



connections newsletter



**AUGUST 2019
UPDATE**

**Serving the NC Life
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NCBIO This Month

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Governor and Legislators Working on Budget Compromise



The General Assembly and Governor Roy Cooper remain deadlocked over different priorities for the state budget. A key difference between the parties is Medicaid expansion. Governor Cooper seeks to expand coverage to a group of people who make

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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too much money to qualify for Medicaid right now, but not enough to afford health insurance. A group of House members has been working on a plan that would provide some expansion, but Senate leaders are opposed to any changes in Medicaid.

The budget passed by the Assembly and vetoed by Cooper includes funding for priorities sought by NCBIO. The budget includes \$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. The General Assembly budget also includes \$500,000 in additional recurring funding for the North Carolina Biotechnology Center, and \$500,000 in non-recurring funding for the 2020-21 fiscal year. The additional funding for the Center would be used to expand the Center's business recruitment and start-up loan programs.

The Legislative proposal also provides \$2M for each year of the biennium for North Carolina's participation in the National Institute for Innovation in the Manufacturing of Biopharmaceuticals (NIIMBL). These funds will be managed by North Carolina State University and distributed to support work force development or biomanufacturing process innovation projects at participating institutions across the state.

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Growing Pains in Available Lab Space in North Carolina



Lab Space Panel Bill Bullock, Ed Field, Andy Schwab, Neill Sherron and Matthew Cooke

Lab space for start-up companies moving to the next stage of development is limited in a maturing market according to panelists at the July 16 NCBIO Luncheon and Forum. Bill Bullock, Senior VP, Economic Development & Statewide Operations, North Carolina Biotechnology Center (NCBiotech), moderated a lively discussion with four panelists who shared a range of views about the lab space market.

Matthew Cooke with Davis Moore called the RTP area a maturing market now attracting institutional and international investors. As a result, rent is going up and vacancy rates are going down to less than 5%, making it difficult to find space.

Neill Sherron with Longfellow Real Estate Partners noted that many life science companies choose to locate adjacent to universities and other research companies with only 14% making decisions based on cost.

Andy Schwab, President of First Flight Venture Center, said companies planning to move into lab space need to begin preparations six months to one year ahead of time to get lab space, noting that getting lab space is one of the biggest challenges that startup companies face.

"Help with graduation space" is one of the key things needed by emerging companies according to Ed Field, President of BioLabs North Carolina. He said companies need access to capital and the ability to move and grow.

The panel noted the growth of resources in the State for emerging companies and advances that have been made in the last 10 years.



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Thanks to our Lab Space Forum Sponsors: David Bauer (VWR), Matthew Cooke (Davis Moore) and Neill Sherron (Longfellow Real Estate Partners)

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More Growth in NC Life Science Sector

Merck will invest more than \$650M and create more than 400 jobs in North Carolina, building a new production facility at its Durham location and expanding the packaging operations in Wilson. The expansion will enable Merck to meet growing demand for GARDASIL and GARDASIL 9 recombinant human papillomavirus (HPV) vaccine, which is used to prevent several cancers associated with HPV.

“The life science industry cluster in North Carolina enjoys a well-earned reputation as one of the nation’s leading centers for biotech innovation,” said North Carolina Commerce Secretary Anthony M. Copeland. “Merck’s long experience in our state gave them the confidence to bring this important new operation to North Carolina.”

In a statement, Sanat Chattopadhyay, Executive Vice President, Merck, and President, Merck Manufacturing Division said, “Merck is delighted to bring additional investment and jobs to North Carolina. Our Durham and Wilson plants are key strategic sites in the Merck global manufacturing network. And the strong support of the state is critical for the success of businesses such as ours.” [More](#)

Precision BioSciences, Inc. opened its Manufacturing Center for Advanced Therapeutics (MCAT), the first in-house current Good Manufacturing Process (cGMP) compliant manufacturing facility in the United States dedicated to genome-edited, off-the-shelf chimeric antigen receptor (CAR) T cell therapy products. This is part of a larger investment by the company in its cancer immunotherapy platform and facilities expansions in North Carolina in 2019. [More](#)

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NCBio Members Find Out More about Discount Savings Program at July Networking Event



NCBIO members, guests, BIO representatives and vendors with [BIO Business Solutions](#) held a networking and discussion session July 24th. Vendors including Airgas, Chubb, UniFirst, UPS, and VWR shared information about the [discount purchasing program](#) and savings available to members.

