



# connections newsletter



**JAN 2019  
UPDATE**

**Serving the NC Life  
Sciences Industry**

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## NCBIO This Month

- Lawmakers Return for 2019 Session
- NCBIO's Life Science Forum, January 31-Emerging Therapies: Reshaping How We Treat Disease
- NCBIO Legislative Reception, March 20
- Demand for Life Science Workers Continues to Increase
- Register for 2019 Life Science Conference
- BPD Spotlight on Education
- NCBiotech Awards \$1M in Company Loans



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## Lawmakers Return for 2019 Session



The General Assembly will return January 9 for a one-day organizational session to elect leaders and set rules for its 2019 "long session." Senator Phil Berger (R-Rockingham) and Representative Tim Moore (R-Cleveland) are expected to once again

## NCBIO - Media

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

## NCBIO Links

[CED](#)

[NCBIO](#)

[NC Biotech Center](#)

[BRITE](#)

[BTEC](#)

[BioNetwork](#)

[NCBioImpact](#)

[North Carolina  
Pharmaceutical Services  
Network](#)

[NCABR](#)

[National Center for  
Biotechnology Workforce](#)

## NCBIO Sustaining Members

[Biogen](#)

be elected President Pro Tempore of the Senate and Speaker of the House, respectively. Forty new legislators will be taking the oath of office on opening day, and one additional member, Bob Steinberg (R-Chowan), seated as a state senator after serving three terms in the State House.

Republicans will hold 29 of 50 seats in the Senate and 65 of 120 seats in the State House. The Party will no longer hold super majorities in either chamber. The change will strengthen the hand of Democratic Governor Roy Cooper, since Republicans will not control sufficient votes in either chamber to override a gubernatorial veto.

After the January 9th organizational session, legislators will return to their districts until the Assembly reconvenes on January 30 for the 2019 regular session, when regular legislative business will begin in earnest.

NCBIO has identified four preliminary policy objectives for the 2019 session:

- Tax relief for small R&D companies
- Increased funding One North Carolina Small Business Fund program, which provides matching grants for small businesses receiving Small Business Innovation Research grants from federal agencies
- Funding for biomanufacturing research and workforce training
- Funding for the North Carolina Biotechnology Center

In addition, NCBIO will be working with its member companies and national allies BIO and PhRMA to assure that life science companies remain free to set and negotiate fair prices for their products.

Additional information and updates on the session will be included in the February newsletter.

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## NCBIO's Life Science Forum, January 31–Emerging Therapies: Reshaping How We Treat Disease

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Join NCBIO members on January 31 from 11:30 a.m. to 1:30 p.m. at the NC Biotechnology Center to learn about new technologies that are reshaping the way we treat disease. Come hear leaders discuss their cutting-edge therapies in gene therapy, cell therapy, gene editing, and nanotechnology. Speakers will discuss how these technologies work, what the companies need to succeed, and pricing/reimbursement models. This session will be moderated by [Cartier Esham](#), Executive Vice President for Emerging Companies, at [BIO](#).

Speakers include:

- [Michael Dombeck](#), Vice President of Business Development, [Precision BioSciences](#)
- [Tom Jede](#), Site Head and Senior Director, Vector Manufacturing, [bluebird bio](#)
- [Susan Nichols](#), Chief Executive Officer, [Falcon Therapeutics](#)
- [Alden Pritchard](#), Chief Executive Officer, [Kaio Therapy](#)

Learn more and register [here](#). For questions about registering, contact [Amber Niebauer](#).

Thank you to our sponsors: [Aperio Clinical Outcomes](#), [Hughes Pittman & Gupton](#), and [Smith Anderson](#).

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## NCBIO Legislative Reception, March 20

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Lilly



Novartis



Pfizer



We Work For Health



## NCBIO Supporting Members

Cook Medical



Merck





## Legislative Reception // March 20

Join NCBIO members and legislators on March 20 from 5:30 to 7:30 p.m. for an evening reception highlighting the State's life sciences industry. You will have the opportunity to discuss workforce training, life science program funding, innovation and tax policy, and other topics of interest with legislators and policy makers. More than 200 life science representatives and legislators come out for this event, which features a slide show of some of the companies located across the state.

