



# FEBRUARY 2020 UPDATE

Serving the NC Life Sciences Industry

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# NCBIO This Month

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- · Life Science Growth Continues with Eli Lilly Coming to RTP
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- · Lawmakers Adjourn with No Action on Budget
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# P Life Science Luncheon and Forum − Intellectual Property Strategy, February 19



Join us at the NC Biotech Center on February 19 from 11:30 a.m. to 1:30 p.m. for our first Life

## **NCBIO - Media**

Find the latest news from NCBIO on the website ncbioscience.net, on LinkedIn and on Twitter at

## **NCBIO Links**

CED

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**NCBIO** 

**NC Biotech Center** 

**BRITE** 

**BTEC** 

**BioNetwork** 

**NCBioImpact** 

North Carolina Pharmaceutical Services Network

**NCABR** 

National Center for Biotechnology Workforce

# NCBIO Sustaining Members

Biogen

Science Luncheon and Forum of 2020. This panel discussion will focus on intellectual property strategy around drug pricing, product development and protection, artificial intelligence, and licensing.

The panel will be moderated by **Julie Meigs**, **J.D.**, **Ph.D.**, Partner, Womble Bond Dickinson, and feature:

- Shawn Glidden, J.D., Vice President, Legal Affairs & Secretary, Liquidia Technologies
- Gary Pace, J.D., Ph.D., Chief Executive Officer, Cell Microsystems
- Mike Penn, J.D., Principal Counsel, Intellectual Property & Litigation, Amgen
- Tim Wilson, J.D., Director of Patents, SAS Institute

Our panelists will highlight bills covering penalties for "pay for delay," "patent thicketing," and "product hopping" as well as federal issues surrounding the patent review board and "what is patentable." Members will leave this session feeling empowered to be better advocates. Learn more and register. For registration questions, contact Amber Niebauer, events director.

Thank you to our sponsors: <u>Aon; Hughes Pittman & Gupton; Jenkins, Wilson, Taylor & Hunt;</u> and <u>Womble Bond Dickinson</u>.

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# **P**Life Science Growth Continues with Eli Lilly Coming to RTP



Eli Lilly CEO David Ricks, Governor Roy Cooper, Durham officials and state economic development leaders participated in the announcement that Lilly will invest \$470M and bring 462 jobs to the Research Triangle Park. "Life science companies like Lilly continue to choose North Carolina," said Governor Cooper. "Our exceptional workforce draws global companies as we continue to grow North Carolina into a worldwide hub for the biotechnology industry."

This new manufacturing site will be a state-of-the-art facility that produces parenteral (or injectable) products and delivery devices. "This next-generation manufacturing facility will allow us to expand our capacity to make the Lilly medicines that are helping people with serious illnesses today, and help us prepare for new medicines coming from our robust pipeline in the future," said Ricks. "In the past two years, we have invested billions of capital in new U.S.-based manufacturing because the 2017 tax reform rebalanced the playing field in favor of the American worker. We're excited to be bringing more of these high-skill, high-wage advanced manufacturing jobs to North Carolina." More

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Pfizer



We Work For Health



# NCBIO Supporting Members

Cook Medical



Merck







North Carolina's United States Senators, Richard Burr (R-NC) and Thom Tillis (R-NC), have joined in a letter to United States Trade Representative (USTR) Ambassador Robert Lighthizer expressing strong support for a robust 2020 review of American trade policy towards countries that undermine patent protections.

NCBIO President Sam Taylor praised the effort, saying that "This action by our Senators is particularly important given the steps taken by the Administration and Congress in the new United States Mexico Canada Agreement that eliminated protections for American innovators who develop biologic medicines."

The renegotiated USMCA eliminated a ten-year period of biologics data exclusivity that protected American drugs from foreign competition within Canada and Mexico. Within the United States, data exclusivity extends for twelve years. More

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# <sup>⊸</sup>Lawmakers Adjourn with No Action on Budget



Republican leaders of the North Carolina Senate this month scrapped a plan to override Governor Roy Cooper's veto of the legislature's primary 2019-21 appropriations legislation. The action came as legislators convened briefly in Raleigh on January 14 for a special session to consider the veto. Without an override, the appropriations bill cannot become law.

