noted that, "For growth-stage companies, having solid IP can be essential to securing funding that is necessary for next steps. Likewise, for established companies having strong intellectual property is essential for maintaining a competitive advantage in a very high risk and costly industry."

Shawn Glidden of Liquidia Technologies says that, "In an early-stage company you have to jump on the IP, get it reviewed, and hopefully patented. IP is your property, the thing that investors kick the tires on. In later stage companies, the question is how to extend the life of the product. It is critical to look at the back end of the patent life because your return on investment comes much later in the pharmaceutical industry."

Mike Penn with Amgen noted that, "In our industry right now, the difficulty is in maintaining patent protection. It takes an average of \$2.6 billion to bring a product to market. You need to maintain strong intellectual property to recover that cost. You don't patent things for frivolous reasons."

Gary Pace of Cell Microsystems discussed the importance of staying focused. He said, "In early-stage companies it is very difficult to throw away patent protection you fought for, but you have to stay focused on the company's current suite of products. The quality of a company's earliest IP is usually not as high as the IP developed later. So, you sometimes spend a lot of time trying to adjust the scope of your initial claims."

The panel also noted that artificial intelligence is playing a growing role in pharmaceutical development. Patent protection is difficult in the current environment according to Tim Wilson of SAS, who told attendees that artificial intelligence, while still an emerging technology, has a key role to play in pharmaceutical development. "AI is used most effectively now in aiding human decision making. We can help people who are making lifesaving decisions more efficient and more effective."



Sponsor representatives Tom Fagley (Hughes Pittman & Gupton), Julie Meigs (Womble Bond Dickinson), Rebecca McCabe (Aon) and Arles Taylor (Jenkins, Wilson, Taylor & Hunt).

Thank you to our sponsors: [Aon](#); [Hughes Pittman & Gupton](#); [Jenkins, Wilson, Taylor & Hunt](#); and [Womble Bond Dickinson](#).

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Sen. Mike Woodard, Rep. Robert Reives, Rep. Lisa Barnes, Sen. Paul Newton, Rep. Donna McDowell White and Doug Burns (Grifols).

The Life Science Caucus toured the Johnston County Workforce Development Center and the Grifols' plasma fractionation facility in Clayton on Monday, February 3. Caucus Co-Chair Representative Donna McDowell White (R-Johnston) who represents Johnston County hosted the event and spoke about the amazing partnership that's been forged by the community college, Grifols and Johnston County's second major biomanufacturer, Novo Nordisk. Caucus Co-chairs Senator Paul Newton (R-Cabarrus), Senator Mike Woodard (D-Durham) and Representative Robert Reives (D-Chatham) reiterated White's remarks.

After a lunch and a tour of the Workforce Development Center, the group traveled to Grifols for an overview and tour of that facility. Doug Burns, site lead at Grifols, explained the fractionation process that allows Grifols to separate proteins in blood plasma that become life-saving medicines and noted that "Grifols' employees know that what we do everyday matters and we are impacting patients' lives."

Other attendees included Representative Lisa Barnes (R-Nash) and staff from the offices of Speaker Tim Moore (R-Cleveland), Senator Brent Jackson (R-Duplin), Representative Pat Hurley (R-Randolph), and Representative Perrin Jones (R-Pitt).

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Life Science Growth Continues



Audentes

Another gene therapy company announces plans to locate in North Carolina. Governor Roy Cooper, state and local officials were in Sanford for the Audentes Therapeutics announcement that it would locate its second manufacturing facility in North Carolina.

"With our powerhouse research centers and highly-skilled workforce, biotech pioneers recognize North Carolina's role as a leader in the life sciences," said Governor Cooper. "Lee County is a perfect fit for Audentes as they seek to become a global leader in genetic medicines."

Donald Wuchterl, Senior Vice President, Technical Operations at Audentes, says the company had a list of criteria in considering a new location. He said a skilled and talented workforce was a key issue, and the company found that in North Carolina and Lee County. [More](#)



AveXis

AveXis, a Novartis company, hosted a ribbon cutting ceremony at its Durham location to mark the site becoming operational after an 18-month buildout. The sophisticated gene therapy facility employs nearly 400 skilled workers to meet the needs of complex gene therapy production and includes 170,000-square-foot of manufacturing, laboratory and administrative space with multiple functional areas.