Thank you to [Astellas](#), [Biogen](#), [Grifols](#) and [Syngenta](#) for sponsoring this Legislative Reception. Learn more and register [here](#). For questions about registering, contact [Amber Niebauer](#). If you're interested in sponsoring this event, contact [Laura Gunter](#).

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### Demand for Life Science Workers Continues to Increase



[Stephen Williams, Joey Bastine and Cindy Hammond](#)

NCBIO Biotech Manufacturers Forum (BMF) members heard about challenges of recruiting and retaining workers at the December meeting. "The life science industry in Raleigh is projected to grow 6.6% compared the national average of 3.7%," Stephen Williams and Joey Bastine of Aerotek stated during panel presentations.

They said strategies that can help companies are:

- Know the market – understand what is happening the market
- Compare market wages – what are competitors paying
- Job descriptions matter – provide candidates realistic views of the job
- Employee value proposition – what can the employee gain working at your company
- Keep an eye on competitors – what perks, benefits and wages are being offered

Cindy Hammond with Qualified Staffing discussed US Bureau of Labor Statistics on the

changing workforce, noting that “people born in the 1960s and 1970s averaged two jobs changes by 32 years old.” Now, “Americans born in the early 1980s averaged 7-8 jobs from age 18 through 30.”

For more information about BMF contact [John Wagner](#).

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## Register for 2019 Life Science Conference

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Sign up for the [2019 CED Life Science Conference](#), in partnership with [NCBIO](#) and [NC Biotechnology Center](#), February 26-27 at the Raleigh Convention Center.

Announced speakers include:

- **John Carreyrou**, Pulitzer Prize-Winning Journalist & Author, *Bad Blood*
- **Laura Deming**, Partner, The Longevity Fund
- **Terry-Ann Burrell**, Managing Director, J.P. Morgan moderates a panel on homegrown companies:
- **Neal Fowler**, CEO, Liquidia
- **Mark Velleca**, MD., Ph.D., CEO, G1 Therapeutics

[Register now](#) and save more as an NCBIO member. Early rate ends February 1. Contact [Amber Niebauer](#) for discount code.

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## BPD Spotlight on Education

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The [Bioprocessing and Development Group](#) will host a “Spotlight on Education” January 17, 12:30-4:00 pm at the North Carolina Biotechnology Center. The event is focused on providing information about the outstanding local education and training opportunities in biopharmaceuticals.

The event is for students of all ages and education levels, including community college and university students and professionals looking for education opportunities to enhance career growth.

[Click](#) to find out more and register.

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## NCBiotech Awards \$1M in Company Loans

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Loans from the North Carolina Biotechnology Center totaling \$1M will help three bioscience companies develop novel products for better human health. The awards, made in the first quarter of the Center’s 2018-19 fiscal year, will support development of therapies for type 1 diabetes and a chronic skin disorder, and a medical device for better hemodialysis in patients with kidney disease. [More](#)

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## At the National Level

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### **BIO Applauds Farm Bill**

[BIO](#) President and CEO Jim Greenwood issued the following statement regarding passage of the Bipartisan Farm Bill. “At a time of uncertainty for our nation’s farmers, the agricultural economy, and rural America, this bipartisan Farm Bill will provide the much-needed confidence and certainty for many Americans who rely on its programs and funding. As a result of BIO’s advocacy, the conference committee provided mandatory funding for key programs in the Farm Bill’s energy title. While BIO would have preferred the conference committee adopt the Senate-passed funding levels for the title, we applaud the conferees for understanding the importance of these programs and thank them for providing mandatory funding to allow these programs to continue. As I testified to Congress when work first began on this important legislation, the Farm Bill’s energy title programs are critical to our nation’s farmers and rural communities as they develop new renewable chemicals, bio-based products, advanced biofuels, and other products of industrial biotechnology.” [More](#)

