



# connections newsletter



**FEB 2019  
UPDATE**

**Serving the NC Life  
Sciences Industry**

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## NCBIO This Month

- Members Hear about Emerging Therapies: Reshaping How We Treat Disease at NCBIO Life Science Forum
- NC Lawmakers Return for Lengthy Session
- NCBIO Legislative Reception, March 20
- Less Than a Month Until 2019 Life Science Conference
- Grants and Loans Made by North Carolina Biotechnology Center



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## 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](#)

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[BTEC](#)

[BioNetwork](#)

[NCBioImpact](#)

[North Carolina  
Pharmaceutical Services  
Network](#)

[NCABR](#)

[National Center for  
Biotechnology Workforce](#)

## Members Hear about Emerging Therapies: Reshaping How We Treat Disease at NCBIO Life Science Forum



Michael Dombeck (Precision Biosciences), Tom Jede (bluebird bio), Susan Nichols (Falcon Therapeutics), Al Pritchard (Kaio Therapy) and Cartier Esham (BIO)

The opportunities, the challenges and the financing of gene therapies and other

## NCBIO Sustaining Members

Biogen

innovative cell technologies were topics at the recent NC BIO Life Science Forum. Four panelists outlined plans by their companies in developing treatments for patients.

[Cartier Esham](#), Executive Vice President for Emerging Companies, at [BIO](#) moderated the session. She noted that the FDA is looking at a number of areas related to cell therapies including manufacturing issues for cell products. She noted that BIO is working with federal policymakers to make sure they understand issues related to gene therapies and ensure proper regulation of them.

[Michael Dombeck](#), Vice President of Business Development, [Precision BioSciences](#), outlined qualities of the ARCUS therapeutic-grade gene editing platform developed by his company. He called it "a selective, specific approach" that is driven by a natural safety-switch, which can fit within all common delivery systems. He also noted the efficacy and repair system of the platform.

[bluebird bio](#) selected North Carolina over other locations for its manufacturing site primarily because of the talent here. [Tom Jede](#), Site Head and Senior Director, Vector Manufacturing, said the company made a strategic decision to develop its own internal vector manufacturing capability. An available facility, the timing to get it up and running, cost and other factors along with available workforce helped North Carolina win over biotech clusters in Maryland and Massachusetts.

[Susan Nichols](#), Chief Executive Officer, [Falcon Therapeutics](#), discussed the Trilogy cells, a new class of cells, that can seek out tumor cells and destroy them. She said cell therapy can be a game changer for patients and scale-up is critical for the company. She adds Trilogy cells can all use a single manufacturing platform.

[Kaio Therapy](#) is developing an Immune Activating Hyperthermia Treatment that CEO [Al Pritchard](#) says "awakens your body's immune system to fight your specific cancer." With this process, the immune system response is trained by a single treated tumor promoting cancer specific immune cells to target and destroy untreated distant tumors.

During the question and answer session, the panelists discussed the availability of talent and plans to grow their companies, the issues related to scalability of cell manufacturing and establishing reimbursement payments/models since there are currently no similar products on the market.



Forum Sponsors, [Brian Johnston \(BIO\)](#), [Faye Woolf \(Aperio Clinical Outcomes\)](#), [Chris Capel \(Smith Anderson\)](#) and [Tom Fagley \(Hughes Pittman & Gupton, LLP\)](#)

Thanks to our sponsors who made the event possible for members: [Aperio Clinical Outcomes](#), [BIO](#), [Hughes Pittman & Gupton](#), and [Smith Anderson](#).

To find out more about sponsoring future NC BIO events, contact [Laura Gunter](#).

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We Work For Health



## NC BIO Supporting Members

Cook Medical



Merck



Legislators convened on January 9th for a ceremonial opening and then recessed until January 29th. Now, lawmakers are getting briefings on budget proposals, revenue outlook for 2019-20, and potential tax changes.

NCBIO is focusing on several areas for the 2019 session:

- Tax relief for small R&D companies
- Protect sales tax exclusion for R&D equipment
- Secure funding One North Carolina Small Business Fund program, which provides matching grants for small businesses receiving Small Business Innovation Research (SBIR) grants from federal agencies
- Support funding for NIIMBL and workforce training
- Assist with funding for the North Carolina Biotechnology Center

NCBIO will again be working with the Legislative Life Science Caucus. The new Chairs for the Caucus will be announced this month.

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## NCBIO Legislative Reception, March 20

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**2019** NCBIO Life Sciences  
Legislative Reception

**Wednesday, March 20**  
**5:30 – 7:30 p.m.**

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Join NCBIO members and legislators on March 20 from 5:30 to 7:30 p.m. for an evening reception highlighting North Carolina's life sciences industry. You will have the opportunity to discuss workforce training, 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](#), [BIO](#), [Biogen](#), [Grifols](#), [Lilly](#), [PhRMA](#), 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](#).