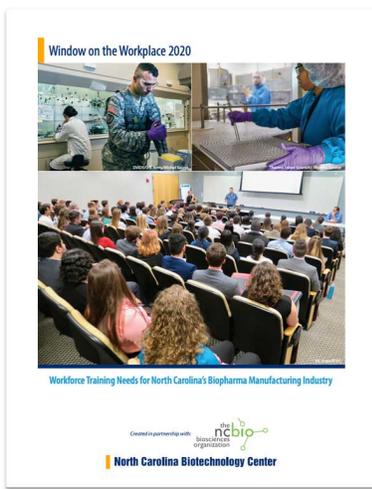
“This North Carolina facility is dynamic, with deliberately adaptable areas that will allow for us to efficiently execute both clinical and commercial production of our gene therapy portfolio. We look forward to pursuing licensure for the site,” said Dave Lennon, President, AveXis.



Fujifilm Diosynth

Fujifilm Diosynth held a Ground-breaking Ceremony on February 25 to signal the start of its North Carolina facility expansion project. The 31,778 square foot addition includes the expansion of its cell culture and microbial manufacturing trains through the addition of new recovery and purification suites. The North Carolina site will increase its cell culture manufacturing capacity by approximately 25% and microbial capacity by approximately 50%. A new receiving warehouse is also included in the project. The facility is expected to be online by mid-2021.

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The latest version of the *Window on the Workplace* (WoW) report indicates the number of manufacturing jobs in North Carolina will increase by at least 5,000 in the next five years. The survey for the report was conducted by NCBIO and the North Carolina Biotechnology Center (NCBiotech) in late 2018 and 2019.

In the opening letter of the document, the leaders of the two organizations, Doug Edgeton and Sam Taylor wrote, “WoW 2020 both confirms the success of North Carolina’s biopharma manufacturing workforce development strategy and shows that North Carolina must do more to ensure continued growth and assure our state’s status as an internationally recognized hub for biopharma manufacturing. Moreover, WoW 2020 strongly suggests that we will not adequately address North Carolina’s biologics and pharmaceutical manufacturing workforce needs through traditional recruitment strategies. To meet future demands for labor, we will need strategies that

inspire young people to understand the advantages of a career in biopharma manufacturing. We will need to reach transitioning military and veterans considering civilian career opportunities. Finally, we will need to ensure that all of our citizens, regardless of social or economic status, have opportunities to join North Carolina’s biopharma manufacturing workforce.”

The growth has been evident in the announcements of the last year. The article above outlines just some of the activity in February. In addition to a review of survey responses from companies, the report looks at comments from interviews and listening sessions with the industry on skills workers will need in the future. It also includes a roadmap for new curricula, equipment, facilities, and outreach to attract employees in a variety of ways.

NCBIO thanks NCBiotech, the companies, academic institutions, and others that assisted with this report. [Find out more.](#)

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Legislative Reception, May 6



Join NCBIO members at our annual Legislative Reception on May 6 from 5:30 to 7:30 p.m. at the NC Museum of History in downtown Raleigh. This is your chance to speak directly with lawmakers and policy makers about your organization and the impact of the life science industry on the State’s economy. In 2019, more than 200 NCBIO members, legislators and staff attended. [Learn more and register.](#)

If you have registration questions, contact [Amber Niebauer](#), events director. Thanks to [BIO](#), [Biogen](#), [PhRMA](#) and [Pfizer](#) for sponsoring this year’s Reception. For information on [sponsorship opportunities](#), contact [Laura Gunter](#), membership director.

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NCBiotech Awards \$2.1 Million in Grants, Loans

The North Carolina Biotechnology Center awarded 23 grants and loans totaling \$2.1 million during the past fiscal quarter to bioscience companies, universities and non-profit organizations.

The awards, made from Oct. 1 to Dec. 31, will support life science research and technology commercialization throughout North Carolina and help companies attract follow-on funding from other sources. [More](#)

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Cross-Border Life Sciences Agreements to be Discussed March 11

Find out about “International Arbitration and Risk Management in Cross-Border Life Sciences Agreements” March 11, 12:00 p.m. – 2:00 p.m., at the NC Biotechnology Center. The event is presented by the International Chamber of Commerce.

For companies with international dealings, arbitration is often preferable to litigation as a practical, party-led process to resolve disputes and achieve confidential, widely enforceable decisions in a neutral setting. Attend this luncheon program to discuss best practices and tips for using international arbitration to protect clients in international deals and how to avoid common mistakes that can cost time and money. This event is free of charge, however prior registration is required [here](#).