The impasse means that appropriations for several life-science programs will remain in limbo. Furthermore, the prospect for an override when lawmakers begin their regular session April 28 is also bleak. Senate President Pro Tempore Phil Berger indicated during a news conference the day of the January session that the state might go until 2021 without a new budget.

The pending life science items include:

- \$1M in non-recurring funding in both years of the 2019-21 biennium for the State's SBIR/STTR matching grant program, commonly known as the One North Carolina Small Business Program,
- \$500,000 in additional recurring funding for the NCBiotech Center, and \$500,000 in

non-recurring funding for the 2020-21 fiscal year, and

 \$2M for each year of the biennium for North Carolina's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

NCBIO President Sam Taylor stated, "We will keep pushing for these items and others during the short session starting in April; however, our prospects do not look promising at this point."

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# Poin NCBIO for the Annual Legislative Reception May 6

NCBIO's annual Legislative Reception will be held May 6 at the NC Museum of History on from 5:30 to 7:30 p.m. The Reception will be catered by Caffé Luna. (The event was originally scheduled for June 3rd so make sure to update your calendar.)

Don't miss 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. Last year, more than 200 NCBIO members, legislators and staff attended. <u>Learn more and register</u>. If you have registration questions, contact <u>Amber Niebauer</u>, events director.

Thanks to our sponsors <u>Biogen</u> and <u>Pfizer</u>. For information on <u>sponsorship opportunities</u>, contact <u>Laura Gunter</u>, membership director.

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# Post Jobs for Free on the NCBiotech Jobs Board through February 7

The NCBiotech Jobs Board is the best place to advertise life science jobs in North Carolina. Now is a great time to find out why.

Are you starting the new year looking for your next great employee? Now is a perfect time to try the NCBiotech Jobs Board. Job postings, which are normally \$20 per post, are free until February 7.

The NCBiotech Jobs Board is focused on connecting the local workforce with North Carolina-based jobs in the life science industry. The jobs board attracts new candidates daily who are looking for their next opportunity in R&D, regulatory affairs, business development and marketing, and beyond.

Register with the Jobs Board or log in to your existing account to get started.

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# Properties Innovation Conference

The NCBiotech Center and the Duke University School of Nursing will be hosting the inaugural Healthcare Innovation Conference on February 21. This one-day event is designed to help nurses and other healthcare providers understand how to accelerate ideas into reality. Get insights into product development, financial resources and hear success stories from fellow innovators. Register.

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# Regional Engineering Meeting at NC State Focuses on Emerging Therapies

North Carolina State University is hosting the <u>National Academy of Engineering (NAE) Regional Meeting</u> on Tuesday, March 10 at the <u>James B. Hunt Jr. Library</u> on NC State's Centennial Campus in Raleigh, N.C. The central theme of the symposium is transferring innovation from the laboratory through commercialization to the clinic to improve healthcare across the planet.

Topics and speakers include:

• "Engineering the Future of Health"

by Bruce Tromberg (Director, National Institute of Biomedical Imaging and Bioengineering, NIBIB)

- "Will Engineering Tissues Change Clinical Care?"
   by Laura Niklason (National Academy of Medicine, NAM)
- "The CRISPR Genome Editing Craze: Opportunities and Challenges" by Rodolphe Barrangou (NAE/National Academy of Sciences, NAS)
- "Advanced Retinal Implants" by Mark Humuyan (NAE/NAM)
- "Polymers in Implantable Medical Devices" by Len Pinchuk (NAE)
- "Distributed Healthcare Through Wearable and Implantable Devices" by Stephen Oesterle (Venture Partner, New Enterprise Assoc.)
- "A New Science of Therapeutics"
   by Jay Bradner (President, Novartis Institutes for BioMedical Research)

See NC State's College of Engineering website for more information and to register.