### **New Report Shows Nearly 300 Cell and Gene Therapies in Development**

A new report finds there are 289 novel cell and gene therapies in development for a variety of diseases and conditions. The therapies represent the translation of basic scientific insights into innovative new treatment options for patients. These medicines in development are either in clinical trials or awaiting review by the U.S. Food and Drug Administration. [More](#)

### **FDA Releases Report on Digital Health Tools**

“The FDA is continuing to advance an approach to digital health that promotes innovation and protects patient safety, while recognizing that this is a rapidly evolving field. We’re releasing a report on the benefits and risks of digital health tools that are not regulated by the FDA as medical devices, so we can better understand how these products affect patient care,” said FDA Commissioner Scott Gottlieb, M.D. “While we’ve been working to streamline the agency’s oversight of digital health products that we regulate, we also know that there are many digital products consumers are using for their general wellness or to track their health information that aren’t regulated as devices by the FDA. The health care system is also increasingly relying on digital tools like electronic health records to advance patient care.” [More](#)

### **New Study Illustrates MedTech Industry Response to Digital Innovation and Value-based Care Models**

MedTech R&D leaders are adopting a variety of strategies to navigate the changing U.S. health care ecosystem, according to [a new study](#) from the Deloitte Center for Health Solutions and the Advanced Medical Technology Association (AdvaMed). The new study, “The next wave of innovation: Technology and value-based care are transforming medtech R&D,” details how a growing emphasis on value-based care models and a constant emergence of new technologies are influencing medtech companies’ business strategies. [More](#)

### **BIO CEO & Investor Conference**

Sign up for the BIO CEO & Investor Conference, one of the largest investor conferences focused on established and emerging publicly traded and select private biotech companies. The event is February 11-12 in New York City. The BIO CEO & Investor Conference provides a neutral forum where institutional investors, industry analysts, and senior biotechnology executives have the opportunity to shape the future

investment landscape of the biotechnology industry. [More](#)

## Time Running Out to Get Discount for BIO Convention

Sign up now to receive the discount BIO is offering NCBio members on two premier registration packages for the 2019 BIO International Convention in Philadelphia, June 3-6: Convention Access and Convention Access & Partnering. Click this [link](#) to complete the form by Friday, January 18 to receive the code.

Registration for BIO 2019 is not required at this point. Simply complete the form, and you will be sent your discount code prior to registration opening.

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## Member News

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*To be included in Member News, send information about your organization to Brenda Summers*

[Baebies Inc.](#) celebrated the shipment of its 4 millionth test to newborn screening programs. Six states are now using Baebies SEEKER, the first FDA-cleared newborn screening platform for lysosomal storage disorders (LSDs). [More](#)

[BioCryst Pharmaceuticals, Inc.](#) announced the dosing of the first subject in a randomized, placebo-controlled phase 1 clinical trial to evaluate intravenous (IV) galidesivir in healthy volunteers. BioCryst has global rights to galidesivir, a broad-spectrum antiviral drug in development to treat Marburg virus disease and Yellow Fever. [More](#)

[Biogen](#) has exercised its option to obtain from Ionis a worldwide, exclusive, royalty-bearing license to develop and commercialize BIIB067 (IONIS-SOD1RX), an investigational treatment for amyotrophic lateral sclerosis (ALS) with superoxide dismutase 1 (SOD1) mutations. ALS with SOD1 mutations is a subtype of familial ALS and accounts for approximately two percent of all ALS cases. [More](#) Biogen Inc. has been awarded the 2018 International Prix Galien as Best Biotechnology Product for SPINRAZA (nusinersen), the first and only treatment for spinal muscular atrophy (SMA). The prestigious honor marks the seventh Prix Galien for SPINRAZA, following country recognitions in the U.S., Germany, Italy, Belgium-Luxembourg, the Netherlands and the U.K. [More](#)

[bioMérieux](#) announced the Food and Drug Administration (FDA) 510(k) clearance of the BIOFIRE® FILMARRAY® Pneumonia Panel and the CE-Mark of the BIOFIRE® FILMARRAY® Pneumonia Panel plus. The BIOFIRE® FILMARRAY® Pneumonia Panels aid in the diagnosis of lower respiratory tract infections. [More](#)