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Venture Connect March 17-19

[Venture Connect Summit](#) is right around the corner, March 17-19, at the Raleigh Convention Center and will be an event you don't want to miss.

This year you can expect the best of the best as CED highlights the talent of the Southeast's most notable tech and life science companies. You can expect 125 companies on-stage, over 1400 attendees and over 30 hours of content delivered by the nation's top talent over three days.

Explore more about the speakers, the jam-packed agenda and the 125 companies by visiting the CED site or purchasing a [ticket now](#).

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NCBIO Welcomes New Members



Representatives for new and recently admitted members:

FR: Nassar Hassan (Breakthrough BioAssets), Folger Tuggle (bluebird bio), Erin Frey (CureDuchenne), Amy Watkins and Kaler Walker (Lincoln Harris), BR: Sam Cronin (Cushman & Wakefield), Tim Fleischman (Deloitte), and Tom Jede (bluebird bio)

Five companies were welcomed as new members at the January 30 NCBio Board Meeting. New members are:

[Casimir Jones](#) is a Madison, Wisconsin based law firm that fulfills the intellectual property needs of their local, national, and international clients.

[Cushman & Wakefield](#) is a commercial real estate company with a solid foothold across the globe, with approximately 400 offices in 70 countries employing 51,000 people.

[inSoma Bio](#) borrows nature's own designs, integrating biology and materials science to create unique biomaterials to solve problems in tissue engineering and regenerative medicine.

[Lincoln Harris](#) is a full service commercial real estate firm providing management, brokerage and development services.

[MAA Laboratories Inc.](#) is a specialty pharmaceutical company that has developed the NanoCont™ drug development platform as a broadly applicable solution for addressing a variety of drug delivery and development challenges in a variety of therapeutic areas, including oncology, neurological, and cardiovascular diseases.

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At the National Level

New Report on National Impact of BioPharma Industry

Across the country, the biopharmaceutical sector supports millions of jobs in its pursuit to discover ground-breaking treatments and cures for patients around the world.

The impact of the industry is far-reaching. Along with the researchers who play pivotal roles in driving biopharmaceutical research forward, the industry employs people with a diversity of educational backgrounds in a wide range of occupations, all of whom play a crucial part in the development, production and delivery of medicines.

A new [report](#) from TEconomy Partners found that the biopharmaceutical industry supports over four million jobs and over \$1.1 trillion in economic output. [More](#)

Industry Challenges Outlined at BIO CEO & Investor Forum

The 22nd annual BIO CEO & Investor Forum kicked off with a welcome and update on BIO's 2020 Initiatives on Behalf of the Industry given by Jeremy Levin, CEO of Ovid Therapeutics and Chair of the Board of Directors of BIO.

The industry was established in the 1970's during an era of bipartisan cooperation and growth in wealth across the country. Today, despite unprecedented technological advancements in biology, chemistry, and digital health, plus an enormous amount of available capital, the industry is facing serious challenges that threaten its continued existence. Among these challenges are the declining public perception of the pharmaceutical industry, the unprecedented pressure from consolidation, and legislative challenges. [More](#)

BIO Has a Podcast

Get your earbuds ready, because BIO has big news: [We've launched a podcast!](#) Hosted by BIO CEO Jim Greenwood, BIO's new podcast [I AM BIO](#) will showcase incredible biotech breakthroughs, the people they help, the problems they solve, and give you a chance to meet the politicians who can fast-track a better future—or stop it in its tracks.

Upcoming Events by National Partners

Register for BIO 2020

The [2020 BIO International Convention](#), June 8-11, provides unique opportunities for companies of all sizes to pitch their ideas, share successes, and inform the global biotech community of their latest innovations. BIO is still accepting applications for several speaking opportunities at BIO 2020 in San Diego including Company Presentations, Startup Stadium, Global Innovation Hubs, and more!

Registration for the world's largest biotechnology partnering event is now open! [Register now](#) to take

advantage of the lowest registration rates and begin planning your BIO 2020 experience in San Diego, June 8-11.

BIO is partnering with OnPeak as the official, exclusive housing provider for the BIO International Convention in San Diego. BIO has several hotels near the San Diego Convention Center and your hotel reservations, personal data, and privacy are protected and secure. [Book housing](#).

MDMA FDA Forum, March 12-13

Join others at [MDMA's FDA Forum](#) on March 12-13, 2020 in Palo Alto, CA to get your questions answered. Find out about the FDA's criteria for reviewing your PMA/510(k) submission.