# **Venture Connect March 17-19**

The <u>event</u> at the Raleigh Convention Center, March 17-19, will recognize the innovation potential across the Tech & Life Science communities. Hosted by <u>CED</u>, the event is focused on creating an environment that supports stronger connections, valuable programming, and learning for all.

#### Speakers include:

- Safi Bachall, Physicist and Biotech Entrepreneur
- John Crowley, Board Chairman and CEO, Amicus Therapeutics
- Shelia Mikhail, Summit Leader, CEO, AskBio
- Sapan Shah, Ph.D., CEO, StrideBio
- · Michael Solomon, CEO, Ribometrix

<u>Find out</u> about the presenting companies for the event. Companies will take the stage to present their big ideas in front of a captive audience and potential investors. Early registration runs through February 14. <u>Click to register</u>.

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# At the National Level

# Two Reports Show Drug Spending Only a Fraction of Health Care Spending

New data shows that, when it comes to health care spending, prescription drugs aren't the biggest problem. The Altarum Center for Value in Health Care released the latest Health Sector Economic Indicators, finding national health spending in November 2019 was 5.4% higher than spending in November 2018.

But prescription drug spending was a FRACTION of other categories. Prescription drug spending was \$369 billion, just 9% of total health care spending in November, while hospital spending was \$1.291 trillion (33%), physician and clinical services were \$757 billion (19%).

"Once again, the numbers show that prescription drugs represent a small portion of overall health care spending – especially when compared with hospital and physician services. Politicians should be working to address the real drivers of rising health care costs, rather than targeting innovative drug developers with price controls and dangerous importation schemes," stated Alex Keeton, BIO's Director of Policy Research and Analytics.

Nearly half of total spending on brand medicines – the sum of all payments made at the pharmacy or paid on a claim to a health care provider – went to the supply chain and other entities in 2018, according to a <u>new analysis</u> from the Berkeley Research Group (BRG). Innovative biopharmaceutical companies that research, develop and manufacture medicines retained just 54% of total point-of-sale spending on brand medicines. The share of spending received by other stakeholders increased from 33% in 2013 to 46% in 2018.

"This data reaffirms that we need to look at the entire supply chain in order to solve patient affordability challenges," said Stephen J. Ubl, president and chief executive officer of PhRMA. "We need to fix the misaligned incentives in the supply chain, including the broken rebate system, to ensure patients benefit at the pharmacy counter from the significant discounts and rebates." More

#### **Upcoming Events - National Partners**

#### BIO CEO & Investor Forum February 10-11 in New York

The BIO CEO & Investor Conference is your next stop after JPM Week, where you can continue and expand your networking among a focused group of more than 1,400 senior decision makers, more than half of whom are investors. Meet under one roof to utilize the BIO One-on-One Partnering™ system and optimize your time at this two-day event.

Fireside Chats will focus on: Where is the industry headed in 2020? Hear from Amy P. Abernethy, FDA; Barbara Dalton, Pfizer Ventures; Ted W. Love, Global Blood Therapeutics; and Michael M. Morrissey, Exelixis, among others. Learn more.

View the <u>schedule of events</u> and proposed educational topics. <u>Register</u> now. NCBIO members can save up to \$200 off the biotech/pharma rate. Contact <u>Amber Niebauer</u> for the discount code.

#### Registration Open for BIO 2020



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 <u>BIO 2020</u> experience in San Diego, June 8-11.

In just 4 months, 17,000+ biotechnology and pharma leaders from around the world will come together for an exciting week of intensive networking to discover new opportunities and promising partnerships. Join the global biotech community in San Diego, June 8-11, to discover the next generation of cutting-edge products, innovation, therapies, and cures at events all week long. Register now.

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. <u>Book housing</u>.

## MDMA FDA Forum, March 12-13

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

<u>MDMA's 2020 FDA Forum</u> continues to grow as a conference to engage with leading policy makers and experts. Be sure not to miss out hearing from **FDA officials** on how to get your technologies into the marketplace.