Last year BIO saved 4,200 companies nearly \$460 million through BIO Business Solutions with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

As a NCBIO member, you are eligible! This is a benefit of your NCBIO membership. If you did not attend the meeting, review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email biobusinesssolutions@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!](#)

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Sign Up Now for NCBIO Annual Meeting October 3



Two months until NCBIO's 25th [Annual Meeting](#) on October 3 from 8:00 a.m. to 3:00 p.m. at the NC Biotech Center. We anticipate more than 200 NCBIO members will attend this membership event. In addition to a great line up of speakers and discussion topics - two panels and two keynotes - there will be ample networking opportunities at break, lunch and the dessert reception to celebrate our 25th anniversary.

The Access and Availability panel will be moderated by **Dr. Marianne Lopez**, Research Director, Value-Based Payment Reform, Duke-Margolis Center for Health Policy. We will discuss the policies necessary to make both novel and established therapies available to patients. Learn more about value-based reimbursement, pharmaceutical rebate reform, and other important topics from our featured panelists.

- **Vadim Lubarsky**, Executive Director, CMS Policy and Reimbursement, Novartis
- **Robin Levy**, Senior Director, Public Policy and Advocacy, International Myeloma Foundation
- **Dora Hughes, M.D., M.P.H.**, Associate Research Professor, Department of Health Policy and Management, Milken Institute School of Public Health, George Washington University
- **Reginald Munden, M.D.**, Interim Vice President Clinical Operations and Cancer Services, Wake Forest Baptist Health

The Ag and Human Microbiome panel discussion will be moderated by **John Ryals, Ph.D.**, Former President and Chief Executive Officer, and Chair Emeritus, Board of Directors, Metabolon, and will focus on acknowledging the microbiome and understanding how to manipulate it for nutritional and therapeutic purposes. Panelists include:

- **Anne Ballou**, Research and Development Scientist, Premex
- **Nick Gillitt, Ph.D.**, Chief Science Officer, David H Murdock Research Institute
- **Jared Jensen, Ph.D.**, Nematologist and Project Leader, AgBiome

To learn more about sessions and speakers or to register, [click here](#). If you need assistance with registration, contact [Amber Niebauer](#). More than 100 members are already registered to attend. Don't miss your opportunity!

Thank you to our current sponsors:

Platinum: [BIO](#), [Bioventus](#), [Cook Medical](#), and [VWR](#)

Gold: [BDO](#), [FUJIFILM Diosynth Biotechnologies](#), and [Grifols](#)

Silver: [Charter Medical](#), [Office Depot](#), [The Conafay Group](#), and [UCB](#)

Bronze: [Business Wire](#), [G1 Therapeutics](#), [GSK](#), and [Novozymes](#)

If you are interested in sponsoring the Annual Meeting, please contact [Laura Gunter](#).

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NCBIO Members, BioNetwork and University Research Featured in Publication

Four NCBIO members are highlighted in the [Life Science Handbook 2019](#) published in the June edition of [Business North Carolina](#). [Pairwise](#), [Humacyte](#), [Glenmark Pharmaceuticals](#) and [Thermo Fisher Scientific](#) are profiled. In the July [Research NC 2019](#) section, the North Carolina Community College BioNetwork training [BioWork](#), the research at [RTI International](#) and [UNC-Chapel Hill](#), and innovation at [UNC-Wilmington](#) and [Wake Forest School of Medicine](#) are featured.

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Register Now for Informing Innovation 2019



To bring a solution from bench to bedside, life science companies have a myriad of information needs at every stage of development. [Life Science Intelligence](#) at the North Carolina Biotechnology Center (NCBiotech) is hosting Informing Innovation on September 19. You can find out about market projections for specific therapeutic areas, intelligence about competitors' research programs, and scientific literature. Critical information can be expensive to access and time-consuming to search. Time spent hunting for information is time spent away from developing technologies that can heal and feed the world.

At [Informing Innovation 2019](#), staff will help you get up to speed in life science market research techniques, learn the landscape of scientific literature and business information resources, and equip you with sources and strategies for finding the data you need to innovate. You will also be able to connect with content providers to learn more about the industry tools and resources that are essential to discovery. [Find out more](#) and [register](#).

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Presentation Application Deadline August 15 for SEBIO 2019

The [SEBIO 2019 Investor and Partnering Forum](#) will be held in Miami, Florida November 6-7. More than 300 biotech and medtech investors, corporate executives, university representatives, and entrepreneurs will attend the event this year. Companies interested in making a presentation at the event should submit [applications](#) by August 15. Click for [more information](#) about the event and to [register](#).