[MDMA's 2020 FDA Forum](#) continues to grow as a conference to engage with leading policy makers and experts. NCPIO members can get a \$100 discount. Contact [Amber Niebauer](#). For more information and to register, [click here](#).

BIO IMPACT Ag & Environment Conference



The BIO IMPACT Ag & Environment Conference will be held in Raleigh on September 21-24. This conference (formerly known as BIO World Congress) is centered on overcoming today's global challenges – and set forth towards a more sustainable future – by embracing the key role biotechnology plays in protecting our planet's resources, driving a strong economy and improving people's lives.

Join 1,000 leaders from all over the world for three days of education, networking and BIO One-on-One Partnering™. Learn more about the conference at bio.org/impact.

You can submit Breakout Session Proposals in food and farm innovation, bio-based manufacturing and sustainable fuels. Deadline March 6.

Submissions for Company and Technical Presentations and Start-up Stadium will be reviewed on an ongoing basis.

Visit bioevents.hubb.me to submit your proposal!

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Member News

To be included in Member News, send information about your organization to [Brenda Summers](#).

[Aperio Clinical Outcomes](#) has relocated its headquarters to the American Tobacco Campus, a hub for innovation in downtown Durham. "Aperio's culture is based on innovation," says Aperio Founder and CEO Faye Woolf. "It was essential that our new location be around like-minded organizations in an environment that shares our passion for innovation and developing medicines to improve patients' lives. The American Tobacco Campus was a clear fit, and we are so excited to be contributing to the pioneering advancements that have come from this innovative and eclectic campus." [More](#)

[Aerotek](#) has released a report on "Workforce Strategies Every Employer Should Know" to help companies in a tight labor market. [More](#)

[AskBio](#) announced that the first patient has been dosed in its Phase 1 clinical study of NAN-101 gene therapy. NAN-101 is designed to stimulate protein phosphatase inhibitor 1 (I-1c) to block the action of protein phosphatase 1 (PP1), a substance that plays an important role in the development of heart failure. Additional patients with NYHA Class III heart failure are being enrolled. [More](#)

[Bioventus](#), a global leader in orthobiologic solutions, has updated the indications for use for its [EXOGEN Ultrasound Bone Healing System](#). EXOGEN uses low-intensity pulsed ultrasound (LIPUS) to help stimulate the body's natural bone healing process and promote fracture healing. [More](#)

[bluebird bio, Inc.](#) has announced the launch in Germany of ZYNTEGLO™, a one-time gene therapy

for patients 12 years and older with transfusion-dependent β -thalassemia (TDT). The drug is designed to treat certain patients who rely on blood transfusions, but for whom a matching blood donor is not available. The launch is the first time bluebird has made ZYNTEGLO commercially available. The company has manufacturing facilities in Durham. [More](#)

[Liquidia Technologies, Inc.](#) has announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for LIQ861. LIQ861 is an inhalable dry powder for the treatment of pulmonary arterial hypertension (PAH). The drug is manufactured using Liquidia's PRINT® nanotechnology platform. [More](#)

[Merck](#) announced its intention to spin-off products from its Women's Health, trusted Legacy Brands, and Biosimilars businesses into a new, yet-to-be-named, independent, publicly traded company. The spinoff will allow both management teams to drive increased responsiveness to the particular needs of their patients and customers and achieve faster growth through focused and fit-for-purpose operating models. [More](#)

[Pappas Capital](#), a Durham-based investor in early-stage life sciences companies, has appointed Karen LeVert as venture partner. She will help expand the firm's Specialized Fund Management business – which handles customized investments for third parties – by focusing on opportunities in agricultural and related technologies, the company said. [More](#)

[PPD, Inc.](#) announced the pricing of its initial public offering of 60 million shares of its common stock at \$27.00 per share. Shares of PPD's common stock began trading on The Nasdaq Global Select Market on Feb. 6 under the symbol "PPD." [More](#)

[Seqirus](#) has received FDA approval for a vaccine to fight a strain of bird flu that kills 60% of people infected. While the strain of flu is not prevalent now, the vaccine will be available should an outbreak occur. AUDENZ is the first-ever adjuvanted, cell-based influenza vaccine designed to protect against influenza A (H5N1) in the event of a pandemic.