*The North Carolina Museum of History does not sponsor or endorse this event.*

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## Less Than a Month Until 2019 Life Science Conference

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# CED Life Science Conference

FEBRUARY 26, 2019 TO FEBRUARY 27,  
2019 | RALEIGH, NC

29th Annual Conference is 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
- **Arie Beldegrun**, D. FACS, Executive Chairman and Co-Founder, Allogene

## Investor Panel

Featuring Janis Naeve, Amgen Ventures; Ben Auspitz, F-Prime Capital; Hongbo Lu, Lilly Asian Ventures; and John Gustofson, AbbVie Ventures

## The Journey to Becoming a Public Company,

Featuring Terry-Ann Burrell, Managing Director, J.P. Morgan and moderator with panel on homegrown companies: Neal Fowler, CEO, Liquidia, and Mark Velleca, M.D., Ph.D., CEO, G1 Therapeutics.

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

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## Grants and Loans Made by North Carolina Biotechnology Center

The North Carolina Biotechnology Center awarded 17 grants and loans totaling nearly \$1.4 million to universities, bioscience companies and other organizations in the second quarter of its current fiscal year.

The awards, made from Oct. 1 to Dec. 31, 2018, will support life science research, technology commercialization and entrepreneurship throughout North Carolina. The funding will also help universities and companies attract follow-on funding from other sources. [More](#)

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## At the National Level

### Federal Administration Proposal on Out-of-Pocket Cost for Medicines

BIO's President and CEO Jim Greenwood issued the following statement after the Trump administration released a proposed rule that would alter safe harbor policies under the

federal anti-kickback statute:

"BIO strongly supports the goal of this proposed rule to lower out-of-pocket costs for consumers. Every year innovative drugmakers provide tens of billions of dollars in rebates to help expand affordable access to prescription medicines. But far too often these rebates are not passed along to patients and are instead used to pad the profits of middlemen. The current system creates perverse incentives that are driving the affordability crisis many patients face today." [More](#)



### **Senator Tillis Co-Sponsored Legislation to Combat Alzheimer's Signed into Law**

Bipartisan legislation co-sponsored by Senator Thom Tillis (R-NC) that would, for the first time, create a public health infrastructure across the country to combat Alzheimer's disease and preserve brain health was signed into law by President Trump. "Successfully getting this legislation signed into law has a deep personal meaning for me, as I was a caregiver for my grandmother during her battle with Alzheimer's disease," said Senator Tillis. "The BOLD Infrastructure for Alzheimer's Act will create the framework necessary to preserve brain health for millions of Americans, and I am proud to be a part of the fight to combat, and hopefully one day, end this terrible disease." [More](#)

### **New Platform for Food and Agriculture Launches**

Biotechnology Innovation Organization (BIO) and the [American Seed Trade Association](#) (ASTA) jointly announce the launch of Innovature, a new platform to spark a thoughtful dialogue around innovation in food and agriculture, with an initial focus on gene editing. Growing understanding of gene editing is spurring new developments in food and agriculture to address some of our most pressing societal challenges. [More](#)

### **BIO CEO & Investor Conference February 11-12**

Dr. Roger Crystal will be a headliner at the upcoming [BIO CEO & Investor Conference](#), leading a fireside chat at noon on Tuesday, February 12. Crystal is CEO of Opiant Pharmaceuticals, the company that developed NARCAN® Nasal Spray, the first FDA-approved nasal form of naloxone, an opioid antagonist. [More](#)

More than 600 investors are expected to attend the 21st annual event in New York City. Find out [more](#) and [register](#). NCPIO members receive a \$250 discount. Contact [Laura Gunter](#) for the code.

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## **Member News**

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

[Aerie Pharmaceuticals, Inc.](#) announced that the U.S. Food and Drug

Administration (FDA) has reviewed the Investigational New Drug Application (IND) for AR-1105 (dexamethasone intravitreal implant) and it is now in effect, allowing Aerie to initiate human studies in the treatment of macular edema due to retinal vein occlusion (RVO). The IND was submitted in December 2018. Aerie expects to initiate a Phase 2 clinical study later in the first quarter of 2019. [More](#)

[BD](#) announced the U.S. Food and Drug Administration 510(k) clearance of its second-generation BD Nano™ pen needle, designed for more reliable subcutaneous injection depth. BD Nano™ 2nd gen pen needles offer people who inject diabetes medications a more reliable subcutaneous delivery of their medication, designed to help people better manage their diabetes. [More](#)

[Biogen's](#) work with middle and high school students at the RTP site is featured in an article by EdNC, titled "The Biogen Community Lab: Bringing students to real-world STEM." [More](#) Biogen and C4 Therapeutics (C4T) announced that they have entered into a strategic collaboration to investigate the use of C4T's novel protein degradation platform to discover and develop potential new treatments for neurological conditions, such as Alzheimer's disease and Parkinson's disease. [More](#)