# **Confirmed FDA Speakers Include:**

- William Maisel, Director, Office of Product Evaluation & Quality and CDRH Chief Medical Officer
- Patrick Axtell, Ph.D., Senior Tools & Templates Engineer, Office of Regulatory Products, CDRH
- Sergio M. de del Castillo, RAC, De Novo Program Lead, Premarket Notification & Classification Team, DRP1, Office of Product Evaluation & Quality, CDRH
- Lili Duan, Tools & Templates Engineer, Office of Regulatory Products, CDRH
- Owen Faris, Ph.D., Principal Deputy Director, Office of Product Evaluation and Quality, CDRH
- Bakul Patel, MSEE, MBA, Director, Digital Health, CDRH
- John Weiner, Associate Director for Policy & Product Classification Officer, Office of Combination Products, CDRH

NCBIO members can get a \$100 discount. Contact <u>Amber Niebauer</u>. For more information and to register, <u>click here</u>.

#### **BIO World Congress in Raleigh September 21-24**

The BIO World Congress on Industrial Biotechnology and Agriculture is being held September 21-24 in Raleigh. It is the largest industrial biotechnology event for business leaders, investors, and policy makers in biofuels, biobased products, and renewable chemicals.

By presenting at this conference, you can share your corporate message and present research to 1,000+ attendees. Additionally, presenters receive a **discounted registration** rate which provides access to networking, sessions, BIO One-on-One Partnering Meetings, and more!

#### Submission Deadline for Breakout Sessions: February 21, 2020

Submissions for Company and Technical Presentations and Start-Up Stadium will be reviewed on an ongoing basis. Visit <u>bioevents.hubb.me</u> to submit a proposal.

#### FFAR Seeks Nominations for 2020 New Innovator Award

The <u>Foundation for Food and Agriculture Research</u> (FFAR) is now accepting nominations for the <u>2020 New Innovator in Food and Agriculture Research Award</u>. FFAR intends to grant up to ten awards to early-career scientists pursuing research that supports the Foundation's <u>Challenge Areas</u> and promotes global, sustainable food production. Each applicant is eligible to receive up to \$150,000 per year for a maximum of three years totaling \$450,000 from FFAR. For the first time, FFAR is not requiring awardees to secure matching funds, opening this opportunity to a wider pool of applicants.

The deadline for submitting nominations is March 4 at 5:00 pm ET. Complete submission guidelines and program deadlines are available on the <u>FFAR website</u>.

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# **Member News**

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

<u>Biogen Inc.</u> announced an agreement to acquire from <u>Pfizer Inc.</u> PF-05251749, a novel CNS-penetrant small molecule inhibitor of casein kinase 1 (CK1), for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases. In particular, Biogen plans to develop the Phase 1 asset for the treatment of Sundowning in Alzheimer's disease (AD) and Irregular Sleep Wake Rhythm Disorder (ISWRD) in Parkinson's disease (PD). <u>More</u>

Boragen, Inc. announced that the company has entered into an exclusive research and development agreement with a global leading Animal Health Company to advance compounds targeting Canine Atopic Dermatitis. As part of this R&D agreement, the company will have an exclusive option to a license to develop and commercialize lead compounds in the Animal Health Field. More

G1 Therapeutics, Inc. and Quantum Leap Healthcare Collaborative™ announced a collaboration to evaluate trilaciclib, an investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy, in a new randomized, investigational treatment arm for the ongoing I-SPY 2 TRIAL™ for neoadjuvant treatment of locally advanced breast cancer. More

PPD, Inc. announced the launch of its initial public offering of 60 million shares of its common stock pursuant to a registration statement filed with the Securities and Exchange Commission (SEC). The initial public offering price is expected to be between \$24.00 and \$27.00 per share. PPD has applied to have its common stock approved for listing on The Nasdaq Global Select Market under the symbol "PPD." More