[Cook Medical](#) announced that it has completed an agreement with Whitaker Park Development Authority Inc. to acquire a long-standing facility at Winston-Salem's Whitaker Park. The agreement was completed on December 27, 2018. Cook will begin converting a portion of the R.J. Reynolds building in Whitaker Park into a world-class medical device manufacturing facility this year. [More](#)

[G1 Therapeutics, Inc.](#) announced preliminary anti-tumor efficacy and myelopreservation data from its randomized, open-label Phase 2 trial evaluating trilaciclib in combination with chemotherapy as a treatment for metastatic triple-negative breast cancer (mTNBC). [More](#) G1 Therapeutics, Inc. also announced positive topline data showing multi-lineage myelopreservation benefits in its randomized, double-blind, placebo-controlled Phase 2 trial evaluating trilaciclib in combination with topotecan as a treatment for 2nd-/3rd-line small cell lung cancer (2/3L SCLC). [More](#) G1 Therapeutics announced that Chief Executive Officer Mark Velleca, M.D., Ph.D., will present a company overview at the 37th Annual J.P. Morgan Healthcare Conference. The presentation will take place on Tuesday, January 8, at 9:30 a.m. PT (12:30 p.m. ET) at the Westin St. Francis Hotel in San Francisco.



[Grifols](#) is partnering with the Republic of Liberia to explore an innovative approach to combat Ebola virus disease. In December, Grifols began purifying the first batch of plasma at the Clayton facility from healthy Ebola survivors from Liberia. The plasma will be used to produce anti-Ebola immunoglobulin, a potential treatment for patients affected by the Ebola virus in Africa, as part of a longer-term Grifols clinical research program. This project is the result of collaborative efforts among Grifols, several non-profit organizations and Liberian scientists at the National Public Health Institute of Liberia (NPHIL). [More](#)

[ImmunoReagents, Inc.](#) is a global key contributor in Flow Cytometer Reagents and the global Porcineserum market according to recent studies. The Global Flow Cytometer Reagents market report more focuses on top industry leaders and explores all essentials facets competitive landscape. [More](#) The Porcineserum report looks at the market in detail reviewing types, applications and other information. [More](#)

[IQVIA™](#) announced that it was awarded the 2018 Scrip Award for Best Contract Research Organization — Full-Service Provider. This marks the seventh time in the last 10 years that the company has received this award. [More](#)

[Locus Biosciences Inc.](#) has entered into an exclusive collaboration and license agreement with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop, manufacture and commercialize CRISPR-Cas3-enhanced bacteriophage ("crPhage™") products targeting two key bacterial pathogens for potential treatment of infections of the respiratory tract and other organ systems. Under terms of the agreement, Locus will receive \$20M in initial payments, and is eligible to a total of \$798M in potential future development and commercial milestone payments, and royalties on any product sales. [More](#)

[Mayne Pharma Group Limited](#) announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Tolsura™ (SUBA®-itraconazole) 65mg capsules. Tolsura is a new formulation of itraconazole indicated for the treatment of certain systemic fungal infections in adult patients. [More](#)

[Novan, Inc.](#) announced several leadership promotions and business updates. Paula Brown Stafford has been promoted to President and the newly created role of Chief Operating Officer while remaining a member of the Board of Directors. Dr. Carri Geer has been promoted to Senior Vice President and Chief Technology Officer of Novan. Dr. Elizabeth Messersmith, Senior Vice President, has been promoted to the role of Chief Development Officer with oversight of the clinical, medical, statistical, and regulatory activities of the Company. [More](#)

[Novo Nordisk](#), which employs almost 1,200 manufacturing workers in Johnston County, will invest \$22 million at its Clayton facility, creating 22 full-time jobs. The move comes just ten months after the world's leading diabetes care company unveiled plans for a \$65 million expansion there. Johnston County's Board of Commissioners voted to approve a seven-year package of financial incentives for Novo Nordisk's latest investment, the company's fourth in Johnston County since 2010. [More](#)