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At the National Level

We Work for Health Fly-In

NCBIO Membership Director Laura Gunter attended the We Work for Health (WWFH) fly-in on July 17 and 18. WWFH is the PhRMA led grassroots coalition focusing on PhRMA's interaction with the community. The NC group included the team from Randolph Cloud and Associates, the National Association of Social Workers – NC, the Durham Chamber of Commerce, and NCBIO. The group visited with Representatives Butterfield, Holding, Walker, McHenry, Meadows and Hudson and Senators Burr and Tillis.



We Work of Health NC Representatives present Congressman Holding with Rising Start Award

NCBIO also delivered letters of appreciation for support of the rebate rule to Representatives Foxx, Budd and Rouzer. Key issues were the administration's recent pulling of the rebate rule that would have ensured that industry rebates were used to reduce the price consumers pay at the pharmacy, the International Pricing Index (IPI) and its problems with access and innovation for Medicare Part B, the industry's support for out of pocket caps and dislike for inflation rebates in Medicare Part D, and concern for harmful changes to Intellectual Property rules.

Representatives Holding and Walker received the We Work for Health-NC Rising Star Awards.

Push to Repeal Medical Device Tax Continues

AdvaMed called on Congress to repeal the medical device excise tax in light of passage by the U.S. House of Representatives of legislation to repeal the Affordable Care Act's so-called "Cadillac tax."

"The House vote sent a clear message that taxes on our health care system are a bad idea – and that the case for keeping the medical device tax in place no longer holds water," said Scott Whitaker, President and CEO of AdvaMed. "Passage of the Cadillac tax repeal opens the door to passage of the device tax repeal, which would be a win for innovation, for patients, and for job creation." [More](#)

White House Withdraws Plan to Lower Out-of-Pocket Drug Costs

BIO's President and CEO Jim Greenwood issued the following statement after it was reported that the Trump administration is withdrawing its proposed rebate rule that

would have required savings from drugmakers' rebates be passed along to seniors enrolled in the Medicare drug benefit program.

"The administration has abandoned one of the only policy solutions that would have truly lowered what patients are forced to pay out of pocket for the medicines they need. This decision discards a proposal that would have also delivered meaningful transparency to an opaque system that puts the financial interests of middlemen ahead of the well-being of patients." [More](#)

PhRMA issued these comments: "The Administration's decision to not move forward on the proposed rule to reform the rebate system in Medicare Part D is a blow to seniors who could have paid less for their medicines at the pharmacy counter. Of all the policies proposed in Washington right now, this was the only proposal that would provide immediate savings at the pharmacy counter, instead of only saving the government or insurance companies money. It is disappointing that despite support from policymakers on both sides of the aisle and from a wide array of consumer, patient, pharmacist and provider groups that they have decided to backtrack. Our industry remains committed to fighting for patients by advancing policies that will actually lower what they pay out of pocket for their medicines."

NCBIO Members Receive \$100 Off Registration for MDMA Event

Plan to attend [MDMA's 12th Annual Medical Technology Executive Forum](#) on September 13th at the Crowne Plaza Cabana in Palo Alto, CA.

As FDA continues to examine the regulatory pathways and provide new reform proposals, hear from the CDRH Director on what steps they are taking and to have your questions answered on the latest priorities for the agency. CDRH Director Jeff Shuren will share his insights and answers attendees' questions at this must-attend one day interactive forum. MDMA's Medical Technology Executive Forum will bring together 150 CEOs and senior executives to discuss the critical issues that affect product commercialization and the common challenges faced by med-tech companies today.

The CDRH Director (*via video conference*) will share how the agency envisions the latest proposals and agency realignments to spur improvements for patient care, and how stakeholders can continue working together to improve the regulatory pathways.

Other interactive sessions include:

- Trends in Healthcare Investments & Exits
- Best Strategies for Raising Capital
- CEO Perspective - Lessons Learned from C-Suite
- Reimbursement Reforms - Accelerating Patient Access

[Register today](#) to ensure your spot at this unique event for medical device entrepreneurs. Contact NCBIO Events Director [Amber Niebauer](#) for your \$100 discount code off nonmember registration. For additional information, contact Sheri DeVinney at sdevinney@medicaldevices.org or call 202-354-7171.