[Wake Forest Innovation Quarter](#) has a new branding effort and new name. In response to the increasingly diverse ecosystem developing in one of the leading districts of its kind in the country, Innovation Quarter today announced new branding, including [a new interactive website](#), a redesigned logo and a simplifying of its name, shifting from Wake Forest Innovation Quarter to Innovation Quarter. [More](#)

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BIO Business Solutions



In 2019 BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions® with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible! This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email save@bio.org with your choices and they will get you started. For all the latest news, promos, and event information, follow [BIO Business Solutions on LinkedIn!](#)



BIO's program with Clean Harbors provides special discounts and benefits for members! Clean Harbors disposal capabilities include incineration, recycling, wastewater treatment, fuels blending, landfill and more...

- Hazardous and non-hazardous waste transport, including direct pickup from your location
- Pre-negotiated Not-To-Exceed competitive rates
 - Lab Pack Disposal starts at 35% off list
 - Reduced Recovery Fee
- Free site consultation, waste stream review and record keeping, regardless of company size
- CleanPack®, Clean Harbors' laboratory chemical packing services, provides for the safe handling, packaging, transportation and disposal
- Full online services capability through an exclusive waste-management software (track waste, manage profiles, view reporting, download biannual report data, etc.), reducing costs and liability
- Recommendations for staff training to ensure compliance with applicable state and federal laws.
- Robust recycling and sustainability capabilities applicable for waste and unused products.
- 100% Compliance and Liability Minimization

[Learn More](#)



Transparency is critical to understanding the real value of working with any supplier. The new BIO-UPS program is no different. BIO is excited to announce that we have negotiated major savings enhancements with UPS that took effect on February 17, 2020. If you are an existing BIO-UPS program participant, your contract will automatically be updated – you won't need to lift a finger to realize the new benefits.

UPS Service	Savings
UPS Next Day Air®	Up to 74%
UPS 2nd Day Air®	Up to 59%
3 Day Select® Services	Up to 59%
UPS® Ground Commercial	Up to 51%
UPS® Ground Residential	Up to 44%
UPS Worldwide International services	Up to 68%

Hundreds of members have already signed up and saved nearly \$2 million in aggregate in 2019 on shipping services using the [BIO-UPS cost-savings program](#). Online enrollment is easy. Please sign up today!!

[Join in the Savings](#)

ABOUT BIO BUSINESS SOLUTIONS

BIO Business Solutions is the largest cost savings purchasing program for the biotech industry, operated by the Biotechnology Innovation Organization (BIO). BIO leverages the purchasing power of the industry to negotiate with top suppliers to secure exceptional savings, favorable terms, and superior service for members. BIO Members can participate for no charge as a benefit of their membership and to save on items they need to run a successful biotechnology enterprise.

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Calendar

To view full calendar, [click](#).

[Lucid Dream's VR/AR for Life Science Professionals Webinar](#)

Wednesday Mar 4, 2020

... [read more](#)

[LaunchBio: Larger than Life Science](#)

Thursday Mar 5, 2020

... [read more](#)

[BTEC Short Courses: Hands-On cGMP Biomanufacturing Operations](#)

Monday Mar 9, 2020 - Thursday Mar 12, 2020

... [read more](#)

[ISPE-CaSA 27th Annual Life Sciences Technology Conference](#)

Tuesday Mar 10, 2020

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[National Academy of Engineering Regional Meeting: Engineering Therapies for the Future](#)

Tuesday Mar 10, 2020

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[International Chamber of Commerce: International Arbitration and Risk Management in Cross-Border Life Sciences Agreements](#)

Wednesday Mar 11, 2020

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[WIB-RTP: The Life of a Drug: Women Working in Clinical Research](#)

Wednesday Mar 11, 2020

... [read more](#)

[MDMA's FDA Forum](#)

Thursday Mar 12, 2020 - Friday Mar 13, 2020

... [read more](#)

[CED Venture Connect 2020 Summit](#)

Tuesday Mar 17, 2020 - Thursday Mar 19, 2020

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[Women in Global Health Leadership](#)

Tuesday Mar 17, 2020

... [read more](#)

[Durham Public Schools' Ready, Set, GO! Career Readiness Event](#)

Tuesday Mar 24, 2020

... [read more](#)

[LaunchBio: Larger than Life Science](#)

Thursday Apr 2, 2020

... [read more](#)

[SBIR Road Tour Prep Course](#)

Tuesday Apr 14, 2020

... [read more](#)

[NCBiotech Ag Tech Professional Forum](#)

Wednesday Apr 15, 2020

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