[Bioventus](#) is launching OSTEOMATRIX+, its next generation biphasic bone graft for use in bone remodeling in a variety of orthopaedic and spine applications. OSTEOMATRIX+ is a moldable bone graft substitute consisting of bovine collagen and biphasic, hydroxyapatite/ $\beta$ -tricalcium phosphate granules designed to produce a reliable, porous scaffold and sustained osteoconductivity throughout the bone remodeling process. [More](#)

[BioResource International, Inc.](#) (BRI) will present on the comparative effects of their newest product, EnzaPro™, a combination xylanase-direct-fed microbial feed additive. Sarah Page, Senior Nutrition Associate at BRI, will present findings on Tuesday, February 12th, at 9:15 a.m. in Room B314 at the International Poultry Scientific Forum at the International Production & Processing Expo (IPPE) 2019 in Atlanta, GA. [More](#)

Christa Myers of [CRB](#) has been named ISPE's Women in Pharma (WIP) Chair! WIP provides women in the industry a forum for connecting and collaborating on technical and career advancement topics. Myers is a founding member and has been on the WIP Steering Committee since its inception. [More](#)

[FUJIFILM Corporation](#) announced plans to invest approximately JPY 10 billion (approximately \$90 million U.S. dollars) in order to expand its Bio Contract Development and Manufacturing Organization (CDMO) Business. This new round of investments will include the addition of 2000L single use cell culture manufacturing trains, cell culture purification suites and new microbial recovery suites to its existing facilities in North Carolina. These additions will increase cell culture manufacturing capacity by approximately 25% and microbial capacity by approximately 50% at its North Carolina location. [More](#)

[ImmunoReagents, Inc.](#) announced that company President Dr. Ann Black was recognized with the 2018 Governor's Export Award on January 14. The export award program recognizes five North Carolina companies annually for international trade and takes place at the Governor's mansion. The Raleigh company, which exports to more than 20 countries, is a leading manufacturer of antibodies and reagents used in pharmaceutical research and in vitro diagnostics. [More](#)

[IQVIA](#)™ announced its development of a Software as a Service (SaaS) safety platform that scales to address the drug safety and surveillance challenges of life sciences organizations, ranging from emerging biopharma to large pharmaceutical companies. [More](#)

[Vast Therapeutics, Inc.](#) announced that the Company has received an award from Cystic Fibrosis Foundation (CFF), to support the continued development of its lead NO-release drug candidate, BIOC51 for the treatment of Pseudomonas aeruginosa in patients with cystic fibrosis. [More](#)

[vTv Therapeutics Inc.](#) announced the publication of a paper in *Science Translational Medicine* showcasing the discovery and development of TTP399, an investigational, oral, small molecule, liver-selective glucokinase (GK) activator, as a potential treatment for diabetes. The paper reviews the scientific rationale underpinning the development of TTP399 and its progression from preclinical to clinical development concluding with the positive results of the AGATA study, a phase 2 study of TTP399 in patients with type 2 diabetes. [More](#)

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

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4,000 companies saved nearly \$400 million in 2018 through BIO Business Solutions®.

Your peers have opted in for the cost-savings on lab and office essentials through BIO Business Solutions. Have you? Take advantage of these savings today! Getting started is as easy as 1-2-3... and "1" is already done!

As an NCBIO member, you are eligible! This is a benefit of your NCBIO membership.

- Review the cost-savings offered by clicking [this button](#) and choose the programs you're interested in.
- Email [biobusinessolutions@bio.org](mailto:biobusinessolutions@bio.org) with your choices and we will get you started. For all the latest news, promos, and event information, [follow BIO Business Solutions on LinkedIn!](#)

Find out more about [NCBIO discounts](#).

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## Calendar

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

### [Environmental Compliance Conference](#)

Wednesday Feb 6, 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](#)

### [5th Annual Biogen Career Night](#)

Thursday Feb 7, 2019

... [read more](#)

### [NCBioNetwork Validation of Automated Equipment & Process Control Systems](#)

Monday Feb 11, 2019 - Tuesday Feb 12, 2019

... [read more](#)

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

Monday Feb 11, 2019

... [read more](#)

### [WINNING SBIR/STTR Grants for Science and Technology Start-ups](#)



Wednesday Feb 13, 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: Climate Change](#)**

Wednesday Feb 20, 2019

... [read more](#)

**[2019 SciTech Lecture Series: A View of the Clinical Trials Enterprise in the Twenty First Century](#)**

Thursday Feb 21, 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](#)

**[Government Affairs Reception](#)**

Wednesday Feb 27, 2019

... [read more](#)

**[LaunchBio: Larger than Life Science](#)**

Thursday Mar 7, 2019

... [read more](#)

**[NCBIO Legislative Reception 2019](#)**

Wednesday Mar 20, 2019

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[Register Now](#)

**[NC Chamber Annual Meeting](#)**

Thursday Mar 21, 2019

... [read more](#)

**[NCBioNetwork Aseptic Processing I](#)**

Monday Mar 25, 2019 - Thursday Mar 28, 2019

... [read more](#)



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