NCBIO Members get Discount for The MedTech Conference

Join AdvaMed on September 23-25 as 3,000+ of the world's top medtech executives gather in Boston for [The MedTech Conference](#). The event features world-class plenary speakers, cross-cutting programming, valuable networking and business development opportunities. NCBIO members can save 10% on [registration](#). Contact NCBIO Events Director [Amber Niebauer](#) for the discount code.

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Member News

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

Three individuals with NCBIO member companies were recognized by the *Triangle Business Journal* at the "40 under 40 Leadership Awards" event in late June. They are Felicia Browne of [RTI](#), Maeve Gardner with [GSK](#), and Jill Walters at [Womble Bond Dickinson](#).

AgBiome Innovations, the commercial organization of [AgBiome](#), announced it has brought aboard Adam Burnhams to serve as Vice President of Market and Customer Strategy. In this role, Mr. Burnhams will be focused on AgBiome Innovations' customer and branding strategy. [More](#)

[BioCryst Pharmaceuticals, Inc.](#) announced the appointment of Megan Sniecinski as Chief Business officer. [More](#)

[Grifols](#) announced that Xembify, its new 20% subcutaneous immunoglobulin, has been approved by the U.S. Food and Drug Administration (FDA). Xembify is used to treat primary immunodeficiencies. [More](#)

[Pappas Capital](#) announced the promotion of Kyle Rasbach, PhD, PharmD to a Managing Partner of Pappas Ventures, the firm's venture capital business. In his new role, Dr. Rasbach will help oversee Pappas Ventures and lead fundraising and investment efforts for its future venture funds. Pappas Capital also announced that Matthew Boyer has been named Chief Financial Officer, succeeding Ford Worthy who will continue with the firm as a Partner and Senior Advisor. [More](#)

Optimal Just-in-Time, a service of [PPD's](#) Accelerated Enrollment Solutions (AES) business unit, and Cancer Treatment Centers of America® (CTCA) are collaborating to speed patient enrollment in oncology clinical trials, enhancing patient access to potentially life-changing therapies and saving time in drug researchers' quest to conquer cancer. [More](#)

Scott Shone, PhD, a Senior Researcher in [RTI's](#) Center for Newborn Screening, Ethics, and Disability Studies, has been named Director of the North Carolina State Laboratory of Public Health. [More](#)

[Seqirus](#) announced that it is first-to-market with shipping its portfolio of seasonal influenza vaccines to customers in the United States for the 2019/20 influenza season. Seqirus expects to distribute over 50 million doses to the U.S. market this year, with the majority of doses coming from its adjuvanted and cell-based technology platforms. [More](#)

[Smith Anderson](#) Attorney Richard Stevens has been appointed Chairman of the Board of Trustees at the University of North Carolina at Chapel Hill for a term commencing July 8. [More](#)

[TCG](#) announced the expansion of its West Coast office and welcomed Nat Bowditch as its newest partner. Nat brings more than 30 years of experience and leadership in the medical device field. Nat has been responsible for sales and marketing efforts at numerous companies in medical imaging and cardiac surgery. [More](#)

[vTv Therapeutics Inc.](#) made an oral presentation at the 2019 Alzheimer's Association International Conference (AAIC) held in Los Angeles, California, July 14 – 18. The presentation highlighted data from the phase 3 STEADFAST study and preceding phase 2b study of azeliragon to further support the biological hypothesis for the potential beneficial effects of azeliragon on the ADAS-cog and CDR-sb in patients with mild Alzheimer's disease and type 2 diabetes. [More](#)

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Calendar

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

[LaunchBio: Larger than Life Science Winning Combination](#)

Thursday Aug 1, 2019

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[BTEC Downstream Biopharmaceutical Processes: Fundamentals and Design](#)

Tuesday Aug 6, 2019 - Thursday Aug 8, 2019

... [read more](#)

[GSK and UNC: Jointly venturing to find a cure for HIV/AIDS](#)

Thursday Sep 5, 2019

... [read more](#)

[NCSU International Symposium: Precision Systems and Data Analysis in Animal Agriculture](#)

Monday Sep 9, 2019 - Tuesday Sep 10, 2019

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[MDMA 2019 Medical Technology Executive Forum](#)

Friday Sep 13, 2019

... [read more](#)

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

Wednesday Sep 18, 2019

... [read more](#)

[Informing Innovation 2019](#)

Thursday Sep 19, 2019

... [read more](#)

[MedTech Conference 2019](#)

Monday Sep 23, 2019 - Wednesday Sep 25, 2019

... [read more](#)

[NCBIO Annual Meeting 2019](#)

Thursday Oct 3, 2019

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