[Pharmaceutical Product Development, LLC](#) (PPD) is adding significant therapeutic expertise in cardiovascular disease, critical care, endocrinology, metabolism and diabetes to further broaden its global product development portfolio. Darell Heiselman, D.O., will lead cardiovascular and critical care and David Klein, M.D., Ph.D., will oversee endocrinology, metabolism and diabetes. [More](#)

[Pfizer Inc.](#) and [GlaxoSmithKline plc](#) announced they have entered into an agreement to

create a premier global consumer healthcare company with robust iconic brands. The Boards of Directors of both companies have unanimously approved the transaction under which Pfizer will contribute its consumer healthcare business to GlaxoSmithKline's existing consumer healthcare business. [More](#)

[Syneos Health™](#) released a trend forecast outlining critical shifts and the underlying dynamics that will shape biopharmaceutical decision making in 2019. The [Health Trend Ten](#) looks beyond numbers and statistics, turning industry uncertainties into informative trends, relevant questions and actionable insights. [More](#)

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## **NCBIO Member Benefits – New Discounts from NCBIO Member Companies**

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[BIO Business Solutions®](#) provides NCBIO members with numerous discount prices. With more than \$350 million in annual sales, BIO Business Solutions® aggregates the purchasing power of over 3,000 life science companies from North America. Find out more about [NCBIO discounts](#).

### **Turn Your Surplus Lab Equipment into Capital**

As a life science professional, you understand first-hand that lab equipment can become idle or surplus as new equipment arrives. That's where American Laboratory Trading (ALT), comes in. ALT is BIO's preferred surplus strategy services partner. ALT can also uninstall, pack and ship your equipment, saving you additional time and cost. Are one or more of these instruments sitting idle in your lab?

- Biosafety Cabinets
- Centrifuges
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ALT can offer you a no-obligation offer on your idle equipment. Submit your request [ONLINE](#), email [sell@alt-inc.com](mailto:sell@alt-inc.com), or give ALT a call today at (860) 691-2213.

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## **Calendar**

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

### **[BTEC Microbial Contamination Control in Bioprocessing Operations](#)**

**Tuesday Jan 15, 2019 - Thursday Jan 17, 2019**

... [read more](#)

### **[Biomanufacturing and Process Development \(BPD\) Spotlight on Education](#)**



Thursday Jan 17, 2019

... [read more](#)

[2019 SciTech Lecture Series: How Climate Change Effects the Planet's Finite Water Resources and the Need for New Technologies to Improve the Aging Water Infrastructure](#)

Thursday Jan 17, 2019

... [read more](#)

[FuseCR Fast Track to Clinical Research Careers: Regulations and Good Clinical Practice, Part 1](#)

Monday Jan 28, 2019

... [read more](#)

[NCBIO Life Science Forum - Reshaping How We Treat Disease](#)

Thursday Jan 31, 2019

... [read more](#)

[FuseCR Fast Track to Clinical Research Careers: Regulations and Good Clinical Practice, Part 2](#)

Monday Feb 4, 2019

... [read more](#)

[Kymanox Knowledge Bar "Training on Tap"](#)

Thursday Feb 7, 2019

... [read more](#)

[LaunchBio: Larger than Life Science](#)

Thursday Feb 7, 2019

... [read more](#)

[FuseCR Fast Track to Clinical Research Careers: Documentation and Essential Documents](#)

Monday Feb 11, 2019

... [read more](#)

[FuseCR Fast Track to Clinical Research Careers: Drug Safety and Risk Management](#)

Monday Feb 18, 2019

... [read more](#)

[NCBiotech Ag Tech Professional Forum February 2019](#)

Wednesday Feb 20, 2019

... [read more](#)

[CED Tech Conference 2019](#)

**Monday Feb 25, 2019 - Tuesday Feb 26, 2019**

... [read more](#)

**[FuseCR Fast Track to Clinical Research Careers: Trial Integrity](#)**

**Monday Feb 25, 2019**

... [read more](#)

**[CED Life Science Conference 2019](#)**

**Tuesday Feb 26, 2019 - Wednesday Feb 27, 2019**

... [read more](#)

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