<u>TriPharm Services</u> ("TriPharm"), a new state-of-the-art sterile fill-finish manufacturing center located near RTP announced it has been acquired by Alcami. "As drug makers increasingly shift their focus toward more specialized, targeted therapeutics, and current injectable drug shortages hamper patient care, sterile fill-finish operations at proper scale are highly valued," said TriPharm Co-Founder and Chief Executive Officer Patrick D. Walsh. "Our Research Triangle Park facility is designed to address this highly specialized industry demand." <u>More</u>



In 2019 BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions<sup>®</sup> 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 <a href="here">here</a> and choose the programs you're interested in. Email <a href="mailto:save@bio.org">save@bio.org</a> with your choices and they will get you started. For all the latest news, promos, and event information, follow <a href="mailto:BIO Business Solutions on LinkedIn">BIO Business Solutions on LinkedIn</a>!



BIO and Aon have teamed up to bring comprehensive coverage for Executive Liability and Cyber Insurance programs. Aon has undertaken an extensive request for proposal process to vet and select an elite group of insurers based on their ability to deliver distinctive value to life sciences clients. Through these programs, BIO members can access and benefit from expansive coverage of offerings, and competitive pricing utilizing broad Aon-negotiated policy language, along with a unique array of defined services, all designed to enhance program efficiency and effectiveness through these reputed insurance carriers.

For questions or help, NCBIO members also have access to a dedicated BIO Business Solution's representative. Bob Dearth can be reached via <a href="mailto:bdearth@bio.org">bdearth@bio.org</a> or 718-716-7555. He's available to help you maximize your savings!

# Contacts for BIO Business Solutions Programs

For information about specific programs, local contacts are:

### **Airgas**

Greg Eccleston

greg.eccleston@airgas.com

Packaged and Bulk Gases

#### **ALT**

Jayson Bernstein

<u>Jayson@alt-inc.com</u>

Refurbished Lab Equipment – Buy and Sell

#### Aon

Rebecca McCabe
Rebecca.mccabe@aon.com
Executive Liability Insurance

#### **Business Wire**

Jim Liebenau

jim.liebenau@businesswire.com

News Distribution

#### Chubb

Andrew (Andy) Totman

Andrew.Totman@Chubb.com

Insurance

#### **Clean Harbors**

Gregg Campbell

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**Environmental Services** 

#### Humboldt

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Moving and Storage

## Nikon

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Microscope Systems

# Office Depot

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Office Supplies

# ShareVault

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Secure Document Sharing and Storage

### UniClean

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Cleanroom services

## UniFirst

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Workwear

## **UPS**

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Shipping

# VWR

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Lab Supplies and Equipment

#### Brex

Steve Joseph <a href="mailto:steve.joseph@brex.com">steve.joseph@brex.com</a> Corporate Credit Card

## Scientist.com

Tristan Cook <u>tristan@scientist.com</u> Scientific Research Services

## **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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To view full calendar, click.

ACS CAN Premiere Screening: Left Behind: Health and Hope in North Carolina

Thursday Jan 30, 2020

... read more

Learn How to Write a Competitive Proposal to Access Hundreds of Thousands of Dollars through SBIR/STTR Grants!

Wednesday Feb 5, 2020 - Friday Feb 7, 2020

... read more

WIB-RTP presents "Interview with Confidence: Actionable Tips to Put into Place Today"

Wednesday Feb 5, 2020

... read more

LaunchBio: Larger than Life Science

Thursday Feb 6, 2020

... read more

Triangle Global Health Career Day

Friday Feb 7, 2020

... read more

**BIO CEO & Investor Conference** 

Monday Feb 10, 2020 - Tuesday Feb 11, 2020

... read more

# Life Science Women's Conference Wednesday Feb 19, 2020 - Thursday Feb 20, 2020 ... read more NCBIO Life Science Forum: Intellectual Property Strategy Wednesday Feb 19, 2020 ... read more NCBiotech Ag Tech Professional Forum Wednesday Feb 19, 2020 ... read more Healthcare Innovation Conference Friday Feb 21, 2020 - Saturday Feb 22, 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 ... read more National Academy of Engineering Regional Meeting: Engineering Therapies for the Future Tuesday Mar 10, 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

... read more

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